Research Committee

Rules and Regulations for Research

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مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

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مركز البحوث الطبية
Medical Research Center

HAMAD MEDICAL CORPORATION

RESEARCH COMMITTEE

RULES AND REGULATIONS

FOR

RESEARCH

(UPDATED MAY 2011)

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It is with great pleasure and a sense of achievement that we present the updated edition of the "Rules and Regulations for Research"..

Al- Khater

Dr. Al-Hareth M. Al-Khater
Chairman, Medical Research Center

Rules & Regulations

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SECTION I

REQUIREMENTS OF THE RESEARCH COMMITTEE

1. GENERAL REQUIREMENTS

1.1 Purpose / Background

This policy establishes the authority of the Hamad Medical Corporation (HMC) Research Committee (RC). The RC is charged with a twofold mission: (1) to determine and certify that all projects reviewed by the RC conform to the regulations and policies set forth by the Qatari laws and by the principals of the Belmont Report regarding the health, welfare, safety, rights, and privileges, and privacy of human subjects in Research; and (2) to assist investigators in conducting ethical Research which complies with the set forth regulations in a way that permits safe accomplishment of the Research activity.

1.2 Policy

It is the policy of the HMC that human research activities conducted under the oversight of the Corporation will be conducted in accordance with Qatari law and regulations, the principles of the Belmont Report and the local RC requirements as stated in below in III of this section. Belmont Report articulates the basic ethical principles that guide the conduct of research with human subjects according to predefined three principles, which are basic to the protection of human subjects: (1) "***respect***", in this context, investigators are required to seek voluntary, written informed consent for potential subjects. Voluntary informed consent means that subjects are given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and assure subjects that they are not under pressure to participate in the proposed

Research; (2) "***beneficence***", the principle of beneficence requires that researchers maximize the potential benefits to the subjects and minimize the potential risks of harm. Direct benefits to subjects, or indirect benefits in the form of generalized knowledge gained from the research, should always outweigh the risks; and (3) "***justice***", the principle of justice means that subjects are selected fairly and that the risks and benefits of Research are distributed equitably to all. Investigators should take precautions not to systematically select subjects simply because of the subjects' easy availability, their compromised position, or because of social, racial, sexual, economic, or cultural biases institutionalized in the society.

The HMC authorizes the RC of the Corporation to review and have authority to:

1. Approve, modify (to secure approval), or disapprove all human research conducted at the HMC,
2. Suspend or terminate research not conducted in accordance with the regulations, statutes and principles or RC's requirements mentioned above or that has been associated with unexpected serious harm to subjects,
3. Observe, or to have a third party observe, the consent process,
4. Observe, or have a third party observe, the conduct of the research, and

5. Serve as the Privacy Board for the HMC that approves waivers of authorization in accordance with protection of medical information rules.

Research covered by this policy that has been approved by the RC may be subject to further appropriate review and approval or disapproval by officials of the HMC. However, those officials may not approve the research if the RC has disapproved it.

1.3 RC Requirements

- All research that is to be conducted in human at Hamad Medical Corporation must be submitted to Medical Research Centre for review by the Research Committee (RC).

- No research in human subjects can be initiated without the approval of RC (unless specifically categorized as exempted from Research Committee review).

- The period of approval will be indicated in a written communication from the Office of Medical Research to the Contact Principal Investigator.

- It is important to note that the RC approves a project only for a **maximum period of 365 days**.

- To renew and request for extension of the project period of a project, the Investigator must submit a **progress report** to the Research Committee for review and renewal of approval by the RC.

- It is the responsibility of the Principal Investigator to provide a progress report on time for uninterrupted RC approval.

- Progress reports must be submitted at least one month prior to the date that approval terminates.

- In the progress report, it is essential that investigators indicate whether or not the application includes any modification in the research protocol and / or the consent form.

- All progress reports must be accompanied by a copy of the consent form that will be utilized during the requested period of the renewal.

- Scientific and ethical issues will be evaluated by the RC.

- Human subject is defined as an individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (e.g., medical records).

- In reviewing research protocols involving human subjects, the REC considers the expertise and experience of the investigators to be a major indicator that risks to the subjects will be minimized and benefits from the study maximized.

- The RC encourages the principal investigators to include co- investigators who are knowledgeable and experienced in the performance and evaluation of procedures to be used in the research.

- The co investigators should have an active role in developing the research proposal and they must assume responsibility for the accuracy and appropriateness of those parts of the proposal related to their particular expertise.

- They are responsible to have knowledge of all study procedures including the risks and benefits. (This information is provided to subjects as part of the informed process).

- To document the acceptance of this responsibility and the agreement to participate in the study once it is approved, each co investigator must sign the **Investigator's Assurance Form.**

- Principal Investigators are urged to consult with the appropriate Co – investigators early in the process of protocol development and arrange to obtain the required signature before the application is submitted to the MRC.

1.4 Policy and Procedures for the Ethical Conduct and Reporting of Research

1.4.1 General Provisions

1.4.1.1 Definitions

a. "***Research***" means all scholarship, creative activity, program evaluation, and other research, including without limitation, Empirical Research.

b. "***Empirical Research***" means Research that is designed to generate knowledge of objectively measurable phenomena.

c. "***Principal Investigator, PI***" anyone with a formal relationship with the HMC can act as a Principal Investigator (PI)/Program Director (PD) on an approved research project. That relationship can be as a professional staff such as physician or pharmacist; postdoctoral fellow or student. The individual must also meet all of the agency guidelines for eligibility in extramurally funded research grants. If an individual is not a permanent employee of the HMC, the term of appointment must be sufficient in length to complete the proposed project. Such individuals must obtain formal approval by the appropriate chair and/or dean to submit the application in the name of the HMC with assurances that adequate resources and supervision will be available for the project to be successful should it be approved/ funded by the RC.

d. "***Human subjects"*** are defined in the "Common Rule" as "living individuals about whom an investigator (whether professional or student) conducting Research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

1.4.1.2 Applicability

The goal of this Policy and procedures is to establish a basic standard of honesty for all Research conducted, and all grant proposals submitted, by or under the supervision of PI's from the HMC.

1.4.2 Standards for Designing and Conducting Research

Guidelines. Research should be undertaken only when it offers the opportunity to advance knowledge. The undertaking of "trivial" studies primarily for the purpose of yielding numerous and rapid scholarly results should be discouraged in favour of more substantial studies that yield fewer, but more important, scholarly results. For large Research projects that meet the mentioned definition of Empirical Research, it is crucial that PI's and/or supervisors ensure that every member of the project (co-investigator or otherwise) adhere to ethical standards. PI's and/or Research directors (and even department and unit heads) often share responsibilities with the investigators of record for the ethical conduct to Research. For Empirical Research projects, the retention of primary data, data analyses, and information leading to the results of the Empirical Research presents an additional set of issues. In many cases of alleged academic and scientific misconduct, a common concern is the absence of a complete set of verifiable data. The retention of accurate records easily retrieved is of utmost importance for the progress of scholarly and scientific inquiry. Errors within records and missing records may be mistaken for misconduct. Statistics used in the conduct of Research should be appropriate to the study, and the original data must be recorded, preserved, and made accessible to the RC on request. Data is defined as information that is generated in or as a result of empirical research activities and recorded in any tangible or electronic medium, including without limitation laboratory notebooks and worksheets, memoranda, notes, clinical protocols, computer databases, computer images, and all other records.

1.4.3 Standards of Reporting of Research Results "Publication"

Guidelines. Although there is some disagreement about the particulars, certain publication practices are widely regarded as unethical. One of the leading antecedents for unethical behaviour is the pressure to publish. Early career investigators in particular, but not exclusively, may yield to this pressure as a result of the tendency for promotion. Some assume that publication in peer-reviewed journals perceived as "prestigious" automatically satisfies the requirement for quality. Journal editors and referees, on the other hand, are admittedly often not in the best position to detect deceptive and careless research and reporting practices that could adversely affect the perceived quality of a paper. Some of the most celebrated cases of scientific fraud have involved hundreds of publications in "prestigious" journals many of which were subsequently proved to be fraudulent. Practically all of this fraudulent activity was ultimately detected, however, not by the journals, but either by the institutions of origin or by other scientists interested in the Research. Certain practices that make it difficult for reviewers and readers to follow a complete experimental sequence are:

a. Rapid publication of data without adequate tests of reproducibility or assessment of significance, or the publication of fragments of a study, and the submission of multiple manuscripts differing only slightly in content.
b. Spread the results out over multiple publications merely, or even primarily, to "pad" his or her *vitae* or Research productivity effort.

The issue of authorship as it relates to Research reporting involves certain unique ethical considerations. In general, authorship and order of authorship should be tentatively decided before the paper is written, and reconsidered as necessary. Authorship should reflect only substantive contributions to the work. Each author should have participated sufficiently in the Research to be able to take public responsibility for, and to defend, the content of the paper that falls within his or her

specialty area. In other words authorship in publication is solely responsibility of principal investigator and requires substantial participation and involvement in conception and design, data analysis and interpretation, drafting the article or revising it critically and finalizing the manuscript of the study to be published. Whereas, contributing solely to the acquisition of funding or the collection of data does not justify the authorship.

1.4.3.1 General Standards for Research Results Reporting

a. **Definitions.** As used in this subsection

1. "**Publication**" (and "publishing" when used as a verb) includes any presentation of information to a person not involved in the Research, regardless of whether such presentation occurs in writing, orally, or in electronic format. Without limiting the foregoing, publishing includes published books and articles, speeches, interviews, and grant applications.

2. "**Plagiarism**" occurs when one purposefully suggests, by either an active representation or a failure to disclose, that another's work or idea is one's own. However, plagiarism does not include a simple failure to name the source of a work or idea in which it is clear from the context that one is not claiming the work or idea as one's own.

3. "**Fabrication of data**" occurs when one knowingly or recklessly reports data that is forged (whether by the person reporting or another), and

4. "**Falsification of data**" occurs when one knowingly or recklessly reports data that has been altered from its raw form in a misleading manner (whether the distortion was made by the person reporting or another).

b. Under no circumstances shall a person publishing material related to Research engage in (i) plagiarism, (ii) fabrication of data, or (iii) falsification of data.
c. All claims and conclusions made in connection with publishing Empirical Research shall be supportable by the data.

1. An investigator shall not publish the same results, or results that represent only an insignificant modification of an original publication, in more than one written publication without acknowledging the earlier publication or publications. The prior sentence will not apply to abstracts and grant applications, unless an acknowledgment is required by the granting party.
2. An investigator must often determine whether the results of a given Research project should be published in one publication or divided into multiple publications. In making that choice, the investigator shall make an honest evaluation, from the point of view of others in the discipline, of how the results can be presented most effectively.

1.4.3.2 Authorship

a. Only individuals who have made a significant, substantive contribution (including data analysis) to a publication shall be named as author. Without limiting the foregoing, the following relationships do not, in themselves, warrant authorship:

1. Financial and/or material support,
2. Routine technical assistance,

3. Collection of data, and
4. Furnishing research space.

b. Order of authorship for a publication shall be determined in accordance with the standard prevailing in academic disciplines.

c. Notwithstanding subsection b, with respect to a student pursuing dissertation that fulfils the degree requirements of an affiliated academic institution, the degree candidate shall always receive first authorship. If the candidate completes all obligations except for preparing a manuscript, decisions regarding authorship of any ensuing publication shall be made after consultation with co-authors, the candidate's committee or advisors, and the Department Chair.

d. In the case of multiple authorship listed in any given paper, each co-author will share collective responsibility for the entire publication.

Reference: Please check HMC Intranet web portal: http://intranet/deptportal/show_news.asp

1.4.3.3 HMC and Other Policies

All Research shall be designed, conducted, and reported in full accordance with all other policies of the HMC and granting agencies that may apply, including the Conflict of Interest Policy, Intellectual Property Policy, and polices dealing with the protection and welfare of human and animal subjects.

1.4.3.4 Unanticipated Problems Involving Ricks to Research Subjects and Others

1.4.3.4.1 Purpose / Background

This policy establishes the reporting requirements and the types of unanticipated problems that a Hamad Medical Corporation (HMC) principal investigator or designee must report to the Research Committee (RC) to ensure prompt reporting of unanticipated problems involving risks to Research subjects or others.

1.4.3.4.2 Definitions

a. Adverse event: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation.

b. External adverse event: From the perspective of one particular institution engaged in a multi-center clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.

c. Internal adverse event: From the perspective of one particular institution engaged in a multi-center clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at that institution. In the context of a single-center clinical trial, all adverse events would be considered internal adverse events.

d. Adverse event possibly related to the research: There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the

procedures involved in the research.

e. Serious adverse event: Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death;
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability/incapacity;
- Results in a congenital anomaly/birth defect; or
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

f. Unanticipated problem involving risks to subjects or others: Any incident, experience, or outcome that meets all of the following criteria:

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedure(s) that is/are described in the protocol-related documents, such as the RC-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to a subject's participation in the research; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

If the answer to all three questions is yes, then the adverse event is an anticipated problem and must be reported to the RC.

g. Unexpected adverse event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol–related documents, such as the RC-approved research protocol, any applicable investigator brochure, and the current RC-approved informed consent document, and
- other relevant sources of information, such as product labeling and package inserts; or the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

1.4.3.5 Policy

HMC's principal investigator or designee must promptly report any of the following events to the RC:

- Unanticipated problems, including serious adverse events related to a drug or device (whether occurring on-site or reported to the investigator by a sponsor or other site), which in the opinion of the principal investigator are:
    - unexpected,
    - related or possibly related to participation in the research, and
    - The research places subjects or others at a greater risk of harm than was previously known or recognized.
- Problems that required prompt reporting to the sponsor or funding agency,
- Accidental or unintentional change to the RC approved protocol that involved risks to subject or others, or that has the potential to recur,
- Changes to the protocol taken without prior RC review to an eliminate apparent immediate hazard to a research subject,
- Information (publication in the literature, safety monitoring report, interim result, or other finding) that indicates a change to the risks or potential benefits of the research,
- DSMB summary reports that indicate a change to the risks or potential benefits of the research,
- Breach of confidentiality of research data,
- Incorrect labeling of study medication/test article,
- Incorrect dosing of study medication/test article,
- Study medication/test article accountability discrepancies that trigger a study subject to be withdrawn from a study,
- Breach of privacy/confidentiality/data security/loss of study data/destruction of study data due to noncompliance,
- Unauthorized use or disclosure of protected health information,
- Subject complaints that indicate an unanticipated risk, or that cannot be resolved by the research staff,
- Incarceration of a subject while participating in research,
- Suicide attempt related to participation in a research study,
- Death of a healthy volunteer while participating in research or within 30 days of participation,
- Injury (needle stick, drug ingestion, chemical exposure, etc.) of study personnel related to preparation or administration of study drug,
- Unanticipated adverse device effect, or
- Any other event which in the opinion of the principal investigator was:
    - unexpected,
    - related or possibly related to participation in the research, and
    - the research places subjects or others at a greater risk of harm than was previously known or recognized.

1.4.3.6 Procedure for Policy

The principal investigator will report to the RC using the reporting process described in the forms link on the Medical Research Centre website. Death/Serious adverse event requires reporting to the RC within 24 hours by phone. Principal investigators may also report events by email or letter by providing the same information as requested in the Report Form.

If, in response to the report, the RC chair/ RC member/designated RC alternate, conducting the initial review, believes that immediate action is needed to ensure research subject safety; the reviewer may request that the investigator suspend research procedures or take action to suspend research procedures pending discussion of the event at the next convened meeting of the RC. Suspensions suggested by the reviewer, and in concurrence with the RC chair, will follow RC policies and procedures regarding suspensions.

Each report will have initial review by a primary reviewer (usually RC chair/ RC member/designated RC alternate).

In a case of suspended research procedures pending discussion of the event at the next convened meeting of the RC the reviewer will provide the following documents to the RC meeting:

- A copy of the event report and all attachments provided by the investigator,
- A copy of the protocol,
- A copy of the current informed consent, and
- Any other material that the RC staff believes relevant to the event.

1.4.3.7 Genetic Research and Practice

I. Purpose/ Background:

Genetic scientific enquiry is powerful tool involving the study, pursuit and application of research. The possibility of human benefit from this tool may be subject to the possibility of contingent or inadvertent harm caused by a breach of values. This section embraces international viewpoints together with the values and heritages enshrined in the State of Qatar to place the ethics of genetic research and practice within the State of Qatar framework.

II. Definitions

a. **Gene therapy*:*** essentially involves the practice or research related to two groups of cells - somatic cells and germ-line cells. i) a germ-line cell is a cell which, during the first few weeks after conception, is put aside in the embryonic sex organs to provide, possibly decades later, ova or sperm. ii) a somatic cell is any body cell except a germ-line cell. Genes which are carried by germ-line cells may be transmitted to offspring and successive generations. Genes which are carried by somatic cells have their role in the corporate life of those cells within the tissues and organs of the individual whom they endow.

So far as is known, an alteration to the genes of somatic cells will affect only that individual, but an alteration to the genes of germ-line cells might affect offspring and successive generations, and therefore gene therapy practice or research related to germ-line cell are not embraced.

b. **Genetic Screening:** a search in a population to identify individuals who may have, or be susceptible to, a serious genetic disease, or who, though not at risk themselves, as gene carriers may be at risk of having children with that genetic disease. Genetic screening programmes play a useful part in public health care systems in identifying potentially serious risks that can be prevented by timely treatment. Testing allows couples the possibility of making informed choices about parenthood

and, possibly, in identifying genetic susceptibility to common serious diseases. Three goals have been identified for genetic screening:

1. To contribute to improving the health of persons who suffer from genetic disorders;
2. To allow carriers for a given abnormal gene to make informed choices regarding reproduction; and
3. To move towards alleviating the anxieties of families and communities faced with the prospect of serious genetic disease.

c. **Genetic Testing:** the analysis of a specific gene, its product or function, or other DNA and chromosome analysis, to detect or exclude an alteration likely to be associated with a genetic disorder, and leads to definitive diagnosis in individuals. Individuals may desire testing where there is a family history of a specific disease, if they exhibit symptoms of a genetic disorder; or if they are concerned about passing on genetic disorders to their children. In addition, genetic testing in individuals is used as a 'fingerprint' in forensics. The areas of focus for genetic testing at present are thus carrier and susceptibility testing, prenatal diagnosis, newborn testing, and forensic testing.

d. **Genetic Counselling:** Genetic counselling is the provision of accurate, full and unbiased information that individuals and families require to make decisions in an empathetic relationship that offers guidance and assists people to work towards their own decisions

1.4.3.8 Policy of Gene Therapy

Any proposal to conduct *Somatic* gene therapy should be subject to approval following authoritative ethical review, which includes critical scrutiny of its medical and scientific merit, religious and the legal implications, and wider public concerns. It should also be subject to the following conditions as prerequisites to *Somatic* gene therapy research:
a. There must be sufficient scientific and medical knowledge, together with knowledge of those proposing to undertake the research, to make sound judgements on:

1. The scientific merit of the research;
2. Its probable efficacy and safety;
3. The competence of those who wish to undertake the research;
4. The requirements for effective monitoring.

b. The clinical course of the disorder must be known sufficiently well for the investigators and those entrusted with counselling to:

1. Give accurate information and advice;
2. Assess the outcomes of therapy.

1.4.3.9 Policy of Genetic Research

Every individual undergoing either genetic screening or genetic testing has the right to be fully informed of the results concerning a suspected disorder. A difficulty arises when an individual is to be informed of results that are "unexpected, unwanted, and have not been covered by consent. For example, a sex chromosome abnormality may be revealed when carrying out prenatal testing for Down's syndrome or a different inherited disease may show up on a test designed for another purpose. Unexpected information can present ethical dilemmas for which there are no easy answers, or indeed correct answers. The information which is to be given to any patient undergoing

genetic screening should include:

1. The seriousness of the condition to which the genetic disorder may give rise and how variable its effects are;

2. The therapeutic options available;

3. How the disorder is transmitted, the significance of carrier status and the probability of development of the serious genetic disease;

4. The reliability of the screening procedure and the results of the test;

5. Information detailing how the results of the screening test will be passed on to the patient, and what will be done with the samples;

6. The implications of a positive result for their future and existing children and for other family members;

7. A warning that the screening test may reveal unexpected and awkward information; for example, about paternity.

In genetic counselling, the following ethical principles should be applied:

a. respect for persons, families and their decisions according to the principles underlying informed consent;
b. preservation of family integrity;
c. full disclosure to individuals and families, of accurate, unbiased information relevant to health;
d. protection of the privacy of individuals and families from unjustified intrusions by employers, schools, and third parties;
e. informing families and individuals about possible misuses of genetic information by institutional third parties;
f. informing individuals that it is their ethical duty to tell blood relatives of the genetic risks to which they may be exposed;
g. informing individuals about the wisdom of disclosing their carrier status to a spouse if children are intended, and the possibility of harmful effects on the marriage from non-disclosure;
h. informing people of their moral duty to disclose a genetic status that may affect public safety;
i. unbiased presentation of information, insofar as this is possible;
j. adopting a non-directive approach, except when treatment is available, although the person being counselled may still decline treatment;
k. involving children and adolescents whenever possible, in decisions affecting them;
l. observing the duty to re-contact if appropriate and desired

In the context of genetic screening, where large numbers of tests are undertaken, this may be recorded in the form of a genetic register or similar database. Special consideration should be given to the implications for security of these grouped results.

A register may be defined as a *systematic collection* of relevant information on a group of individuals. Genetic registers record information on individuals with specific genetic

disorders, and may include relatives at risk of developing or transmitting the condition. The information may be recorded by hand, or may be held on computer. Genetic registers may be set up for a variety of reasons, including research on the disorder, the effective provision of services to those on the register, and the systematic offer of genetic counselling to family members. The amount and type of information recorded varies greatly, as does the presence of identifying details.

There are several general ethical issues concerning genetic registers. Here we outline issues relating to genetic screening. They should be seen against the background of the following points:

1. A genetic register may be the starting point for genetic screening; for example, the systematic testing of relatives of individuals with fragile X syndrome or Duchenne muscular dystrophy;

2. Genetic screening may also be based on a register not specifically genetic in its basis; for example, registers of specific cancers or of those with severe learning difficulties;
3. a genetic register may be the product of a genetic screening programme; for example, a register of carriers of cystic fibrosis or sickle cell disease in a population screened for the purpose.

It is essential to obtain individuals' consent before placing their names on a register. It is also important that individuals know that they are on the register, and what use will be made of the information.
Consent of individuals to long-term storage of information resulting from genetic screening is mandatory. However, if this is to form the foundation of a genetic register, separate and specific consent should be sought for subsequent tests or other measures, also for further use which may generate financial benefits for the investigator.

Confidentiality of all medical information is essential, and this is particularly the case with genetic registers, which may contain highly sensitive and potentially identifiable data on large numbers of individuals with, or at risk of, serious genetic disorders. Access to this information should be restricted to only those specifically responsible for a register, and the removal of identifying information when data are used for research purposes.

Reference: Please check HMC Intranet web portal: http://intranet/deptportal/show_news.asp

2. REQUIREMENTS FOR INFORMED CONSENT

Listed below are the basic elements and additional elements that are to be provided to each research subject.

2.1 Basic elements of informed consent that must be provided to each subject

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any

procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others, which may reasonably be expected from research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers pertinent to questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject; and

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at anytime without penalty or loss of benefits to which the subject is otherwise entitled.

2.2 Additional elements of informed consent, which must be provided to each subject, when appropriate

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

SECTION II

ETHICAL CONSIDERATIONS

1. RULES AND REGULATIONS

The Research Committee must determine that all of the following requirements are satisfied before it can approve the initiation of research in human subjects.

1) Risks to subjects are minimized:

    a. By using procedures which are consistent with research design and procedure which minimize a participant's risk.

    b. Whenever appropriate, by using procedures already being performed on the participant for diagnostic or treatment purposes.

2) Any risks to subjects are reasonable in relation to anticipated benefits, and the importance of the knowledge that may be reasonably expected to result. In evaluating risks and benefits, the RC should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Research Committee should not consider possible long – range effects of applying knowledge gained in the research, (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3) Selection of subjects is equitable. In making this assessment the RC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by this Rules and Regulations of the Research Committee. (See above requirements for informed consent, and see below, waiver of signed consent).

5) Informed consent will be appropriately documented, in accordance with, and to the extent required by this Rules and Regulations of the Research Committee. (See below, waiver of signed consent).
6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7) When appropriate, there is adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.

8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons,

additional safe guards have been included in the study to protect the rights and welfare of these subjects.

2. RESEARCH THAT REQUIRES REVIEW AT A CONVENED MEETING OF THE FULL RC

All research on human subjects, other than those which the RC has the authority to review and approve by expedited review (and elects to review and approve by expedited review) or is exempt from RC review must be reviewed at a convened meeting of the full RC. (See below for research that can be reviewed by Expedited Review and research that may be *Exempt from RC*.

3. RESEARCH THAT MAY BE REVIEWED BY THE RC BY AN EXPEDITED REVIEW PROCESS

Research that may be reviewed by an expedited review process (review by the REC Chairman) must **NOT** involve more than minimal risk and may **NOT** involve more than a minor change in a research project during an approved project period. Categories of research that the RC has the authority to approve by expedited review are itemized below. It should be noted that the HMC RC has the authority to be more stringent and may require that full review rather than expedited review be used for any of these categories.

3.1 Categories of new and continuing research that may be reviewed by the RC through an expedited Review procedure:

3.1.1 Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs that are registered at the Ministry of Public Health of Qatar. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

b. Research on medical devices that are cleared /approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

3.1.2 Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency in which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3.1.3 <u>Prospective collection of biological specimens for research purpose by noninvasive means:</u>

a. Hair and nail clippings in a non-disfiguring manner;

b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

c. Permanent teeth if routine patient care indicates a need for extraction;

d. Excreta and external secretions (including sweat);

e. Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying dilute citric solution to the tongue;

f. Placenta removed at delivery;

g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

h. Supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i. Mucosal and skin cells collected by buccal scrapping or swab, skin swab, or mouth washings;

j. Sputum collected after saline mist nebulization.

3.1.4 <u>Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications):</u>

Examples:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b. Weighing or testing sensory acuity;

c. Magnetic resonance imaging;

d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electro retinography, ultra sound, diagnostic

infrared imaging, Doppler blood flow, and echo cardiography;

e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

3.1.5 Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non research purposes (such as medical treatment or diagnosis):

3.1.6 Collection of data from voice, video, digital, or image recordings made for research purposes.

3.1.7 Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

3.1.8 Continuing review of research previously approved by the convened RC as follows:

a. where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research related interventions; and (3) the research remains active only for long term follow up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

3.2 Modifications in research that may or may not be reviewed by the RC through an Expedited Review Procedure during an approved project period:

The RC Chairman is authorized to approve by expedited review any change that falls into expedited categories 1 through 7, with the exception of interviews and surveys with children.

Modifications to the protocol or consent form that the RC Chairman is **NOT** authorized to approve by expedited review include:

1. Addition of a new drug

2. Addition of a new device

3. Addition of an invasive procedure

4. Increase in medication dose or a decrease in dose that may increase the risk to the subject.

5. Addition of vulnerable subjects as a study population.

6. Prolongation of a patient's participation in the study other than for observational purposes.

7. Change in the inclusion/exclusion criteria which may involve incorporation of populations at greater risk.

8. Identification of new potentially significant risks.

9. Collection of additional blood samples that exceed the limits set in expedited category.

4. RESEARCH THAT MAY BE EXEMPT FROM RC REVIEW

Some very specific forms of research may be exempt from RC review and may not require a subject's consent. It is important to note that the study of existing data (retrospective chart reviews) or the use of discards of tissue taken for clinical reasons can **only** be exempted from RC review **if** the information is recorded in such a manner that the subject can **not be** identified, either directly or through a code linked to the subject (i.e., the identity of the subject is not or may not be readily ascertained by the Investigator or associated with the information). It is also important to note that the types of research that can be exempted must pose **NO** risks to the subjects.

Research protocols that may be eligible for exemption from RC review must be submitted to the Research Committee for registration and approval by RC and must contain a statement that justifies the request for exemption.

NOTE: None of the exemptions apply to Research Minor, Prisoners, Fetuses, Pregnant Women or Human in Vitro Fertilization.

4.1 Categories of research that may be exempt from RC review

1. Research involving the collection or the study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the Investigator in such a manner that **SUBJECTS CANNOT BE IDENTIFIED, DIRECTLY OR THROUGH IDENTIFIERS LINKED TO THE SUBJECTS.**

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior UNLESS:

a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

b) Any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or

be damaging to the subject's financial standing, employability, or reputation.

3. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

a) Research on regular and special education instructional strategies, or

b) Research on the effectiveness or of the comparison among instructional techniques, curricula, or classroom management methods.

5. SUSPENSION/TERMINATION OF RESEARCH PROJECTS BY THE RC

The Research Committee rules and regulations require that all research in human subjects be reviewed by the RC annually. Consequently, administrative extensions **cannot** be granted beyond the approved project period. (Maximally one year). Enrollment of new subjects and or performance of research beyond the RC approved project period is prohibited by RC regulations. Accordingly, any project that has not received the RC's final approval for continuation, prior to the project's expiration date, will be automatically suspended on completion of one year from approval.

For the safety of subjects who are enrolled in research projects in which investigational therapy is being administered, the Research Committee may approve short-term continuation of the therapy beyond the RC approval date ONLY IF abrupt cessation of that therapy would be detrimental to the patient's health. Although all Investigators are reminded of the upcoming expiration of RC approval of their projects, it is the investor's ultimate responsibility to ensure that the RC approval is continuous. If RC approval has expired, and a research subject requires the investigational therapy, then it is critically important that the Investigator rapidly reinstates the research project.

5.1 Reinstatement: Reinstatement and approval of a research project requires that the RC review and approve the following at a convened meeting of the RC:

1. A complete progress report;
2. A memo to the RC Chairman that incorporates the following information:

    a. An explanation of circumstances that led to the failure to submit the application at the appropriate time;
    b. A statement indicating whether patients were enrolled during the period that the project was not RC approved; **AND**
    c. A statement indicating the number of patients maintained on a therapeutic intervention after the expiration date of RC approval and why abrupt cessation of that therapy would have been detrimental to patient's health.

NOTE: Funding agencies and sponsors in general require that the RC notify them of any suspension or termination of a research project. Consequently, it is clearly in the best interest of the research subjects and all investigators that progress reports receive RC approval prior to their date of expiration of RC approval.

SECTION III

CONSENT PROCEDURE

1. PROCEDURE FOR CONSENT IN RESEARCH AT HMC

What is consent?

Research consent is the prospective subject's agreement to participate in a study as a subject, which is reached after assimilation of essential information. The process of informing involves the transmission of essential ideas and contents from the investigator to the prospective subject, before his participation in a study.

1.1 Requirements for an informed consent:

To be ethically and procedurally correct, the informed consent process has to consider 4 essential requirements which are:

a. Disclosure of essential information

b. Ability of the prospective subject or legal guardian to comprehend and retain the disclosed information

c. Competency to take decisions

d. Voluntariness

Requirement 1: Disclosure of essential information

The process of educating subjects about the study is the first step of the consent process. This is an ongoing process and continues through out the duration of the participant's involvement in the research. Informed consent requires the researcher to disclose specific information to each prospective subject.

The following important information is required to be disclosed to each prospective subject.

1. **Introduction to the research:** An introduction is given to each prospective subject before his/her participation in a study. This should include the fact that
   - A study is going to be conducted
   - The subject is being invited to participate in the study
   - Routine care / Research :If the subject is a patient already under the care of the care giver, he is required to be informed of what parts of the study come under the purview of routine care and what under

research activities

2. **Statement of the research purpose :**

   (State the purpose of the research – what it hopes to achieve)

   - State the long term goals and specific aims/objectives of the research

3. **State that the subject can withdraw/ decline participation in the study at any point , even before commencement of the study:**

4. **State the expected duration of the subject's participation in the study:**

5. **State that the results from the study might be publicized through the print media, at conferences etc:**

6. **Selection of research subjects :**

   - State why the subject was chosen as a possible subject for the research
   - What the inclusion and exclusion criteria were that were used
   - Information on the number of subjects that will participate in the study

7. **Explanation of procedures to be used :**

   - Give a description of all the procedures or courses of treatment that would be used in the study , should the subject consent to participate in it
   - Disclosure of those procedures which are possibly experimental in nature (not tested before or tested on animals only)
   - Description of all the study elements that would be measured or the variables that would be used in the study
   - Description of all the procedures that would be used to measure those variables
   - Information on when the study procedures would be done
   - Information on how many times the procedures would be done
   - Information on where the procedures would be done
   - Information on who would conduct the procedures

8. **Description of risks and discomforts involved**

   Prospective subjects are informed of:

   - Any reasonably foreseeable risks or discomforts to the subjects

- The risks or benefits of the study , which should include a description of the physical, emotional, social and economical costs to the subjects
- Description of what the investigators would do to reduce those risks
- For studies involving more than minimal risk, a description of any compensation to be provided in case of injury because of the study
- A description of any medical treatments available for the prospective subjects if injury occurs to the prospective subjects during the course of the study
- An exact description of the type and extent of the medical treatments available in case of injury during the research, duration of the availability of the treatment, costs of the treatment, who will provide such treatment, the person to contact in case of such an injury etc..,
- In certain researches, a description is provided as to whether the particular treatment involves risks to the subject, his/ her reproductive function, injury to unborn embryos, or fetuses or genetic cells, which may or may not be currently foreseeable
- A description of whom to contact for answers pertinent to questions about the research injuries and also whom to contact to get answers pertinent to questions
- About the research and the research subject's rights

9. <u>Description of Benefits:</u>

- A description of any benefits the prospective subject may get as a result of participation in the research
- A description of benefits any others may get as a result of the prospective subject's participation in the research
- Any financial, or material advantages that the subject may receive are also described in detail

10. <u>Description of alternatives :</u>

- A description of all appropriate, alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.
- A statement that even if the subject chooses to have the alternative treatment, there will be no costs for him /her because of refusal to participate in the research

11. <u>Assurance of anonymity and confidentiality:</u>

- Description of the extent and the period during which their responses

and records will be kept confidential.

- Description of whether any of the data collected during the research will be included in the patient files and could be accessed by those not conducting the study.

- An assurance to the prospective subject that their identity will remain anonymous in reports and publications made from the study.

- Offer to answer questions or get doubts clarified at any time during the conduct of the study.

- An offer is made to the prospective subject to get answers to any questions that might be asked at any time during the study

12. **Contact details of whom to contact for answers related to the research and research subject's rights, in case of injury or for compensation and how to contact that person:**

13. **An offer to the participant to consult a trusted person to discuss the study and whether to participate in it (especially in studies that involve more than minimal risk):**

14. **Non coercive disclaimer:** A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is other wise entitled. The caregiver participant relationship will continue as such in spite of the participant's refusal to participate in a study

- Description is given to the subject that there is no element of coercion for participation in the study.

- A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject might otherwise be entitled

15. **Option to withdraw from the study:** Subjects are informed that they may discontinue participation or withdraw from the study at any time without any penalty or loss of benefits.

- Researcher can ask if the participant will be able to participate in the study until its completion and they have the right to not include a subject who they feel might not continue to participate until the end of the study

16. **Termination of the study :**

- A description is provided to the participant about what the circumstances are in which a subject's participation may be terminated, notwithstanding the agreement on the consent form.

- Description of when it might be dangerous to continue the study as it may be dangerous to the participant and under what circumstances the researcher can

terminate the study

- Description of when the study itself might be terminated

17. <u>Conditions for incomplete disclosure of information :</u>

- In certain studies , the subjects are not informed before hand of the purpose of the study as that knowledge might alter the subject's actions and affect the outcomes of the study

- In certain situations, the prospective subjects have to be informed that certain information is being deliberately withheld from them during the conduct of the study.

- Information is also provided that there are no undisclosed risks to the subjects that are more than minimal and that all questions from the subjects are being truthfully answered except that certain information is being deliberately withheld from him/her.

- Information has to be given to such participants as to when they can be debriefed about the study after its completion.

- At the end of such a study, and if requested by the subject, the researcher is obliged to debrief the subjects by informing them about the actual purpose of the study and the results obtained from the study.

<u>Requirement 2</u>: Ability to comprehend all the above information

All the prospective subjects must have the ability to comprehend the information given them by the researchers. Adequate time should be spent to teach the prospective subjects about the research. Amount of information to be provided depends on the already existing knowledge on the topic of the research that the subject might have. The following points must be kept in mind;

1. Benefits and risks have to be explained with relevant examples.

2. Language used should be one that the participant or his representative understands and comprehends.

3. The procedures specifically to be used in the study and the subject's rights have to be explained in the presence of witnesses

4. Consent information has to be written and explained in lay terminology and not professional jargon and presented in a simple and straightforward way such that there is no coercion to participate in the research.

5. The wording of the consent form may be different for different researches and this difference in consent forms occurs under the assumption that the prospective

subject has the ability to understand and comprehend simple statements in that language.

6. Comprehension of the subject can be checked by asking questions like:

   - What is the purpose of the study?
   - What are the risks involved in the study procedures?
   - What will your participation in the study involve?
   - How long will you need to participate in the study?
   - Can you move out of the place while the study is going on?
   - Can you withdraw from the study?
   - Will your name appear anywhere in the research?
   - Will anyone else be able to identify your participation in the research?
   - Who are the people who might have access to your information?
   - What are the possible benefits of your participation in the study?

Requirement 3: Competence to take decisions

The first part of the competence to take decisions is the competence to give consent, which is elaborated below.

1. **Competence to give consent**: Any adult, who is capable of understanding and weighing the risks vs. benefits of a research, is competent to give consent for participation in that research. For minors under 18 years it is the legal guardian.

2. **Incompetence to give consent**: Persons with diminished autonomy like subjects with legal or mental incompetence, persons with terminal illness, persons confined to institutions (e.g. refugees, prisoners, minors etc.) may not be competent to give consent.

The researcher must make every conceivable effort to make sure that information for consent is provided to these potential subjects or their legally authorized representative at a level that they understand, and will be involved in a research project requiring their consent.

In addition, the researcher has to provide all the consent information to the legally authorized representatives or guardians of the prospective subjects.

Requirement 4: Voluntariness of consent

This means that the prospective subject has decided to take part in the study of his or

her own volition, without coercion or any undue influence. This can be achieved only after complete information has been provided to the subject and the ability of the subject to comprehend the information has been assessed and ensured. The authority certain researchers might have over potential subjects, in the course of the caregiver patient relationship should not be misused to exert subtle coercion on the subjects. Also the rewards offered to potential subjects must be congruent with the risks the subjects might take.

1.2 Add Additional Elements of the Informed Consent Which Should Be Provided To Each Subject When Appropriate

1. **Unforeseeable risks**: A statement must be added in the consent form in certain researches that there might be hitherto unforeseen risks to the subject, to the embryos, fetuses or to germ cells, especially in subjects who are women in the reproductive age group, which are currently unforeseen.

2. **Termination of participation**: A statement must be added in the consent form of certain researches about anticipated circumstances under which the subject's participation might be terminated by the PI, without regard to the subject's valid consent for termination in the research.

3. **Costs of participation in the research**: Any additional costs that might occur to the participant because of participation in the study.

4. **Consequences of withdrawal from the study**: The consequences of withdrawal from the study must be clearly explained to the participant both orally and on the consent form. The consequences for termination of participation in the research by the participant must be also clearly explained.

5. **Findings of the research**: A statement that significant new findings developed during the course of the research will be intimated to the subject (if requested by the subject) as and when developed. This may or may not relate to the subject's willingness to continue participation in the research.

6. **Post trial access** : A statement (for clinical trials) that at the end of a trial, every subject should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study , proved to be beneficial in the study or to access other appropriate care. Such post trial benefits should be carefully arranged for and reviewed by the Research committee.

7. **Benefit sharing in the event of commercialization of the products obtained from a research**: In instances of possibilities of commercialization of products obtained from a research, the agreement between the participant and the Researcher must be drawn clearly up on the consent form and information given to the participant verbally too. The details of this agreement must be informed to the Research Committee too.

8. **Contact details of the Chairman of the Research Committee** in the event of appeal against violation of rights of the subjects: The contact details of the

Chairman of the Research committee can be included in the consent forms and in the investigators' assurance forms, to give the participant the opportunity to ask questions about the research from a competent uninvolved third party.

9. **For genetic studies or for HIV testing**, counseling for consent has to be given: In special situations which involve genetic material, adequate time must be spent with the participant to explain the risks and benefits and confidentiality issues.

10. **Information about the storage period of biological samples** and related data offered to the participant , regarding future use of sample, refusal for storage and receipt of the results : Details of where the genetic material collected during the course of a study will be stored, how long they will be stored etc .., must be included in the consent form .

11. **For case reports or case series**: involving live participation signed informed consent must be taken from the subject (s) if the report is planned to be published.

12. **Fresh or re-consent is done under the following circumstances** :

- Availability of new information which would necessitate deviation from the research protocol.
- When a research participant regains consciousness from an unconscious state or becomes mentally competent from a state of incompetence or becomes legally competent to understand the study and give consent.
- When long terms follow up or extensions of the study are planned for the future.
- When there is a change in treatment modality, procedures, frequency of site visits etc.
- Before publication, if there is a possibility of disclosure of identity of the subject through data presentation or photographs – this is especially in the case of case reports.
- Obtaining legal adult age.

2. ETHICAL ASPECTS OF THE INFORMED CONSENT

The use of patients or healthy volunteers or children or participant information in research is a privilege, which carries with it moral and ethical obligations that must be met with scrupulously by the investigators.

a. **Respect of the rights, dignity and safety of the research subjects** (participants) must be the primary determinant of the researcher's actions. The ethical principles of respect for human dignity, beneficence and justice must be scrupulously adhered to.
b. **At all stages of a research project involving human subjects or use of their private and confidential information,** vigilance must be

maintained by the investigators in order not to jeopardize these rights.

c. **As autonomous individuals,** research subjects have a right to be fully informed about the nature of the research and the extent of their participation.
d. **They must be free** to agree to or to refuse to participate in the research.
e. **There should be fairness** in the selection of subjects, access to research findings, information or research outcomes from the outset till the completion of the research.
f. **Participants are entitled** to the right of confidentiality and anonymity of their private information throughout the course of the research.
g. **In addition,** subjects must be free to withdraw their participation at any time, with or without explanation.

Circumstances which could put subjects at risk if they withdraw and procedures of withdrawal must be described in the consent document.

3. GUIDELINES FOR INVESTIGATORS ABOUT CONSENT ISSUES

3.1 Who can provide consent?

- Consent must be provided by the prospective participant him/herself before the study has commenced.

- In case of a minor / child, the parent or legally authorized representative must provide consent.

- In case of children who are able to comprehend things, (child above 7 years; comprehending ability assessed by the investigator) an assent should be taken from them in writing in addition to the signed consent from the parent or legally authorized representative.

3.2 Participant advocate

In certain researches, the Research Committee might allow the use of an individual who has no vested interest in the research and who agrees to act as an impartial third party in the consent process to act in the best interests of the participant by sharing in discussions with the investigator and with those responsible for providing consent. Individuals who fulfill these roles might be the participant's primary care physician or other health care professional not involved in the research. The participant advocate is responsible along with the PI to ensure that the participant understands the research procedures and the risks and potential benefits of participation and that his/her consent is free and voluntary. When a participant advocate is used in the research, he/she must also sign and date the consent form. Participant advocates might be used when:

- When the risks to the participants are significant and the participant is the patient of the investigator and as such may feel obligated to participate.
- When consent is to be obtained in the emergency room or in an emergency situation when the time frame to obtain consent prior to the start of the

study related procedures is limited

- When surrogate consent is to be obtained for research involving more than minimal risk with the potential for direct benefit to the participant.

3.3 Who can solicit an informed consent? What is the process?

- **The Principal Investigator**: Obtaining informed consent is the legal and ethical responsibility of the Principal investigator. For most studies involving more than minimal risk and all experimental interventional studies, a qualified physician investigator listed on the research protocol's list of investigators must obtain informed consent.
- **The Co investigator**: The Principal investigator might delegate this task to a named co- investigator of the research proposal, who is familiar with all aspects of the proposed research and who may have made a substantial contribution to the design and writing up of the research proposal.
- **Study nurses**: Study nurses or nurses who assist physicians in routine clinical care might assist the consent process but physicians should take the responsibility for conveying the information about the research study to the prospective participant and should not delegate this vital responsibility to nurses. A study nurse might be allowed to obtain informed consent only if that nurse would be permitted in a clinical setting to perform the procedures for which the consent is required.
- **Delegation of consent responsibility**: For studies involving more than minimal risk or procedures other than those done in the process of routine clinical care, consent must be obtained by the Principal Investigator or the investigator performing the procedure. At times when it would be impracticable and when it might prevent the research from being performed (if only the Principal investigator or his Co-investigator is allowed to obtain consent), the RC might allow the delegation of the consent responsibility to other appropriate professionals only if the rationale and justification for this are provided to the RC - requests to delegate this responsibility will be considered by the RC on a case by case basis.
- **Training of delegated individuals in the consent process**: Delegated individuals must be specifically trained by the P.I. or Co- investigator in all aspects of the research protocol, the information to be provided to the prospective research participant, the procedure of obtaining consent, the

names, positions in the corporation, professional affiliations etc.., must be submitted for RC approval when the delegates are chosen and before they are authorized to obtain any consents. Documentation of the qualifications and training of the relevant staff must be submitted to the RC for review and approval. The Delegated personnel are not responsible for the conduct of the research.

- **Enrolling participants from the physician's own patients:**

  In case the PI plans to enroll participants from the investigator's own patients, consent procedures must be put in place to ensure that participants do not feel obligated to participate because the investigator is their treating physician. There should be absolutely no coercion or obligation on the patient to participate in the research. If patients are being enrolled, there can be 3 options for obtaining consent;

  - Physicians can obtain consent from their own patients if there is no coercion or obligation involved from both sides.
  - If physician investigators feel that they may be putting their own patients under obligation to participate in view of the dependent relationship between them, then they could do it thus:

a) The physician can contact the patient in writing and allow him/her to make the first contact about participation in the research with him/her.

b) The physician can delegate the responsibility to a physician colleague, approved by the Research Committee, to make the initial contact with the physician.

c) The physician could after the initial contact has been established, have a nurse or approved colleague re-contact the patient and offer him/her the opportunity to ask additional questions, raise concerns or opt out. This is after the study has been explained to the patient.

4. WHEN AND WHERE MUST CONSENT BE SOLICITED?

- The setting in which consent is requested or obtained must be one in which the potential subject can consider the request as an autonomous individual, free from time constraints or a sense of obligation or dependency.
- For all but emergency care protocols, it is inappropriate to solicit consent immediately before beginning a procedure or instituting a therapeutic regimen.

A crowded waiting room, public area or operating room / holding area are examples of ***inappropriate sites.***

- **Patients who have received drugs (e.g. sedatives or pre- anesthetic medication) that may impair their ability to understand and weigh the information provided are clearly not capable of giving informed consent.**

- Research proposals must detail where and when consent would be obtained – e.g. Pre admission screening , day of admission , waiting room, hospital room , emergency room , evening before surgery etc..,

- **At all stages of the consent process, every effort must be made to avoid coercion in any form or to any degree.**

5. EFFECTIVE PERIOD OF CONSENT

Although an individual consent document is stamped with the period of RC approval (up to 12 months), the consent does not need to be re-signed by the subject on an annual basis if it is explicitly stated in the consent document that the duration of the study will be greater than one year. However, consent must be re obtained if:

a) The consent document has been altered or amended since the subject signed the document.
b) The subject was a minor at the time of entry into the study and has since attained the age of maturity;
c) The original consent document did not specify the duration of the subject's participation in the study.

6. HOW TO ACCESS THE CONSENT FORMS?

The consent forms can be accessed at: the intranet site of the Medical Research center. **:** http://intranet/deptportal/dept_homepage.asp

6.1 Consent documents

- Only consent documents officially dated with exclusive RC approval dates may be used in the conduct of human subject studies.
- When RC approval is granted, the consent documents will be stamped with the date of approval.
- Under no circumstances may consent documents be used beyond their expiration date.
- The forms used in soliciting consent must provide in writing, all of the information that the subject would reasonably want about the study and the extent of his/her involvement in it
- An investigator shall seek such consent only under such circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.

- The informed consent, whether oral or written , may not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator , the sponsor , the institution or the agents from the liability of negligence.
- By completing the documents, all of the international requirements for informed consent should be fulfilled.

7. LANGUAGE USED IN CONSENT DOCUMENTS

The language used in consent forms must be of the level of grade 8 Arabic and English, understandable by the participant.

If the participant is a non Arabic / English speaker, the consent document must be read to him in his native language and appropriate translations provided.

For translations of consent documents into languages other than Arabic / English, the principal investigator has to use the services of language experts and get the consent form translated appropriately. In addition the help of such language experts must be taken during the consent process itself so that accurate information on the research is provided to the participant.

8. SPECIAL CONSIDERATIONS IN INFORMED CONSENT

In the case of research participants who are likely to be vulnerable to exploitation, such as pregnant women, prisoners, children, students, employees or adults unable to consent, additional safeguards are required to ensure that the rights of those are protected.

8.1 Consent Procedure

a. **Recruitment of subjects:** Protocols submitted to the RC for review and approval must specify how subjects will be identified and recruited.

Patients expect that information on their medical condition will be kept confidential, although an investigator may access this information in the conduct of an RC approved research project. However, many patients would consider it a serious breach of confidentiality and of medical ethics that someone not involved in their care obtained this information and contacted them. For this reason, permission to recruit a patient as a subject in a research study should be obtained from the patient's physician before the patient is contacted. Where possible, the physician should first get permission from the potential subject, to allow the investigator to contact him/her. If this is impractical, a letter can be sent out by the physician informing the patient that the investigator would like to contact him/her. The letter should include a reply card to be returned granting or refusing permission.

b. **Special circumstances during the recruitment of subjects:** If the nature of the study makes the use of these procedures unrealistic, this must be fully justified to the RC by the investigator.

Such studies may require very narrow time durations for the collection of data or involve large numbers of physicians and potential subjects.

In addition, it must be clear that the patients would very likely not be distressed through being contacted by some one not involved in their care. For such studies, individual or "blanket permission" may be obtained from the physician(s) (preferably in writing) to contact a particular patient or all of the physicians' eligible patient. The blanket permission is defined the as consent which is solicited from the treating physician of a patient participant, in circumstances where the patients might not like to be distressed by being contacted by some one not involved in their care, in which case a blanket permission may be obtained from the physician, in writing for contacting patients' who are eligible for participation in the study.

- The investigator may then contact the patient(s) directly, without previous notification, indicating that their physician had given permission for the contact. If blanket permission is obtained and used, the investigator must inform the physician each time a patient is contacted.

c. **Recruitment of family members:** If recruitment of family members is planned, for confidentiality reasons, the index patient should not be asked to provide the name of the family member(s) directly to the investigator. Rather, the index patient should be asked to contact family members for the investigator. If the family member is willing to speak with the investigator, then the family member should be asked to contact the investigator. Therefore, when the research involves family members, the protocol and the consent form must indicate how family members will be contacted.

- Subjects recruited for a research must be free of any outside influences while deciding whether to participate in the research. Even in the absence of overt coercive or inducing statements, an element of coercion may be introduced because of the relationship between the potential subject and the investigator.

Patients may feel obliged to agree because their physicians asked them to participate. Co -workers in an investigator's laboratory, office or clinic may agree in order to preserve the good will of the physician (investigator).

Prospective research subjects must be reassured verbally, that refusal to participate will in no way affect the care that they receive from their physicians. In addition, the

RC strongly feels that workers under the direct supervision of the investigator should not be induced to serve as control subjects. Co-investigators and colleagues (in the specific sense of having a comparable position in the institution) are appropriate potential control subjects.

d. **Advertisement for Research subjects:** All forms of advertising or dissemination of information for the purposes of recruitment of subjects into a research protocol, including newspaper advertisements, posters and fliers or newspaper articles which include recruitment information must be approved by the RC prior to the distribution or publication of the material.

In addition, letters to fellow physicians, both within and outside the institution must be approved. The following information must be present in the advertisement;

1. The purpose of the study
2. The characteristics which would qualify the individual for enrollment
3. A straightforward description of any and all benefits to the subjects
4. The RC number of the protocol and the date of proposed completion of the project
5. The name and number of the person who should be contacted for the participant to get further information about the project.

Nothing in the text of the advertisement should serve as an undue inducement to potential subjects to enter the study. Such inducements might include claims (implicit or explicit) about the safety or efficacy of an investigational drug or device, equivalence or superiority as compared to existing treatments, or closer monitoring of the patient's condition. The availability of compensation for time and effort related to participation can be included without any mention of any specific amount.

8.2 The Consent Process

Step 1: Pre-screening of prospective research participants

This is a process of determining the interest of a participant in a research. If the person is found to have interest, his/her eligibility for participation is verified.

Those participants who respond to advertisements or recruitment letters have shown their interest in the study and also their willingness to be considered for eligibility for the research. Questions to be asked during the pre-screening process address the specific inclusion and exclusion criteria for the study and other issues of suitability like

willingness and ability to come to the research site multiple times.

a. **Pre-screening over the telephone:** Sometimes if prospective participants have been identified through their private medical information like medical records or patient databases, they might be contacted over the telephone.

Important points for consideration are:

- Is this an appropriate time for them to answer these questions?
- Would they like to conduct the pre-screening in person?
- Tell them that only the subject's first name or initials would be recorded at the beginning of the screening conversation.
- Explain to them that he/she would be asked a set of questions to determine eligibility and in the end only if he/she appears to be eligible and is interested in pursuing the study will he or she be asked to provide contact or identifying information.
- For those who are likely to meet eligibility criteria, identifiable health care information is created.
- For those who do not meet entry criteria, only non-identifiable health care information is created.
- If it is feasible, offer the person the option of completing the pre-screening in person.

b. **Pre-screening in person:**

- Investigators may conduct pre-screening in person. This can occur during routine clinical care or while visiting the hospital.
- Complete medical histories and screening physical examinations are unacceptable as they are part of the actual research. These should be taken only after the participant has signed the consent form.
- At times, limited routine clinical procedures might be performed as part of the pre-screening if they directly relate to the eligibility criteria and if the individual verbally consents to having them done before signing the consent forms. In such situations, the investigator must mention this possibility in the proposal and make the Research Committee and its reviewers aware of this possibility.

c. **Retaining information from individuals who are pre-screened but have not been enrolled:**

- It is accepted by the Research Committee that at times, non-identifying information about individuals who have been pre-screened for a research

might be retained by the investigator. This is necessary when the population from which the sample was taken is needed for the data analysis of the research findings.

- Pre-screening sheets from individuals who did not provide identifying information can be retained with no further action.
- Pre-screening sheets with identifying information gathered to obtain written authorization and prior to enrollment may be retained in the research documents but must have the identifiers blacked out if these people are not going to be enrolled.
- If identifiable information is going to be retained, the investigator must obtain written authorization from the persons screened or written authorization from the Research Committee if it is not practical for this to be done.

Step 2: **Providing understandable information**

Information conveyed through any means to the potential participants must be understandable to them and must enhance their understanding of the research.
The language and the medical terminology that should be used are mentioned in detail in part 4 of this book under the section on the recruitment of participants.
If the participants are interested in learning more about the study, they contact the study personnel whose names and contact information are mentioned on the advertisements for the research.

Step 3: Meeting of the investigator with the potential participant.

1. The prospective participant is taken to an appropriate environment. (A crowded waiting room, public area or operating rooms holding area are examples of inappropriate sites).
2. The setting in which consent is requested and obtained must be one in which the potential participant can consider the request as an autonomous individual, free from constraints, a sense of obligation or dependence.
3. The investigator must introduce himself/herself with his name, name of the department, phone number etc...
4. Steps 1-2 can be done on one day and the rest over 2-3 days. The informed consent is not a one time event. It is a continuous process.
5. For all but emergency care research protocols, it is inappropriate to solicit

consent immediately before beginning a procedure or instituting a therapeutic regimen.

6. The potential research subjects are given the information contained in the consent form both verbally and in a copy of the complete form itself.
7. They are allowed time to think about the request, to ask questions and have them answered to their satisfaction.
8. If they agree to participate, the subjects sign in the appropriate place.
9. The person obtaining consent (investigator or legally authorized representative) signs the attestation at the end of the form.
10. Subjects are informed about the purpose of the research.
11. Subjects are informed why they have been selected to participate in the research.
12. Subjects are informed they can ask any questions during the time and if they have any questions after going home, they could contact----------at ---------- phone number at any time of the day or the night.
13. Subjects are informed about the procedures in the research.
14. Subjects are informed about the risks of the research. Describe physiological, psychological and social factors of discomfort or risks involved in the study. Follow these procedures for **Possible Pregnancy Risks**. If there are no risks to pregnant females or females of child bearing age, you do not need to include any of the following statements in the informed consent. If pregnant or nursing women are excluded from the study, a statement supporting the rationale for not including pregnant women needs to be included in the informed consent. For studies that involve the use of drugs, devices or procedures with risks to the fetus in females of child bearing potential, choose one of the following statements: a. There is evidence of potential for birth defects; or b. Animal studies have shown potential for birth defects and there are no human studies; or c. There are no known animal or human data on the potential for birth defects
15. Subjects are informed about the benefits of the research.
16. Subjects are informed about alternative treatments if any.
17. Subjects are informed that there is no compulsion for them to participate in the research.
18. At all stages of the consent process, every effort must be made to avoid coercion in any form or to any degree. The consent must be freely given.

19. Subjects are informed about the duration of the research.
20. Subjects are informed how many times they may have to come to the clinic for the research.
21. Subjects are informed if there is any compensation that will be provided for participation.
22. Subjects are informed about insurance coverage, liability issues etc.., in the research.
23. Subjects are informed about whether the results of the research would be used for their benefit. Would they have access to the results of the research?
24. Subjects are informed about the measures taken to protect their confidentiality and privacy of the participant.
25. Subjects are informed they can withdraw from the research at any time without penalty. Even if such withdrawal takes place, the subject will be eligible for the benefits of the research.
26. Comprehension of the subject is checked by asking a few questions.
27. It would be preferable that potential subjects are given a copy of the informed consent document to take home so that they can carefully read the document and discuss the research with their family members.
28. It is preferable that the investigator allows the potential subjects at least 12 hours to consider participation.
29. If the research includes subjects who will be discharged on the same day as the day of admission or who have come for investigations,, it may be permissible by the Research Committee that the patient's attending physician may be asked to provide potential subjects with research information well in advance to when the study or test or examination is scheduled.
30. When convinced about the comprehension, the subject may be asked to sign on the informed consent form, in triplicate. They need also to date the informed consent document.
    a) Give one copy of the consent form to the subject.
    b) Keep one copy of the consent form in the Medical Record files.
    c) The Principal investigator must keep one copy of the consent form with him/herself for at least 3 years after the completion of the Research. The original completed and signed consent form must be retained for inclusion in the principal investigator's research records.
    d) Use only HMC Research Committee approved informed consent forms

with the seal of the Research Committee on it.

e) All subjects who sign a consent form are considered to have entered the study. The consent documents that they have signed must be retained by the principal investigator, even if they have withdrawn from the study or do not actually participate in the study.

f) Required signatures on the consent forms: Participant or legally authorized representative or the witness is only needed when a third party verbally transmits the consent form to a subject who is unable to read the consent. The third party must sign as a witness to affirm that the consent was accurately translated and that the subject understood the information provided. Finally the investigator or a RC approved delegate must sign the consent form.

g) Persons delegated to obtain consent by the principal investigator should make every effort to notify the principal investigator of the recruitment of a subject before that subject actually begins participation in the research project.

h) It is the responsibility of the PI to ascertain that a properly completed consent form, as required for the particular protocol, has been obtained by the delegate(s) and those copies of the consent have been filed or distributed as required above.

31. Consent process may need to be repeated if there is any change in the protocol, if any additional samples are needed from the participant etc..,
32. Some participants may want to give part consent to some parts of the research and not others- this is called layered consent.

8.3 Types of Consent

1. **Signed informed consent:** This is taken for all prospective studies which involve more than minimal risk to the participant. **Minimal risk** is defined as the risk that a person might be exposed to in the course of his activities of daily living or during the performance of routine physical or psychological tests. For research purposes, minimal risks is taken as research that involves no procedures for which written consent is normally required outside of the research context.
2. **Waiver of signed informed consent:** Waiver of signed informed consent is given in those situations in which research presents no more than minimal risk

of harm to the subject and the research involves no procedure for which written consent is normally required outside of the research context and the consent document would be the only identifiable link between the subject and the research and there would be potential harm to the subject if the confidentiality of the consent document is breached.

- Waiver of a signed consent may granted for researches that involve activities like **drawing** of additional blood samples when blood is already being obtained for clinical reasons or blood donation, **sampling** of additional bodily secretions when such secretions are already being sampled for routine procedures, researches using **questionnaires** without participant identifying information being recorded**,** researches which involve **interviews** with participants where again collected information cannot be traced back to the person from which it was obtained **and /or chart reviews** as a preliminary to other prospective studies.
- A waiver of signed consent may be obtained by an investigator, but it does not exempt an investigator from obtaining informed consent from the participant. In this form, a research participation information sheet is read to the patient and signed by the PI or a person delegated to obtain informed consent. A copy of the signed information sheet must be given to the subject and the investigator must keep the original form in his research records.
- Investigators must be aware that procedures that physicians consider to be minimal risk are not necessarily viewed as such by patients or research subjects. They should be sensitive to the subject's perception of the procedure when classifying procedures as minimal risk.
- All of the elements of informed consent required in signed consent must be included. At the end of the information sheet include the following paragraph verbatim and include the signature lines.

I have fully explained to Mr./ Mrs…… the nature and purposes of the above described research program. I believe that he/she understands the nature, purposes and any risks of these studies. I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions.

Signature:

Date:

Name of the Investigator:

Title:

3. Waiver of informed consent: Investigators may ask for waiver of informed consent for a study. The RC can only grant a waiver of informed consent when all five of the following are applicable:

a. No more than minimal risk, as defined above, to the subject involved.
b. The research could not practically be carried out without the waiver.
c. The research will not adversely affect the rights and welfare of the subject.
d. The subjects will be provided with additional pertinent information after participation, whenever applicable.
e. Chart reviews and retrospective studies.

NOTE: A request for waiver of informed consent must be submitted to RC with the research proposal.

4. **Re- consent: Participants who have once consented for a research might be asked to sign a new consent form if:**

   - When they are actively involved in a research and there have been major changes in the consent form e.g. drug dose, device, study procedures, risks, discomforts, benefits and alternatives. This has to be done if knowledge of the new information might affect the subject's willingness to continue participation.

5. **Layered consent:** "Layered consent" refers to the option of permitting research subjects to consent to some parts of a protocol and not others.

6. **Fully restricted consent:** Here the participant restricts the use of the samples to the immediate research only and does not consent to its use in any future research.

7. **Partially restricted consent:** The participant consents to the use of the samples in the immediate research and in future researches of a specified type(s) and unto a specified time in the future.

8. **Unrestricted consent:** The participant consents to the use of the samples in the immediate research and in future researches and also at any time in the

future (indefinitely).

8.4 Elements of the different types of consent outlined above

Signed informed consent: This is taken for all prospective studies which involve more than minimal risk to the participant. **Minimal risk** is defined as the risk that a person might be exposed to in the course of his activities of daily living or during the performance of routine physical or psychological tests.

Medical Research Centre has prepared guidelines for writing consent forms for prospective studies. This is a general consent form format to be used according to the need of the research study design. Each item should be described according to its given description.

A. GENERIC CONSENT FORM

(Format to be used for the signed informed consent)

Format:

1. Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. The information in this form is meant to better inform you the purpose of the research and any possible risks or benefits. You are free to ask questions at any time before, during, or after your participation in this research.

2. **Project ID No. & Title:**

3. **Principal Investigator:**

4. **Location:**

5. **Phone:**

6. **Purpose of this Research Study**: (Describe the purpose of the research in simple, non-medical, non-scientific terms easily understood by participants at a lower reading

level, including the number of participants)

7. **Procedures:** (Describe procedures that are experimental/investigational/non-therapeutic and define expected duration of the subject's participation along with indicating type and frequency of monitoring during and after the study. If research is involving randomization of participation into different arms/groups of studies, specify the randomization procedures. Define the dose, placebo and other terms clearly i.e. if blood is drawn, describe the amount to be drawn and to common measures such as teaspoons or tablespoons etc)

8. **Possible risks or discomfort:** (Describe each intervention with subheading for known/unknown possible risks. If there are special risks to women of childbearing age; if relevant, state that study may involve risks that are currently unforeseeable, e.g., to developing fetus. Any new information developed during the study that may affect willingness to continue participation should also be communicated. It should also be mentioned that a particular treatment or procedure involves risks that are currently unforeseeable to the subject. Give measures which will be employed to minimize the risks and discomforts listed)

9. **Possible benefits:** (Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit to the subject, explain possible benefits helpful to others)

10. **Financial considerations for subjects:** (If applicable explain any financial compensation involved, describe the amount to be paid, and when payment is scheduled etc. Also describe any additional costs i.e. reimbursement for expenses such as parking, bus/taxi, travel etc. to the subject that might result from participation in this study for more than minimal risk or state there is no financial compensation for participation in this research for minimal risk.)

11. **Payment to Researchers:** (If applicable, describe any compensation being paid to the Institution or Principal Investigator by a third party).

12. **Available alternative treatment** (if applicable)
    (If the procedure involves an experimental treatment and non-experimental or

conventional treatments are available, provide all the pros and cons with relative risks (if known) of each)

13. **Available Medical treatment for adverse experiences:** (if applicable)
    (If the study involves greater than minimal risk and the subject is injured as a direct result of taking part in this research, describe the procedure of emergency medical care, name of responsible persons, contact numbers etc with available facilities like transportation and concerns about the intervention or procedure. Also describe, if any, about long-term medical treatment or financial compensation or whatever remedies available at law)

14. **Confidentiality: It should consist of** "Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you. However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor, by any relevant government agency, by the RC, or by the persons conducting this study provided that such inspectors are legally obligated to protect any identifiable information from public disclosure, except where disclosure is otherwise required by law or a court of competent jurisdiction. The records will be kept private in so far as permitted by law". In addition, list of steps to protect confidentiality such as codes for identifying data should be provided.
15. **Termination of research study:** You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study, the potential consequences that may result are …….. (Give list). You can notify (Name, telephone no, etc) of your decision or follow this procedure (describe), so that your participation can be orderly terminated. In addition, the investigator may terminate your participation in the study without your consent under the following circumstances (describe). It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the subjects in the event that (describe circumstances, such as loss of funding etc.)
16. **Available source of information:** Any further query you may have about this study or

your rights as a research subject will be answered by the Principal Investigator:

Name:

Phone Number:

Please call in case of research related emergency:

Day emergency Number and Night number emergency number:

17. Authorization:

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Qatari laws.

Participants Name (Printed or typed):

Date:

Participant Signature:

Date:

Principal Investigator Signature:

Date:

Signature of Person obtaining consent with Date:

B. CONSENT IN CASE OF A MINOR CHILD/STUDENT (AGE LESS THAN 18 YEARS) PARTICIPATING IN RESEARCH STUDY

Format:

Your child has been invited to participate in this research study. You are requested to read this consent form carefully and can ask as many questions as you like before you decide whether you want your child's participation in the research. You are free to ask questions at any time before, during, or after your child's participation.

- **Name of principal investigator:**
- **Project title:**
- **Location:**
- **Phone:**

- Describe the terms given below as they are described in generic consent form and relate them in relation to child/student wherever applicable:
    a. Purpose; 2. Procedures; 3. Possible risks or discomfort; 4. Possible benefits; 5. Financial considerations for participation (if applicable); 6. Payment to researchers (if applicable); 7. Available alternative treatment; 8. Available medical treatment for adverse experiences (if applicable); 9. Confidentiality; 10. Termination of research study; 11. Available source of information, for any further query you may have about this study or your rights as research participant, will be answered by the Principal Investigator.

Authorization: I have read this parental permission form and have been given the opportunity to ask questions. I give my permission for my child to participate in this study.

Parent's/ Guardian's Name:

Parent's/ Guardian's Signature:

Date:

Child/student's Name:

Student's Signature:

Principal Investigator Signature with Date:

Signature of person obtaining consent with Date:

C. WAIVER OF SIGNED INFORMED CONSENT /VERBAL/ORAL CONSENT

Waiver of signed informed consent is given in those situations in which research presents no more than minimal risk of harm to the subject and the research involves no procedure for which written consent is normally required outside of the research context or the consent document would be the only identifiable link between the subject and the research and there would be potential harm to the subject if the confidentiality of the consent document were breached.

Waiver of a signed consent may be granted for researches that involve activities like **drawing** of additional blood samples when blood is already being obtained for clinical reasons or blood donation, **sampling** of additional bodily secretions when such secretions are already being sampled for routine procedures, researches using **questionnaires** without participant identifying information being recorded**,** researches which involve **interviews** with participants, where again collected information cannot be traced back to the person from which it was obtained **and/or chart reviews** as a preliminary to other prospective studies.

- A waiver of signed consent may be granted to the PI, but it does not exempt an investigator from the obtaining informed consent from the subject. In this form, a research participation information sheet is read to the patient and signed by the PI or a person delegated to obtain informed consent. A copy of the signed information sheet must be given to the subject, a copy should be placed in the subject's record, and the investigator must keep the original form in his research records.
- Investigators must be aware that procedures that physicians consider to be minimal risk are not necessarily viewed as such by patients or research participants. They should be sensitive to the subject's perception of the procedure when classifying procedures as minimal risk.
- All of the elements of informed consent required in signed consent must be

included. At the end of the information sheet include the following paragraph verbatim and include the signature lines.

-

General Instructions

1. **Purpose of research study**: (Describe the intended goal of the research and also that a sample of blood or tissue from the participant will be used for genetic research)
2. **Procedures:** (Brief, clear explanation of procedures involved in a chronological order and state how much time will be required for clinic visit or for procedures; if blood is to be drawn, indicate the amount that will be drawn in the participant's language; if there is a possibility that other investigators might be given access to samples of genetic information for research in the future, the participants must be informed of this and specifically must consent to this possibility
3. **Gathering of background information:** (If there is any intention to gather genetic information from the participant's medical records , permission must be obtained for this too; in addition, if there is any intention to gather information about participant's relatives, the participant must be informed of this possibility and the type of information gathered should be described; if information from relatives will be collected, explain what measures will be taken to protect the privacy of the participant's relatives).
4. **Duration of storage of samples/ specimens / information:** (Provide information to the subject about how long the samples will be used/stored. If samples might be stored for potential future use or commercialization, participants must be informed of this and should be given the option to provide layered consent)
5. **Risks and discomfort** (Describe physiological, psychological and social factors of discomfort or risks)
6. **Safety** (Describe about the safety precautions that will be taken during study period)
7. **Injury or enquiry** (In case of any types of injury or enquiry, provide name of supervisor and office phone number to contact)
8. **Benefits** (Brief description of any direct or indirect benefits to the subject)
9. **Financial considerations for participants if any.**

10. **Alternative treatment if available** (including the option to participate in the research and if the study involves an experimental treatment, participants must be offered the option to participate in the treatment arm of the study without participating in the genetic or tissue storage part of the study)
11. **Costs of the study:** (mention if there are any costs to the participants; inform participants of costs not covered etc.; if participants are compensated for expenses associated with participation, indicate how the amount will be paid etc..,)
12. **Conflict of interest:** (Mention that the participants' samples will be used or not used for commercial development, whether the developed products might be patented or licensed to a company; mention if there are plans to provide financial compensation for such use, financial conflict of interest etc ..,)
13. **Confidentiality** about the results/specimen/laboratory or any other data (Describe steps to protect confidentiality of data in HMC or in other places; who will be the recipient of such information; the fact that the participant's name will not be used for publication).
14. **Identifiers:** (Mention that the blood samples taken from the participants will not be stored with your name or identifier; withdrawal from participation will result in the destruction of all blood/tissue samples or genetic or other information)
15. **Subject access to genetic information:** (If findings of the research are to be disclosed to the participant, describe the disclosure procedures, who would make the disclosure, to whom must be provided; participants are to be informed if they will be contacted if the results of the study are found to have clinical relevance in the future or for any other reason; also explain that a participant may be informed of new findings that may affect the participant or his/her wish to continue participation ; if no disclosures will be made, explain why)
16. **If the investigator is also the participant's health care provider:** (Mention that the participant's health care provider is one of the investigators in the research and that as an investigator , he/she is interested in both the clinical welfare and the conduct of the study; the participant can take a second opinion before entering the study or at any

time during the study; the participant is not under any obligation to participate in the research)

17. **If employees of HMC /residents/ students etc are being included as research participants:** (A statement must be included that such participation is purely voluntary and that he/she is free to choose to participate/not to participate in the research; that he/she might withdraw from the research at any time without any change in his/her relationship with the investigator, the investigator's department, HMC or his/her grades)
18. **Consent:** I have read (or someone has read to me), have understood this consent form; have been given opportunity to ask questions, and also all my questions have been answered to my satisfaction. By signing this form, I willingly agree to participate in the research it describes.

I have fully explained to Mr./ Mrs…… the nature and purposes of the above described research program. I believe that he/she understands the nature, purposes and any risks of these studies. I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions.

Signature:

Date:

Name of the Investigator:

Title:

D. <u>WAIVER OF INFORMED CONSENT</u>

In general, RC Bylaws require that research subjects sign a consent document. Under very specific circumstances, the RC may totally waive the requirement for obtaining informed consents. The information below is intended to provide investigators with clear guidelines regarding instances where informed consent may be waived.

A waiver of informed consent **<u>can only be granted</u>** when **ALL 5** of the following are applicable:

1) No more than minimal risk to the subject is involved; <u>and</u>

2) The research could not practically be carried out without the waiver; and
3) The research will not adversely affect the rights and welfare of the subject; and
4) The subjects will be provided with additional pertinent information after participation, whenever appropriate; and
5) Chart reviews & retrospective studies.

Definition of minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests. (A test or medication is indicated and needed for the subject condition according to standard practice).

Note: A request for waiver of informed consent must be submitted to RC with the research proposal.

For any query/clarification Researchers may contact Medical Research Centre via e-mail (research@hmc.org.qa) or phone (+97444392440).

E. GENERIC SIGNED INFORMED CONSENT FORM FOR GENETIC RESEARCH AT HAMAD MEDICAL CORPORATION (HMC), DOHA, QATAR

(Format for the genetic consent form)

Format:

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits.

General information

1. Project title:
2. Name of Principal Investigator:
3. Names of co-investigators :
4. Address and phone number of :

General Instructions:

1. **Each item given below has to be filled in. Please write NA, if not applicable.**
2. **One copy of this consent form must be given to the research participant.**
3. **One copy of the consent form must be filed in the subject's file in the Medical**

Records department.

4. **Purpose of research study**: (Describe the intended goal of the research and also that a sample of blood or tissue from the participant will be used for genetic research)
5. **Procedures:** (Brief, clear explanation of procedures involved in a chronological order and state how much time will be required for clinic visit or for procedures; if blood is to be drawn, indicate the amount that will be drawn in the participant's language; if there is a possibility that other investigators might be given access to samples of genetic information for research in the future, the participants must be informed of this and specifically must consent to this possibility
6. **Gathering of background information:** (If there is any intention to gather genetic information from the participant's medical records , permission must be obtained for this too; in addition, if there is any intention to gather information about participant's relatives, the participant must be informed of this possibility and the type of information gathered should be described; if information from relatives will be collected, explain what measures will be taken to protect the privacy of the participant's relatives).
7. **Duration of storage of samples/ specimens / information:** (Provide information to the subject about how long the samples will be used/stored. If samples might be stored for potential future use or commercialization, participants must be informed of this and should be given the option to provide layered consent)
8. **Risks and discomfort** (Describe physiological, psychological and social factors of discomfort or risks)
9. **Safety** (Describe about the safety precautions that will be taken during study period)
10. **Injury or enquiry** (In case of any types of injury or enquiry, provide name of supervisor and office phone number to contact)
11. **Benefits** (Brief description of any direct or indirect benefits to the subject)
12. **Financial considerations for participants if any.**
13. **Alternative treatment if available** (including the option to participate in the research and if the study involves an experimental treatment, participants must be offered the option to participate in the treatment arm of the study without participating in the genetic or tissue storage part of the study)
14. **Costs of the study:** (mention if there are any costs to the participants; inform participants of costs not covered etc.; if participants are compensated for expenses

associated with participation, indicate how the amount will be paid etc..,)

15. **Conflict of interest:** (Mention that the participants' samples will be used or not used for commercial development, whether the developed products might be patented or licensed to a company; mention if there are plans to provide financial compensation for such use, financial conflict of interest etc ..,)
16. **Confidentiality** about the results/specimen/laboratory or any other data (Describe steps to protect confidentiality of data in HMC or in other places; who will be the recipient of such information; the fact that the participant's name will not be used for publication).
17. **Identifiers:** (Mention that the blood samples taken from the participants will not be stored with your name or identifier; withdrawal from participation will result in the destruction of all blood/tissue samples or genetic or other information)
18. **Subject access to genetic information:** (If findings of the research are to be disclosed to the participant, describe the disclosure procedures, who would make the disclosure, to whom must be provided; participants are to be informed if they will be contacted if the results of the study are found to have clinical relevance in the future or for any other reason; also explain that a participant may be informed of new findings that may affect the participant or his/her wish to continue participation ; if no disclosures will be made, explain why)
19. **If the investigator is also the participant's health care provider:** (Mention that the participant's health care provider is one of the investigators in the research and that as an investigator , he/she is interested in both the clinical welfare and the conduct of the study; the participant can take a second opinion before entering the study or at any time during the study; the participant is not under any obligation to participate in the research)
20. **If employees of HMC /residents/ students etc are being included as research participants:** (A statement must be included that such participation is purely voluntary and that he/she is free to choose to participate/not to participate in the research; that he/she might withdraw from the research at any time without any change in his/her relationship with the investigator, the investigator's department, HMC or his/her grades)
21. **Consent:** I have read (or someone has read to me), have understood this consent form; have been given opportunity to ask questions, and also all my questions have been answered to my satisfaction. By signing this form, I willingly agree to participate in the research it describes.

Participant / Parent(s)/ Guardian's Name:

Participant / Parent(s)/ Guardian's Signature:

Child/Student's Name:

Student's Signature:

Date:

Witness Signature:

Principal Investigator's Signature:

*Subjects must not be asked to release their relatives' contact information without obtaining their permission. Researchers are not permitted to contact relatives of the proband without both the participant's and the relatives permission.

** Studies that involve transfer of identified samples to other researchers will not be approved, unless a compelling justification for the retention of identifiers is provided.

*** No information may be disclosed to anyone other than the research participant without his/her permission. If such information will be disclosed to the participant's physician, permission for this must be taken from the Research Committee.

F. GENETIC INFORMATION IN YOUR SAMPLE: POSSIBLE LIMITS TO INDIVIDUAL CONFIDENTIALITY

Every tissue or fluid sample contains genetic information. Recent studies have found normal and disease producing genetic variations among individuals. Such variations may permit identification of individual participants. Despite this possible limitation, every precaution will be taken to maintain your confidentiality now and in future.

- Past research has identified that it is not always possible to predict future research findings and new technologies. You should be aware

that unforeseeable problems might arise from new developments. Possible problems include insurance or employment discrimination based on genetic information.

- (Sometimes genetic information suggesting different parentage is obtained during research. The principal investigator does not plan to report such findings to participants- if applicable)
- Within the limits imposed by technology and the law, every effort will be made to maintain the privacy of your genetic information

G. PREGNANT WOMEN AND NEONATES

Pregnant women, fetuses and neonates involved in research are identified as 'Special populations'. There are additional requirements on investigators. These requirements may vary, depending on the expected risks and benefits to the pregnant woman and her fetus or neonate, the age of the pregnant woman, the study timeframe and the expected viability of the neonate.

General principles for research that involves the pregnant woman alone, or the pregnant woman and her fetus or neonate:

1. When the pregnant woman is an adult (18 years of age or older):Consent of only the adult pregnant woman is required when the following conditions are met:
    a. Either the risk to the pregnant woman and /or the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means Or

    b. The research is more than minimal risk but holds out the possibility of direct benefit to the pregnant woman or to both the pregnant woman and her fetus.

Note: *For either of these two conditions, identifiable private information about the neonate during this hospitalization (i.e. birth) may be collected using this consent process (i.e. a single consent form signed by the adult mother). If identifiable private follow up information about the neonate will be collected over time an additional separate consent form will be required due to the child now becoming a research subject in his or her own right. Based on the follow up study's level of risk, the RC can determine whether the permission of one of the parents is sufficient, or whether the permission of both parents is required. Usually, research that is minimal risk will require the signature of only one of the parents.*

2. When the possibility of direct benefit or harm is limited solely to the fetus, consent of both the pregnant woman (regardless of her age) and the father (if available) is required.

3. Note: the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or if the pregnancy resulted from rape or incest.

Format:

Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. The information in this form is not meant to frighten or alarm you, it is only meant to better inform you of all possible risks or benefits. You are free to ask questions at any time before, during, or after your participation in this research.

1. **Project Title:**

2. **Principal Investigator:**

3. **Location:**

4. **Phone:**

5. **Describe the terms given below as they are described in generic consent form and relate them in relation to pregnant woman wherever applicable:**

1. Purpose; 2. Procedures; 3. Possible risks or discomfort; 4. Possible benefits; 5. Financial considerations for participation (if applicable); 6. Payment to researchers (if applicable); 7. Available alternative treatment; 8. Available medical treatment for adverse experiences (if applicable); 9. Confidentiality; 10. Termination of research study; 11. Available source of information and

6. **Authorization:**

I have read consent form and have been given the opportunity to ask questions. By signing this form, I willingly agree to participate in the research it describes and I give too my permission for my child to participate in this study.

Name of the subject and her signature:

Date:

Child's Name:

Principal Investigator Signature with Date

Signature of person obtaining consent with Date:

H. CONSENT IN CASES OF RESEARCH INVOLVING A SPECIMEN IN A RESEARCH STUDY

Format:

You are being asked to allow the Principal Investigator to use your specimen in a research study. You are asked to consent to HMC for storage of your specimen for future research- if researcher wants to store for further or future research. Specimen means body or organ tissue, blood or other bodily substances that the researcher feels is important to study in order to better understand the disease (describe). The information only meant to better inform you of all purpose of research and any possible risks or benefits so that you can decide whether or not to give your consent to participate in this research study. You must read the following information and ask as many questions as necessary to be sure that you understand what your participation will involve.

Name of principal investigator:

Project title:

Location:

Phone:

Place where specimen will be stored:

Describe the terms given below as they are described in generic consent form and relate them in relation to specimen wherever applicable: 1. Purpose; 2. Procedures; 3. Possible risks or discomfort; 4. Possible benefits; 5. Financial considerations for participation (if applicable); 6. Payment to researchers (if applicable); 7. Available alternative treatment; 8. Available medical treatment for adverse experiences (if applicable); 9. Confidentiality; 10. Termination of research study; 11. Available source of information

Information about your sample:

You are asked to let the Principal Investigator know if you would like to receive information about the results of this study. There are three choices about the information you may receive. (Tick them):

- General information about what this study found (or conclusion of the study);
- Specific information about what the study found about your sample.

- You may choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

I. IN CASE THE AGE OF THE PREGNANT WOMAN IS LESS THAN 18 YEARS OF AGE

If the pregnant woman is a 'minor' according to Qatari law and the research activity focuses solely on her, she can not consent for her own participation in research; consent from her parents or legally authorized guardian is required, as is her permission and assent.

If the research includes both the pregnant minor and her neonate or infant, she can assent for the research procedures involving her infant, but if she is also a participant in the research; her legal guardian are still required to provide consent for her participation. In this instance, the consent form would be signed by her (for the research participation of her fetus or neonate) and by one or both parents (for her own research participation). Both the protocol and consent form must describe the research activities for both the mother and the neonate or infant.

With the above precautions, Investigators are advised to utilize the below mentioned generic consent form.

Format:

Read this consent form carefully and ask as many questions as you like before you decide whether you want to participate in this research study. The information in this form is not meant to frighten or alarm you, it is only meant to better inform you of all possible risks or benefits. You are free to ask questions at any time before, during, or after your participation in this research.

Project Title:

Principal Investigator:

Location:

Phone:

Describe the terms given below as they are described in generic consent form and

relate them in relation to pregnant women wherever applicable.

1. Purpose; 2. Procedures; 3. Possible risks or discomfort; 4. Possible benefits; 5. Financial considerations for participation (if applicable); 6. Payment to researchers (if applicable); 7. Available alternative treatment; 8. Available medical treatment for adverse experiences (if applicable); 9. Confidentiality; 10. Termination of research study; 11. Available source of information.

Authorization: I have read this parental permission form and have been given the opportunity to ask questions. By signing this form, I willingly agree to participate in the research it describes and I also give my permission for my child to participate in this study.

Legal Guardian's signature

Date:

Child's Name:

Name of the subject and her signature:

Principal Investigator Signature with Date:

Signature of person obtaining consent with Date:

Format of Consent forms used at HMC

1. Signed informed consent
2. Waiver of signed informed consent
3. Waiver of informed consent
4. Genetic Consent (A-D)

Reference: Please check HMC intranet web portal for more information with the following link: http://intranet/deptportal/show_news.asp or please refer page No: in this booklet

SECTION IV

MODIFICATION IN THE DOCUMENTATION OF THE INFORMED CONSENT (Waiver of Signed Consent)

In general, RC bylaws require that research subjects sign a consent document. Under very specific circumstances, the RC may waive the requirement for the subject's signature on a consent document.

The information provided below is intended to provide investigators with clear guidelines regarding instances where the RC may waive the need for a subject's signature on a consent document.

Investigators are cautioned that each waiver that is requested will be considered at a convened meeting of the RC on a case-by-case basis within the framework provided by these guidelines, and that the RC will consider a broad spectrum of factors before a waiver is granted

Signed consent may only be waived in those situations where either:

1. The research presents no more than minimal risk of harm to the subject AND the research involves no procedure for which written consent is normally required outside of the research context, OR

2. The consent document would be the ONLY identifiable link between the subject AND the research and there would be potential harm to the subject if the confidentiality of the consent document were breeched.

Situations in which waiver of a signed consent may be granted include:

1. Drawing of additional blood samples when blood is already being obtained for clinical reasons or blood donation;
2. Sampling of additional bodily secretions when such secretions are already being sampled;

3. Questionnaires

4. Interviews

5. Chart reviews

Investigators must be aware that procedures which physicians consider to be minimal risk are not necessarily viewed as such by patients or subjects.

They should be sensitive to the subject's perception of the procedure when classifying procedures as minimal risk.

Thus it is unlikely that the RC would approve a waiver for any invasive procedure, (e.g. venipuncture, catheterization, skin biopsy, etc.) **that is performed solely for research purposes** despite the fact that such procedures do not normally require written consent.

When requesting a waiver of signed content, The RC form "Request for Modification in Documentation of Informed Consent" must be completed and submitted with the application form. A copy of this form is included in the Forms Sections.

Waiver of signed Consent Format

A waiver of signed consent does not exempt an investigator from obtaining informed consent.

The first part of the consent form (Research Participation Information sheet) is read to the patient and signed by the PI or a person delegated to obtain informed consent. A copy of the signed information Sheet must be given to the subject, a copy should be placed in the subject's chart, and the investigator must keep the original form in his / her research records.

All of the elements of informed consent required in signed consent must be included. At the end of the information sheet include the following paragraph verbatim and include the signature lines:

I have fully explained to Mr. / Mrs. ---------- the nature and purposes of the above described research program.

I believe that he/she understands the nature, purposes and any risks of these studies.

I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions.

Signature Date

Print Name Title

SECTION V

PEDIATRIC SUBJECTS IN RESEARCH STUDIES

The enrollment of pediatric subjects requires that the research participant information sheet worded as “You/Your child”. This is required because permission must be obtained from the parent and, in instances as specified below, the assent of the child must be obtained. In addition, documentation must be kept that assent was obtained freely and without coercion.

1. ADDITIONAL PROTECTIONS FOR CHILDREN

1.1 For research not involving greater than minimal risk:

Research that presents no greater than minimal risk [defined as the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests] may only be performed if a*dequate provision is made for obtaining the assent (an affirmative agreement to participate in the research) of the child and the permission of the parent or guardian*.

1.2 For research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects:

Research that offers direct benefit to the individual and is likely to contribute to the subject’s well being but has greater than minimal risk may only be performed if:

a. The risk is justified by the anticipated benefit;
b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
c. Adequate provision is made for obtaining the assent of the child and the permission of the parent or guardian.

1.3 For research involving greater than minimal risk but no prospect of direct benefit to individual subjects, but likely to yield information regarding the subject’s disorder condition:

Research that involves greater than minimal risk but likely to yield information regarding the subject's condition may only be performed if:

a. The risk is a minor increase over minimal risk;
b. The research presents subjects with experiences that are commensurate with those in their actual expected, medical dental, psychological, social or educational situations;
c. The research is likely to yield generalizable knowledge of vital importance to understanding or ameliorating the subject's condition; and
d. Adequate provision is made for obtaining the assent of the child and the permission of the parent or guardian.

1.4 For research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children:

Research in this category may require the approval of the SCH in addition to the RC approval.

2. REQUIREMENTS FOR PERMISSION BY PARENTS OR GUARDIAN AND FOR ASSENT BY CHILDREN

2.1 Provision must be made for soliciting the assent of children when in the judgment of the RC the children are capable of providing assent.

a. It is important to note that failure to object to participate as a research subject cannot be construed as assent.
b. When applicable, a certification of assent form must be completed to document that assent was freely obtained and without any coercion. Investigators must maintain each signed certification of assent form on file with the consent document as signed by the parent or guardian and other research records relevant to the individual research subject.

2.2 Provision must be made for soliciting the permission of each child's parents or guardian and the permission must be documented in the consent document:

a. The RC may require permission of only one parent if the research involves no greater than minimal risk or involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.
b. If the research involves greater than minimal risk and offers no prospect of direct benefit to individual subjects or the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

2.3 Under very special circumstances the RC may waive the requirement for parental consent:

Waivers can only be granted for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g. neglected or abused children), if an appropriate mechanism for protecting the child is provided, and if the waiver is not inconsistent with regulations and laws of the State of Qatar.

3. PEDIATRIC ASSENT GUIDELINES

All Pediatric research subjects should be fully informed about a research study, in language appropriate for their age, maturity and previous experiences, whether assent is to be requested or not.

This information can be provided verbally and should include all tests and procedures to be performed, frequency of interventions, duration of participation in the study, risks, discomforts and potential benefits.

The child should be encouraged to ask questions, all of which should be answered.

Depending on the nature of the study and on the maturity, psychological state and previous experiences of the child, assent should be obtained, and documented, from children ages 14 and older. ?

For children ages 13 – 14, assent should be obtained and documented unless the

child's pediatrician considers him/her to be too immature to provide a true assent. Children age 7 – 11 should be fully informed about the research, using language appropriate to their age or maturity, and documented assent should be obtained from those deemed capable of making a meaningful decision.

Below age 7, information about study should be provided in a manner appropriate to child's age, but documented assent need not be obtained.

When enrolling minors into therapeutic research studies of potential therapies for their severely debilitating or life – threatening illness, the patients should be fully informed about the nature of the study and should be included in discussions of their participation, as is common pediatric practice. In such situations, however, documented assent need not be obtained since the wishes of parents or guardian would prevail. It would be inappropriate to ask for assent since a refusal by the child could be over – ruled by the parents or guardian.

4. Documentation of Assent

The assent as given by the subject must be documented by a witness who is not a family member and not associated with the research study. The signed certification must be retained in the research study records.

If the documented assent is not obtained from minors, above 11 (ages 12 and older) the reason for not obtaining assent must be noted in the research record for that subject.

SECTION VI

STUDIES ONLY INVOLVING BLOOD DRAWING

There are a number of research projects in which the drawing of blood is the only research activity, which involves human subjects. In these projects, one of two situations may exist.

In the first, an additional sample maybe obtained at the time of venipuncture for clinically indicated reasons. **Signed consent for the drawing of additional blood may be waived** and **investigators proposing** such protocols should refer to the guidelines for waiver of signed consent prior to submitting their proposal to the Research Committee.

Venipuncture may also be performed independent of any clinical procedure, such as occurs when obtaining samples from normal controls. A sample consent intended to be used as a model for all studies involving independent venipuncture, except those studies in which blood is **drawn for HIV-antibody** or Hep testing, is detailed below. Investigators are strongly urged to make use of this model, as it will hopefully prevent the need for revisions.

Model of consent for blood drawing

You are being asked to participate in a research study. The purpose of this study is _____. You qualify for participation in this study because you have ---------- / you are a normal, healthy individual. There will be ----------subjects enrolled in this study in this upcoming year.

Your participation in this study will involve drawing a blood sample from a vein in your arm. The total amount drawn will not exceed ---------- teaspoons/tablespoons/ounces each time. We will draw blood ----------times, approximately once every ---------- days/weeks/months.

You will/will not be informed of the results of these tests. You may experience some minor pain and may develop a black and blue mark as result of the blood drawing. You may experience some minor pain and may develop a black and blue mark as result of the blood drawing. You will receive QR. ---------- for your time and expenses incurred as a result of participating/will not receive any financial compensation for participating.

While there is no direct benefit to you, it is hoped this study will yield more information about ----------. You may withdraw from this study at any time by informing the individual drawing your blood or by contacting the Investigator.

FORMS

SECTION VII

FORMS

GUIDELINES FOR SUBMISSION OF A RESEARCH PROPOSAL

1 Plan your application carefully before you commence writing.

2 Establish deadlines for the preparation of the proposal.

3 Write your proposal according to the Research Committee application formats. **Use basic English. Number all pages.**

4 Have your proposal reviewed and proof - read by an objective colleague, if possible. This will draw your attention to some issues in your proposal that you may have overlooked.

5 If an Investigator wishes to participate in a multi-centre study which has been initiated and previously approved by an acknowledged academic, medical or research institution, he/she can submit a copy of that proposal and indicate the exact contribution/involvement of HMC in the covering letter. Such proposals may be eligible for an Expedited Review.

6 The Principal Investigator (PI) should submit the proposal with all relevant forms completed to the Chairman of Research Committee.

7 The Research Committee office screens the proposals for compliance with submission guidelines, forwards them for peer review and sends them to the appropriate committee (s) for evaluation. Only completed submissions will be processed. Incomplete submissions will be returned to the PI. The PI will be informed of the receipt of the complete proposal by the Research Committee Office and will be contacted if the Committee(s) requires clarification or recommends modification. The Research Committee Office will communicate the final decision to the PI.

Research proposal submission form

For Medical Research Centre use ONLY

Date of receipt	ID Number	Budget	
		Amount requested	Amount granted

1. Title of the project:

2. Principal Investigator(s):

Name	Title	Department	Contact details (Tel/Bleep/E-mail)	Signature

3. Address for Correspondence: (with Telephone/Bleep/Mobile Nos. and e-mail address)

Name of Head of Section(s)	Signature
Name of Chairman/Director of the Department(s)	Signature

5. Co-Investigators:

Name	Title	Department	Contact details (Tel/Bleep/E-mail)	Signature

6. Details of previous research projects submitted in HMC:

TITLE	Investigators	AMOUNT GRANTED	Duration	Status

7. Background:

(Description of topic and with justification (rationale) of the study by stating the problem and its public health importance) **(Recommended length is around 2 pages*)***

8. Objective of the study

8(a) Goal of the study: (State the goal you need to achieve)

8(b) Specific Objective: (State the details of each objective that will finally lead to achievement of the goal)

8(c) Secondary Objective: (There are subsidiary objectives that could be studied during the course of the project but are not the main objective of the study, they are optional and vary according to the type of the study):

9. Materials and Methods: (Describe the research methods that could best achieve the study objectives. These cover items 9.a to 9.g)

9. a. Study area/setting: (Describe the area or setting where the study will be conducted.)

9. b. Study Subjects: (Inclusion and exclusion criteria of the study subjects should be mentioned)

9. c. Study Design: (Mention the type of study design to fulfill aims & objective of the study (eg. retrospective, cross-sectional, case- control, cohort, intervention study, etc.)

9. d. Sample Size: (Mention the input criteria for sample size estimation like existing prevalence rates, previous study data, pilot study results etc...)

9. e. Sampling Technique: (Mention the sampling technique that will be used in order to obtain a representative sample for your target population- this could be probability(random) or non probability techniques)

9. f. Data Collection methods, instruments used, measurements:

9. f. 1. Describe the instruments used for data collection (Questionnaire, Observation recording form, Survey forms, instruments etc. and studied variables included from these instruments with references should be described. Methods used to test for the validity and reliability of used questionnaire, recording forms and survey forms should also be described)

9. f. 2 Procedure of data collection, how the data will be collected?

(Please describe in detail)

9. f. 3. Describe the quality control measures and good practices followed during the study implementation (e.g. Good laboratory practices (GLP), Good Clinical Practices (GCP), methods used to make sure that data collected is accurate, methods used to ensure reliability and validity, methods used to ensure compliance of research with the research protocol, methods in place for ensuring data safety etc .., can be described here)

9. f. 4. Study definitions should be mentioned (e.g. Define all the important variables mentioned in the study with their references)

9. g. Data Management and Analysis plan:

(Describe the analysis plan, tests used for data analysis and statistical package(s) used)

10. Implications of study results on disease/public health problem control:

(Expected results and a description of the diseases or public health problem that the researcher hopes to control or decrease as a result of this study, which might give clues for future research)

11. Areas of Integration of research activities (If applicable)

(E.g. integration of research activities related to more than one disease- these might be extrapolated from the secondary objectives or may be the results of the study which revealed areas which could benefit because of collaborative research etc . has to be described,)

12. Bibliographic Reference:

(Reference all articles relevant to study used in background for review of literature)

13. Ethical consideration:

13. a. Informed Consent form
(It is a process in which a subject/patient learns key facts about a trial including potential risks and benefits, before deciding whether or not to participate in the study. Informed consent continues throughout the study and used according to research designs. Informed Consent Form is available on the intranet portal of the Medical Research Center and which should be translated into a language understood by the research participant)

13. b. From whom and how will consent be obtained? (Participant or legally authorized representative and Research Committee (in case of retrospective study) should be indicated here)

13. c. Confidentiality: (How and where will the study data can be stored and secured and how will subject's confidentiality be protected, who will have access to confidential research information etc..,)

14. Other funding agency:

Is your study funded by another funding agency? (If yes, specify the agency and available funds)

15. Required reports:

15. a. Research Reports: (A progress report should be submitted in every 6 months of the project's implementation and a final report at the completion of the project. A list of participants recruited into the clinical trial should be submitted to the MRC at the end of every month where as a progress report should be submitted in every 6 months and final report at the completion of the all types of projects. If the study duration extends beyond a year, an application for extension with progress report must be submitted to the Research Committee to review and renewal of the project. Once research is published, copy of the published article should be submitted to MRC for updating database.)

15. b. Strategies to enhance the dissemination and utilization of results.(Mention the measures that might be taken to make the research findings generalizable knowledge- could include departmental meetings, journal clubs, articles etc

16. Timeline:

(Please indicate the activities to be conducted and mark(X) the corresponding month on the Gantt chart. The research team should be strongly committed to these timelines and to submit the reports on time.)

Task	Month											
Getting the final approval of the project	1	2	3	4	5	6	7	8	9	10	11	12
Design of the questionnaire												
Data collection												
Data analysis												
Writing up												
Progress Report												
Final report												

17. Budget (requirement of each item should be justified)

Budget Breakdown	Unit cost (Qrs.)	Budget (Qrs.)	Other Sources (Qrs.)
Material (Supplies & Equipments)			
Subtotal			
Manpower (if any)			
HMC staff (if any)			
Personnel appointed from outside HMC (if any)			
Personnel appointed from outside Qatar (if any)			
Subtotal			

Local Travel			
Travel outside Qatar (if any)			
Subtotal			
Patients Cost (if any)			
Subtotal			
Training (if any)			
Education (if any)			
Subtotal			
Others (please specify and justify)			
Subtotal			
Grand Total			

18. INVESTIGATORS ASSURANCE FORM

Title of Proposal:

The Investigators named below affirm that they:

1. Will have a substantial contribution and adhere to the approved proposal.
2. Will abide by the rules and regulations guidelines' of the Research Committee, HMC for intellectual property, conflict of interest, authorship and financial issues.
3. Will submit progress and final reports and correspond with the Research Committee in a timely manner (Principal Investigator).
4. Will accept responsibility to maintain original data and consent forms and submit them for review if requested.
5. Will use scientific rigor and integrity in obtaining, recording and analyzing data; and in reporting and publishing results according to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) Guidelines.
6. Will be responsible to inform adverse event within one working day, to Research Committee, HMC, at 4392440,4396166, email: research@hmc.org.qa (applicable only for clinical trials)
7. Have completed the CITI training and obtained the certification

Name (s) of PI (s) and Co-PI (s)	Designation	Department	Signature	Date

Note: Research Committee (RC) approves a project only for a maximum period of 365 days. To renew the approval period of a project, the investigator must submit a progress report to the RC for review and renewal of the approval.

CHECK LIST FOR INVESTIGATORS

1. Signature(s) of Principal Investigator(s) (PI(s)) and Co-Investigator (s)
2. Head/ Chairman's Signature of PI (s) department/ Section
3. Curriculum Vitae of PI.
4. Consent Form both in Arabic and English (Signed informed consent/ Informed consent i.e. Verbal or Oral
5. Investigator(s) assurance form.
6. Prepared Data sheet/ Questionnaire for data collection.
7. Budget details (if required).
8. CITI Certificate for HMC Researchers
9. Conflict of interest (Statement of interest form)
10. One copy of the proposal should be sent by email to research@hmc.org.qa and one hard copy of the same should be delivered to The Chairman, Research Committee, Medical Research Center, Building No. 20, 3rd Floor, Hamad Medical City, HMC. Tel. Extn. 439 2440 / Fax: 439 5402. E-mail: research@hmc.org.qa.

Procedure for Letter of Endorsement:

Letter of endorsement from Dean of the organization or equivalent in support of the research proposal and the Principal Investigator(s), verifying that the proposal complies with the organization's policies and certain QNRF policies stated in the RFP will be provided to QNRF only to those research proposals submitted to Medical Research Centre. Investigators are also advised to read carefully all the rules and regulations from the website: www.qnrf.org

Other Information: (if needed, please add any further information).

Note: *Researchers may contact Medical Research Centre for study design, sample size calculations, sample techniques, and terminology used in the Submission Form for clarification. Researchers are also advised to read about intellectual property, conflict of interest, authorship and financial issues from departmental intranet portal http://intranet/deptportal/dept_homepage.asp Medical Research Centre in rules and guidelines for submission of research.*

CASE(S) REPORT SUBMISSION FORM

For Medical Research Centre use ONLY

Date of receipt	ID Number	Budget	
		Amount requested	Amount granted

1. Title of the project:

2. Principal Investigator(s):

Name	Title	Department	Contact details (Tel/Bleep/E-mail)	Signature

3. Address for Correspondence: (with Telephone/Bleep/Mobile Nos. and e-mail address)

4. Name & Signature of Department Chairman/Head:

5. <u>Co-Investigators</u>:

Name	**Title**	**Department**	**Contact details** (Tel/Bleep/E-mail)	**Signature**

6. <u>Details of previous research projects submitted in HMC</u>:

TITLE	Investigators	AMOUNT GRANTED	Duration	Status

7. Background:

(Description of Case(s) and Case(s) with justification of the study by stating the problem and its public health importance)

8. Materials and Methods:

8. a. Study area/setting: (Describe the area or setting where the study is conducted.)

8. b. Number of case(s)

8. c. Data Collection methods/procedure, instruments used, measurements collected: (Describe procedures followed for Case(s))

9. Implications of study results on disease control:

(Expected results and potential contribution of the project to the relevant control program)

10. Bibliographic Reference:

(Mention articles relevant to the study used in review of literature in background)

11. Ethical consideration:

11. a. Consent form
(Attach copy of consent of treatment / photographing / videotaping and other imaging of patient(s) followed by HMC policy)

11. b.Confidentiality :(How will subject(s) confidentiality be protected in results and publication?)

12. Budget (Requirement of each item should be justified)

Budget Breakdown(Please specify and justify)	Unit cost (Qrs.)	Budget (Qrs.)	Other Sources (Qrs.)
Grand Total			

13. Other Information: (if needed, please add any further information).

Note: Researchers may contact **Medical Research Centre** for study design, sample size calculations, sample techniques, and terminology used in the Submission Form for clarification and may take help from departmental intranet portal *http://intranet/deptportal/dept_homepage.asp* **Medical Research Centre** for rules and guideline

14. Investigators Assurance Form

The Investigators named below affirm that they:

1. Will have a substantial contribution and adhere to the approved case(s) report.
2. Will abide by the rules and regulations guidelines' of the Research Committee, HMC for intellectual property, conflict of interest, authorship and financial issues.
3. Will accept responsibility to maintain original data and consent forms (when applicable) and submit them for review.
4. Will use scientific rigor and integrity in reporting and publishing according to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP)

Name (s) of PI (s) and Co-PI (s)	Designation	Department	Signature	Date

Application for Authorization to Use Laboratory Animals in Research and Teaching or Testing

Instructions

General

The Supreme Health Council (**SCH**) and the Hamad Medical Corporation (**HMC**) require the Animal Care Committee and Use (**IACUC**) of **HMC** to review and approve all proposals intended to use laboratory animals in Research, Teaching or Testing. The use of animal tissue for the same intended purposes must also be reviewed by the **IACUC**. Both animal and animal tissue *Proposal Applications* are available from the HMC's Medical Research Centre (**4439-2440**). No activity involving animals may be conducted at HMC without prior review and approval by the **IACUC**. The use of plants, bacteria, protozoa or invertebrate animals is excluded from the IACUC review process.

Proposal Preparation and Submission

Applicants who wish to use animals in Research, Teaching or Testing initiate an **IACUC** review by completing a *Proposal to Use Laboratory Animals in Research Teaching or Testing.* Please read the directions carefully and answer each question.

- Be concise, specific, and use terms that nonscientists can understand.
- All *Proposals* should be submitted in typed form. A copy of the proposal form is available in Microsoft Word from the Administrative Office of the Medical Research Centre (**439-2440**) or on the Intranet at: http://intranet/deptportal/show_news.asp .
- *Proposals* submitted using word processing techniques should adhere to the font/type set on the form. If, due to print or other equipment constraints, alternate font/type commands are used, Applicants should be certain that responses can be easily distinguished by duplicating the proposal in a bold format and printing responses in regular (non-bold) type.
- Completed proposals must be submitted electronically in Word or PDF format to: research@hmc.org.qa . A hard copy of the signature page, with original signatures, should be forwarded to the Administrative Office of the Medical Research Centre at the following address:

  Administrative Office
  Medical City
  Medical Research Centre
  Building 20, 3rd Floor, Room 2

New Proposals

General

All sections listed in the *Proposal Application* must be completed. **If more than one species is to be used, an additional set(s) of sections VII and VIII must be completed**. Use additional space if there is insufficient space on the form (there is not limit for the space provided in the form except for the last section, i.e. Lay Research

Summary. *A copy of any associated grant applications or other related information (if applicable) must also be submitted.*

Proposals That Involve Hazards

Proposals that include the use of hazardous agents, such as toxic or dangerous chemicals, carcinogens, microbials, or research associated with radiation risks or recombinant DNA will be reviewed by the **IACUC** after consultation with the Occupation Health and Safety (OHS) Office at the **HMC**. **IACUC** *Approval is contingent upon the OHS Safety Approval.*

Modifications of Previously-Approved Proposals

IACUC approval to use laboratory animals in Research and Teaching is granted for a period of three (3) years and is subject to annual review. Annual review is required by the Supreme Health Council and continuation of approval will be accomplished through communication(s) with the Project director/Principal Investigator. A new application, which is reviewed *de novo*, must be submitted at the end of three years. During the three-year approval to use animals, it is the responsibility of the Project Director to notify the **IACUC** of **any** change in the protocol (*e.g.,* animal species, animal use, personnel, procedures, project classification, funding source(s), study site, and/or use of hazardous materials). Modifications are reported by submitting a *complete* revised electronic version of the *Proposal* that includes all changes (please change the font or highlight the changed areas to facilitate review). A hard copy of the revised signature page is also required. Signature of Department Chair is only required if the modification includes a significant increase in the number of animals used (over 25%), laboratory location, or a change in project pain/distress classification. The revised *Proposal* must be accompanied by a cover letter that clearly identifies those sections of the proposal that have been revised and the justification for each revision.

Project Directors/Principal Investigators must reconcile actual and estimated animal use during ***annual review*** of proposals. The aim of such reconciliation is confirm the log record of animal purchase. A reduced estimate of animal use is handled administratively and does not require a formal modification. ***Any request to increase animal numbers, does, however, require a Proposal modification.***

Instructions for Specific Form Sections:

Section IV, Signatures and Approvals

Please note*: Except for research sponsored by the Medical Research Centre of HMC, funding agencies including Qatar National Research Fund (QNRF) require that the institution "verify, before award, that the* **IACUC** *has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. It is the PI's responsibility to ensure that experiments, procedures, etc., described in grant applications are included in an approved* **IACUC** *Proposal.* ***All*** *work involving animals must be approved by the* **IACUC** *regardless of what may or may not be included in a grant application. Failure to ensure this consistency could be interpreted as a breach of the contract with the granting agency and could threaten future funding from that agency.*

Section V. A., Project Goals

The response to this item should be in adequate detail such that the reviewers will understand what will actually be done to each individual animal. Timelines and tables are not required, but may be of assistance in ensuring reviewers' understanding.

Section V.B., Project Director/ Principal Investigator Assurance that proposed work is not unnecessarily duplicative

Research ethics require that that a Project Director/ Principal Investigator "*must provide written assurance that the proposed activities do not unnecessarily duplicate previous experiments*." The **IACUC** must be assured that the Project Director/ Principal Investigator has made a "reasonable good faith effort" to determine that the proposed study is not unnecessarily duplicative and, therefore, minimizes the use of animals. To satisfy the requirements, the Project Director/ Principal Investigator must make a "good faith review of available sources" (*e.g.,* Biological Abstracts, Index Medicus, Current Research Information Service, Animal Welfare Information Center) and ***communicate review sources and results*** in the assurance statement. For information on ways in which this requirement may be met, including the Internet addresses of the sources listed; please contact the Administrative Office of the Medical Research Centre (**439-2440**).

Section V.C., Project Director/ Principal Investigator Assurance that there is no alternative to animals to do the proposed work

Research ethics require that a Project Director/ Principal Investigator always consider replacement of animals (especially vertebrates) with other research tools like mathematical modeling and computer simulations. Replacement also means choosing lower order animals, i.e. mice over swine.

Section VI. Project Participants

Training requirements are outlined in the **IACUC** Policy entitled, "Required Training." Effective January 2011, all participants must complete Level II Training within 90 days of **IACUC** authorization to serve as participants in the proposed project.

Section VII. A. Classification of Study

Project Directors/Principal Investigators are required to classify animal use according to the following scheme:

- *Class I* - Studies in which animals will experience ***no pain or distress*** greater than that produced by routine injections or venipuncture and will therefore receive ***no pain-relieving agents***.
- *Class II* - Studies in which there is a ***potential for pain or distress*** which is ***minimized or eliminated by anesthetics, analgesics, and/or tranquilizers.*** Examples include biopsy, endoscopy, vascular cut-down, footpad injections, use of adjuvants, implantation of chronic catheters, as well as ***survival and non-survival surgery.***
- *Class III* - Studies in which animals will ***experience pain or distress*** greater than that produced by routine injections or venipuncture and will ***not receive pain-relieving agents***. Examples include exposure to agents or radiation levels that cause serious illness, research involving significant stress, or procedures involving prolonged restraint.

Note: Studies characterized by the likelihood of severe, prolonged ***unrelieved pain or distress will not be considered*** by the **IACUC** without comprehensive and explicit scientific justification.

Section VIII. Experimental Protocol for Animal Species Described

Research ethics requires that Project Directors/Principal Investigators consider alternatives to painful procedures. An alternative is any procedure which results in the ***reduction*** in the numbers of animals used, ***refinement*** of techniques to minimize pain, or ***replacement*** of animals. With respect to pain, a painful procedure, as applied to animals, is defined as the one "that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures" regardless of whether or not the pain can be relieved with analgesics. For Class II and III *Proposals*, Project Directors/Principal Investigators must provide a ***written narrative description of the methods and sources*** used to determine that alternatives (***reduction of animal numbers, minimization of pain/distress, and/or replacement of animals***) were not available (*e.g.,* Biological Abstracts, Index Medicus, Current Research Information Services, Animal Welfare Information Center). In order to satisfy research ethics requirements, "the minimal written narrative should include the *databases searched* or other sources consulted, the *date of the search*, the *years covered* by the search, and the *key words* and/or search strategy used when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to the painful or distressful procedure. The narrative should be such that the **IACUC** can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough." The ***replacement*** of animals with a non-animal model, the ***reduction*** of animal numbers, and/or the ***refinement*** of study protocol to reduce pain or stress must be addressed. Additionally, those study protocols that may include elements of pain or distress for which pain relieving agents will not be provided (Class III proposals), Project Directors/Principal Investigators *must include written scientific justification for withholding such agents*. Justification must be presented in a format similar to that described above (See Class III, Section VII). For additional information on ways in which this requirement may be met, including the Internet addresses of the sources listed; please contact the Administrative Office of the Medical Research Centre (**4439-2440**).

Section VIII.F. Anesthesia/Analgesia

Although the use of pain-relieving drugs (sedatives, anesthetics, analgesics) should be described in the body of the *Proposal*, each drug used should also be included in section VIII. F. to ensure that all required information is provided.

Section IX, Lay Research Summary

A non-technical summary of the proposed research is required. The summary must express the significance attached to the project and reasons for which it has been proposed. The summary may be needed for public information purposes and should be written in terms which nonscientists can easily understand.

Animal Procurement

A copy of the **IACUC** proposal with the signature of the **IACUC Chairperson and assigned *Proposal* number will be returned to the Project Director/Principal Investigator**. **IACUC** approval is required before animals may be purchased or otherwise acquired for the research project. Animal orders must indicate an approved **IACUC** *Proposal* number and only the species and number of animals approved may be ordered. *Project Directors/Principal Investigators are required to maintain an Animal Procurement log book as a reference document to the IACUC's annual review.*

References:

"Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training"
"Animal species covered by the Animal Welfare Act"
"Animal Care Regulations"
"The Guide for the Care and Use of Laboratory Animals"
Supreme Council of Health documents "Laboratory Animal Welfare Guidelines" and "Terms of Reference for Animal Care Committees"

Definitions

Replacement: Replace animals with other research tools or techniques to adequately address the research question. For example use of *in vitro* methods, mathematical modeling or computer simulations instead of animals whenever possible. It also means replacing higher order vertebrate animals with lower order animals whenever possible. Examples: "*Microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals. Alternately, live animals may be replaced with non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audiovisual aids, or in vitro modeling."*

Reduction: Means minimizing the number of animals needed to perform an experiment or teach a concept.

- Examples "Performing **pilot studies** to determine some of the potential problems in an experiment before numerous animals are used
- Designing a study to **utilize animals** as their own controls.
- Gathering a **maximum amount of information** from each animal, perhaps gathering data for more than one experiment concurrently
- Consulting with a statistician to use only the **number** of animals required to achieve significance
- **Minimizing variables** such as disease, stress, diet, genetics, etc., that may affect experimental results
- Performing appropriate **literature searches** and consulting with colleagues to ensure that experiments are not duplicated
- Using the **appropriate species** of animal so that useful data is collected
- **Again Replacement** whenever possible.

Refinement: Means refining experimental protocols to minimize pain or distress whenever possible.

- Examples" Identifying **pain and distress** and making plans for preventing or relieving them.
- Setting the earliest possible **endpoint** for termination of the experiment before the animal experiences any ill effects.
- Receiving **adequate training** prior to performing a procedure.
- Using proper **handling techniques** for animals.
- Ensuring that **drug doses** are correct and that the drugs used are not expired.
- Ensuring that **procedures** to be performed on the animal are reasonable for that species.

- Using appropriate **analgesics and anesthetics** for potentially painful procedures.
- Performing **surgeries** and procedures **aseptically** to prevent infection.
- Performing only a **single major survival surgery** on any one animal, whenever possible.
- Performing appropriate **post-surgical care**, including thermoregulation and fluid balance.

Proposal Application

Any changes to animal use beyond what is described in an **IACUC**-approved *Proposal to Use Laboratory Animals in Research and Teaching ("Proposal")* are prohibited. Alterations to animal use protocol must be reviewed and approved by the **IACUC** before occurring.

FOR ACC USE ONLY
PROPOSAL#_____

CLASSIFICATION(S)_____

PROPOSAL TO USE LABORATORY ANIMALS IN RESEARCH AND TEACHING
(PLEASE TYPE SPECIES i.e mice and rats)

I. ADMINISTRATION

Project Director/Principal Investigator (Individual with responsibility for the proposed study):

Name_____ **Title**_____

Department_____ **Division** _____

Address (Bldg./Room#) _____

Phone Number_____ E-**mail ID**_____

FAX #_____

Co-Director(s)/Co-Investigators_____

Project Title _____

_____

Funding Source(s) _____

Please list the title and grant number of all grants post-awarded associated with this Proposal: _____

_____

_____

Dates of Proposed Project – From: _____ **To:** _____

II. PROPOSAL TYPE

☐ **New Proposal**

☐ **3-Year Renewal**

☐ **Modification of Previously Approved Proposal**

Provide the following information (if applicable):

Current IACUC Proposal Number (If Applicable) _____
Date of Current IACUC Approval _____

III. PROPOSAL PURPOSE

☐ **Research**

☐ **Education**
- ☐ **Professional Education**
- ☐ **Undergraduate Education**
- ☐ **Graduate Education**
- ☐ **Continuing Medical Education**

IV. SIGNATURES AND APPROVALS

I certify that the statements herein are true and that if protocol changes are required, I will resubmit the proposal according to instructions given for the modification of a previously approved proposal.

As Project Director/ Principal Investigator,** I will conduct the proposed research according to the principles of the "Laboratory Animal Welfare Guidelines" of the Supreme Council of Health and will conform to the Hamad Medical Corporation's designated IACUC guidelines concerning the care and use of animals in research, teaching, or testing.

I understand that the IACUC has concern for the ethical aspects and implications of all studies involving animals and I will cooperate with the Committee in its consideration of these issues. I also understand that the individuals listed as project participants must comply with all IACUC training and occupational health and safety requirements. I have notified the individuals listed as project participants of the possible health risks involved when working with research animals.

I also understand that it is my responsibility to ensure consistency between awarded grants (in awarded phase) and IACUC Proposals. Failure to submit projects described in grant awards for IACUC review and approval could be interpreted as a breach of the contract with a granting agency and threaten future funding from that agency.

**Project Director must be a member of the HMC

_____ _____

Signature of Project Director/Principal Investigator **Date**

DEPARTMENTAL APPROVAL: Approval implies that the Department has reviewed and endorses the proposed research, including the use of laboratory animals.

_____ _____

Signature of Department Chair **Date**

****

IACUC ACTIONS

Approved _____
Contingent Approval _____
Disapproved _____

CONTINGENCIES/REMARKS:

_____ _____

IACUC Chair Signature **Date**

V. PROJECT GOAL(S)

a. Describe specific aim(s), long-term project objective(s), and a brief description of experimental groups.
b. Provide WRITTEN ASSURANCE that the proposed activities do not unnecessarily duplicate previous or ongoing experiments. Describe methods and sources (journals, abstracts, etc.) to support this assurance. Include the date the search was performed, years included in the search, and keywords used.
c. Could the proposed study be conducted without the use of animals? Give the rationale for animal use.

VI. INDIVIDUALS ASSOCIATED WITH RESEARCH/TEACHING DESCRIBED IN THIS PROPOSAL

TRAINING REQUIREMENTS

Research ethics requires that personnel conducting procedures on the species proposed must be appropriately qualified and trained. Effective January 2011, all individuals listed as project participants on this proposal, regardless of experience, must attend an IACUC Level II Training Seminar. In addition, individuals who have limited experience with the research protocol described must arrange with the Administrative Office of the Medical Research Centre (4439-2440) to receive IACUC Level III Training. Information related to training requirements will be forwarded with a letter informing project directors of the results of IACUC proposal review. The Administrative Office of the Medical

Research Centre (4439-2440) may also be contacted for information.

OCCUPATIONAL HEALTH AND SAFETY MEDICAL SURVEILLANCE REQUIREMENTS

Effective January, 2011, all personnel listed as project participants on this proposal must enroll in the HMC Occupational Health and Safety Program for Animal Handlers. This program has two components: Training and Individual Assessment. Training is provided by reading the brochure entitled "Occupational Hazards Associated with the Care and Use of Laboratory Animals". Completion of the training component is documented with a passing score on the associated quiz. Individual Risk Assessment is provided by completion of the "Periodic Animal Contact Health Survey". These completed forms must be forwarded to the Administrative Office of the Medical Research Centre (4439-2440) Detailed information related to occupational health and safety requirements are available in the Administrative Office of the Medical Research Centre (4439-2440).

LIST PROJECT PARTICIPANTS

Provide name(s) (in order of greatest involvement) of individual(s) participating in experimental procedure(s) and/or care of animal subjects and describe their role in the proposed study. Please make sure to fill out the information as COMPLETELY as possible. (Fill in all lines)

1. Name_____ **Degree/Title**_____

Employee ID #_____

Identification Number: _____

Department & Division_____ **E-mail** _____

Address(Bldg./Room #)_____

Office/Lab Phone_____ **Emergency Phone**_____

Experience (Specific to EACH species and procedure utilized in this Proposal):_____

_____

Role in Study (outline the animal-related procedures to be performed):

_____

_____

Level II Training Seminar Attendance (Y/N) _____

Enrollment with Occupational Health and Safety Program (Y/N) _____

☐ **YES** ☐ **NO – The Project Investigator grants authorization to this individual to request new project participants.**

2. Name_____ **Degree/Title**_____

Employee ID #_____Identification Number: _____

Department & Division_____ E-mail _____

Address _____

Office/Lab Phone_____ Emergency Phone_____

Experience (Specific to EACH species and procedure utilized in this Proposal):_____

_____

Role in Study (outline the animal-related procedures to be performed):

_____

_____

Level II Training Seminar Attendance (Y/N) _____

Enrollment with Occupational Health and Safety Program (Y/N) _____

☐ YES ☐ NO – The Project Investigator grants authorization to this individual to request new project participants.

3. **Name_____ Degree/Title_____**

Employee ID #_____Identification Number: _____

Department & Division_____ E-mail _____

University Address _____

Office/Lab Phone_____ Emergency Phone_____

Experience (Specific to EACH species and procedure utilized in this Proposal):_____

_____

Role in Study (outline the animal-related procedures to be performed):

_____

_____

Level II Training Seminar Attendance (Y/N) _____

Enrollment with Occupational Health and Safety Program (Y/N) _____

☐ YES ☐ NO – The Project Investigator grants authorization to this individual to request new project participants.

4. **Name_____ Degree/Title_____**

Employee ID #_____Identification Number: _____

Department & Division_____ E-mail _____

University Address _____

Office/Lab Phone _____Emergency Phone_____

Experience (Specific to EACH species and procedure utilized in this Proposal):_____

_____

Role in Study (outline the animal-related procedures to be performed):

_____

_____

Level II Training Seminar Attendance (Y/N) _____

Enrollment with Occupational Health and Safety Program (Y/N) _____

☐ YES ☐ NO – The Project Investigator grants authorization to this individual to request new project participants.

****

COMPLETE SECTIONS IX and X FOR EACH SPECIES PROPOSED FOR THIS PROJECT

****

VII. A. Animal Use

A. CLASSIFICATION OF STUDY (See Explanation Below)

Please check one of the following:

☐ Class I - Studies in which animals will experience NO PAIN OR DISTRESS greater than that produced by routine injections or venipuncture and which do not require PAIN RELIEVING AGENTS.

☐ Class II - Studies in which there is a POTENTIAL FOR PAIN OR DISTRESS which is MINIMIZED OR ELIMINATED BY ANESTHETICS, ANALGESICS, AND/OR TRANQUILIZERS. Examples include biopsies, endoscopy, vascular cut-down, footpad injections, use of adjuvants, implantation of chronic catheters as well as NON-SURVIVAL AND SURVIVAL SURGERY.

☐ Class III - Studies in which animals will EXPERIENCE PAIN OR DISTRESS greater than that produced by routine injections or venipuncture and will NOT RECEIVE PAIN RELIEVING AGENTS. Examples include exposure to agents or

radiation levels that cause serious illness, research involving significant stress or procedures involving prolonged restraint. A WRITTEN JUSTIFICATION (including supporting sources, journals, abstracts, etc.) for withholding pain relieving agents must be provided in the space below (see instructions, page iii, section VII):

B. Minimizing the number of animals used in a research project is an important consideration for IACUC reviewers. Do not overestimate the number of animals needed to conduct the proposed research.

C. SPECIES / STRAIN _____

Project Year	Animal Numbers	Age/ Wgt	Procurement Budget ($)	Maintenance Budget ($)	Number Housed Simultaneously	Housing Duration
#1						
#2						
#3						

D. Give specific justification for the number of animals to be used. Justification must address statistical significance as it relates to experimental design. (Please be as detailed as possible.)

E. Special Animal Housing/Care -- Detail special housing, diet, isolation, temperature and other requirements for this species. When experimental situations require food or fluid restriction, such restrictions must be scientifically justified and a program must be established to monitor physiologic or behavioral indexes, including criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol. BRIEFLY address in the space provided special conditions and, if applicable, the justification and program for dietary or fluid restriction.

VII.B. APPROVAL TO USE HAZARDOUS AGENTS

A. Will animals be exposed *in vivo* to hazardous agents?

☐ **YES _____** ☐ **NO _____**

B. Will animals be housed following exposure to hazardous materials?

☐ ****YES _____** ☐ **NO _____**

**If animals are to be housed following exposure to hazardous materials, a written Special Animal Safety Protocol (SASP) may be required. These SASP's must include procedures to ensure safe handling of treated animals, bedding, caging and waste.

HAZARDOUS CHEMICALS

***Material Safety Data Sheets (MSDSs) must be obtained from vendors for all listed material.*

☐ **Carcinogens, mutagens, teratogens**
List:
_____

☐ **Neurotoxins**
List:
_____

☐ **Anesthetic Gases/Vapors**
List:
_____

☐ **Investigational drugs (those without FDA approval for human use)**
List:

_____

☐ **Other Chemical Toxins:**
List:
_____

☐ **Other Hazards**
List:
_____

PLEASE NOTE: If any of the above boxes are checked the IACUC Protocol will be forwarded for additional review. If animals are to be housed following exposure to the above specific agents, a written statement may be required.

BIOLOGICAL HAZARDS

☐ **Biological Agents (viral, bacterial and fungal organisms, or human/animal parasites)**
List:
_____

☐ **Biological Toxins or Products:**
List:

_____

☐ **Human Blood, Blood Products, Tissues, or Cell Lines**
List:
_____

☐ **Recombinant DNA (plasmids, genes, vectors)**
List:
_____

☐ **Transgenic Animals**
☐ **Animal production in Qatar** ☐**Yes** ☐**NO, if No**
Please Specify:_____

☐ **Animal production off-site or commercially**
Please Specify: _____

☐ **Other Biohazards:**
List:
_____

PLEASE NOTE: If any of the above boxes are checked the IACUC Protocol will be forwarded for additional Biological Safety review. If animals are to be housed following exposure to the above specific agents, a written statement may be required.

RADIATION HAZARDS

☐ **Radioactive Material (radioisotopes or tracers)**
List:
_____

☐ **Radiation (Irradiator, X-Ray Machines, Densitometry)**
List:
_____

Location Used: _____
☐ **Lasers** **List:**
_____

Location Used: _____

PLEASE NOTE: If any of the above boxes are checked the IACUC Protocol will be forwarded for additional Radiation Safety review. If animals are to be housed following exposure to the above specific agents, a written statement and approval are required.

B. Will animals or animal tissue be exposed to controlled substances?

☐**Yes** ☐**No**

If yes, check below:
( ) Controlled substances (including but not limited to anesthetic agents)
List: _____

C. Personnel Risk(s)

1. **Describe personnel risk(s) posed by experimental procedure(s), live animals, carcasses or tissues, caging and/or caging equipment including contaminated bedding and excrement.**
2. **Describe preliminary plan to eliminate or reduce risks to safe levels.**
3. **Additional comments or explanation regarding the handling of hazardous agent(s).**

VII. C. STUDY SITE

Identify the building(s) and room(s) where animals/animal tissues will be transported and studied. (Please specify the procedure that will occur in each location)
_____
_____

NOTE: Animals may NOT be held in the laboratory overnight without IACUC approval. In cases where overnight housing may be approved, a written animal care and use protocol must be developed in conjunction with and approved by the Committee. The approved animal care protocol must be posted or otherwise available for easy reference in the laboratory.

VIII. EXPERIMENTAL PROTOCOL FOR ANIMAL SPECIES DESCRIBED

A. <u>Give rationale for the selection of this species.</u>

(NOTE: In all cases, a lower species should be given primary consideration.)

B. <u>Check the following procedures that may be associated with this species.</u>

☐ **Behavioral tests** ☐ **Exposure to agents or radiation levels**

☐ **Nonsurgical Procedures that cause serious illness Surgical Procedures:**

☐ **Restraining devices**

☐ **Non-Survival Surgery** ☐ **Other**

☐ **Single Survival Surgery:**
- ☐ **Major**
- ☐ **Minor**

☐ **Multiple Survival Surgery**

SURGICAL DEFINITIONS:

Major Survival Surgery - Any surgical intervention that penetrates and exposes a body cavity; any procedure that has the potential for inducing permanent physical or physiologic impairment; and/or any procedure associated with orthopedics or extensive tissue dissection or transection.

Minor Survival Surgery - Any surgical intervention that does not expose a body cavity and causes little or no physical impairment. Examples include laparoscopy; wound suturing; peripheral vessel cannulation; percutaneous biopsy; routine farm-animal procedures such as dehorning, castration; prolapse repair; and most procedures done on an "outpatient" basis in veterinary clinical practice.
Multiple Survival Surgery - Animal recovers from initial surgery (major and/or minor) and is subsequently reanesthetized for one or more survival surgical procedures (major and/or minor) related to this study. NOTE: No animal may be used in more than one MAJOR operative procedure from which it is allowed to recover, unless, 1) justified for scientific reasons, 2) required as routine
veterinary procedure or to protect the health or well-being of the animal.

B. Alternatives to Painful Procedures

Project Directors/Principal Investigator must consider alternatives to procedures that may cause more than momentary or slight pain or distress. For Class II and III Proposals, provide a WRITTEN NARRATIVE DESCRIPTION OF THE METHODS AND SOURCES used to determine that alternatives to painful procedures were not available.

C. Studies involving NON-SURGICAL procedures performed on this species

- **Describe the procedure(s) to be performed.**
- **Describe the use of any devices that may be employed for prolonged restraint. Provide details regarding the 1) duration of the prolonged restraint, 2) procedures for acclimating animals for prolonged restraint and 3) plans for monitoring animals during prolonged restraint. NOTE: Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described unless the procedures will cause pain or distress.**
- **Describe methods used to avoid discomfort, stress, pain, and/or injury. If anesthesia/analgesia is included in these methods, The Section on anesthesia/ analgesia must be completed.**

E. Studies involving SURGERY performed on this species

NOTE: For projects that involve surgery in NON-RODENT MAMMALLIAN SPECIES, project participants may be required to meet with an IACUC designated veterinary staff in a presurgical planing session to develop appropriate pre, intra, and post-op animal care procedures. The need for a planning session is determined by the veterinary staff at the time of proposal review. A detailed description of the animal care procedures developed as a result of such a session must be approved by the veterinary staff and filed with the IACUC office before animals may be ordered.

1. **Outline plans for preoperative clinical evaluation, care and treatment.**
2. **Outline methods used to avoid discomfort, stress, pain, and/or injury. The use of anesthetics and analgesics must be completely described in Section on anesthesia/ analgesia.**
3. **Outline provisions for maintaining asepsis during survival surgery.**

NOTE: All survival surgery must be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures conducted on non-rodents may be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all survival surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures.

4. **Describe surgical technique.**
5. **Outline plans for animal care and treatment and the maintenance of clinical records following survival surgery.**
6. **Identify the person(s) responsible for the delivery of postoperative care and treatment. Note: The maintenance of clinical case records is required for rabbits and other higher species.**

F. Analgesia/Anesthesia for this species

NOTE: Procedures that may cause more than momentary or slight pain or distress must be performed with appropriate sedatives, analgesics or anesthetics (unless withholding such agents is justified for scientific reasons - see Class III study definition, page 3), and may continue for only the necessary period of time. Furthermore, paralytic drugs in surgery and other painful procedures may not be used without anesthesia. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved must be painlessly euthanatized at the end of the procedure or, if appropriate, during the procedure.

1. **List ALL preanesthetic, anesthetic, analgesic and/or tranquilizing agents to be used (even if their use has been described elsewhere in this Proposal):**
   Agent Purpose (anesthesia, *etc.*) Dose Route of Administration
   a.

b.

c.

d.

2. Describe the regimen for the use of these agents

G. <u>Describe euthanasia technique</u>

1. Include agent, dose, and route of administration. Any variance from the recommendations on the application of a barbiturate, paralyzing agent, and potassium chloride delivered in separate syringes or stages for euthanasia as contained in the American Veterinary Medical Association's (AVMA): Must be justified. (http://vetmed.duhs.duke.edu/documents/reference/pdf/avma_panel_on_euthanasia.pdf)

IX. LAY RESEARCH SUMMARY

In the space provided on the following page, please include a nontechnical summary of the proposed research. The summary must express the significance of the project and reasons for which it has been proposed. The summary may be needed for public information purposes and should be written in terms which nonscientists can easily understand.

FOR IACUC USE ONLY

PROPOSAL# _____

CLASSIFICATION(S)_____

LAY RESEARCH SUMMARY

Project Director/Principal Investigator_____

Project Title_____

(To be written for the understanding of persons not trained in biomedical science—250 words or less)

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

مركز البحوث الطبية
Medical Research Center

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

GENERIC SIGNED CONSENT FORM

موافقة مستنيرة للمشاركة بدراسة بحث طبى

○ HGH ○ WH ○ RH ○ AAH
○ AKH ○ OTHERS

○ م. حمد العام ○ م. النساء ○ م. الرميلة ○ م. الأمل
○ م. الخور ○ م. أخرى

HC NO:
PATIENT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المريض:
تاريخ الميلاد:
الجنس (ذكر | أنثى) :
الجنسية:

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of rights or other benefits to which you are entitled. The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل , أثناء إجراء, أو بعد إكمال إجراء البحث إذا قررت إعطاء الموافقة على المشاركة في هذا البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة والمشروعة. لأعضاء فريق البحث العلمى الخاص بهذه الدراسة الحق في إيقاف أو إلغاء مشاركتكم في هذه الدراسة إذا رأو مصلحة لكم فى هذا الإيقاف أو الإلغاء أو فى حالة عدم التزامكم بخطة البحث الموضوعة أو إذا تبين لهم ضرر أو إصابة نتيجة إجراء الدراسة وذلك دون أخذ موفقتكم

Project Title:

عنوان المشروع:

Name of Principal Investigator: **اسم الباحث الرئيسي :**

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends]*

موقع إجراء البحث وأرقام الهواتف ***(أثناء أوقات الدوام, بعد الدوام و في العطلات):***

Each item given below has to be filled. Please write NA, if not applicable

يجب ملئ كل البنود أدناه وفي حال عدم توافر الإجابه الرجاء كتابة غير متوفر.

Introduction to the research: *[A brief introduction is given about the research, what it hopes to achieve, who is conducting it etc.,]*

1. مقدمة عن البحث الطبى *(وصف موجز للدراسة وما يمكن تحقيقه من إجراء البحث ومن يقوم بإجراء البحث).*

Purpose of the research: *[Brief, clear description of the purpose, goals and objectives of the research are provided here]*

2. الغرض من إجراء دراسة البحث *(وصف مختصر و واضح للغرض و الاهداف من وراء البحث).*

Selection of research subjects: *[A brief description on how research participants are selected, the inclusion and exclusion criteria used to select the sample population and an explanation of why this particular participant is being considered for inclusion in the study]*

3. إختيار المشاركين بالدراسة *(وصف موجز عن الكيفية التي تم عليها اختيار الأشخاص المشاركين في البحث و المعايير التي تم عليها الإنضمام أو إستثناء العيّنة السكانية مع إيضاح اسباب إختيار هذا الشخص للإنضمام في هذه الدراسة)*

Distinction between routine care and research activities: *[In case the prospective participant is to be recruited from the patient clientele of treating physicians who also are investigators in the research a description is given to the participant about what parts of the treatment constitutes routine treatment and what constitutes research activities]*

4. عرّف الفرق بين خدمة الرعاية الإعتياديّة والأنشطة البحثيّة *(فى حالة إختيار مشارك/مشاركة بالدراسة من ضمن الأشخاص اللذين تقدم لهم خدمات رعاية صحية او طبية من قبل احد أعضاء فريق البحث، يجب على فريق البحث أن يوِّضح لمن وقع عليه الإختيار أى جانب من خطة الرعاية الصحية أو الخدمة العلاجية يقع تحت طائلة الخدمة العلاجية اللتى يحتاجها المشارك واى جانب من هذه الخطة يقع تحت طائلة دراسة البحث الطبى المقترحة)*

Explanation of the procedures to be used: *[Brief, clear explanation of procedures involving the subject]*

5. أشرح الاجراءات التي يتعين استخدامها فى الدراسة *(شرح واضح و موجز للإجراءات المتعلقة بالافراد المشاركين).*

Description of the risks and discomfort involved: *[Describe physiological, psychological and social factors of discomfort or risks involved in the study]*

6. وصف للمخاطر والإزعاج الناجمة عنه (*وصف الفيزيولوجية,العوامل النفسية والإجتماعية والأخطار المترتبة والناتجة عن البحث*).

POSSIBLE PREGNANCY RISKS – If there are no risks to pregnant females or females of child bearing age, you do not need to include any of the following statements in the informed consent. If pregnant or nursing women are excluded from the study, a statement supporting the rationale for not including pregnant women needs to be included in the informed consent. For studies that involve the use of drugs, devices or procedures with risks to the fetus in females of child bearing potential, choose one of the following statements: a. There is evidence of potential for birth defects; or b. Animal studies have shown potential for birth defects and there are no human studies; or c. There are no known animal or human data on the potential for birth defects

فرضية إحتمال وجود مخاطر أثناء الحمل: (*في حال تأكد الباحث من عدم وجود مخاطر للدراسة على* ***الحوامل أو الإناث في سن الإنجاب***,*لا يجب علك إدراج أي من الملاحظات التالية في الموافقة المستنيرة. . في حال إستثناء المرأة الحامل أو المرضعة من الدراسة يجب إدراج وشرح اسباب هذا الإستثناء في الموافقة المستنيرة. في الدراسات التي تتضمن استخدام الأدوية, الأجهزة أو الإجراءات التي قد تتسبب في مخاطر للجنين إختار أحد الملاحظات التالية (أ : تشير الدلائل إلى وجود أسباب قد تنتج بموجبها تشوهات تكوينية محتملة اثناء نموء الجنين داخل الرحم; أو (ب. وقد أوضحت الدراسات التي أجريت على حيوانات بالمختبر إمكانية حدوث عيوب وتشوهات تكوينية اثناء نموء جنين الحيوان داخل الرحم ولكن لا توجد دراسات أجريت على الإنسان. (ت لا توجد معلومات سواء على الحيوان أو الإنسان عن إمكانية حدوث تشوهات خلقيّة.*)

Description of Safety precautions in this research: *[Describe about the safety precautions that will be taken during study period]*

7. وصف إجراءات و إحتياطات السلامة (*صف إحتياطات السلامة التي سوف تتخذ أثناء فترة الدراسة*).

Descriptions of the benefits of the study: *[Brief description of any direct or indirect benefits to the subject]*

8. وصف لفوائد المشاركة بالدراسة إن وجدت (*وصف بإيجاز للفوائد المباشرة أو غير المباشرة والمترتبة للمشارك بهذه الدراسة*).

Description of the alternative procedures or treatments for this research: *[A description of all alternative procedures or treatment options available to the potential research participant , so that the participant is free to choose which treatment modality to adopt]*

9. وصف الإجراءات أوالعلاج البديل لهذه الدراسة *(وصف كافة الإجراءات البديلة أو خيارات العلاج المتاحة والمحتملة للمشاركِ بحيث تتوفر حرية إختيار المشارك لإسلوب العلاج)*.

Details of the options to remain on the research treatment after termination of the research: *[A description is provided about whether the research treatment would be available to the participant even after the study has concluded]*

10. تفاصيل عن خيارات البقاء على العلاج المتبع أثناء فترة البحث حتى بعد انتهاء البحث *(تقديم إيضاح للمشارك حول ما اذا كان البحث أوالعلاج سيكون متاحا وحق للمشارك حتى بعد انتهاء الدراسة)*.

11. **Details of the person to contact in case of Injury or enquiry during the research:** *[In case of any types of injury or enquiry, provide name of Supervisor and office phone number to contact at any time of the day or night]*

11. تفاصيل عن الشخص الممكن الإتصال به في حالة وجود استفسار أو حدوث إصابة خلال فترة البحث (إسم المشرف, رقم تليفون المكتب للتصال به في حالة وجود أي ضرر سواء ليل أو نهارا .

Details of the financial or other compensation which might be provided to the research participants if any: *[Provide details of any compensation which might be provided in lieu of their participation in the research]*

12. تفاصيل عن التعويضات الماليّة أو غيرها المحتمل إعطائها للمشاركين في البحث *(وضح بالتفصيل إن كان هنالك مكافأة مالية أوعينية للمشارك بالدراسة)*.

13. مدة إجراء البحث (*صف المدة المتوقعة للمشاركة في البحث و ما هي توقعات الباحث للوقت المستغرق في إجراء البحث*).

Duration of the research: *[Describe how long the prospective participant is expected to be in the research and what expectations the investigator might have about the participant's time spent in the research]*

14. أسماء مصادر تمويل البحث (*إذا تواجد أعطى تفاصيل للمشاركين عن إسم الجهات اللتى قامت بتمويل البحث، وما إذا كان لهذه الجهات مصلحة أو عائد مادى منتظر*).

Names of the sponsors of the research: *[if applicable, and details about where the research is going to be conducted. Give information to the participant about all the sponsors of the research, any issues of conflict of interest and also where the research will be conducted]*

15. السرية حول النتائج، العينةالمختبرية أو أي بيانات أخرى (*صف خطوات حماية سرية البيانات، العينةالمختبرية أو أي بيانات أخرى من شأنها الكشف عن هوية او أسم أى مشارك بالدراسة*).

Assurance of anonymity and confidentiality: *[Confidentiality about the results/specimen/laboratory or any other data) Describe steps to protect confidentiality of data and anonymity of the participant information]*

16. تنويه بعدم القسرية (*إقرار بعدم ممارسة ضغوط على المشارك للموافقة و انه حر في اختيار الوسيلة المناسبة للعلاج و انه غير ملزم بالاستمرار في الدراسة حتى بعد التسجيل*)

Non-coercive disclaimer: *[A statement that there is no pressure on the prospective subject to participate in the study , that he/she is free to choose any of the treatment modalities offered and that there is no pressure on the participant to continue in the study even after enrollment]*

Option to withdraw from the study without penalty: *[An option is given to the potential participant to continue or withdraw from the study even after enrollment in the research]*

17. إمكانية إنسحاب المشارك من الدراسة أو البحث دون عواقب *(أعطي الخيار للمشارك في البحث للاستمرار أو الإنسحاب من الدراسة حتى بعد التسجيل في الدراسة.)*

Details about termination of the study: *[A description is given on when and how the study is expected to be completed, what happens when the study is completed, whether the participant is further entitled to contact the investigators after such time, whether the findings of the research will be revealed to them and if the results of the research would be applied to them or not]*

18. تفاصيل عن إنهاء الدراسة أو البحث *(أعطى شرحا وافيا عن التوقعات بشأن المدة الزمنية والطريقة التى يتم بموجبها إعلان إكتمال الدراسة أو البحث. أشرح ماذا يحدث بعد إنتهاء الدراسة أو البحث، حدد ما إذا كان للمشارك الحق فى الإتصال بفريق البحث بعد فترة من الزمن، الإطلاع على نتائج البحث، وما إذا كانت النتائج ستطبق على المشاركيين*

Details of the instances in which there might be incomplete disclosure of information: *[Description of the instances in the study in which the investigator might not provide all information needed to take an informed consent at the outset of the study, why this is so and when there will be debriefing if any of the undisclosed information to the participant]*

19. تفاصيل عن الحالات التي قد يكون فيها افشاء المعلومات غير مكتمل *(وصف الحالات في الدراسة والتى قد يقدم فيها الباحث عن عدم توفير أو إفشاء جميع المعلومات المطلوبة لاتخاذ إجراء الحصول على الموافقة المستنيرة الخطية في بداية الدراسة, وضّح لماذا إتخذ الباحث هذا الموقف ومتى يتم استخلاص المعلومات إن وجدت وتوفرها لكى يضطلع عليها المشارك بالدراسة)*.

Signed Consent for Study Participation

Consent: You (the participant) have read or have had read to you all of the above. Dr. *[insert name]* or his/her authorized representative has provided you with a description of the study including an explanation of what this study is about, why it is being done, and the procedures involved. The risks, discomforts, and possible benefits

الموافقة المستبينة للمشاركة فى البحث

*الموافقه المستبينة الخطية: عزيزي المشارك في هذا البحث قد قمت بقراءة أو قد قرىء عليك المرفق أعلاه. د. اسم الباحث الرئيسي **أو من** ينوب عنه قد قام بإعطائك شرح للدراسة متضمناً اسباب القيام بهذه الدراسة و الإجراءات المتضمنة في هذه الدراسة. كما تم إعطائك شرح عن الإزعاج و المخاطر و الفوائد المحتملة من وراء هذه الدراسة و إذا ما كان لك خيارات بديلة للعلاج. لك حق الاستفسار و طرح أي سؤال متعلق بهذه الدراسة أو مشاركتك فيها. تم القيام بتقديم شرح عن حقوقك كمشارك في هذه الدراسة و ان موافقتك على المشاركة في هذا البحث هي عمل تطوعي.

of this research study, as well as alternative treatment choices, have been explained to you. You have the right to ask questions related to this study or your participation in this study at any time. Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. By signing this form, you willingly agree to participate in the research study described to you. You will receive a copy of this signed consent form. As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified

بالتوقيع على هذه الورقة, إقرار منك بالموافقة على المشاركة في هذا البحث.
سوف تعطى لك نسخة من هذا الإقرار بالموافقة. توقيعك على هذه الوثيقة يعتبر صالح في حال تم تجديد هذا البحث طوال فترة الدراسة البحثية. سوف يتم إبلاغك في حال حصول أي تغيير في الدراسة مما قد يؤثر على موافقتك على المشاركة.

Participant / Parent(s)/ Guardian's Nam	Signature & Date	التوقيع وتاريخه	إسم: المشارك ، الوالد (الوالدين) أو الوصي
Child's Name	Signature & Date		إسم الطفل المشارك
Witness Name	Signature & Date	التوقيع وتاريخه	إسم الشاهد
Principal Investigator's Name	Signature & Date	التوقيع وتاريخه	إسم الباحث الرئيسي
For use of Medical Research Center only		**إستخدام مركز الأبحاث الطبية فقط**	

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

WAIVER OF SIGNED INFORMED CONSENT/VERBAL/ORAL CONSENT FORM

تخويل موافقة خطية / لفظية / شفوية

○ HGH ○ WH ○ RH ○ AAH
○ AKH ○ OTHERS

○ م. الأمل ○ م. الرميلة ○ م. النساء ○ م. حمد العام
○ م. أخرى ○ م. الخور

HC NO:
PATIENT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المريض:
تاريخ الميلاد:
النوع (ذكر | أنثى) :
الجنسية:

Information to Participants

1. You are free to ask as many questions as you like before, during or after this research, should you decide to consent to participate in this research study.
2. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is entirely voluntary.
3. You are entitled to participate in this study if you satisfy certain eligibility criteria
4. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled.
5. You may decide not to participate in this study at any time without penalty or any loss of rights or other benefits to which you are otherwise entitled.

(1) لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل , أثناء أو بعد إكمال إجراء البحث الذي قررت موافقة المشاركه فيه.

(2) الهدف الرئيسي من المعلومات الواردة في هذا النموذج هو أن نقدم للمشارك الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعي.

(3) لك حق المشاركة فى البحث المطروح وذلك بعد إستيفاء الشروط المطلوبة.

(4) لك الحق الكامل فى إتخاذ قرارعدم المشاركة بالبحث. قرارك بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقك المستحقة.

(5) لك مطلق الحرية فى إتخاذ قرار عدم المشاركة بالبحث وذلك فى أى وقت من غير تبعات او حرمان من حقوقك المستحقة.

Research Project #: **رقم المشروع:**

Project Title : **عنوان المشروع :**

Name of Principal Investigator: **اسم الباحث الرئيسي:**

Contact address and phone number: *[Provide appropriate information for contact during daytime, after working hours and during weekends]*

موقع إجراء البحث وأرقام الهواتف *(أثناء أوقات الدوام , بعد الدوام وفى العطلات)*:

Each item given below has to be filled in. Please write NA, if not applicable. This form may be read to the participant or the participant's legally authorized representative by the principal investigator or his/her representative.

يجب ملئ كل البنود أدناه وفي حال عدم توفر الإجابه الرجاء كتابة غير متوفر. يمكن للباحث الرئيسى أو احد مساعديه فى إجراء الدراسة قراءة هذا النموذج للمشارك بالبحث أو الوصى الشرعى للمشارك بالبحث.

1. Introduction: *[Give details that the study involves research, who the investigators will be, where it would be conducted, the number of sessions it will be conducted in, the duration of the research and the expected time of completion of the research, approximate number of participants, the costs of participation and why the person has been selected for inclusion in the study]*

(1) مقدمة عن البحث الطبى *(صف وصفاً موجزا للدراسة مع تحديد مكان إجراء الدراسة، الوقت المطلوب من المشارك تخصيصه لمشاركته والمدة الزمنية المتوقعة لإتمام الدراسة، ومن يقوم بإجراء البحث. أعطى بالتقريب العدد المتوقع للمشاركين بالدراسة والتكلفة الفعلية للمشاركة. إشرح للمشارك الاسباب والدوافع التى تم بموجبها إختياره للمشاركة بالدراسة)*.

2. Purpose of the research study: *[Give a brief description of the purpose, goals, aims/ objectives of the study]*

(2) الغرض من إجراء الدراسة البحثية *(قدم وصفا موجزا عن الغرض من إجراء هذه الدراسة)*.

3. Description of the procedures that will be followed during the research: *[Give a brief description of the procedures involves. Explain how the research data will be handled. Include any alternative procedures or courses of treatment than the ones proposed by the study]*

(3) شرح الاجراءات التي يتعين استخدامها فى الدراسة *(أشرح بإيجاز الاجراءات المطلوبة والمتعلقة بالدراسة. قدم شرح وجيز عن كيفية التعامل مع المعلومات المتحصل عليها. وصف كافة الإجراءات البديلة أو خيارات العلاج المتاحة و غير المطروحة في الدراسة البحثية والمحتملة للمشارك بحيث تتوفر حرية إختيار المشارك لإسلوب العلاج البديل.*

4. Description of any foreseeable risks or discomforts to the participants: [*Describe risks and discomforts to participants. Include risks of the procedures, and any physiological, psychological or social discomforts that the participants might face because of their involvement in the study and where they might get information on these aspects]*

(4) وصف المخاطر والإزعاج الذي قد يتعرض لهما المشارك: *(صف مخاطر الإجراءات المتخذه و أي إزعاج فيزيولوجي, نفسي أو إجتماعي قد يتعرض له المشارك بسبب مشاركته في الدراسة و أين يمكنه الحصول على المعلومات في هذا الجانب).*

5. Description of any benefits to the participant or to others which might be reasonably expected from the research: [*Give a description in brief of the expected benefits – direct or indirect from the research in straightforward statements, without introducing elements of bias or coercion into them*]

(5) شرح الفوائد المتوقعة من البحث لصالح المشارك بالدراسة أو لغير المشاركين *(وصف بإيجاز وبدون تحيز للفوائد المتوقعة المباشرة أو غير المباشرة والمترتبة للمشارك بهذه الدراسة).*

6. Confidentiality : [*Give a description of the steps that would be taken to ensure confidentiality of the records ,laboratory specimens, or results which might identify the participant will be maintained]*

(6) السرية: *(صف خطوات حماية سرية البيانات، العينة المختبرية أو أي نتائج أخرى من شأنها الكشف عن هوية او أسم أى مشارك بالدراسة).*

I, ---------- have fully explained to Mr. / Mrs. ---------- the nature and purposes of the above describe research project.

أقر انا _____ بأني قدمت الشرح الوافى والمستفيض للسيد/السيدة _____ وذلك عن طبيعة ودوافع دراسة البحث المنتظرة.

I believe that he/ she understands the nature, purpose and risks of the study.

وبحسب الشرح الوافى والمستفيض، أعتقد أن السيد/السيدة قد فهم طبيعة ودوافع البحث وكذلك ما يمكن أن ينجم من اخطار نتيجة مشاركتهم بالبحث.

I have also offered to answer any questions relating to this study that he/she might have and I declare hereby that I have completely and fully answered all such queries.

كما أقر بأنني قد قمت بطرح إستعدادي للإجابة عن كل الاسئلة والاستفسارات الخاصة بالدراسة والبحث. وبموجب ذلك اكون قد إستوفيت الشرح الكامل للبحث المنتظر واجبت عن كل ما يمكن أن يطرح من سؤال او إستفسار.

Signature of the person obtaining the consent:

توقيع الشخص طالب الموافقة

Name of the person obtaining the consent:

إسم الشخص طالب الموافقة:

Date:

تاريخه:

Note : Waiver of signed informed consent or informed consent is given to prospective studies in the situations given below:

ملاحظة : تخويل موافقة خطية / لفظية / شفوية وذلك بغرض إجراء دراسة بحث طبى أو الموافقة الخطية للابحاث السريرية في مؤسسة حمد الطبية , لا تعطى إلا للدراسات المستقبلية في الحالات الواردة أدناه :

1. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. (When the Research Committee waives the requirement for documentation of consent under this condition, each participant must be asked whether he/she wants documentation linking him/her with the research, and the participant's wishes will govern.)

1. ان تكون هذه الموافقة هي حلقة الوصل بين المشارك و البحث و ان الخطر الرئيسي سيكون الأذى نتيجة خرق الخصوصية. (عندما تخول لجنة الابحاث الى طلب لهذا المستند, في هذه الحاله يتم سؤال المشارك ان كان يرغب في مستند يصل بينه و بين البحث و رغبة المشارك لها الأحقية.)

2. That the research presents no more than

2. ان يقدم البحث أقل مخاطر أو أذى للمشارك و ان لا يحتوي على إجراءات تتطلب الموافقة خارج إطار البحث ذاته.

كما يمكن استخدام هذه الموافقة لإحدى الحالات التالية:

* للأبحاث التي تتضمن سحب عينات إضافية اخرى غير التي سحبت للأسباب السريرية , أو عند التبرع بالدم .

minimal risk or harm to the participants and involves no procedures for which written consent is normally required outside of the research context.

It could be used in situations such as the ones given below:

1. For researches which involve drawing of additional blood samples when blood is already being obtained for clinical purposes or during blood donations
2. For researches which involve sampling of additional bodily secretions when such secretions are already being sampled for clinical purposes
3. For researches that involve no more than minimal risk of harm to the participant and the research does not involve any intervention/procedure/invasion of privacy of the participant
4. For qualitative researches like surveys using questionnaires or interviews with participants.

* للأبحاث التي تتضمن أخّذ عينات إضافية من جسم المريض كإفرازات غير التي سحبت للأسباب السريرية .

*للأبحاث التي يكون الأضرار والأذى المتسبب من هذا البحث طفيفة على ان لايكون للبحث صلة بالإجراءات المطلوبة الأخرى,

* للأبحاث النوعية, الاستبيانات و المقابلات.

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

HC NO:

PATIENT NAME:

DOB:

GENDER:

NATIONALITY:

HAMAD MEDICAL CORPORATION

HGH☐ WH☐ RH☐ AAM☐ AKH☐ Others ☐

WAIVER OF INFORMED CONSENT

Proposal Title:

Name of the PI:

A waiver of all the consent requirements is requested because this research involves no risk to the subjects. Their rights and welfare will not be adversely affected since data related to patients on sensitive issues will not be collected.

This research also could not be carried out practicably without a waiver of the consent requirements. Information regarding collected data will be kept confidential.

Signature of PI

Note: Waiver of Informed consent is given only for retrospective studies in the situations given below:

1. No more than minimal risk to the subject;
2. The research could not practically be carried out without the waiver;
3. The research would not adversely affect the rights and welfare of the subject and
4. The subject should be provided with additional pertinent information after participation, where appropriate.

A

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

○ HGH ○ WH ○ RH ○ AAH ○ AKH ◉ OTHERS

○ م. حمد العام ○ م. النساء ○ م. الرميلة ○ م. الأمل ○ م. الخور ○ م. أخرى

HC NO:
PARTICIPANT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المشارك:
تاريخ الميلاد:
الجنس (ذكر | أنثى) :
الجنسية:

Consent form template for studies involving genetic testing

نموذج موافقة مستبينة للمشاركة بدراسة تنطوى على الإختبارات الجينية

Identifiable Samples and Intent to Disclose the Testing Results

إستخدام عيّنات معّرفة وذلك بهدف الكشف عن نتائج الإختبارات أو الفحص

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of rights or other benefits to which you are entitled.

كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل, أو أثناء, أو بعد إكمال إجراء البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة.

NOTE: This template is best for studies using identifiable samples and there is an intent to disclose results of the genetic testing to subjects, families, or subjects' health care providers

ملاحظة: هذا النموذج هو الأفضل لإستخدامه فى الدراسات التى تنطوى على الإختبارات الجينية وذلك فى عيّنات معّرفة ومحددة بحيث تكون لدى فريق البحث النية فى الكشف عن نتائج هذه الإختبارات للمشاركين بالدراسة أو لأسرهم أو لمن يقدمون الخدمات الصحية للمشاركين بالدراسة كالطبيب مثلا.

PLEASE DO NOT CHANGE THE FORMAT OF THIS TEMPLATE

فضلا لا تغير فى الشكل العام لهذا النموذج

Project Title: **عنوان المشروع :**

Name of Principal Investigator: **اسم الباحث الرئيسي :**

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends]*

وفي موقع إجراء البحث وأرقام الهواتف *(أثناء وخارج أوقات الدوام عطلة نهاية الاسبوع)*

Each item given below has to be filled in. Please modify according to your study needs. The tips *[in blue]* can be erased.

يجب تعبئة كل البنود أدناه حسب إحتياج الدراسة. النصائح الإرشادية المبينة باللون الأزرق يمكن مسحها من النموذج.

Invitation to participate and summary: *[State the overall purpose of the study in simple terms]*

You are invited to participate in a research study being conducted by **Dr. X** and others at the Hamad Medical Corporation. Researchers at other Institutions in the State of Qatar and other countries are also working on this study. They will be studying blood cells looking for mutations (changes in genes) that might cause people with hepatitis to develop liver cancer later in life. You are being invited to participate in this study because you have hepatitis or have had it in the past. This form reviews several things you should know before you agree to participate. Participation in all

دعوة للمشاركة وملخص

إرشاد : إشرح الغرض العام من إجراء هذه الدراسة وذلك بعبارات بسيطة

انتم مدعوون للمشاركة في هذه الدراسة البحثية التي يقوم بها **الدكتور س** وزملاؤه في مؤسسة حمد الطبية وباحثون من جامعات أو مؤسسات صحية أخرى في دولة قطر ودول أخرى تعمل أيضا على هذه الدراسة. فى هذا البحث سوف نقوم بدراسة خلايا الدم وذلك للإستكشاف أو البحث عن ما يعرف بالطفرات (التغيرات في الجينات) والتي قد تسبب الإصابة بسرطان الكبد في وقت لاحق في الحياة وذلك حصريا لدى المرضى أو الأشخاص الذين يعانون من مرض التهاب الكبد. ولذلك أنت مدعو للمشاركة في هذه الدراسة لأنه لديك التهاب الكبد أو كنت تعانى من هذا المرض في الماضي. من خلال هذا النموذج نود استعراض العديد من الأشياء والتى يجب أن تعرفها قبل أن توافق على المشاركة فى هذا البحث. المشاركة في البحوث التى تُجرى فى مؤسسة حمد الطبية كما فى هذا البحث طوعية تماما، وقرار المشاركة أو عدمها يعود

research done in Hamad Medical Corporation is voluntary, and you may refuse to participate without any loss of rights or privileges to which you are otherwise entitled.

بالكامل لك. نود أن نؤكد أنه إذا قررت عدم المشاركة فى هذا البحث ، فإن ذلك القرار لن يترتب عليه أي فقدان للحقوق أو الامتيازات التي تستحقها.

What is the purpose of the study?
[Explain to potential subjects why the study is being done]

Liver cancer (hepatocellular carcinoma) is a common cause of death around the world. It has been known for many years that people who have certain types of hepatitis have a somewhat higher chance of developing liver cancer later in life. However, not all people with hepatitis will go on to develop cancer. **Dr. X** and his colleagues are trying to find out if there is something different in the genes of people who develop liver cancer after having hepatitis. If such a difference can be found, it might allow doctors to identify people who have an increased risk of developing liver cancer. If so, it is possible that following those people more closely will allow earlier detection of the cancer so that it can be treated more effectively. Finding mutations that increase the risk of cancer may also lead to additional research, which could someday help doctors develop more effective treatments for liver cancer, or even ways to prevent the cancer from developing in the first place.

ما هو الغرض من الدراسة؟
إرشاد : إشرح للمشارك المحتمل فى هذا البحث لماذا تُجري هذه الدراسة

سرطان الكبد هو سبب شائع للوفاة في جميع أنحاء العالم. والمعلوم لسنوات عديدة أن الأشخاص الذين لديهم أنواع معينة من التهاب الكبد لديهم فرصة أو قابلية أعلى من المعتاد للإصابة بسرطان الكبد في وقت لاحق في الحياة. ومع ذلك ، فإنه ليس كل الناس الذين لديهم التهاب الكبد يمكن أن يتطور مرضهم قدما للإصابة بالسرطان. **الدكتور س** وزملاؤه يحاولون معرفة ما اذا كان هناك شيء مختلف في جينات الناس الذين يصابون بسرطان الكبد بعد إصابتهم بمرض التهاب الكبد. إذا أمكننا العثور على مثل هذا الفرق فى الجينات، فإن ذلك قد يسمح للأطباء لتحديد الاشخاص الذين لديهم قابلية للإصابة بسرطان الكبد. وإذا كان الأمر كذلك ، فمن المحتمل أنه في حالة متابعة الحالة المرضية لهؤلاء الناس على نحو أوثق فقد يسمح ذلك بالكشف المبكرعن السرطان بحيث يمكن التعامل معه على نحو أكثر فعالية. العثور على الطفرات التي قد تزيد من خطر أو قابلية الاصابة بالسرطان يؤدي أيضا إلى إجراء المزيد من البحث والدراسة فى هذا الشأن، وهذا يمكن أن يساعد الأطباء في يوم من الأيام على تطوير علاجات أكثر فعالية لسرطان الكبد ، أو حتى فى إستحداث وسائل لمنع حدوث مرض السرطان فى المقام الأول

What does participation in this study involve? *[Explain (1) the procedures that subjects will undergo for the study, the information that will be collected from subjects, how the information will be collected, and why the information will be collected; (2) the type of sample and how it will be collected (e.g., by blood draw, skin biopsy, cheek swab); (3) in simple terms what will be done with the sample; and (4) whether there are an specified or unspecified future plans for use of the sample]*

Some mutations are more common among people from particular racial or ethnic groups, or in people who have had other medical problems in the past. Knowing background information about you will help **Dr. X** determine whether this is true for the mutations he is looking for. You will be asked to give your age, race, sex, ethnic background, family history, and your health history. We will also ask permission to review your medical records, in order to confirm your health history and fill in any details you might have forgotten. We will then ask your permission to take like 2 spoons of your blood from a blood vessel in your arm. This blood will be used in this research.

DNA will be removed from your blood sample in the laboratory. DNA is present in your genes. Genes are the material passed from parents to child that influences the make-up of the body and mind, such as how someone looks and if someone is more likely to get a disease. Some of the DNA may be saved for future testing, and some of the cells from your blood may be kept alive and growing in the laboratory as a "cell line". This will allow **Dr. X** to get more DNA if he needs it (see below). The rest of your blood sample will be thrown away. The DNA will be studied, and patterns in your DNA markers will be recorded and compared to those of other people with hepatitis, some of whom have had liver cancer. If any patterns are found consistently in those who have cancer but not in those who have not had cancer, further testing will be done to see if those patterns are markers of a nearby gene or genes that are responsible for the increased risk of cancer. If that turns out

ماذا تشمل المشاركة في هذه الدراسة ؟

إرشاد : إشرح (1) الإجراءات التي سيخضع لها المشارك بالدراسة ، مع التركيز فى المعلومات التي سيتم جمعها من المشارك، وكيف يتم جمع المعلومات هذه ، ولماذا يتم جمع المعلومات ، (2) نوع العينة، وكيف سيتم جمعها (على سبيل المثال، عن طريق سحب الدم ، أوخزعة الجلد ، أو عن طريق المسحة الاختيارية من الفم) ، (3) بعبارات بسيطة أشرح ما سيتم عمله مع العينة ، و (4) ما إذا كانت هناك خطط محددة أو غير محددة لاستخدام العينة في المستقبل.

تعتبر بعض الطفرات أكثر شيوعا بين الناس خاصة من مجموعات عرقية أو أصول معروفة ، أو في الناس الذين لديهم مشاكل طبية أخرى محددة في الماضي. معرفة المعلومات الخلفية عنك سيساعد **الدكتور س** من تحديد ما إذا كان هذا صحيحا وينطبق على الطفرات التى نحاول أن نستكشفها من خلال هذا البحث. ولذلك سوف يطلب منك بيان عمرك والعرق والجنس والخلفية العرقية والتاريخ العائلي ،هذا بالإضافة الى التاريخ الصحى الخاص بك. ونسأل أيضا أن تأذن لنا بمراجعة السجلات الطبية الخاصة بك ، وذلك من أجل تأكيد صحة التاريخ الخاص وملء أي تفاصيل قد تكون قد نسيت أن توفينا به. بعد ذلك سوف نطلب منك السماح لنا بسحب عينة من دمك من وريد فى ذراعك. تقدر كمية الدم المطلوبة والتى سوف نستعملها فى هذا البحث بمقدار ملعقتين.

ستتم إزالة الحمض النووي من عينة الدم في المختبر. الحمض النووي موجود في الجينات الخاصة بك. والجينات هي المادة التى من خلالها تنتقل الموروثات والخصائص من الوالدين الى الطفل وبذلك تحدد الصفات الجسمانية والعقلية لدى الطفل، مثل كيف يبدو الطفل فى مظهره العام وما اذا كان قد إكتسب قابلية تجعله أكثر احتمالا فى الحصول على المرض. قد يتم حفظ بعض من الحمض النووي للاختبار في المستقبل، أيضا قد يتم حفظ بعض الخلايا من عينة الدم والإبقاء عليها على قيد الحياة والنمو في المختبر كخط "خلية". هذا سوف يسمح **للدكتور س** الحصول على مزيد من الحمض النووي إذا دعت الحاجة (انظر أدناه). بعد ذلك سيتم التخلص من ما تبقى من عينة الدم الخاصة بك. فى هذا البحث، ستتم دراسة الحمض النووي, وكذلك الأنماط السائدة فى الحمض النووى الخاص بك بحيث يتم تسجيلها ومقارنتها مع الأنماط الأخرى لمرضى آخرين يعانون من التهاب الكبد ، الذين تطور المرض لدى بعض منهم لسرطان الكبد لمعرفة ما اذا كانت هناك جينات مسؤولة عن زيادة خطرالتعرض للإصابة بالسرطان. إذا تم العثور على أية أنماط متناسقة فى أولئك الذين يعانون من السرطان وليس فى من لا يعانون من السرطان فسوف يتعّين إجراء المزيد من التجارب لمرفة ما إذا كانت هذه الأنماط مؤشرات على جين قريب أو هى جينات مسؤولة عن زيادة خطر الإصابة بالسرطان. إذا تبين أن ذلك صحيحا ، فسوف يترتب

to be true, further testing will be done to identify those genes and study them.

إجراء مزيد من التجارب وسوف يتم تحديد طبيعة هذه الجينات ودراستها.

MODEL LANGUAGE FOR WHEN SAMPLE WILL BE DESTROYED:

The information you provided and some of the DNA from your sample will be saved and the cell line will be kept alive in the laboratory until the study is completed, which is expected to be within the next 2 years. It will then be discarded.

اللغة النموذجية التى يجب إستعمالها للإخطار بالمدة التى يتم بموجبها إتلاف العينة

المعلومات التى زودتنا بها وبعض من الحمض النووي الذى إستخلصناه من عينة الدم الخاصة بك سيتم حفظها. ذلك ينطبق أيضا على خط الخلية والذى سيبقى على قيد الحياة في المختبر قدر المستطاع حتى الانتهاء من الدراسة ،والذى يتوقع أن يكون في غضون السنتين القادمتين. سيتم بعد ذلك التخلص من العينة.

MODEL LANGUAGE FOR WHEN SAMPLE WILL BE KEPT FOR FUTURE RESEARCH:

The information you provided and some of the DNA from your sample will be saved and the cell line will be kept alive as long as possible, hopefully for many years. This way, as more is learned about hepatitis and cancer, your DNA may be used for additional research. For example, it is possible that more accurate genetic testing may become available in the future, or that a follow up study will be done years from now. If so, the research team may contact you to update your health history and family history unless you initial below.

اللغة النموذجية التى يجب إستعمالها للإخطار بنية البحث فى الإحتفاظ بالعينة لغرض إستعمالها فى بحوث مستقبلية

المعلومات التى زودتنا بها وبعض من الحمض النووي الذى إستخلصناه من عينة الدم الخاصة بك سيتم حفظها. ذلك ينطبق على خط الخلية والذى سيبقى على قيد الحياة في المختبر قدر المستطاع ، ونأمل لسنوات عديدة. بهذه الطريقة ،على قدر ما نتعلم عن التهاب الكبد؛ وبذلك يمكن استخدام الحمض النووي لإجراء المزيد من البحث على ضوء المعلومات التى توفرت. على سبيل المثال ، فمن الممكن إستحداث أو تطور الاختبارات الجينية بحيث تكون أكثر دقة وأيضا يمكن أن تصبح متاحة بصورة أمثل في المستقبل ، أو قد نحتاج إلى متابعة الدراسة الحالية على ضوء معلومات جديدة وذلك بعد مضى سنوات من الآن. إذا كان الأمر كذلك ، فإن فريق البحث قد يتصل بك لتحديث التاريخ الصحي الخاص بك والتاريخ العائلي إلا إذا كنت لا ترغب فى ذلك حسب توقيعك بالأحرف الأولي أدناه.

☐ Mark here if you do **not** want us to contact you in the future for additional information. If you agree to be contacted and there have been any significant changes in your history, we may use DNA from this sample, and may also ask for another sample of blood, in order to do further testing. Please let the study coordinator know if you move or change doctors so you can be contacted if this happens.

ضع علامة هنا إذا كنت لا ترغب فى الإتصال بك في المستقبل ☐ للحصول على معلومات إضافية. إذا وافقت على ان يتصل بك فريق البحث أوكانت هناك أي تغييرات في تاريخكم الصحى أو المرضى ،سوف نستخدم الحمض النووي من هذه العينة ، ويمكن أيضا أن نطلب الحصول على عينة أخرى من الدم من أجل القيام بإجراء مزيد من الفحوصات. نرجو منك أن تقوم بإخطار منسق البحث أو أى من فريق البحث إذا حدثت تغيرات مثل عنوانك أو طبيبك المعالج حتى نتمكن من الإتصال بك إذا دعت الحاجة.

Dr. X may also want to use your cells or stored DNA in other research in the future, or share them with other researchers for use in their

الدكتور س قد يحتاج أيضا إلى استخدام الحمض النووي أو خط الخلية والتى تم تخزينها من قبل في بحوث أخرى في المستقبل ، أو فى إستخدامها من قبل باحثين آخرين في بحوثهم العلمية ذات الصلة. بعد قراءة الجزء أدناه بشأن مخاطر المشاركة ، سوف يطلب منك إخبارنا ما

work. After you read the section below on the risks of participation, you will be asked to let us know whether or not we may do that.

Will the results of the research tests be shared with anyone?
It is possible that the testing performed on your sample will reveal information that may be important for you to know. If that happens, you may be contacted and given this information unless you indicate below that you do not want to be contacted. If you are contacted, you might be told:

1) information is too sketchy to give you results from your own sample, but you will receive a letter updating you on the progress of the study, or

2) you have a high (or low) risk of developing a treatable or preventable medical problem, or

3) you have a high (or low) risk of developing a condition which is not currently treatable,

4) you have a high risk of developing a medical condition, and other members of your family may also have a similar risk. You may want to share this information with those members of your family and it may be recommended that you see a genetic counselor to discuss this in more detail.

After you read the sections about the risks and alternatives to participating in this study, you will be asked whether or not you wish to be contacted, and if so, whether anyone else should be given the information.

What are the risks of participating in this study? *[Address the potential risks associated with (1) the disclosure of information obtained in the study; (2) racial or ethnic associations that might be drawn from the study results; and (3) the risks associated with the collection of the sample. Because of the nature of genetic research and not all risks can be known at this, this section also should include a statement that there may*

.إذا كان يمكننا القيام بذلك أم لا

هل سيتم إستخدام نتائج الاختبارات فى هذا البحث من قبل آخرين؟
من الممكن أن الاختبارات التي أجريت على العينة الخاصة بك سوف تكشف عن معلومات قد تكون من المهم بالنسبة لك أن تعرفها. اذا ما حدث ذلك ، فسوف يتم الاتصال بك لغرض إطلاعك على هذه المعلومات إلا إذا كنت كما مبّين أدناه قد أبديت الرغبة فى عدم الإتصال بك. أما إذا تم الاتصال بك، فيمكن أن تتوقع إحتمال إخطارك بالآتى:

1) المعلومات المتوفرة حاليا نتيجة تحليل العينة الخاصة بك قد تكون سطحية جدا ، ولكنك سوف تتلقى رسالة تحديث وتنوير عن التقدم المحرز في هذه الدراسة، أو

2) لديك خطورة كبيرة (أو صغيرة) في خطر الاصابة بمشكلة طبية يمكن علاجها أو الوقاية من حدوثها. أو

3) لديك مخاطر جسيمة أو ضئيلة للإصابة بمشكلة طبية لا يتوفر حاليا علاج بالنسبة لها.

4) لديك مخاطر جسيمة للإصابة بمشكلة طبية ، وأعضاء آخرين من عائلتك قد يكون لديهم أيضا مخاطر مماثلة. قد تحتاج إلى تداول هذه المعلومات مع أعضاء العائلة وأنه قد يكون من المستحسن أن تقوم بمقابلة مستشار علم الوراثة لمناقشة هذا بمزيد من التفصيل

بعد قراءة الجزء المتعلق بالمخاطر والبدائل للمشاركة في هذه الدراسة ، سوف يطلب منك إيضاح ما إذا كنت ترغب أو لا ترغب في الاتصال بك ، وإذا كان الأمر كذلك ، نود أيضا أن نعرف ما إذا كنت ترغب فى أن تحدد أي شخص آخر يمكننا إعطاءه هذه المعلومات

ما مخاطر المشاركة في هذه الدراسة؟
إرشاد : ناقش المخاطر المحتملة المرتبطة مع (1) الكشف عن المعلومات التي تم الحصول عليها في هذه الدراسة ،(2)العلاقة العرقية او الأصولية التي يمكن استخلاصها من نتائج الدراسة ، و (3) المخاطر المرتبطة بعملية جمع العينة. ونظرا لطبيعة الأبحاث الجينية فإنه ليس بالإمكان أن نعرف كل المخاطر المرتبطة بهذه الأبحاث حاليا، وينبغي أن يشمل هذا القسم أيضا بيان أنه قد تكون هناك مخاطر غير

be unknown risks associated with participation in such studies]

معروفة ومرتبطة بالمشاركة في مثل هذه الدراسات

Risks of disclosure

There are risks in knowing the results of the testing on your sample. Knowing you have an increased risk of developing a problem may have a harmful psychological effect on the way you think about your future or your relationships with members of your family, especially if this changes their risks. If you agreed to allow your tissue to be used for other studies in the future, this information may come to you years from now.

There are also risks in not knowing the results. If the study of your sample shows that you have an increased risk of developing a treatable problem, and you have chosen not to be contacted, you may miss out on the benefit of detecting that problem early, if any such benefit exists. If you have chosen to be contacted and important information becomes available months or years from now, and we are unable to contact you (because of a move or other change), we will not be able to pass that information on to you.

It is also possible that the result of testing your sample may be unclear or misleading. This is not uncommon since many genes work together with other genes and environmental factors to produce diseases. In other words, finding a "high risk" marker in your DNA does not necessarily mean you will develop a problem, and there is still a chance you will develop a problem even if no such marker is found. See the "Alternatives" section for information about other ways to have the results of genetic testing explained to you.

Risks of racial or ethnic associations

It is possible that this study will show that

مخاطر الكشف

هناك مخاطر في معرفة نتائج الاختبار على العينة الخاصة بك. من المهم أيضا أن نذكر أن معرفتك لمعلومات تتعلق بإحتمال زيادة خطر التعرض لمشاكل صحية لديك قد يكون لها أيضا تأثير ضار لوضعك النفسي وقد تؤدى بك الى التفكير فى ماذا سوف يحدث لك في مستقبلك. كما يمكن أن يؤثر ذلك أيضا على علاقاتك مع أفراد عائلتك ، وخاصة إذا كانت هذه التغييرات سوف تزيد من المخاطر التي قد يتعرضون لها بنفس القدر عندك. فى حال موافقتك على إستخدام العينة\الأنسجة الخاصة بك فى أبحاث مستقبلية يمكن أن تتوقع موافاتك بهذه المعلومات فى غضون سنوات من الآن.

ينطوى عدم معرفة النتائج على مخاطر أيضا . إذا كانت نتائج دراسة العينة الخاص بك تدل على ان لديك زيادة مخاطر الاصابة بمشكلة صحية قابلة للعلاج ، وكنت قد اخترت عدم الاتصال بك لإخطارك بالنتائج ، فى هذه الحالة قد تفوت عليك فرصة الاستفادة من الكشف عن هذه المشكلة في وقت مبكر إذا كان هناك فائدة متوفرة من هذا الكشف للتعامل مع حالتك. وإذا كنت قد اخترت أن نتصل بك لنفيدك بأى معلومات جديدة فإنه من المحتمل أن نتوصل خلال أشهر أوسنوات من الآن الى معلومات جديدة وهامة بالنسبة لك، كما اننا قد لا نتمكن من إيصال هذه المعلومات لك نسبة لتعذر الاتصال بك بسبب تغّير عنوانك أو تغييرات أخرى لم تطلعنا عليها.

من الممكن أيضا أن تكون نتيجة اختبار العينة غير واضحة أو مضللة. هذا يمكن أن يحدث لأن عدة جينات عادة ما تعمل مع جينات أخرى وتفاعل الجميع مع عوامل بيئية لإحداث الأمراض. وبعبارة أخرى ، إذا تم التوصل إلى "احتمال كبير" لوجود علامة في الحمض النووي الخاص بك وتدل هذه العلامة زيادة فرضية إصابتك بمشكلة صحية فإن هذا لا يعني بالضرورة أنك سوف تصاب بهذه المشكلة، كما وأنه لا تزال هناك إمكانية أن تصاب بهذه المشكلة الصحية حتى لو تعذر العثور على أي علامة من هذا القبيل فى حمضك النووى. الرجاء مراجعة قسم "البدائل" فى هذه الوثيقة للحصول على معلومات حول الطرق الأخرى المتاحة لإطلاعك على نتائج الاختبارات الجينية.

مخاطر تتعلق بالإنتماء لمجموعة عرقية أو إثنية

من الممكن أن هذه الدراسة سوف تظهر أن أعضاء عرقك أو جماعة عرقية محددة تنتمى إليها قد تكون أكثر عرضة للاصابة بمرض السرطان أكثر من غيرها. هذا يمكن أن يؤدى لإعتبار ذلك وصمة أو

members of your race or ethnic group may be at higher risk of developing cancer than others. This may be seen as stigmatizing or discriminatory information.

Risks of sample collection
There is a small chance that drawing your blood will be painful or will cause bleeding, infection, or dizziness, as normal with blood drawing for any other purpose.

Other Risks
These are the best known risks of research in which tissue samples are used. There might be other risks we do not know about yet.

سببا للتمييز.

مخاطر جمع العينات
عملية سحب العينة كالدم مثلا يمكن أن تسبب بعض الألم فى موضع السحب أو تتسبب في حدوث نزيف موضعى أو إلتهاب، أو دوار عند بعض الأشخاص كما يحدث فى عملية سحب الدم العادية لأى أغراض أخرى.

المخاطر الأخرى
هذه هى المخاطر المعروفة عن المشاركة فى البحوث التي تستخدم فيها عينات الأنسجة. قد تكون هناك مخاطر أخرى نحن لا نعرف عنها حتى الآن.

What are the benefits of taking part in this study?
[Generally genetic testing is not believed to directly benefit subjects, although there are cases when there is an expected therapeutic benefit.]

Participating in this study is not expected to benefit you directly. If the study is successful, it may some day help prevent liver cancer in others or lead to more effective treatments. Some people also find satisfaction in contributing to scientific knowledge.

ما هي فوائد المشاركة في هذه الدراسة؟
إرشاد : من المعلوم أن الاختبارات الجينية عموما ليست لها فائدة مباشرة أو آنية بالنسبة للمشارك بالبحث، وإن كانت هناك حالات تكون فيها فائدة علاجية يمكن أن تفيد المشارك

كمشارك فى هذا البحث لا نتوقع أن تكون لك فوائد مباشرة تجنيها. إذا كانت الدراسة ناجحة ، فإنها قد تساعد يوما ما في منع حدوث سرطان الكبد لدى مرضى آخرين أو أن تؤدي إلى إستحداث علاجات أكثر فعالية. بعض الناس أيضا يبدون الإرتياح والشعور بالرضا على إسهامهم الشخصى في تطور المعرفة العلمية.

Are there any alternatives to taking part in this study?
[In the case of non-therapeutic research, clarify in this section that participation in the research is not required for participants to treatment or a diagnosis that would normally be available to them outside the research context.]

Participation in this research study is voluntary. The results of the tests conducted for this study will not be shared with you because their reliability and value in treating or diagnosing conditions is not known.

If you would be interested in determining your risk of developing cancer once such a test becomes available, reliable, and helpful, you should periodically ask your doctor or a genetic counselor if the test is available, and

هل هناك أي بدائل للمشاركة في هذه الدراسة؟
إرشاد : في حالة البحوث غير العلاجية ، وضّح في هذا القسم أن المشاركة في هذا البحث لا تتطلب من المشاركين الخضوع لعلاج أو تشخيص مما قد يكون متاحا لهم خارج إطار البحث.

المشاركة في هذه الدراسة البحثية طوعية تماما. نتائج التجارب التي أجريت لهذه الدراسة لن يتم إطلاعكم عليها وذلك نظرا لأن قيمتها في علاج أو تشخيص الحالات المرضية غير معروفة.

إذا كنت ترغب في معرفة أى مخاطر قد تكون لديك بالنسبة للإصابة بالسرطان متى ما تم إستحداث الاختبارالخاص بذلك ومن ثم التأكد من فعاليته وفائدته، فإنه يجب عليك أن تسأل الطبيب دوريا أو تستشير مستشار علم الوراثة إذا أصبح الاختبار متاحا، وان تناقش مع أى منهما مزايا و مساوئ هذا الإختبار (مستشار علم الوراثة هو شخص مدرب تدريبا مهنيا لمساعدتك على فهم نتائج الاختبارات الجينية وما تعنيه ومالاتعنيه بالنسبة لك ولأفراد عائلتك.)

ask him or her to discuss its advantages and disadvantages with you. (A genetic counselor is professionally trained to help you understand what genetic test results mean and don't mean for you and members of your family.)

How will my confidentiality be protected?

[Describe in this section how the data will be protected, where it will be stored, who will have access to directly identifiable information, and whether any oversight committees will be able to review research records.]

The results of this study may be published in a medical journal, but the only people who would be able to identify you from published information will be those involved in the research. Study records may be reviewed by representatives of the Research Committee of Hamad Medical Corporation or by corporate research sponsors. The results of your tests will be kept in a locked file cabinet or protected computer files only accessible to the principal investigator for this study. The tests will be given a code number and the list that links the code back to your name will be stored separately from this information. No information from this study will be placed in your medical records, except this consent form.

كيف سيتم حماية الخصوصية الخاصة بي؟

إرشاد : صف في هذا القسم كيف سيتم حماية البيانات ، كيف وأين سيتم تخزينها ، من الذين سيتعين عليهم الحصول على المعلومات الشخصية والمعرفة للشخص المشارك، وما إذا كانت هناك أي لجان رقابية سوف تكون قادرة على استعراض سجلات البحث.

قد تنشر نتائج هذه الدراسة في مجلة طبية ، ولكن الأشخاص الوحيدين الذي سيكونون قادرين على التعرف عليك من خلال المعلومات التى تم نشرها هم أعضاء فريق البحث ومن لهم علاقة مباشرة بهذه الدراسة. يمكن أيضا استعراض نتائج الدراسة من قبل ممثلين عن لجنة البحوث بمؤسسة حمد الطبية أو عن طريق الشركات الراعية والممولة لهذا البحث. عموما ستبقى نتائج الاختبارات الخاصة بك في ملف مغلق فى خزانة أو فى صورة ملفات مشفرة فى حاسوب. فقط الباحث الرئيسي لهذه الدراسة له الحق فى الوصول لهذه المعلومات. سيكون لكل إختبار أو فحص رمز خاص. أما القائمة التي تربط هذا الرمز مباشرة مع اسمك فإنه سيتم تخزينها بشكل منفصل عن هذه المعلومات. لن يتم وضع أية معلومات عن هذه الدراسة في السجلات الطبية الخاصة بك عدا هذه الوثيقة.

Will commercial products be developed from my sample?

[This information should be included if any potential exists for the tissue or blood sample to lead to a test, technology, cell line, or other product that could be patented or sold for commercial gain.]

Cells obtained from your tissue sample may be used to establish a cell line which will be used to help identify genes, or genetic markers. A cell line is one which will grow indefinitely (permanently) in the laboratory. These cell lines may be shared in the future with other researchers with no identifying information about you. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. These cell lines may be of commercial value, but you will not be able to share in the profits from commercialization of products developed from your tissue or blood samples.

هل يتم تطوير منتجات تجارية من العينة الخاص بي؟

إرشاد : ينبغي أن تدرج هنا معلومات عن إمكانية إستحداث منتج جديد من إستخدام عينة المشارك وما إذا كان لهذا المنتج الجديد فائدة تجارية أو مادية أو إستحداث براءة اختراع لتحقيق مكاسب تجارية، مثال لهذه المنتجات إستحداث خط خلية جديد أو إختبار جديد .

الخلايا التي تم الحصول عليها من الأنسجة الخاصة بالعينة التي أُخذت منك يمكن استخدامها لإنشاء خط الخلية والذي سيتم استخدامه عادة للمساعدة على التعرف على الجينات ، أو فى تحديد علامات وراثية. خط الخلية هو مستحدث يتمتع بخاصية النمو إلى أجل غير مسمى (دائم) في المختبر. خطوط الخلية هذه يمكن أن نعطيها الى باحثين آخرين فى المستقبل لإستخدامها فى الأبحاث، من دون تحديد المعلومات الخاصة بك. خطوط الخلية هذه مفيدة جدا فى الأبحاث وذلك بسبب خصائصها وبسبب المنتجات التي قد تنجم عنها ويمكن أن تكون لخطوط الخلايا هذه قيمة تجارية. فى حالة حدوث ذلك، **فسوف لن يكون لك الحق فى المشاركة فى الأرباح المتأتية من تسويق المنتجات المستحدثة من الأنسجة أو عينات الدم**

If I start this study, can I change my mind?

Participation in this study is voluntary. You can stop your sample donation at any time. Once the researchers begin studying your DNA, there are only two ways you can withdraw from the study. One is to ask **Dr. X** and his colleagues to remove all identifying information associated with your sample. The other is to ask them to destroy any of your remaining DNA or tissue.

What if I have questions?

If you have any questions or concerns about the research study or the information in this document it is important that you talk to **Dr. X** or one of the other members of the research team. You may also want to discuss this with your doctor, nurse, or a genetic counselor. For more information about the rights of research subjects, you may call the Research Office of Hamad Medical Corporation at 4392440.

إذا كنت قد بدأت المشاركة فى هذه الدراسة ، هل يمكنني أن أغير رأيي لاحقا؟

المشاركة في هذه الدراسة طوعية تماما. يمكنك إيقاف التبرع بالعينة في أي وقت تشاء. وبمجرد أن يبدأ الباحثون فى دراسة الحمض النووي الخاص بعيّنتك ، لا يوجد سوى اثنتين من الطرق التي يمكنك من خلالها الانسحاب من الدراسة.الاولى هى أن تسأل **الدكتور س** وزملائه لإزالة كافة المعلومات التعريفية المرتبطة بعينتك. والآخرى هى أن تطلب منهم إتلاف أي من الحمض النووي الخاص بك وأيضا التخلص من الكمية المتبقية من الأنسجة.

ماذا أفعل إذا كان لديى أسئلة؟

إذا كان لديك أي أسئلة أو استفسارات عن الدراسة هذه أو المعلومات الواردة في هذه الوثيقة من المهم أن تتحدث مع **الدكتور س** أو أحد الأعضاء الآخرين في فريق البحث. قد تحتاج أيضا لمناقشة هذا الأمر مع طبيبك أو ممرضتك ، أو مستشار علم الوراثة. لمزيد من المعلومات حول الحقوق المتعلقة بك كمشارك فى بحث يجرى بمؤسسة حمد الطبية ، يمكنك الإتصال بلجنة الأبحاث بمؤسسة حمد الطبية على هاتف 4392440

Will my sample be used for future research?

[If you would like to bank the samples or wish to share them with other researchers, this should be described in this section.]

The researchers in this study wish to save your sample for other future research. This research might be done at Hamad Medical Corporation or your samples shared with other researchers outside this institution. It is up to you whether or not you want to allow the researchers to keep your samples for future research.

Let us know whether **Dr. X** or others may use your tissue or DNA for other research by putting your initials by one of the following choices:

☐ We **may not use** your DNA or tissue for any future research or share it with other investigators

☐ We **may use** your tissue or DNA for other research or share it with other researchers only if we remove all identifying information

☐ We **may use** your DNA or tissue as we wish, without any restrictions, but after notification and approval of the Research Committee of Hamad Medical Corporation.

[A fourth option may be added. Some investigators feel it enhances enrollment; others find it too burdensome]

☐ We **may use** your DNA or tissue for other research or share it with other researchers for research purpose only after contacting you and getting your permission

هل تستخدم العينة الخاصة بى لأبحاث في المستقبل؟

إرشاد : إذا كنت ترغب في إيداع العينات في بنك العينات أو ترغب في مشاركتها مع غيرك من الباحثين ، ينبغي أن تذكر ذلك في هذا القسم

يرغب الباحثون في هذه الدراسة في حفظ عينتك لأبحاث مستقبلية أخرى. ويمكن أن يتم هذا البحث في مؤسسة حمد الطبية أو أن العينات الخاصة بك يمكن أن تتبرع بها أو نشاركها مع باحثين آخرين من خارج هذه المؤسسة. والأمر متروك لك إذا كنت ترغب أو لا ترغب فى السماح للباحثين للحفاظ على العينة الخاصة بك وذلك لإستخدامها للبحث في المستقبل.

نود أن نعرف ما إذا كنت تسمح **للدكتور س** أو غيرهم بإستخدام الأنسجة أو الحمض النووي فى أبحاث أخرى فى المستقبل. يمكن أن تعطى قرارا فى هذا الشأن عن طريق التأشير على واحد من الخيارات التالية:

☐ **لا أرغب** فى استخدام الحمض النووي أو الأنسجة الخاصة بى لاستعمالها في أي بحث في المستقبل أو فى إعطائها لباحثين آخرين .

☐ **أرغب** فى استخدام الحمض النووي أو الأنسجة الخاصة بى لاستعمالها في أبحاث أخرى أو فى إعطائها لباحثين آخرين شريطة إزالة كافة المعلومات التعريفية.

☐ **يمكن لفريق البحث** أن يستخدم الحمض النووى أو الأنسجة الخاصة بى فى أبحاث مستقبلية ذات الصلة دون أى قيود من جانبى ولكن بعد إخطار وموافقة لجنة البحوث بمؤسسة حمد الطبية.

(يمكن إضافة الخيار الرابع. يشعر بعض الباحثون فى أن هذا الخيار يعزز الالتحاق بالدراسة ، والبعض الآخر يجده مرهقا جدا)

☐ يمكن لفريق البحث أن يستخدم الحمض النووي الخاص بى أو الأنسجة لبحوث أخرى أو يتم أو إعطائها لباحثين آخرين لغرض البحث ولكن لن يتم ذلك إلا بعد الاتصال بى والحصول على إذن مباشر منى

Who will receive the results of the research tests?

Let us know whether you want to be contacted with information from the results of tests on your sample by putting your initials by your

من الذى يتم تبليغه بنتائج اختبارات البحث؟

نرجو الإفادة ما إذا كنت تريد أن يتم الاتصال بك بغرض إبلاغك بنتائج الاختبارات التي أجريت على العينة الخاص بك. يمكن أن تعطى قرارا بشأن ذلك عن طريق التأشير على واحد من الخيارات التالية:
ليس مطلوبا منك أن تحصل على نتائج الاختبارات إذا كنت لا ترغب

choice. You are not required to receive the results of the tests, if you do not want to.

فى ذلك.

☐ **Do not** contact me with information about the results of testing on my sample

☐ **لا أرغب** فى أن يتصل بى فريق البحث لإطلاعى على نتائج الاختبار التى أجريت على العينة الخاصة بى.

☐ **Contact me** with information about the results of testing on my sample, and (choose from the following):

☐ **أرغب** فى أن يتصل بى فريق البحث لإطلاعى على نتائج الاختبار التى أجريت على العينة الخاصة بى و (اختار من بين ما يلي)

☐ **Do not** provide this information to anyone else, including my doctor

☐ لا تقدم هذه المعلومات إلى أي شخص آخر، بما في ذلك طبيبي

☐ Also share it with my physician:

أرجو إطلاع وإبلاغ هذه المعلومات لطبيبى الخاص وهو الدكتور_____

_____

☐ Also share it with

تبليغ هذه المعلومات ل:

_____

(مثلا، يمكن أن يكون هذا الشخص هو الزوج / الزوجة أو أحد أفراد عائلتك)

_____

[for example, you may want information shared with your spouse or other member of your family]

Names of the sponsors of the research: *[if applicable, and details about where the research is going to be conducted. Give information to the participant about all the sponsors of the research, any issues of conflict of interest and also where the research will be conducted]*

مصادر تمويل البحث ومكان إجراء الدراسة (*أعط تفاصيل للمشاركين عن إسم الجهات اللتى قامت بتمويل البحث، وما إذا كان لهذه الجهات مصلحة أو عائد مادى منتظر* **).**

Option to withdraw from the study without penalty: *[An option is given to the potential participant to continue or withdraw from the study even after enrollment in the research]*

إنسحاب المشارك من الدراسة أو البحث (*أذكر بشكل واضح أن للمشارك الحق الكامل فى الإنسحاب عن المشاركة بالدراسة أو البحث وذلك فى أى وقت شاء دون أن يؤثر ذلك على نوعية العلاج أو الخدمة الطبية المقدمة، أو يترتب على ذلك أى نوع من الضغوط عليه.*)

Signed Consent for Study Participation

الموافقة المستبينة للمشاركة فى البحث

Consent: You (the participant) have read or have had read to you all of the above. Dr. [insert name] or his/her authorized representative has provided you with a description of the study including an explanation of what this study is about, why it is being done, and the procedures involved. The risks, discomforts, and possible benefits of this research study, as well as alternative to this research have been explained to you. You have the right to ask questions related to this study or your participation in this study at any time. Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. By signing this form, you willingly agree to participate in the research study described to you. You will receive a copy of this signed consent form. As long as the study is renewed as required by the Research Committee, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

الموافقه المستبينة الخطية: أقر انا الموقع ادناه بأني قرأت (أو قد ُقرأ لي) المرفق اعلاه الخاص بهذا البحث. **د. إسم الباحث الرئيسي**، أو من ينوب عنه قد قام بشرح الدراسة لى واجاب عن كل اسئلتى واستفساراتى الخاصة بالدراسة والبحث. لقد تم شرح وإيضاح المخاطر وعدم الراحة وكذالك الفوائد المرجوة من اجراء الدراسة, كما تم ايضا شرح وايضاح بدائل هذا البحث والمتاحة لى وفهمت محتواها. كما تم إخطارى بان المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لى مطلق الحرية بالمشاركة او بعدم المشاركة. فى حالة إتخاذى القرار بعدم المشاركة فى هذا البحث العلمى لا يترتب على قرارى هذا اى تبعات او حرمان من حقوقى المستحقة. أيضا يمكننى الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة أشاء دون أن يؤثر ذلك فى حقوقى أو فوائدى المستحقة والمرجوة والمشرعة. و أنه قد أجيبت كل أسئلتي والتى طرحتها , وبتوقعي أدناه اوافق على المشاركة في البحث . سوف أستلم صورة من هذه الوثيقة. توقيعك هذا يدل على موافقتك بالمشاركة حتى تاريخ إنتهائها أو تمديدها من قبل لجنة البحوث. إذا طرأ أى طارىء قد يؤثر على رغبتك فى المشاركة فى هذه الدراسة فسوف نخطرك بذلك.

Participant / Father (Parents)/ Guardian's Name	Signature & Date	التوقيع وتاريخه	إسم: المشارك ، الوالد (الوالدين) أو ولى الأمر
Child's Name	Signature & Date		إسم الطفل المشارك
Witness Name	Signature & Date	التوقيع وتاريخه	إسم الشاهد
Principal Investigator's Name	Signature & Date	التوقيع وتاريخه	إسم الباحث الرئسيي
For use of Medical Research Center only		**إستخدام مركز الأبحاث الطبية فقط**	

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

مركز البحوث الطبية
Medical Research Center

B

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HGH | WH | RH | AAH
AKH | OTHERS

م. الأمل | م. الرميلة | م. النساء | م. حمد العام
م. أخرى | م. الخور

HC NO:
PATIENT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المريض:
تاريخ الميلاد:
النوع (ذكر | أنثى) :
الجنسية:

Consent form template for studies involving genetic testing

نموذج موافقة مستبينة للمشاركة بدراسة تنطوى على الإختبارات الجينية

Identifiable samples but NO intent to Disclose the Testing Results

إستخدام عيّنات معّرفة دون الكشف عن نتائج الإختبارات أو الفحص

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of rights or other benefits to which you are entitled.

كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل, أو أثناء, أو بعد إكمال إجراء البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة.

NOTE: This template is for genetic studies using identifiable samples but there is no intention to disclose results of the genetic testing to subjects or research participants, families, or participants' health care providers

ملاحظة : هذا النموذج يستخدم في دراسات بحث ينطوي على الاختبارات الجينية لعينات المشارك المعرفة ولكن ليس هناك نية لفريق البحث الكشف عن نتائج هذه الإختبارات أو الفحوصات للافراد المشاركين فى الدراسة، أو لعائلاتهم، أو حتى للطبيب أو الأطباء الذين يقدمون للمشارك رعاية طبية ليست ذات صلة بهذه الدراسة.

PLEASE DO NOT CHANGE THE FORMAT OF THIS TEMPLATE

فضلا لا تغير فى الشكل العام لهذا النموذج

Project Title: **عنوان المشروع:**

Name of Principal Investigator: **سم الباحث الرئيسي:**

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends]*

موقع إجراء البحث وأرقام الهواتف *(أثناء وخارج أوقات الدوام وفى العطلات)*:

Each item given below has to be filled. Please modify according to your study needs. The tips *[in blue]* can be erased.

يجب تعبئة كل البنود أدناه حسب إحتياج الدراسة. بعض النصائح الإرشادية كما مبّن باللون الأزرق يمكن مسحها من النموذج.

Invitation to participate and summary

[State the overall purpose of the study in simple terms]

You are invited to participate in a research study being conducted by **Dr. X** and others at the Hamad Medical Corporation. Researchers from_____ in Qatar and other countries _____are also working on this study. They will be studying blood cells looking for mutations (changes in genes) that might cause people with hepatitis to develop liver cancer later in life. You are being invited to participate in this study because you have hepatitis or have had it in the past. This form reviews several things you should know before you agree to participate. Participation in research is voluntary, and you may refuse to participate without any loss of rights or privileges to which you are otherwise entitled; and this will not affect the services provided to you by Hamad Medical Corporation.

دعوة للمشاركة وملخص

إرشاد : أشرح الغرض العام من الدراسة في عبارات بسيطة

انت مدعو للمشاركة في هذه الدراسة والتي يقوم بها **الدكتور س** وفريق البحث في مؤسسة حمد الطبية، بمشاركة باحثين من _____ في دولة قطر ودول أخرى _____ تعمل أيضا على هذه الدراسة. سوف يركز هذا البحث فى دراسة خلايا الدم للبحث عن الطفرات (التغيرات في الجينات) التي قد تسبب سرطان الكبد في وقت لاحق في الحياة وذلك لدى الآشخاص الذين يعانون من التهاب الكبد المزمن. ولذلك أنت مدعو للمشاركة في هذه الدراسة لأنه لديك التهاب الكبد أو كنت تعانى منه في الماضي. من خلال هذا النموذج سوف نشرح ونستعرض العديد من الأشياء والمعلومات التى يجب أن تعرفها قبل أن توافق على المشاركة في هذا البحث. المشاركة في هذا البحث كما فى البحوث الاخرى في مؤسسة حمد الطبية طوعية تماما. يحرص فريق البحث على أن تلم بكل المعلومات التى من شأنها مساعدتك فى إتخاذ قرارك الطوعى. إذا قررت عدم المشاركة فى هذا البحث فلن يترتب على ذلك أي فقدان لآى من الحقوق أو الامتيازات أو نوعية الخدمة الصحية التي تحتاجها، ولن يؤثر ذلك فى علاقتك بمؤسسة حمد الطبية.

What is the purpose of the study?

[Explain to potential subjects why the study is being done.]

Liver cancer (hepatocellular carcinoma) is a common cause of death around the world. It has been known for many years that people who have certain types of hepatitis have a somewhat higher chance of developing liver cancer later in life. However, not all people with hepatitis will go on to develop cancer. **Dr. X** and his colleagues are trying to find out if there is something different in the genes of people who develop liver cancer after having hepatitis. If they find a difference, it may allow doctors to find people who are at a greater risk of developing liver cancer. If so, it is possible that following those people more closely will allow earlier detection of the cancer so that it can be treated more effectively. Finding mutations that increase the risk of cancer may also lead to additional research, which could someday help doctors develop more effective treatments for liver cancer, or even ways to prevent the cancer from developing in the first place.

ما هو الغرض من الدراسة؟

نصيحة : أشرح للمشارك المحتمل لماذا تقوم بإجراء هذه الدراسة

سرطان الكبد هو سبب شائع للوفاة في جميع أنحاء العالم. والمعلوم لسنوات عديدة أن الأشخاص المصابون بأنواع معينة من التهاب الكبد المزمن لديهم فرصة أعلى من المعتاد للإصابة بسرطان الكبد في وقت لاحق في الحياة. ومع ذلك ، فإنه ليس كل الناس المصابون بالتهاب الكبد بالضرورة سوف يتطور المرض عندهم قدما لسرطان الكبد. **الدكتور س** وزملاءه يحاولون معرفة ما اذا كان هناك شيء مختلف في جينات الناس الذين يصابون بسرطان الكبد بعد تعرضهم لالتهاب الكبد. اذا وجد **الدكتور س** وزملاءه فى فريق البحث إختلافا، فإن ذلك قد يمكنهم من العثور على الناس الذين هم في خطر اكبر للاصابة بسرطان الكبد. إذا كان الأمر كذلك ، فمن الممكن إخضاع هؤلاء الناس للمتابعة الصحية على نحو أوثق بما يسمح للأطباء بالكشف المبكر جدا عن حدوث سرطان الكبد بحيث يمكن التعامل مع السرطان على نحو أكثر فعالية وهو فى مرحلته الأولية. العثور على الطفرات التي قد تزيد من خطر الاصابة بسرطان الكبد قد يؤدي أيضا إلى إجراء المزيد من البحوث العلمية، والتي يمكن أن تساعد الأطباء في يوم من الأيام تطوير علاجات أكثر فعالية لسرطان الكبد، أو حتى إستحداث وسائل لمنع حدوث السرطان في المقام الأول لدى مرضى التهاب الكبد المزمن.

What does participation in this study involve?

[Explain (1) the procedures that subjects will undergo for the study, the information that will be collected from subjects, how the information will be collected, and why the information will be collected; (2) the type of sample and how it will be collected (e.g., by blood draw, skin biopsy, cheek swab); (3) in simple terms what will be done with the sample; and (4) whether there are an specified or unspecified future plans for use of the sample.]

Some mutations are more common among people from particular racial or ethnic groups, or in people who have had other medical problems in the past. Knowing background information about you will help **Dr. X** determine whether this is true for the mutations he is looking for. You will be asked to give your age, race, gender, ethnic background, family history, and your health history. We will also ask permission to review your medical records, in order to confirm your health history and fill in any details you might have forgotten. We will then ask your permission to take like 2 spoons of your blood from a blood vessel in your arm. This blood will be used in this research.

DNA will be removed from your blood sample in the laboratory. DNA is present in your genes. Genes are the material passed from parents to child that influences the make-up of the body and mind, such as how someone looks and if someone is more likely to get a disease. Some of the DNA may be saved for future testing, and some of the cells from your blood may be kept alive and growing in the laboratory as a "cell line". This will allow **Dr. X** to get more DNA if he needs it (see below). The rest of your blood sample will be thrown away. The DNA will be studied, and patterns in your DNA markers will be recorded and compared to those of other people with hepatitis, some of whom have had liver cancer. If any patterns are found consistently in those who have cancer but not in those who have not had cancer, further testing will be done to see if those patterns are markers of a nearby gene or genes that are responsible for the increased risk of cancer. If that turns out to be true, further testing will be done to identify

ماذا تشمل المشاركة في هذه الدراسة ؟

إرشاد : أشرح (1) الإجراءات التي سيخضع لها المشارك بالدراسة، مع بيان كامل لنوعية المعلومات التي سيتم جمعها منه وكيف يتم جمع هذه المعلومات ، ولماذا يتم جمع هذه المعلومات، (2) حّدد نوع العينة ، وكيف سيتم جمع هذه العينة (على سبيل المثال ، عن طريق سحب الدم ، خزعة الجلد، أو عن طريق المسحة الاختيارية من الفم) ، (3) بعبارات بسيطة أشرح ما سيتم عمله مع العينة حصريا فى هذه الدراسة، و (4) ما إذا كانت هناك خطط لدراسات أو بحوث مستقبلية محددة أو غير محددة في المستقبل لاستخدام العينة.

من الثوابت أن بعض الطفرات الجينية تكون أكثر شيوعا بين الناس خاصة من سلالات أو مجموعات عرقية عرقية محددة، أو بين الناس الذين لديهم مشاكل طبية معينة في ماضيهم. ولذلك فإن معرفة المعلومات الشخصية عنك سيساعد **الدكتور س** وفريق البحث فى تحديد ما إذا كان هذا صحيحا وينطبق على الطفرات التى يبحثون عنها خلال هذه الدراسة. ولهذا سوف يطلب منك اعطاء عمرك والسلالة التى تنتمى اليها والنوع والخلفية العرقية والتاريخ الصحى العائلي، والتاريخ الصحى الخاص بك. أيضا سوف بطلب منك أن تأذن لنا بالإطلاع على سجلك الطبى وذلك لنتأكد من سلامة ودقة المعلومات الخاصة بتاريخك الصحى والمرضى وإكمال بعض المعلومات التى يمكن أن تكون قد سقطت سهوا ولم تطلعنا عليها بسبب النسيان. بعد ذلك سوف نطلب منك السماح لنا بسحب عينة من دمك من وريد فى ذراعك. تقدر كمية الدم المطلوبة والتى سوف نستعملها فى هذا البحث بمقدار ملعقتين.

ستتم إزالة الحمض النووي من عينة الدم في المختبر. الحمض النووي موجود في الجينات الخاصة بك. والجينات هي المادة التى من خلالها تنتقل الموروثات والخصائص من الوالدين الى الطفل وبذلك تحدد الصفات الجسمانية والعقلية لدى الطفل، مثل كيف يبدو الطفل فى مظهره العام وما اذا كان قد إكتسب قابلية تجعله أكثر احتمالا فى الحصول على المرض. قد يتم حفظ بعض من الحمض النووي للاختبار في المستقبل، أيضا قد يتم حفظ بعض الخلايا من عينة الدم والإبقاء عليها على قيد الحياة والنمو في المختبر كخط "خلية". هذا سوف يسمح **للدكتور س** الحصول على مزيد من الحمض النووي إذا دعت الحاجة (انظر أدناه). بعد ذلك سيتم التخلص من ما تبقى من عينة الدم الخاصة بك. فى هذا البحث، ستتم دراسة الحمض النووي, وكذلك الأنماط السائدة فى الحمض النووى الخاص بك بحيث يتم تسجيلها ومقارنتها مع الأنماط الأخرى لمرضى آخرين يعانون من التهاب الكبد، الذين تطور المرض لدى بعض منهم لسرطان الكبد لمعرفة ما اذا كانت هناك جينات مسؤولة عن زيادة خطرالتعرض للإصابة بالسرطان. إذا تم العثور على أية أنماط متناسقة فى أولئك الذين يعانون من السرطان وليس فى من لآ يعانون من السرطان فسوف يتعّين إجراء المزيد من التجارب لمرفة ما إذا كانت هذه الأنماط مؤشرات على جين قريب أو هى جينات مسؤولة عن زيادة خطر الإصابة بالسرطان. إذا تبين أن ذلك صحيحا ، فسوف يترتب إجراء مزيد من التجارب وسوف يتم تحديد طبيعة هذه الجينات ودراستها.

اللغة النموذجية التى يجب إستعمالها لتحديد المدة الزمنية التى يتم بعدها إتلاف العينة

those genes and study them.

MODEL LANGUAGE FOR WHEN SAMPLE WILL BE DESTROYED:
DNA will be saved and the cell line will be kept alive in the laboratory until the study is completed, which is expected to be within the next 2 years. It will then be thrown out.

MODEL LANGUAGE FOR WHEN SAMPLE KEPT FOR FUTURE USE:
The information you provided and some of the DNA from your sample will be saved and the cell line will be kept alive in the laboratory as long as possible, hopefully for many years. This way, as more is learned about hepatitis and cancer, your DNA may be used for additional research. For example, it is possible that more accurate genetic testing may become available in the future, or that a follow up study will be done years from now. If so, the research team may contact you to update your health history and family history unless you indicate below.

☐ Mark here if you do not want us to contact you in the future for additional information.

If you agree to be contacted and there have been any significant changes in your history, we may use DNA from this sample, and may also ask for another sample of blood, in order to do further testing. Please let the study coordinator or any of the research team members know if you move or change address so you can be contacted if this happens.

Dr. X may also want to use your cell lines or stored DNA in other research in the future, or share them with other researchers for use in their work. After you read the section below on "Risks", and after discussing these "Risks" with you, and answering all the questions that you might have, you will be asked to let us know whether or not we may do that.

☐ I **do not** want my DNA or sample used for any future research or shared with other investigators

سيتم حفظ الحمض النووي وخط الخلية على قيد الحياة في المختبر حتى الانتهاء من الدراسة، والتي يتوقع أن تكون في غضون السنتين القادمتين. بعد ذلك سيتم التخلص من العينة بإتلافها.

اللغة النموذجية التى يجب إستعمالها لطلب الإحتفاظ بالعينة من أجل استخدامها في المستقبل
المعلومات التى تحصلنا عليها وجزء من الحمض النووى المستخلص من العينة سيتم حفظها وأيضا سوف يحفظ خط الخلية التى إستخلصناها والتى سوف نعمل ما بوسعنا لتبقى على قيد الحياة فى المختبر لأطول وقت ممكن ، ونأمل لسنوات عديدة بهذه الطريقة. بمرور الزمن نتعلم الكثير حول العلاقة بين التهاب الكبد وحدوث مرض السرطان. ونسبة لهذه الحقيقة فإنه يمكن استخدام الحمض النووي للحصول على المزيد من البحث. على سبيل المثال ، فمن الممكن أن الاختبارات الجينية في المستقبل قد تصبح أكثر دقة ، أو أنه قد نحتاج لمتابعة الدراسة بمعطيات جديدة نتعلمها بعد سنوات من الآن. فى هذه الحالة أذا نتوقع أن نتصل بك فى المستقبل لتفيدنا عن ما جد أو تغيّر بخصوص حالتك الصحية أو بالتاريخ الصحى لعائلتك. ولكن لن نتصل فى المستقبل إذا أبديت عدم الرغبة فى ذلك بالتأشير فى الفراغ أدناه:

ينبغى التأشير هنا إذا كنت لا ترغب فى أن نتصل بك فى ☐ المستقبل لتعطينا معلومات إضافية.

إذا وافقت على أن نتصل بك فى المستقبل وحدثت تغيرات جديدة فى وضع تاريخك الصحى، سوف نستعمل الحمض النووى المستخلص من عينتك، أو قد نطلب منك عينة دم إضافية نجرى عليها فحوصات إضافية. لهذا نرجو إخطار منسق أو فريق البحث إذا حدث أى تغيير فى عنوانك حتى نتمكن من الإتصال بك إذا دعت الحاجة.

الدكتور س قد يحتاج أيضا إلى استخدام خط الخلايا أو الحمض النووي الخاص بك وذلك لإجراء بحوث أخرى في المستقبل ، أو أو إعطائها لباحثين آخرين لاستخدامها في دراساتهم. نرجو قراءة الجزء الخاص بالمخاطر فى هذا النموذج والذى سوف نقوم أيضا بمناقشته وشرح محتوياته وكذلك الإجابة على أية أسئلة تكون لديك، وبعد ذلك الإفادة بموافقتك من عدمها. بعد ذلك سوف نسالك بعض الأسئلة لنتعرف ما إذا كنت تأذن لنا فى استخدام خط الخلايا أو الحمض النووي الخاص بك وذلك لإجراء بحوث أخرى في المستقبل.

☐ **أنا لا أريد** إستخدام الحمض النووي أو العينة التى أُخذت منى في أي بحث في المستقبل أو إعطائها لباحثين آخرين.

What are the risks of participating in this study? *[Address the potential risks associated with (1) the disclosure of information obtained in the study; (2) racial or ethic associations that might be drawn from the study results; and (3) the risks associated with the collection of the sample. Because of the nature of genetic research and not all risks can be known at this, this section also should include a statement that there may be unknown risks associated with participation in such studies.]*

ما هي مخاطر المشاركة في هذه الدراسة؟

إرشاد : أشر إلى المخاطر المحتملة المرتبطة ب (1) الكشف عن المعلومات التي تم الحصول عليها في هذه الدراسة ، (2) إمكانية إن تنسب نتائج الدراسة لسلالات أو مجموعات عرقية محددة، و (3) المخاطر المرتبطة بعملية جمع وأخذ العينة. ونظرا لطبيعة الأبحاث الجينية وإمكانية ألا تؤدى هذه الأبحاث فى الإلمام بمعرفة كل المخاطر المحتملة، ينبغي أن يشمل هذا الجزء من الموافقة المستبينة أيضا بيان بأنه قد تكون هناك مخاطر غير معروفة في مثل هذه الدراسات.

Risks of disclosure

Even though we will remove identifying information and do not intend to tell you or anyone else the results of the testing on your sample, there is a very small chance this information could accidentally become known to you, your doctor, or others. Knowing you have an increased risk of developing a problem may also have a harmful psychological effect on the way you think about your future. It could also affect your relationships with members of your family, especially if this changes their risks. We will be careful to see that disclosure does not happen, without granting that disclosure could never happen.

مخاطر الكشف

بالرغم من أننا سوف تزيل كل المعلومات التى يمكن أن تدلل أو تؤدى للتعرف على هويتك وبالرغم من أنه ليس في نيتنا أن نطلعك أو أي شخص آخر على نتائج الاختبار على العينة الخاص بك ، هناك فرصة ضئيلة للغاية يمكن لأن تصبح هذه المعلومات بطريق الخطأ معروفة لكم ، أو لطبيبك الخاص ، أو غيره. من المهم أيضا أن نذكر أن معرفتك لمعلومات تتعلق بإحتمال زيادة خطر التعرض لمشاكل صحية لديك قد يكون لها أيضا تأثير ضار لوضعك النفسي تؤدى بك للتفكير فى ما سوف يصير في مستقبلك. كما يمكن أن يؤثر ذلك أيضا على علاقاتك مع أفراد عائلتك ، وخاصة إذا كانت هذه التغييرات سوف تزيد من المخاطر التي قد يتعرضون لها بنفس القدر لديك. سوف نكون حريصين جدا على عدم حدوث ذلك وسوف نبذل كل ما نستطيع للتاكد من عدم الكشف عن نتائج الفحص، دون أن نضمن عدم حدوث ذلك.

Risks of racial or ethnic association

It is possible that this study will show that members of your race or ethnic group may be at higher risk of developing cancer than others. This may be seen as stigmatizing or discriminatory information.

مخاطر تتعلق بالعنصر أو العرق

من الممكن أن هذه الدراسة سوف تظهر أن السلالة أو المجموعة العرقية التى تنتمى إليها قد تكون أكثر عرضة للاصابة بمرض السرطان أكثر من غيرها. هذا يمكن أن يؤدى لإعتبار ذلك وصما أو يودى للتمييز ضدك.

Risks of sample collection

There is a small chance that drawing your blood will be painful or will cause bleeding, infection, or dizziness. The information gained from the study of your DNA cannot be linked to you since no identifying information will be kept.

مخاطر جمع العينات

عملية سحب العينة كالدم مثلا يمكن أن تسبب بعض الألم فى موضع السحب أو تتسبب في حدوث نزيف موضعى أو إلتهاب، أو دوار عند بعض الأشخاص. المعلومات المكتسبة من دراسة الحمض النووي الخاص بك لن تكون مرتبطة بأى معلومات شخصية أو شفرة معينة أو حتى رقمك الصحى وبذلك لا يمكن أن تكون مرتبطة بك وستبقى كذلك.

مخاطر أخرى

هذه لا تخرج عن إطار المخاطر المعروفة من المشاركة فى البحوث التي

Other risks
These are the best known risks of research in which tissue samples are used. There might be other risks we do not know about yet.

تستخدم فيها عينات الأنسجة. قد تكون هناك مخاطر أخرى نحن لا نعرف عنها حتى الآن.

What are the benefits of taking part in this study? *[Generally genetic testing is not believed to directly benefit subjects, although there are cases when there is an expected therapeutic benefit.]*

Participating in this study is not expected to benefit you directly. If the study is successful, it may some day help prevent liver cancer in others or lead to more effective treatments. Some people also find satisfaction in contributing to scientific knowledge.

ما هي فوائد المشاركة في هذه الدراسة؟
إرشاد : من المعلوم أن الاختبارات الجينية عموما ليست لها فائدة مباشرة أو آنية بالنسبة للمشارك بالبحث، وإن كانت هناك حالات يُتوقع فيها حصول فائدة علاجية يمكن أن تفيد المشارك

كمشارك فى هذا البحث لا نتوقع أن تكون لك فوائد مباشرة تجنيها. إذا كانت الدراسة ناجحة، فإنها قد تساعد يوما ما في منع حدوث سرطان الكبد لدى مرضى آخرين أو أن تؤدي إلى إستحداث علاجات أكثر فعالية. بعض الناس أيضا يبدون الإرتياح والشعور بالرضا على إسهامهم الشخصى في تطور المعرفة العلمية من خلال مشاركتهم فى البحوث.

Are there any alternatives to taking part in this study? *[In the case of non-therapeutic research, clarify in this section that participation in the research is not required for participants to treatment or a diagnosis that would normally be available to them outside the research context.]*

Participation in this research study is voluntary. The results of the tests conducted for this study will not be shared with you because their reliability and value in treating or diagnosing conditions is not known.

If you would be interested in determining your risk of developing cancer once such a test becomes available, reliable, and helpful, you should periodically ask your doctor or a genetic counselor if the test is available, and ask him or her to discuss its advantages and disadvantages with you. A genetic counselor is professionally trained to help you understand what genetic test results mean and don't mean for you and members of your family.)

هل هناك أي بدائل للمشاركة في هذه الدراسة؟
إرشاد: في حالة البحوث غير العلاجية ، وضّح في هذا القسم أن المشاركة في هذا البحث لا تتطلب من المشاركين الخضوع لعلاج أو تشخيص مما قد يكون متاحا لهم خارج إطار البحث.

المشاركة في هذه الدراسة البحثية طوعية تماما. نتائج التجارب التي أجريت لهذه الدراسة لن يتم إطلاعكم عليها وذلك نظرا لأن قيمتها في علاج أو تشخيص الحالات المرضية غير معروفة.

إذا كنت ترغب في معرفة أى مخاطر قد تكون لديك بالنسبة للإصابة بالسرطان متى ما تم إستحداث الاختبارالخاص بذلك ومن ثم التأكد من فعاليته وفائدته، فإنه يجب عليك أن تسأل الطبيب دوريا أو تستشير مستشار علم الوراثة إذا أصبح الاختبار متاحا، وان تناقش مع أى منهما مزايا و مساوئ هذا الإختبار (مستشار علم الوراثة هو شخص مدرب تدريبا مهنيا لمساعدتك على فهم نتائج الاختبارات الجينية وما تعنيه بالنسبة لك ولأفراد عائلتك.)

How will my confidentiality be protected?

كيف سيتم حماية السرية الخاصة بي؟

The results of this study may be published in a medical journal, but the only people who would be able to identify you from published

قد تنشر نتائج هذه الدراسة في مجلة طبية ، ولكن الأشخاص الوحيدين الذين سيكونون قادرين على التعرف عليك من خلال نشر المعلومات هم من لهم علاقة مباشرة بالبحث. سريتك الشخصية سوف تكون محمية من

information will be those involved in the research. Your confidentiality will be protected by ensuring no identifiable information is connected to your sample. Nothing will be written on the sample that anyone, including the researchers, will be able to connect back to you.

خلال ضمان السرية الخاصة بك وإنه ليس هناك أى معلومات شخصية أو رموز أو شفرة محددة متصلة بعينتك. لن تتم كتابة أي شيء كإسمك مثلا على العينة وبذلك لن يتمكن أي شخص بما في ذلك الباحثين أنفسهم من تحديد عينتك وبالتالى التعرف علي هويتك كصاحب لهذه العينة.

Will commercial products be developed from my sample? *[This information should be included if any potential exists for the tissue or blood sample to lead to a test, technology, cell line, or other product that could be patented or sold for commercial gain.]*

Cells obtained from your sample may be used to establish a cell line which will be used to help identify genes, or genetic markers. A cell line is one which will grow indefinitely (permanently) in the laboratory. These cell lines may be shared in the future with other researchers with no identifying information about you. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. These cell lines may be of commercial value, but you will not be able to share in the profits from commercialization of products developed from your tissue or blood samples.

هل سيتم تطوير منتجات تجارية من العينة الخاص بي؟

إرشاد: ينبغي أن تدرج فى هذا القسم إذا ما كان هناك إحتمال أو توقع أن نتائج هذه الدراسة والمستخلصة من عينة الدم مثلا قد تؤدي إلى أستحداث اختبار جديد أو تكنولوجيا أو خط خلية جيد أو غيرها من المنتجات التي يمكن أن تُسجل لها براءة اختراع وبالتالى تباع لتحقيق مكاسب تجارية.

الخلايا التي تم الحصول عليها من العينة الخاصة بك يمكن استخدامها لإنشاء وإستحداث بما يعرف بخط الخلية الذى سيتم استخدامه فى الأبحاث التى تتعلق بالتعرف على الجينات ، أو على علامات وراثية. وحدة خط الخلية هى الخلية التي سوف تنمو إلى أجل غير مسمى (دائم) في المختبر. قد نعطى خطوط الخلية هذه في المستقبل لباحثين آخرين. وسوف يتم ذلك من دون تقديم أى معلومات قد تفيد عنك أو تدلل أنك المصدر الاساسى لأى من خطوط الخلية هذه. خطوط الخلية هذه مفيدة جدا للبحث بسبب خصائصها المتعددة و / أو المنتجات التي قد تنجم عنها. يمكن لخطوط الخلايا أن تكون ذات قيمة تجارية أيضا، ولكن فى حالة إستحداث أى منتج ذو قيمة تجارية نتيجة البحوث التى أجريناها على الأنسجة أو عينات الدم **فلن يكون لك أى حق مادى أو فى المشاركة فى الأرباح المتأتية من تسويق المنتجات التى إستحدثناها خلال هذا البحث عن طريق إستخدام عينة الأنسجة أو عينة الدم الخاصة بك.**

If I start this study, can I change my mind?
Participation in this study is voluntary. You can stop your sample donation at any time. After your sample is collected, we will not be able to withdraw it from the study because we will not be able to identify which is your sample. We encourage you think very carefully about participating in this study, and be as sure as you can that you will not change your mind after your blood is drawn.

إذا كنت قد قبلت المشاركة فى هذه الدراسة ، هل يمكنني أن أغير رأيي لاحقا؟

المشاركة في هذه الدراسة طوعية تماما. يمكنك إيقاف مشاركتك والإنسحاب من الدراسة فى أى وقت حتى لحظة سحب العينة وجمعها منك، بعد ذلك لن تستطيع إيقاف مشاركتك والإنسحاب من الدراسة لاننا فى هذه اللحظة لن نكون قادرة على تحديد عينتك وبالتالى لن نستطيع سحبها. ولذلك نحن نشجعكم على التفكير مليا وأخذ الوقت اللازم بشأن قرار المشاركة في هذه الدراسة، وبذلك ننصح عند إتخاذ قرارك بالمشاركة فى هذا البحث أنك قد تأكدت تماما من أنك لن تغير رأيك بعد سحب الدم أو العينة.

What if I have questions?
If you have any questions or concerns about the research study or the information in this document it is important that you talk to **Dr. X** or one of the other members of the research team. You may also want to discuss this with your doctor, nurse, or a genetic counselor. For more information about the rights of research subjects or participants, you may call the Research Committee of Hamad Medical Corporation at 4439 2440.

ماذا أفعل إذا كان لدي أسئلة أو إستفسارات بخصوص هذه الدراسة؟
إذا كان لديك أي أسئلة أو استفسارات عن هذه الدراسة أو البحث أو عن المعلومات الواردة في هذه الوثيقة من المهم أن تتحدث مع **الدكتور س** أو أحد الأعضاء الآخرين في فريق البحث. قد تحتاج أيضا لمناقشة هذا الأمر مع طبيبك أو ممرضتك ، أو مستشار علم الوراثة. لمزيد من المعلومات حول الحقوق المتعلقة بك كمشارك فى بحث بمؤسسة حمد الطبية يمكنك الإتصال بلجنة البحوث بمؤسسة حمد الطبية على الهاتف 4392440

Duration of the research: *[Describe how long the prospective participant is expected to be in the research and what expectations the investigator might have about the participant's time spent in the research]*

مدة إجراء البحث والدراسة *(مدة البحث والوقت المتوقع للمشارك أن يستغرقه لمشاركته المنتظرة وتوقعات الباحث للوقت المستغرق في إجراء البحث والدراسة)*.

Names of the sponsors of the research: *[if applicable) and details about where the research is going to be conducted (Give information to the participant about all the sponsors of the research, any issues of conflict of interest and also where the research will be conducted]*

أسماء مموّلين البحث ومكان إجراء الدراسة *(أعطى تفاصيل للمشاركين عن إسم الجهات اللتى قامت بتمويل البحث، وما إذا كان لهذه الجهات مصلحة أو عائد مادى منتظر)*.

Assurance of anonymity and confidentiality: *[Confidentiality about the results/specimen/laboratory or any other data]*

السرية حول النتائج، العينةالمختبرية أو أي بيانات أخرى *(صف خطوات حماية سرية البيانات، العينةالمختبرية أو أي بيانات أخرى من شأنها الكشف عن هوية او أسم أى مشارك بالدراسة)*.

As participant in this research, the research team will only ask you about your age, race, gender, ethnic background, family history and your health history. This information will be used to document your participation in this research, and to assess your eligibility to participate in this research. This information will not be linked in any way or form to the sample you gave. The sample will be truly un-identified from the moment that you leave the research location.

كمشارك فى هذا البحث سوف يطلب منك فريق البحث إعطاء معلومات عن عمرك والسلالة التى تنتمى إليها والنوع والخلفية العرقية والتاريخ الصحى العائلي، والتاريخ الصحى الخاص بك. هذه المعلومات سوف تستخدم حصريا لإثبات مشاركتك فى هذا البحث. ليس فى نية فريق البحث الإبقاء على أىّ من المعلومات التي من شأنها تحديد هويتك، أو أن تسمح لهم معرفة أي عينة دم جاءت منك تحديدا. عينة الدم التى سوف تشارك بها فى هذا البحث ستصبح غير معّرفة حقيقة بحيث لا ترتبط بأى علامات أو رموز أو شفرة تدلل على هويتك، وذلك منذ اللحظة التى تغادر فيها مركز البحث.

Signed Consent for Study Participation

الموافقة المستبينة للمشاركة فى البحث

الموافقه المستبينة الخطية: أقر انا الموقع ادناه بأني قرأت (أو قد ُقرأ لي) المرفق اعلاه الخاص بهذا البحث. **د. إسم الباحث الرئيسي**، أو من ينوب عنه قد قام بشرح الدراسة لى واجاب عن كل اسئلتى واستفساراتى الخاصة بالدراسة والبحث. لقد تم شرح وإيضاح المخاطر وعدم الراحة وكذالك الفوائد المرجوة من اجراء الدراسة, كما تم ايضا شرح وايضاح أن هذا البحث يعتمد على الفحص الجينى وان فريق البحث لن يخطرنى بنتائج الفحص الخاصة بى حصريا. كما تم إخطارى بان المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لى مطلق الحرية بالمشاركة او بعدم المشاركة. فى حالة إتخاذى القرار بعدم المشاركة فى هذا البحث العلمى لا يترتب على قرارى هذا اى تبعات او حرمان من حقوقى المستحقة. أيضا يمكننى الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة أشاء قبل تسليم العينة الى المختبر ومغادرته دون أن يؤثر ذلك فى حقوقى أو فوائدى المستحقة والمرجوة والمشرعة. وبتوقعي أدناه اوافق على المشاركة في البحث والذى تم شرحه لى. سوف نسلمك صورة من هذه الوثيقة. توقيعك هذا يدل على موافقتك بالمشاركة حتى تاريخ إنتهائها أو تمديدها من قبل لجنة البحوث. إذا طرأ أى طارىء قد يؤثر على رغبتك فى المشاركة فى هذه الدراسة فسوف نخطرك بذلك.

Consent: You (the participant) have read or have had read to you all of the above**.** Dr*. [insert name]* or his/her authorized representative has provided me with a description of the study including an explanation of what this study is about, why it is being done, and the procedures involved. The risks, discomforts, and possible benefits of this research study have been explained to me. I also understand that this research involves genetics testing, and that the results of testing on my sample will not be disclosed to me. I was also informed that participation in this research is voluntary and the decision to participate or not to participate is mine. There will be no consequences If I decide not to participate, and I can withdraw my participation at any time till the moment I gave the blood sample to the laboratory. By signing this form, you willingly agree to participate in the research study described to you. You will receive a copy of this signed consent form. As long as the study is renewed as required by the Research Committee, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

مركز البحوث الطبية
Medical Research Center

C

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

○ HGH ○ WH ○ RH ○ AAH
○ AKH ○ OTHERS

○ م. الأمل ○ م. الرميلة ○ م. النساء ○ م. حمد العام
○ م. أخرى ○ م. الخور

HC NO:
PATIENT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المريض:
تاريخ الميلاد:
الجنس (ذكر | أنثى) :
الجنسية:

Consent form template for studies involving genetic testing

نموذج موافقة مستبينة للمشاركة بدراسة تنطوى على الإختبارات الجينية

Truly Unidentifiable samples
Possible Significant Risk

إستخدام عيّنات غير معّرفة تماما
إحتمال وجود مخاطر حقيقية

You are free to ask as many questions as you like before, during or after in this research. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of rights or other benefits to which you are entitled.

كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل, أو أثناء, أو بعد إكمال إجراء البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة والمشروعة.

NOTE: This template is for studies that use truly unidentifiable samples (i.e., no codes or indirect identifiers will be associated with the samples), but the risks to subjects might be significant should inadvertent disclosure occur.

ملاحظة : هذا النموذج هو الأفضل لإجراء دراسات بحث نيطوي على الاختبارات الجينية لعينات المشارك الغير معرفة والغير مشفرة (أي أن عينات المشارك لن تكون مرتبطة بأي رموز أو معرفات غير مباشرة قد تؤدى للتعرف على هوية المشارك) ، ولكن المخاطر التي يتعرض لها المشارك قد تكون كبيرة فى حالة الكشف عن غير قصد لهوية المشارك بالبحث.

PLEASE DO NOT CHANGE THE FORMAT OF THIS TEMPLATE

فضلا لا تغير فى الشكل العام لهذا النموذج

Project Title: **عنوان المشروع:**

Name of Principal Investigator: **اسم الباحث الرئيسي :**

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends]* **موقع إجراء البحث وأرقام الهواتف** ***(أثناء أوقات الدوام و بعد ساعات الدوام وفى العطلات)*:**

Each item given below has to be filled. Please modify according to your study needs. The tips highlighted in yellow can be erased.

جيِ بـ تعبئة كل البنود أدناه حسب إحتياج الدراسة. النصائح الإرشادية المبينة باللون الأزرق ميكن مسحها من النموذج.

Invitation to participate and summary

[State the overall purpose of the study in simple terms]

You are invited to participate in a research study being conducted by Dr. **X** and others at the Hamad Medical Corporation. Researchers from_____ in Qatar and other countries _____are also working on this study. They will be studying blood cells looking for mutations (changes in genes) that might cause people with hepatitis to develop liver cancer later in life. You are being invited to participate in this study because you have hepatitis or have had it in the past. This form reviews several things you should know before you agree to participate. Participation in research is voluntary, and you may refuse to participate without any loss of rights or privileges to which you are otherwise entitled.

دعوة للمشاركة وملخص

إرشاد : أشرح الغرض العام من الدراسة في عبارات بسيطة

انت مدعو للمشاركة في الدراسة البحثية التي يقوم بها الدكتور س وفريق البحث في مؤسسة حمد الطبية، بمشاركة باحثين من _____ في دولة قطر ودول أخرى _____ تعمل أيضا على هذه الدراسة. وسوف يركز هذا البحث فى دراسة خلايا الدم للبحث عن الطفرات (التغيرات في الجينات) التي قد تسبب سرطان الكبد في وقت لاحق في الحياة وذلك لدى الآشخاص الذين يعانون من التهاب الكبد. ولذلك أنت مدعو للمشاركة في هذه الدراسة لأنه لديك التهاب الكبد أو كنت تعانى منه في الماضي. من خلال هذا النموذج سوف نشرح ونستعرض العديد من الأشياء والمعلومات التى يجب أن تعرفها قبل أن توافق على المشاركة في هذا البحث. المشاركة في هذا البحث كما فى البحوث الاخرى في مؤسسة حمد الطبية طوعية تماما. يحرص فريق البحث على أن تلم بكل المعلومات التى من شأنها مساعدتك فى إتخاذ قرارك الطوعى ومن ضمنها حقك فى إستشارة طبيبك الخاص أو أى من أفراد عائلتك. إذا قررت عدم المشاركة فى هذا البحث فلن يترتب على ذلك أي فقدان لآى من الحقوق أو الامتيازات أو نوعية الخدمة الصحية التي تحتاجها، ولن يؤثر ذلك فى علاقتك بمؤسسة حمد الطبية.

What is the purpose of the study?

[Explain to potential subjects why the study is being done]

Liver cancer (hepatocellular carcinoma) is a common cause of death around the world. It has been known for many years that people who have certain types of hepatitis have a somewhat higher chance of developing liver cancer later in life. However, not all people with hepatitis will go on to develop cancer. **Dr. X** and his colleagues are trying to find out if there is something different in the genes of people who develop liver cancer after having hepatitis. If they find a difference, it may allow doctors to find people who are at a greater risk of developing liver cancer. If so, it is possible that following those people more closely will allow earlier detection of the cancer so that it can be treated more effectively. Finding mutations that increase the risk of cancer may also lead to additional research, which could someday help doctors develop more effective treatments for liver cancer, or even ways to prevent the cancer from developing in the first place.

ما هو الغرض من الدراسة؟

نصيحة : أشرح للمشارك المحتمل لماذا تقوم بإجراء هذه الدراسة

سرطان الكبد هو سبب شائع للوفاة في جميع أنحاء العالم. والمعلوم لسنوات عديدة أن الأشخاص المصابون بأنواع معينة من التهاب الكبد لديهم فرصة أعلى من المعتاد للإصابة بسرطان الكبد في وقت لاحق في الحياة. ومع ذلك ، فإنه ليس كل الناس المصابون بالتهاب الكبد بالضرورة سوف يتطور المرض عندهم قدما لسرطان الكبد. **الدكتور س** وزملاءه يحاولون معرفة ما اذا كان هناك شيء مختلف في جينات الناس الذين يصابون بسرطان الكبد بعد معاناتهم الطويلة وصراعهم مع مرض التهاب الكبد. اذا وجد **الدكتور س** وزملاءه فى فريق البحث إختلافا، فإن ذلك قد يمكنهم من العثور على الناس الذين هم في خطر اكبر للاصابة بسرطان الكبد. إذا كان الأمر كذلك ، فمن الممكن إخضاع هؤلاء الناس للمتابعة الصحية على نحو أوثق بما يسمح للأطباء بالكشف المبكر جدا عن حدوث سرطان الكبد بحيث يمكن التعامل مع السرطان على نحو أكثر فعالية وهو فى مرحلته الأولية. العثور على الطفرات التي قد تزيد من خطر الاصابة بسرطان الكبد قد يؤدي أيضا إلى إجراء المزيد من البحوث العلمية، والتي يمكن أن تساعد الأطباء في يوم من الأيام تطوير علاجات أكثر فعالية لسرطان الكبد، أو حتى إستحداث وسائل لمنع حدوث السرطان في المقام الأول لدى مرضى التهاب الكبد.

What does participation in this study involve? *[Explain (1) the procedures that subjects will undergo for the study, the information that will be collected from subjects, how the information will be collected, and why the information will be collected; (2) the type of sample and how it will be collected (e.g., by blood draw, skin biopsy, cheek swab); (3) in simple terms what will be done with the sample; and (4) whether there are an specified or unspecified future plans for use of the sample]*

ماذا تشمل المشاركة في هذه الدراسة ؟

إرشاد: أشرح (1) الإجراءات التي سيخضع لها المشارك بالدراسة، مع بيان كامل لنوعية المعلومات التي سيتم جمعها من المشارك بالدراسة، وكيف يتم جمع هذه المعلومات ، ولماذا يتم جمع هذه المعلومات، (2) حّدد نوع العينة ، وكيف وسيتم جمع هذه العينة (على سبيل المثال ، عن طريق سحب الدم ، خزعة الجلد، أو عن طريق المسحة الاختيارية من الفم) ، (3) بعبارات بسيطة أشرح ما سيتم عمله مع العينة حصريا فى هذه الدراسة، و (4) ما إذا كانت هناك خطط لدراسات أو بحوث مستقبلية محددة أو غير محددة في المستقبل لاستخدام العينة.

Some mutations are more common among people from particular racial or ethnic groups, or in people who have had other medical problems in the past. Knowing background information about you will help **Dr. X** determine whether this is true for the mutations he is looking for. You will be asked to give your age, race, gender, ethnic background, family history, and your health history. We will then ask your permission to take like 2 spoons of your blood from a blood vessel in your arm. This blood will be used in this research.

من الثوابت أن بعض الطفرات الجينية تكون أكثر شيوعا بين الناس خاصة من مجموعات عرقية أو أصول معروفة، أو بين الناس الذين لديهم مشاكل طبية محددة في ماضيهم. ولذلك فإن معرفة المعلومات الخلفية عنك سيساعد **الدكتور س** وفريق البحث تحديد ما إذا كان هذا صحيحا وينطبق على الطفرات التى يبحثون عنها خلال هذه الدراسة. ولهذا سوف يطلب منك اعطاء عمرك والعرق والنوع والخلفية العرقية والتاريخ الصحى العائلي، والتاريخ الصحى الخاص بك. بعد ذلك سوف نطلب منك السماح لنا بسحب عينة من دمك من وريد فى ذراعك. تقدر كمية الدم المطلوبة والتى سوف نستعملها فى هذا البحث بمقدار ملعقتين طعام.

The researchers won't keep any information that identifies you or that lets them know which blood sample came from you. This will help protect you from the risks of genetic testing (see "Risks" section). It will also have other consequences. For example, if researchers identify a gene that increases the risk of developing a preventable medical problem, this study cannot tell you, members of your family, or your doctor whether or not you have that gene.

ليس فى نية فريق البحث الإبقاء على أىّ من المعلومات التي من شأنها تحديد هويتك، أو أن تسمح لهم معرفة أي عينة دم جاءت منك تحديدا. هذا الإجراء سوف يساعد على حمايتك من مخاطر الاختبارات الجينية (انظر قسم "المخاطر" المقطع)، والتى قد تترتب عليها أيضا عواقب أخرى.

على سبيل المثال ، إذا ما توصل الباحثون من خلال هذه الدراسة التعرف على الجين الذي يزيد من خطر الاصابة بمشكلة طبية يمكن الوقاية منها، فسوف لن يكون بمقدورنا إخطارك أو إخطار أىّ من أعضاء عائلتك ، أو طبيبك ما إذا كان أو لم يكن لديك هذا الجين.

DNA will be removed from your blood sample in the laboratory. DNA is present in your genes. Genes are the material passed from parent to child that influences the make-up of the body and mind, such as how someone looks and if someone is more likely to get a disease. Some of the DNA may be saved for future testing, and some of the cells from your blood may be kept alive and growing in the laboratory as a "cell line". This will allow **Dr. X** to get more DNA if he needs it (see below). The rest of your blood sample will be thrown away. The DNA will be studied, and patterns in your DNA markers will

ستتم إزالة الحمض النووي من عينة الدم في المختبر. الحمض النووي موجود في الجينات الخاصة بك. والجينات هي المادة التى من خلالها تنتقل الموروثات والخصائص من الام الى الطفل وبذلك تحدد الصفات الجسمانية والعقلية لدى الطفل، مثل كيف يبدو الطفل فى مظهره العام وما اذا كان هناك أكثر احتمالا لقابلية الحصول على المرض. قد يتم حفظ بعض من الحمض النووي للاختبار في المستقبل، أيضا قد يتم حفظ بعض الخلايا من عينة الدم والإبقاء عليها على قيد الحياة والنمو في المختبر كخط "خلية". وهذا سوف يسمح **للدكتور س** الحصول على مزيد من الحمض النووي إذا كان يحتاج إليها (انظر أدناه). وسيتم التخلص من بقية عينة الدم الخاصة بك. وستتم دراسة الحمض النووي ، والأنماط السائدة في علامات الحمض النووي الخاص وسيتم تسجيلها وبالمقارنة مع تلك الأنماط الأخرى الخاصة بمرضى آخرين يعانون من التهاب الكبد ، وبعضهم تطور المرض لديهم إلى سرطان الكبد. إذا تم العثور على أية أنماط باستمرار في أولئك الذين يعانون من السرطان ولكن ليس في أولئك الذين لآ يعانون من السرطان ،

be recorded and compared to those of other people with hepatitis, some of whom have had liver cancer. If any patterns are found consistently in those who have cancer but not in those who have not had cancer, further testing will be done to see if those patterns are markers of a nearby gene or genes that are responsible for the increased risk of cancer. If that turns out to be true, further testing will be done to identify those genes and study them.

فسوف يتعين إجراء مزيد من التجارب لمعرفة ما إذا كانت هذه الأنماط مؤشرات على جين قريب أو هى بالتأكيد الجينات المسؤولة عن زيادة خطر الاصابة بالسرطان. إذا تبين لنا أن ذلك صحيحا فسوف يتعين إجراء مزيد من التجارب لتحديد هذه الجينات ودراستها بإسهاب وتفصيل.

MODEL LANGUAGE FOR WHEN SAMPLE WILL BE DESTROYED:

DNA will be saved and the cell line will be kept alive in the laboratory until the study is completed, which is expected to be within the next 2 years. It will then be thrown out.

اللغة النموذجية التى جيب إستعمالها لتحديد المدة الزمنية التى بموجبها تمي إتلاف العينة

سيتم حفظ الحمض النووي وخط الخلية على قيد الحياة في المختبر حتى الانتهاء من الدراسة ، التي يتوقع أن يكون في غضون السنتين القادمتين. بعد ذلك سيتم التخلص من العينة بإتلافها.

MODEL LANGUAGE FOR WHEN SAMPLE KEPT FOR FUTURE USE:

DNA will be saved and the cell line will be kept alive as long as possible, hopefully for many years. This way, as more is learned about hepatitis and cancer, your DNA may be used for additional research. For example, it is possible that more accurate genetic testing may become available in the future, or that a follow up study will be done years from now. It is important to remember, however, that no one will be able to identify which cell line is yours because all identifying information will have been removed.

اللغة النموذجية التى جيب إستعمالها لطلب الإحتفاظ بالعينة من أجل استخدامها في المستقبل

سيتم حفظ الحمض النووي وسيبقى خط الخلية على قيد الحياة فى المختبر لأطول وقت ممكن ولفترة قد تمتد لعدة سنوات. فى حالة تحقيق هذا الهدف وبمرور الوقت سوف نتعلم الكثير حول العلاقة بين التهاب الكبد وحدوث مرض السرطان. ونسبة لهذه الحقيقة فإنه يمكن استخدام الحمض النووي للحصول على المزيد من البحث. على سبيل المثال ، فمن الممكن أن الاختبارات الجينية في المستقبل قد تصبح أكثر دقة ، أو أنه قد نحتاج متابعة الدراسة الحالية ولكن بمعطيات جديدة نتعلمها بعد سنوات من الآن. ومن المهم أن نتذكر ، مع ذلك ، أن أحدا لن يكون قادرا على تحديد أي خط خلية لك وذلك لاننا قد أزلنا جميع المعلومات التى من شأنها أن تؤدى الى الكشف أو التعرف الى هويتك.

Dr. X may also want to use your cells or stored DNA in other research in the future, or share them with other researchers for use in their work. Please initial below if you do not want your sample used in other research studies. If you do not initial this it will not be possible for you to withdraw your sample later because the research team will not be able to identify it.

الدكتور س قد يحتاج أيضا إلى استخدام خلايا الحمض النووي الخاصه بك أو تخزينها لإجراء بحوث أخرى في المستقبل ، أو مشاركتها مع باحثين آخرين لاستخدامها في دراساتهم. الرجاء التأشير بالحرف الاول لإسمك أدناه إذا كنت لا تريد إستخدام العينة في إى بحوث أو دراسات أخرى مستقبلية. إذا لم تقم بالتأشير على الفراغ أدناه فإن هذا يعنى أنه لن يكون من الممكن بالنسبة لك ان تسحب العينة الخاصة بك في وقت لاحق لأن فريق البحث لن يكون قادرا على التعرف عليها.

☐ I **do not** want my DNA or tissue used for any future research or shared with other investigators

أنا لا أريد إستخدام الحمض النووي أو العينة التى أُخذت منى في أي ☐ بحث في المستقبل أو إعطائها لباحثين آخرين

What are the risks of participating in this study? *[Address the potential risks associated with (1) the disclosure of information obtained in the study; (2) racial or ethic associations that might be drawn from the study results; and (3) the risks associated with the collection of the sample. Because of the nature of genetic research and not all risks can be known at this, this section also should include a statement that there may be unknown risks associated with participation in such studies.]*

ما هي مخاطر المشاركة في هذه الدراسة؟

إرشاد : ناقش المخاطر المحتملة المرتبطة ب (1) الكشف عن المعلومات التي تم الحصول عليها في هذه الدراسة ، (2) إمكانية أن تنسب نتائج الدراسة لسلالة محددة أو مجموعة إثنية أو عرقية محددة، و (3) المخاطر المرتبطة بعملية جمع وأخذ العينة. ونظرا لطبيعة الأبحاث الجينية وخصوصية هذه الأبحاث فى عدم الإلمام بمعرفة كل المخاطر المحتملة، ينبغي أن يشمل هذا الجزء من الموافقة المستبينة أيضا بيان بأنه قد تكون هناك مخاطر غير معروفة في مثل هذه الدراسات.

Risks of disclosure

Even though we will remove identifying information and do not intend to tell you or anyone else the results of the testing on your sample, there is a very small chance this information could accidentally become known to you, your doctor, or others. Knowing you have an increased risk of developing a problem may also have a harmful psychological effect on the way you think about your future. It could also affect your relationships with members of your family, especially if this changes their risks. We will be careful to see that disclosure does not happen, without granting that disclosure could never happen.

مخاطر الكشف

بالرغم من أننا سوف تزيل كل المعلومات التى يمكن أن تدلل أو تؤدى للتعرف على هويتك وبالرغم من أنه ليس في نيتنا أن نطلعك أو أي شخص آخر على نتائج الاختبار على العينة الخاص بك ، هناك فرصة ضئيلة للغاية يمكن لأن تصبح هذه المعلومات بطريق الخطأ معروفة لكم ، أو لطبيبك الخاص ، أو غيره. من المهم أيضا أن نذكر أن معرفتك لمعلومات تتعلق بإحتمال زيادة خطر التعرض لمشاكل صحية لديك قد يكون لها أيضا تأثير ضار لوضعك النفسي تؤدى بك للتفكير فى ما سوف يصير في مستقبلك. كما يمكن أن يؤثر ذلك أيضا على علاقاتك مع أفراد عائلتك ، وخاصة إذا كانت هذه التغييرات سوف تزيد من المخاطر التي قد يتعرضون لها بنفس القدر لديك. سوف نكون حريصين جدا على عدم حدوث ذلك وسوف نبذل كل ما نستطيع للتاكد من عدم الكشف عن نتائج الفحص، دون أن نضمن عدم حدوث ذلك.

Risks of racial or ethnic association

It is possible that this study will show that members of your race or ethnic group may be at higher risk of developing cancer than others. This may be seen as stigmatizing or discriminatory information.

مخاطر تتعلق بالعنصر أو العرق

فمن الممكن أن هذه الدراسة سوف تظهر أن أعضاء عرقك أو جماعة عرقية محددة قد تكون أكثر عرضة للاصابة بمرض السرطان أكثر من غيرها. هذا يمكن يؤدى لإعتبار ذلك وصم أو معلومات تمييزية.

Risks of sample collection

There is a small chance that drawing your blood will be painful or will cause bleeding, infection, or dizziness. The information gained from the study of your DNA cannot be linked to you since no identifying information will be kept.

مخاطر جمع العينات

عملية سحب العينة كالدم مثلا يمكن أن تسبب بعض الألم فى موضع السحب أو تتسبب في حدوث نزيف موضعى أو إلتهاب، أو دوار عند بعض الأشخاص. المعلومات المكتسبة من دراسة الحمض النووي الخاص بك يتم تحريرها مباشرة من أى معلومات شخصية أو شفرة معينة أو حتى رقمك الصحى وبذلك لا يمكن أن تكون مرتبطة بك وستبقى كذلك.

Other risks
These are the best known risks of research in which tissue samples are used. There might be other risks we do not know about yet.

مخاطر أخرى
هذه لا تخرج عن إطار المخاطر المعروفة من المشاركة فى البحوث التي تستخدم فيها عينات الأنسجة. قد تكون هناك مخاطر أخرى نحن لا نعرف عنها حتى الآن.

What are the benefits of taking part in this study? *[Generally genetic testing is not believed to directly benefit subjects, although there are cases when there is an expected therapeutic benefit]*

ما هي فوائد المشاركة في هذه الدراسة؟
إرشاد : من المعلوم أن الاختبارات الجينية عموما ليست لها فائدة مباشرة أو آنية بالنسبة للمشارك بالبحث، وإن كانت هناك حالات يتوقع فيها أن تكون هناك فائدة علاجية يمكن أن تفيد المشارك

Participating in this study is not expected to benefit you directly. If the study is successful, it may some day help prevent liver cancer in others or lead to more effective treatments. Some people also find satisfaction in contributing to scientific knowledge.

كمشارك فى هذا البحث لا نتوقع أن تكون لك فوائد مباشرة تجنيها. إذا كانت الدراسة ناجحة ، فإنها قد تساعد يوما ما في منع حدوث سرطان الكبد لدى مرضى آخرين أو أن تؤدي إلى إستحداث علاجات أكثر فعالية. بعض الناس أيضا يبدون الإرتياح والشعور بالرضا على الإسهامهم الشخصى في تطور المعرفة العلمية.

Are there any alternatives to taking part in this study? *[In the case of non-therapeutic research, clarify in this section that participation in the research is not required for participants to treatment or a diagnosis that would normally be available to them outside the research context]*

هل هناك أي بدائل للمشاركة في هذه الدراسة؟
إرشاد : في حالة البحوث غير العلاجية ، وضّح في هذا القسم أن المشاركة في هذا البحث لا تتطلب من المشاركين الخضوع لعلاج أو تشخيص مما قد يكون متاحا لهم خارج إطار البحث.

Participation in this research study is voluntary. The results of the tests conducted for this study will not be shared with you because their reliability and value in treating or diagnosing conditions is not known.

المشاركة في هذه الدراسة البحثية طوعية تماما. نتائج التجارب التي أجريت لهذه الدراسة لن يتم إطلاعكم عليها وذلك نظرا لأن قيمتها في علاج أو تشخيص الحالات المرضية غير معروفة.

If you would be interested in determining your risk of developing cancer once such a test becomes available, reliable, and helpful, you should periodically ask your doctor or a genetic counselor if the test is available, and ask him or her to discuss its advantages and disadvantages with you. (A genetic counselor is professionally trained to help you understand what genetic test results mean and don't mean for you and members of your family.)

إذا كنت ترغب في معرفة أى مخاطر قد تكون لديك بالنسبة للإصابة بالسرطان متى ما تم إستحداث الاختبارالخاص بذلك ومن ثم التأكد من فعاليته وفائدته، فإنه يجب عليك أن تسأل الطبيب دوريا أو تستشير مستشار علم الوراثة إذا أصبح الاختبار متاحا، وان تناقش مع أى منهما مزايا و مساوئ هذا الإختبار (مستشار علم الوراثة هو شخص مدرب تدريبا مهنيا لمساعدتك على فهم نتائج الاختبارات الجينية وما تعنيه بالنسبة لك ولأفراد عائلتك.)

How will my confidentiality be protected?

كيف ستتم حماية السرية الخاصة بي؟

The results of this study may be published in a medical journal, but the only people who would

قد تنشر نتائج هذه الدراسة في مجلة طبية ، ولكن الأشخاص الوحيدين الذين سيكونون قادرين على التعرف عليك من خلال نشر المعلومات هم

be able to identify you from published information will be those involved in the research. Your confidentiality will be protected by ensuring no identifiable information is connected to your sample. Nothing will be written on the sample that anyone, including the researchers, will be able to connect back to you.

من لهم علاقة مباشرة بالبحث. سريتك الشخصية سوف تكون محمية من خلال ضمان السرية الخاصة بك وإنه ليس هناك أى معلومات شخصية أو رموز أو شفرة محددة متصلة بعينتك. لن تتم كتابة أي شيء على العينة والذى قد يمكن أي شخص بما في ذلك الباحثين بإمكانية ربط العينة بك والتعرف عليك كصاحب هذه العينة.

Will commercial products be developed from my sample?

[This information should be included if any potential exists for the tissue or blood sample to lead to a test, technology, cell line, or other product that could be patented or sold for commercial gain]

هل سيتم تطوير منتجات تجارية من العينة الخاص بي؟

إرشاد: ينبغي أن تدرج فى هذا القسم إذا ما كان هناك إحتمال أو توقع أن نتائج هذه الدراسة والمستخلصة من عينة الدم مثلا قد تؤدي إلى أستحداث اختبار جديد أو تكنولوجيا أو خط خلية جيد أو غيرها من المنتجات التي يمكن أن تُسجل لها براءة اختراع وبالتالى تباع لتحقيق مكاسب تجارية.

Cells obtained from your sample may be used to establish a cell line which will be used to help identify genes, or genetic markers. A cell line is one which will grow indefinitely (permanently) in the laboratory. These cell lines may be shared in the future with other researchers with no identifying information about you. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. These cell lines may be of commercial value, but you will not be able to share in the profits from commercialization of products developed from your tissue or blood samples.

الخلايا التي تم الحصول عليها من العينة الخاصة بك يمكن استخدامها لإنشاء وإستحداث بما يعرف بخط الخلية الذى سيتم استخدامه فى الأبحاث التى تتعلق بالتعرف على الجينات ، أو على علامات وراثية. وحدة خط الخلية هى الخلية التي سوف تنمو إلى أجل غير مسمى (دائم) في المختبر. قد نعطى خطوط الخلية هذه في المستقبل لباحثين آخرين فى قطر أو خارجها وسوف يتم ذلك من دون تقديم أى معلومات قد تفيد عنك أو تدلل أنك المصدر الاساسى لأى من خطوط الخلية هذه. خطوط الخلية هذه مفيدة جدا للبحث بسبب خصائصها المتعددة و / أو المنتجات التي قد تنجم عنها. يمكن لخطوط الخلايا أن تكون ذات قيمة تجارية أيضا، ولكن فى حالة إستحداث أى منتج ذو قيمة تجارية نتيجة البحوث التى أجريناها على الأنسجة أو عينات الدم **فلن كيون لك أى حق مادى أو فى المشاركة فى الأرباح المتأتية من تسويق المنتجات التى إستحدثناها خلال هذا البحث عن طريق إستخدام عنةي الأنسجة أو عينة الدم الخاصة بك.**

If I start this study, can I change my mind?

Participation in this study is voluntary. You can stop your sample donation at any time. After your sample is collected, we will not be able to withdraw it from the study because we will not be able to identify which is your sample. We encourage you think very carefully about participating in this study, and be as sure as you can that you will not change your mind after your blood is drawn.

إذا كنت قد قبلت المشاركة فى هذه الدراسة ، هل مكنني أن أغير رأيي لاحقا؟

المشاركة في هذه الدراسة طوعية تماما. يمكنك إيقاف مشاركتك والإنسحاب من الدراسة فى أى وقت حتى لحظة سحب العينة وجمعها منك، بعد ذلك لن تستطيع إيقاف مشاركتك والغاء مشاركتك فى الدراسة لاننا فى هذه اللحظة لن نكون قادرين على تحديد عينتك من ضمن العينات التى بحوزتنا وبالتالى لن نستطيع سحبها. ولذلك نحن نشجعكم على التفكير مليا وأخذ الوقت اللازم بشأن قرار المشاركة في هذه الدراسة ، وينبغى أن تكون متأكدا تماما من أنك لن تغير رأيك بعد سحب الدم أو العينة.

What if I have questions?

If you have any questions or concerns about the research study or the information in this document it is important that you talk to **Dr. X** or one of the other members of the research team.

ماذا أفعل إذا كان لدي أسئلة أو إستفسارات بخصوص هذه الدراسة؟

إذا كان لديك أي أسئلة أو استفسارات عن هذه الدراسة أو البحث أو عن المعلومات الواردة في هذه الوثيقة من المهم أن تتحدث مع **الدكتور س** أو أحد الأعضاء الآخرين في فريق البحث. قد تحتاج أيضا لمناقشة هذا الأمر مع طبيبك أو ممرضتك ، أو مستشار علم الوراثة. لمزيد من المعلومات

You may also want to discuss this with your doctor, nurse, or a genetic counselor. For more information about the rights of research subjects or participants, you may call the Research Committee of Hamad Medical Corporation at 4439 2440.

حول الحقوق المتعلقة بك كمشارك فى بحث بمؤسسة حمد الطبية يمكنك الإتصال بلجنة البحوث بمؤسسة حمد الطبية على الهاتف 4392440

Duration of the research: *[Describe how long the prospective participant is expected to be in the research and what expectations the investigator might have about the participant's time spent in the research]*

مدة إجراء البحث والدراسة *(مدة البحث والوقت المتوقع للمشارك أن يستغرقه لمشاركته المنتظرة وتوقعات الباحث للوقت المستغرق في إجراء البحث والدراسة)*.

Names of the sponsors of the research: *[Give information to the participant about all the sponsors of the research, any issues of conflict of interest and also where the research will be conducted]*

مصادر تمويل البحث ومكان إجراء الدراسة *(أعطى تفاصيل للمشاركين عن إسم الجهات اللتى قامت بتمويل البحث، وما إذا كان لهذه الجهات مصلحة أو عائد مادى منتظر)*.

Assurance of anonymity and confidentiality *[Confidentiality about the results/specimen/laboratory or any other data]*

As participant in this research, the research team will only ask you about your age, race, gender, ethnic background, family history and your health history. This information will be used to document your participation in this research, and to assess your eligibility to participate in this research. This information will not be linked in any way or form to the sample you gave. The sample will be truly un-identified from the moment that you leave the research location.

السرية حول النتائج، العينةالمختبرية أو أي بيانات أخرى *(صف خطوات حماية سرية البيانات، العينةالمختبرية أو أي بيانات أخرى من شأنها الكشف عن هوية او أسم أى مشارك بالدراسة)*.

كمشارك فى هذا البحث سوف يقوم فريق البحث بطلب إعطاء معلومات عن عمرك والعرق والنوع والخلفية العرقية والتاريخ الصحى العائلي، والتاريخ الصحى الخاص بك. هذه المعلومات سوف تستخدم حصريا لإثبات مشاركتك وتقييم أهليتك للإشتراك فى هذا البحث. ليس فى نية فريق البحث الإبقاء على أىّ من المعلومات التي من شأنها تحدد هويتك، أو أن تسمح لهم معرفة أي عينة دم جاءت منك تحديدا. عينة الدم التى سوف تشارك بها فى هذا البحث ستصبح غير معّرفة حقيقة بحيث لا ترتبط بأى علامات أو رموز أو شفرة تدلل على هويتك، وذلك منذ اللحظة التى تغادر فيها مركز البحث.

Signed Consent of Study Participation

الموافقة المستبينة للمشاركة فى البحث

Consent: You (the participant) have read or have had read to you all of the above. Dr. *[insert name]* or his/her authorized representative has provided you with a description of the study including an explanation of what this study is about, why it is being done, and the procedures involved. The risks, discomforts, and possible benefits of this

الموافقه المستبينة الخطية: أقر انا الموقع ادناه بأني قرأت (أو قد ُقرأ لي) المرفق اعلاه الخاص بهذا البحث. **د. إسم الباحث الرئيسى**، أو من ينوب عنه قد قام بشرح الدراسة لى واجاب عن كل اسئلتى واستفساراتى الخاصة بالدراسة والبحث. لقد تم شرح وإيضاح المخاطر وعدم الراحة وكذالك الفوائد المرجوة من اجراء الدراسة, كما تم ايضا شرح وايضاح أن هذا البحث يعتمد على الفحص الجينى وان فريق البحث لن يخطرنى بنتائج الفحص الخاصة بى حصريا. كما تم إخطارى بان المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لى مطلق الحرية بالمشاركة او بعدم

research study have been explained to you. It has also been explained to you that this research involves genetics testing and that I will not be notified of the results. I was also informed that participation in this research is voluntary and the decision to participate or not to participate is mine. There will be no consequences If I decide not to participate, and I can withdraw my participation at any time till the moment I gave the blood sample to the laboratory. By signing this form, you willingly agree to participate in the research study described to you. You will receive a copy of this signed consent form. As long as the study is renewed as required by the Research Committee, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

المشاركة. فى حالة إتخاذى القرار بعدم المشاركة فى هذا البحث العلمى لا يترتب على قرارى هذا اى تبعات او حرمان من حقوقى المستحقة. أيضا يمكننى الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت أو مرحلة أشاء قبل تسليم العينة الى المختبر ومغادرته دون أن يؤثر ذلك فى حقوقى أو فوائدى المستحقة والمرجوة والمشرعة. وبتوقعي أدناه اوافق على المشاركة في البحث. . وبتوقعي أدناه اوافق على المشاركة في البحث والذى تم شرحه لى. سوف نسلمك صورة من هذه الوثيقة. توقيعك هذا يدل على موافقتك بالمشاركة حتى تاريخ إنتهائها أو تمديدها من قبل لجنة البحوث. إذا طرأ أى طارىء قد يؤثر على رغبتك فى المشاركة فى هذه الدراسة فسوف نخطرك بذلك.

D

مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

○ HGH ○ WH ○ RH ○ AAH ○ AKH ○ OTHERS

○ م. حمد العام ○ م. النساء ○ م. الرميلة ○ م. الأمل ○ م. الخور ○ م. أخرى

HC NO:
PARTICIPANT NAME:
DOB:
GENDER:
NATIONALITY:

رقم السجل:
إسم المشارك:
تاريخ الميلاد:
الجنس (ذكر | أنثى) :
الجنسية:

Consent form template for studies involving genetic testing

نموذج موافقة مستبينة للمشاركة بدراسة تنطوى على الإختبارات الجينية

Truly unidentifiable samples
Low Risk

إستخدام عيّنات غير معّرفة تماما
مخاطر منخفضة

You are free to ask as many questions as you like before, during or after in this research, you decide to give consent to participate in this research study. The information in this form is only meant to better inform you of all possible risks or benefits. Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study up to the moment of providing the sample without penalty or loss of rights or other benefits to which you are entitled.

كمشارك فى هذا البحث العلمى لك مطلق الحرية في طرح أى سؤال أو إستفسار عن هذا البحث وذلك قبل , أثناء إجراء, أو بعد إكمال إجراء البحث. الهدف الرئيسى من المعلومات الواردة في هذا النموذج هو أن نقدم لكم الشرح الوافى والمستفيض عن كل الأخطار والفوائد التى يمكن أن تتمخض عن إجراء هذا البحث. المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لكم مطلق الحرية بعدم المشاركة. قراركم بعدم المشاركة فى هذا البحث العلمى لا يترتب عليه اى تبعات او حرمان من حقوقكم المستحقة. أيضا يمكنكم الانسحاب وعدم مواصلة المشاركة فى هذا البحث فى أى وقت حتى لحظة سحب العيّنة دون أن يؤثر ذلك فى حقوقكم أو فوائدكم المستحقة والمشرعة.

NOTE: This template is best for studies using truly unidentifiable samples (i.e., no codes or indirect identifiers will be associated with the samples and the risks to subjects would be low should inadvertent disclosure occur)

ملاحظة : هذا النموذج هو الأفضل لإجراء دراسات باستخدام عينات غير معّرفة حقا (أي أنه لا توجد رموز أو أي معرفات غير مباشرة مرتبطة مع العينات ، والمخاطر على المشاركين فى الدراسة سوف تكون منخفضة فى حالة الإفشاء غير المقصود).

PLEASE DO NOT CHANGE THE FORMAT OF THIS TEMPLATE

فضلا لا تغيير فى الشكل العام لهذا النموذج

Project Title: **عنوان المشروع :**

Name of Principal Investigator: **اسم الباحث الرئيسي :**

Location and phone numbers: *[provide appropriate daytime contact information and after-hours or on weekends]*

موقع إجراء البحث وأرقام الهواتف ***(أثناء أو خارج أوقات الدوام وخلال الأجازات)*:**

Each item given below has to be filled. Please modify according to your study needs. The tips highlighted in yellow can be erased.

يجب ملئ كل البنود أدناه حسب إحتياج الدراسة. بعض النصائح الإرشادية كما مبّن باللون الأزرق يمكن مسحها من النموذج.

Invitation to participate
[State the overall purpose of the study in simple terms]

دعوة للمشاركة
نصيحة : إشرح الغرض العام من إجراء هذه الدراسة وذلك بعبارات بسيطة

Invitation
You are invited to participate in a research study because you have hepatitis or have had it in the past. You do not have to participate in this research; if you choose not to do so it will not affect your care in any way.

دعوة
انتم مدعوون للمشاركة في دراسة بحثية لأنه لديك التهاب الكبد أو كنت تعانى من التهاب الكبد في الماضي. أنت غير ملزم بالمشاركة في هذا البحث ، وإذا اخترت ألا تفعل فلن يؤثر قرارك هذا على الرعاية الخاصة والتى تتلقاها بأي شكل من الأشكال

What is the purpose of the study?
[Explain to potential subjects why the study is being done]

Dr. X is trying to find out why some people who have hepatitis develop liver cancer later in life. If he can, it might someday help doctors develop more effective treatments for liver cancer, or even ways to prevent the cancer from developing in the first place.

ما هو الغرض من الدراسة؟
نصيحة : إشرح للمشارك المحتمل فى هذا البحث لماذا تُجري هذه الدراسة
الدكتور س يقوم بإجراء هذا البحث فى محاولة لمعرفة لماذا يتطور التهاب الكبد لدى بعض الناس للأصابة بسرطان الكبد في وقت لاحق في الحياة. إذا استطاع هذا البحث البحث فى التوصل الى سبب ذلك، فإن ذلك قد يساعد يوما ما الأطباء فى تطوير علاجات أكثر فعالية لسرطان الكبد، أو حتى إستحداث وسائل لمنع حدوث السرطان في المقام الأول.

If you agree to participate, what will be done?
You will be asked to give your [age, race, sex, ethnic background, family history, and your health history]. The researchers will not keep any information that identifies you or that lets them know which blood sample came from you. About 2 tablespoons of blood will be drawn. DNA will be removed from the blood and studied. DNA is present in your genes. Genes are the material passed from parent to child that influences the make-up of the body and mind, such as how someone looks and if someone is more likely to get a disease.

Dr. X may also want to use your cells or stored genetic material (DNA) in other research in the future, or share them with other researchers for use in their work. Please initial below your choice about whether your sample can be used in other research studies.

☐ I **do not** want my DNA or tissue used for any future research.

☐ I **agree** to allow my DNA or tissue to be kept for future research, which might include studies done by researchers not at the Hamad Medical Corporation.

إذا وافقت على المشاركة ، ماذا سيتم القيام به فى البحث؟
سوف نطلب منك اعطاء معلومات عن عمرك (العرق والنوع والخلفية العرقية والتاريخ الصحى العائلي وأيضا تاريخك الصحى). لن يقوم الباحثون بحفظ أو الإبقاء على أي من المعلومات والتى تحصلوا عليها خلال مشاركتك فى هذا البحث والتي من شأنها تحديد هويتك، أو أن تسمح لهم معرفة أي عينة دم جاءت منك. بعد ذلك، سيتم سحب حوالي 2 ملعقة طعام من الدم من ذراعك. ستتم إزالة الحمض النووي من الدم ودراستها. الحمض النووي موجود في الجينات الخاصة بك. الجينات هي المادة التى تنتقل من الام الى الطفل والتى تعطى للطفل صفات ومميزات الجسم والعقل ، مثل كيف يبدو الطفل فى تكوينه وصفاته الجسمانية وما اذا كان أكثر عرضة واحتمالا للحصول على المرض.

الدكتور س قد يحتاج أيضا إلى استخدام الخلايا الخاصة بك أو تخزين المواد الوراثية (الحمض النووي) في بحوث أخرى في المستقبل ، أو فى مشاركتها مع باحثين آخرين داخل أو خارج مؤسسة حمد الطبية لاستخدامها في بحوثهم ودراساتهم. الرجاء إبداء رغبتك حول ما إذا كان يمكن لنا استخدام العيّنة الخاصة بك أو حمضك النووى في بحوث ودراسات أخرى. الرجاء إختيار أحد الإختيارات التالية:

☐ أنا **لا أريد** أن يستخدم الحمض النووي أو الأنسجة المستخلصة في أي بحث في المستقبل

☐ أنا **أريد وأوافق** على السماح للباحثين على الإبقاء على الحمض النووي الخاص بي أو الأنسجة لأغراض البحث في المستقبل والتي قد تشمل دراسات يمكن أن يجريها باحثون في مؤسسات صحية غير مؤسسة حمد الطبية _____

Are there any risks?
There is a small chance that drawing your blood will be painful or will cause bleeding, infection, or dizziness. The information gained from the study of your DNA cannot be linked to you since no identifying information will be kept. Nothing will be written on the sample that anyone, including the researchers, will be able to connect back to you.

هل هناك أية مخاطر نتيجة مشاركتى بالبحث؟
هناك فرصة صغيرة أن عملية سحب عينة دمك قد تسبب ألما بسيطا أو سوف تتسبب في حدوث نزيف دموى بسيط بموضع الإبرة أو عدوى ، أو دوخة. المعلومات المكتسبة من دراسة الحمض النووي الخاص لم تكن مرتبطة بأى معلومات تدل على هويتك وبالطبع ستبقى على هذا الحال ولذلك يصعب التعّرف على هويتك ومشاركتك فى هذا البحث. لن تتم كتابة أي شيء على العينة وبذلك لن يتمكن أي شخص ، بما في ذلك الباحثين على ربط بهويتك.

Are there any benefits?
Participating in this study is not expected to benefit you directly. If the study is successful, it may some day help prevent liver cancer in others or lead to more effective treatments. Some people also find satisfaction in contributing to scientific knowledge.

هل هناك أي فوائد نتيجة مشاركتى بالبحث ؟
لا نتوقع أن تكون هناك فائدة مباشرة تعود عليك نتيجة مشاركتك في هذه الدراسة. و إذا قدر النجاح لهذه الدراسة ، فإنها قد تساعد يوما ما في منع حدوث سرطان الكبد لدى بعض الناس أو أن تؤدي إلى علاجات أكثر فعالية. بعض الناس أيضا يشعرون بالارتياح في الإسهام في المعرفة العلمية

Who will see the results of this study?
The results of this study may be published in a medical journal, but the only people who would be able to identify you from published information will be those involved in the research.

من الذي سيرى نتائج هذه الدراسة؟
قد تنشرنتائج هذه الدراسة في مجلة طبية ، ولكن الأشخاص الوحيدون الذين سيكون فى مقدورهم التعرف عليك من نشر المعلومات ونتائج هذا البحث سيكون فريق البحث ومن لهم صلة مباشرة بالدراسة.

What if you change your mind?
If you have any questions or concerns about this study it is important that you talk to **Dr. X** or one of the other members of the research team before you agree to participate. Because once your blood is donated there is no way to know who the sample came from, it will not be possible for your sample to be identified and removed from this or any other research studies you agreed this sample could be used for.

ماذا لو غيرت رأيك؟
إذا كان لديك أي أسئلة أو استفسارات حول هذه الدراسة نرى من المهم أن تتحدث مع **الدكتور س** أو أحد الأعضاء الآخرين في فريق البحث قبل الموافقة على المشاركة. من الضرورى جدا أن تعلم بأنه بمجرد أخذ عينة الدم منك ومغادرتك المكان لن يكون بمقدورك الإنسحاب من البحث ولن يكون بمقدورنا التعّرف على عينتك من جملة العيّنات الأخرى وبالتالى لن نستطيع سحب عيّنتك وإزالتها من هذا البحث أو أى بحث نريد القيام به فى المستقبل.

Will commercial products be developed from my sample? *[This information should be included if any potential exists for the tissue or blood sample to lead to a test, technology, cell line, or other product that could be patented or sold for commercial gain]*

Cells obtained from your tissue sample may be used to establish a cell line which will be used to help identify genes, or genetic markers. A cell line is one which will grow indefinitely (permanently) in the laboratory. These cell lines may be shared in the future with other researchers with no identifying information about you. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. These cell lines may be of commercial value. If this happens you will not be able to share in the profits from commercialization of products developed from your tissue or blood samples.

هل يتم تطوير منتجات تجارية من العينة الخاص بي؟

نصيحة : ينبغي أن تدرج هنا معلومات عن إمكانية إستحداث منتج جديد من إستخدام عينة المشارك وما إذا كان لهذا المنتج الجديد فائدة تجارية أو مادية أو إستحداث براءة اختراع لتحقيق مكاسب تجارية، مثال لهذه المنتجات إستحداث خط خلية جديد أو إختبار جديد .

الخلايا التي تم الحصول عليها من خلايا الأنسجة الخاصة بالعينة والتي أُخذت منك يمكن استخدامها لإنشاء خط الخلية والتي سيتم استخدامها عادة للمساعدة على التعرف على الجينات ، أو فى تحديد علامات وراثية. خط الخلية هو مستحدث يتمتع بخاصية النموء إلى أجل غير مسمى (دائم) في المختبر. خطوط الخلية هذه يمكن أن نتبرع بها الى باحثين آخرين فى المستقبل لإستخدامها فى الأبحاث، من دون تحديد المعلومات الخاصة بك خطوط الخلية هذه مفيدة جدا فى الأبحاث وذلك بسبب خصائصها / أو بسبب المنتجات التي قد تنجم عنها. يمكن أن تكون لخطوط الخلايا هذه قيمة تجارية. فى حالة حدوث ذلك، **فسوف لن يكون لك الحق فى المشاركة فى الأرباح المتأتية من تسويق المنتجات المستحدثة من الأنسجة أو عينات الدم.**

Signed Consent of Study Participation

Consent: You (the participant) have read or have had read to you all of the above. Dr. *[insert name]* or his/her authorized representative has provided you with a description of the study including an explanation of what this study is about, why it is being done, and the procedures involved. The risks, discomforts, and possible benefits of this research study, as well as alternative to this research have been explained to you. You have the right to ask questions related to this study or your participation in this study at any time. Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. By signing this form, you willingly agree to participate in the research study described to you. You will receive a copy of this signed consent form. As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

الموافقة المستبينة للمشاركة فى البحث

الموافقه المستبينة الخطية: أقر انا الموقع ادناه بأني قرأت (أو قد ُقرأ لي) المرفق اعلاه الخاص بهذا البحث. ***د . إسم الباحث الرئيسي***، أو من ينوب عنه قد قام بشرح الدراسة لى واجاب عن كل اسئلتى واستفساراتى الخاصة بالدراسة والبحث. لقد تم شرح وإيضاح المخاطر وعدم الراحة وكذالك الفوائد المرجوة من اجراء الدراسة, كما تم ايضا شرح وايضاح بدائل هذا البحث والمتاحة لى وفهمت محتواها. كما تم إخطارى بان المشاركة فى هذا البحث عمل طوعى خالص وبالتالى لى مطلق الحرية بالمشاركة او بعدم المشاركة. فى حالة إتخاذى القرار بعدم المشاركة فى هذا البحث العلمى لا يترتب على قرارى هذا اى تبعات او حرمان من حقوقى المستحقة. أيضا يمكننى الانسحاب وعدم مواصلة المشاركة فى هذا البحث حتى لحظة أخذ العيّنة منى دون أن يؤثر ذلك فى حقوقى أو فوائدى المستحقة والمرجوة والمشرعة. و أنه قد أُجيبت كل أسئلتي والتى طرحتها , وبتوقعي أدناه اوافق على المشاركة في البحث .توقيعك هذا يدل على موافقتك بالمشاركة حتى تاريخ إنتهائها أو تمديدها من قبل لجنة البحوث. إذا طرأ أى طارىء قد يؤثر على رغبتك فى المشاركة فى هذه الدراسة فسوف نخطرك بذلك

POLICY AND PROCEDURE OF ADVERSE EVENTS

Instructions to Investigators

1. If there are reportable adverse events that occur in a particular participant during your clinical trial, please fill in the attached form and submit it to the Research Committee, within 24 hours. It is your responsibility to inform the Research committee at HMC within 24 hours in the event of an unexpected sudden adverse drug reaction, a serious adverse event or an unexpected serious adverse event through the Chairman, Research committee, HMC, Doha contactable at: 2440/6166,
   E-mail: research@hmc.org.qa.
2. For further information, please refer to the policy on adverse events of the Research Committee.(Reference book)
3. **Reportable adverse events**: Unexpected sudden adverse drug reactions, serious adverse events and unexpected serious adverse events are classified as reportable adverse events by the Research Committee.
4. **Unexpected sudden adverse drug reaction** : A serious adverse drug reaction that is not identified in the nature , severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug.
5. **A serious adverse event:** It is defined as any event occurring at any dose that results in any of the following outcomes: death, a life threatening event, in patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability /incapacity or a congenital anomaly or a birth defect. Important medical events that may not result in death, be life threatening or require hospitalization also may be considered a serious adverse event when upon the basis of appropriate medical judgment; they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes given in the above definition.
6. **Unexpected serious adverse event :** This is any serious adverse event for which the specificity or severity is not consistent with the risk information available in the current investigators' brochure

7. **Reporting pregnancy that occurred during a clinical trial**: The investigator has to report a pregnancy that occurred during a clinical trial if there is a suspicion that the investigational product under study might have interfered with the effectiveness of a contraceptive treatment or there was a serious complication in the pregnancy (like a miscarriage) or an elective termination of pregnancy was done for medical indications.
8. **Reporting reportable adverse events that occurred at other centers of a multicenter trial :** The investigator must report reportable adverse events that occurred at other centers of the trial if the adverse event was both serious and unexpected and related or possibly related to the study treatment within 30 days' of being notified of the event. Such events must also be reported on the adverse event reporting form of the Research Committee at HMC.
9. For any other queries contact the Chairman of the Research Committee at 2440/6166.

Adverse Event Form

Title of the study :
Research proposal # :
Name of the participant (s):
Date and time of adverse events :

(For all reportable adverse events that occur in a particular participant during the clinical trial)

1. Number of reportable adverse events:

(For individual reportable adverse events)

- Description or name of event:
- Mention particular events and their presence or absence

Eg: Fever: Yes ---------- /No ----------

- Date of resolution.
- Intensity : (Check the one which is applicable)
    - Mild ------
    - Moderate---------
    - Severe ----------
- Relationship to device (*Check the one which is applicable)*
    - probably related----------
    - possibly related----------
    - not related----------
- Seriousness
    - Hospitalization required ----------
    - prolonged hospitalization with a potential disability-------
    - danger to life(sentinel event)---------
    - Intervention required without which death /disability might have resulted ----------

- death----------
- fetal distress----------
- fetal death----------
- congenital anomaly----------
- malignancy----------

- Anticipated
  - Yes ----------
    - No ----------
      - Treatment details : (Give details of treatment provided

Research Project Extension Form

Research Project #:_____ Date of Approval:_____

1. Project Title:

2. Name of the Principal Investigator:

3. Corresponding Address with Phone/Bleep No. and E-mail:

4. Date of expiry of ethical approval:

5. Location of the study(Study area):

6. Previously proposed period for the Research Proposal :

7. Please mention reason for extension:

8. Attach Recent progress report of the study: *(use progress report form)*

9. How much longer do you think your study will take?

10. Any other comments:

Signature of Principal Investigator: ……

Date:

SECTION VII (B)

FORMS FOR EVALUATION

RESEARCH PROJECT EVALUATION FORM

MEMORANDUM

To :

From :

Subject :

We would be grateful, if you kindly review the enclosed Research proposal entitled **:"***……..”*
You are one of the reviewers. We realize that you must be very busy, but your opinion would be appreciated.

We would appreciate receiving your comments in the enclosed Review Form on or before **--------.**

Thank you.

Note: *The reviewers are eligible for Qrs. 250/- as honorarium for the review of a research proposal, provided that, the comments should be received to Research office within the time limit; Plus 3 CME points from Medical Education Department.*

RESEARCH COMMITTEE

RESEARCH PROPOSAL REVIEW FORM

Reviewer #

Research Protocol:

Reviewer's Name & Designation:

***I recommend*:**

Approval of proposal ☐

Revision of proposal ☐

Rejection of proposal ☐

Signature of Reviewer (with stamp):

Date:

Please complete the overall assessment and scoring on the following pages.

Reviewer #

Research Protocol #

Overall assessment:

[This part of the review may be sent to the Principal Investigator for information. Please include an outline of the proposed study and an objective review of its scientific merits. Your opinion should be supported by references whenever possible. Please provide score (1=poor, 10=excellent) for each items with detail description (Use additional sheets if needed)]

Originality [Score:]: Description

Rationale [Score:]: Description

Design & Methods [Score:]: Description

Ethical considerations [Score:]: Description

Statistical considerations [Score:]: Description

PROGRESS REPORT FORM

6 Months	12 Months	18 Months	24 Months
☐	☐	☐	☐

Research Proposal #:_____ **Date:** _____

1. Title:

2. Name of the Investigator with Address with Phone/Bleep No. and E-mail:

3. What sort of Consent Form are you taking from subjects in the study?

(Please tick in the appropriate box)

a. Signed Informed Consent ☐

If yes, are you putting the copies of consent in the medical records file?

Yes ☐ **No** ☐

b. Waiver of signed informed consent form ☐

If yes, are you giving the copy of consent to the participant?

Yes ☐ **No** ☐

c. Waiver of Informed consent ☐

4. Have you had any serious adverse event during the study?

(For Clinical Trial Only)

Yes ☐ **No** ☐

If yes, have you informed Research Ethics Committee, Please Specify?

5. Sample size planned for the study:

6. Subjects / Specimens studied so far:

7. When do you expect to finish data collection and data entry?

8. When do you expect to finish Result Writing and Submission of Final Reports?

9. Amount of budget sanctioned for the study:

Yes ☐ **No** ☐ **NA** ☐

If yes, how much? Qrs:

Amount of the budget you have spent till now: Qrs:

10. Amount of Money reimbursed from MRC:

Yes ☐ **No** ☐

If yes, how much? Qrs:

11. Any difficulty faced in implementation of the study:

If yes, please specify:

12. Would you need any additional help from the Medical Research Department?

Signature of the Principal Investigator:

Medical Research Center- Clinical Research Audit Form

Patient's HC/ HMC #:
Address:

Research Project number:
Principal investigator's name:
Project Title:

Questions	***Yes***	***No***
Do you know that you had agreed to participate in a research?	☐	☐
Did the Principal Investigator introduce him self to you?	☐	☐
Did the PI explained study: • Benefits • Risks • Safety measurements • Contact person in case of adverse event/ emergency • Alternative treatments / therapy if available • Confidentiality	☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐
Did the PI give an opportunity to you to ask a question?	☐	☐
Did the PI answer your question?	☐	☐
Did the PI explain the right to withdraw from the research to you, at any time?	☐	☐
Did the PI take a signed consent from you?	☐	☐
Did the PI give you a copy of the signed consent form?	☐	☐
Have you been offered any compensation for your participation in research?	☐	☐

Remarks;

_____

_____

_____

_____

Name of the staffs who did the interview:

Signature:
Date:

SECTION VIII

CHECKLIST

RESEARCH COMMITTEE CHECK LIST FOR INVESTIGATORS

The proposal material should be collated as follows:

1. Memo of proposal submission to the Chairman, Research Committee from the Principal Investigator, through his/or her Department Chairman.

   Indicate in the memo, the following:

   If an expedited review is requested;

   If there is a potential external sponsor / collaborator for the study (indicate name, contact person, how to contact);

   If the study is a multi-centre study, and if so, if it was approved by a research regulatory body similar to the RC (enclose copy of supporting documents).
2. The proposal (abstract, introduction, specific aims/hypothesis, methods, statistical considerations, ethical considerations, work plan, references).
3. Associated Forms (Research Grant Form, Investigator's Assurance Form, Consent Form (both Arabic and English), Pharmacy Information letter, Proposal Clearances Form etc.)
4. CV of PI and CV summary of Co Investigators.

An original and an electronic copy of the proposal should be delivered to the Research Committee, Medical Research Centre, Building No16, 4th Floor, Hamad Medical City

RESEARCH CHECKLIST

1) What is the merit of this research? Is it worth doing? Will it solve the problem posed?
2) What is the benefit or potential benefit to the study population, to society, to the Hamad Medical Corporation and / or society to the body of "knowledge."
3) What risks, discomforts, side-effects, hazards are involved? Are these justified in view of the potential benefits? How will such effects be dealt with?
4) Have previous animal studies been done or is there a safer way of carrying out the study?
5) How invasive or intrusive is the research?
6) How is the study being funded? Are the researchers or study population likely to be motivated by financial incentives?
7) What costs/resources are involved? Are they justified in terms of the potential benefits of the study?
8) Is the research methodology basically sound? Are there any elements of the methodology which jeopardize the integrity of the study and the value of its results?
9) How will confidentiality be safeguarded? How is the study data collected, stored and secured?
10) Is provision made for obtaining free and informed consent? Will appropriate information be given to subjects and in an appropriate way? Will subjects be free of coercion and will they be aware that they can withdraw at any time? How will consent be sought and obtained?
    a) If subjects are judged incompetent to give consent, what are the grounds for such a judgment, and who will give informed consent? If the subjects for the study are judged to be incompetent, is it essential that they form the study population, or can the research be carried out on competent subjects?
    b) If children are involved, how are they to be informed and their agreement sought? If a child and the parents disagree about consent, how is this to be resolved?
11) Do all aspects of the study demonstrate a high level of veracity (truth-telling)?
12) If study results involve the identification of conditions requiring follow-up or treatment (e.g in screening/prevalence studies), will adequate action be taken?
13) Will the study results be monitored and published free from interference by individuals, organizations, or financial sponsors?

RESEARCH COMMITTEE

CHECK LIST FOR RC MEMBERS

1 Proposal and proposal summary:

1.1 Assessment of level of risk (check appropriate category):

□ No risk

□ Minimal risk. (The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

□ Greater than minimal risk but has potential direct benefit

□ Greater than minimal risk and no direct benefit, but has potential to yield generalisable knowledge about the subjects' disorder or condition.

1.1.1	If risk is greater than minimal, are the risks reasonable in relation to potential benefits?	□ Yes	□ No
1.2	Have risks for all subjects been minimized via use of an appropriate research design?	□ Yes	□ No
1.2.1	Is the subject population equitably distributed?	□ Yes	□ No
1.2.2	Are inclusion and exclusion criteria appropriate?	□ Yes	□ No
1.2.3	Does the study include vulnerable subjects?	□ Yes	□ No

1.2.4	Indicate (circle) vulnerable subjects to be enrolled: Minors, Pregnant women, prisoners, fetuses, mentally disabled individuals, educationally or socially disadvantaged persons.	□ Yes	□ No
1.3	Are additional safeguards in place to protect vulnerable subjects?		
1.3.1	Are all subjects' rights and welfare protected?	□Yes	□No
1.3.2	If minors are to be enrolled in the study, is the assent category indicated?	□Yes	□No
1.3.3	Will privacy and confidentiality of research records be adequately protected?	□Yes	□No
1.3.4	Has safety been maximized for all subjects?	□Yes	□No
2	**Consent Document:**		
2.1	Are the basic elements of informed consent incorporated?	□Yes	□No
2.2	Will the consent document be understandable to an individual with a sixth grade education?	□Yes	□No
2.3	Has the PI requested a modification in the consent process (waiver of informed consent)?	□Yes	□No
	Does it fulfill all four requirements for a waiver?	□Yes	□No
2.4	Has the PI requested a modification in the documentation of informed consent (waiver of signed consent)?	□Yes	□No
	Does it fulfill all four requirements for a waiver?	□Yes	□No

❖

References:

- Mamdani B. The Helsinki Declaration, 2000, and ethics of human research in developing countries. Indian J Med Ethics 2004 Jul;1(3):94-5.
- Burns N, Susan K Grove. The practice of nursing research: conduct, critique and utilization. 2nd Edition. 2011. WB Saunders Company.

  Ref Type: Generic
- Director General I. Ethical guidelines for biomedical research on humanparticipants. 27-30. 2006. New Delhi, ICMR. Ref Type: Generic
- Research Committee 2. Rules and Regulations for research at HMC. 2002.

  Ref Type: Edited Book
- Partners human research committee: Informed consent of research subjects. Human Research Office 2011Available from: URL: http://healthcar.partners.org/phsirb/infcons.htm?bcsi_scan_68E4B8D623C447665=0&bcs
- Guide for the care and use of Laboratory animals. 8th Edition. 2010. National Academy Press.

  Ref Type: Edited Book

Coordinated & typed by Mrs. Sudharma S. Rajan, Research Administrator, Medical Research Center.