POLICY AND PROCEDURE

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<th>SPECIMENS COLLECTED FOR HUMAN SUBJECTS RESEARCH</th>
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<td>IDENTIFICATION NUMBER:</td>
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**1.0 POLICY STATEMENT:**

1.1 The purpose of this policy is to detail the arrangements for the management of samples related to human subjects' research. Hamad Medical Corporation (HMC) is the **custodian/steward** for all **human biological specimens** ("biospecimens") obtained, used or stored for **research** purposes at HMC.

1.2 All initial and subsequent use of HMC biospecimens for research purposes is subject to the standards of research governance, as well as the principles of Good Clinical Practice for research as outlined in the Supreme Council of Health guidelines.

1.3 All data associated with the biospecimens should be managed according to HMC policy Data Ownership & Stewardship.

**2.0 DEFINITIONS:**

2.1 **Human biological specimen (Biospecimen)** – Biological materials originating from the human body, including any derivatives. Examples include but are not limited to: tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, cell lines, skin, hair, nail clippings, urine, saliva and other body fluids.

2.2 **Custodian** – The party overseeing the management of data across all stages of the data life cycle, including its preservation (funding is a separate matter). At HMC, the organization itself is responsible for most parts of the data life cycle, except for its discovery and production, the dissemination and long-term management are organizational issues. Where personal information (PI or PHI) is involved, stewardship includes the management of the data relative to the consent given.

2.3 **Principal Investigators** - An individual who is autonomous regarding their research activities; and has an academic or research appointment which: should commence by the effective date of funding; and allows the individual to pursue the proposed research study, to engage in independent research activities for the entire duration of the funding; to supervise trainees, and to publish the research results; and obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of personnel. A Principal Investigator should be a research scientist of recognized stature in his/her scientific discipline and has the demonstrated ability to ensure quality control and to administer and integrate all components of the program. Individual research study leaders should be individuals whose
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scientific publications demonstrate their potential to contribute to the overall theme of the program study. Core leaders should have appropriate expertise and be qualified for their role(s) in their core unit.

2.4 **Research** - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

2.5 **Steward** - the person or organization responsible for the day-to-day management of a resource entrusted to one’s care.

3.0 **PROCEDURE/ PROCESS:**

3.1 The PI is responsible for ensuring that any research involving the following: prospective collection of data and/or specimens for research purposes (e.g., additional questions added to routine surveys being performed for non-research purposes, an extra tube of blood taken at the time of clinical blood drawing, etc.) is “research involving human subjects,” and IRB review and approval is required.

3.2 Collection and storage of data and/or specimens for future research uses and/or distribution (i.e., rather than using data/specimens only for pre-defined analyses as described in a specific IRB-approved protocol) are activities that meet the definition of “research involving human subjects;” and IRB review and approval is required for any sample and data collection and associated consent procedures (where applicable).

3.3 When the data and/or specimens to be stored for future research uses are generated as part of a research study (e.g., clinical trial), these arrangements should comply with the HMC Specimen Storage Policies.

3.4 In some cases, secondary uses of previously collected data and/or specimens meet the definition of “research involving human subjects,” and IRB approval or exemption is required.
3.5 Biospecimens should be collected, used, stored, transported, and destroyed in a manner specific to the type of specimen and purpose of use to ensure sample integrity, viability, retrievability, confidentiality and safety. Biospecimens should be collected and used in accordance with the consent as approved by the IRB arrangements. Appropriate agreements including material and data transfer provisions are required for any external transfer, acquisition and use of biospecimens (refer to Policy number 008; Research agreements).

3.6 Safety All persons handling human blood, tissue and body fluids or biohazardous agents should successfully complete Clinical Research Safety Training. Personnel and trainees should demonstrate and document competence in safe technique before work is allowed with biohazardous or hazardous agents.

3.7 Risk Assessment Investigators should know, understand and follow standard practices and procedures.

3.8 The Principal Investigator should ensure he/she identifies known and potential hazards and specifies practices and procedures to eliminate or minimize such risks.

3.9 All data associated with the biospecimens should be managed according to HMC policy Data Ownership & Stewardship.

3.10 Biospecimens should be collected, used, stored, transported, and destroyed in a manner specific to the type of specimen and purpose of use to ensure sample integrity, viability, retrievability, confidentiality and safety. Biospecimens should be collected and used in accordance with the consent and JIRB arrangements.

3.11 Appropriate agreements including material and data transfer provisions are required for any external transfer, acquisition and use of biospecimens.

3.12 Academic Health System (AHS) Biosafety Officer

3.12.1 The Research Biosafety Officer is responsible for ensuring that all activities involving biospecimens are conducted in a safe and secure manner and in compliance with HMC policies, government regulations and legislation and generally accepted standards.
3.12.2 The AHS Biosafety Officer conducts inspections of research sites and makes recommendations based on results of the inspection to the Chief of Scientific, Faculty, and Academic Affairs who is expected to act in consultation with the Managing Director, HMC.

3.13 Safety

3.13.1 All persons handling human blood, tissue and body fluids or biohazards agents should successfully complete Clinical Research Safety Training. Personnel and trainees should demonstrate and document competence in safe technique before work is allowed with biohazardous or hazardous agents.

3.14 Risk Assessment

3.14.1 Investigators should know, understand and follow standard practices and procedures. The Principal Investigator should ensure he/she identifies known and potential hazards and specifies practices and procedures to eliminate or minimize such risks.

4.0 DOCUMENTATION:

4.1 Informed consent should be obtained for collection and storage of data and/or biological specimens for future research and may need separate consent to other research participation. (Refer to Policy on Informed Consent.)

4.2 Material Transfer agreements (where applicable)

5.0 REFERENCES:


5.2 http://orrp.osu.edu/files/2012/02/Research-Involving-Data-andor-Specimens.pdf

5.3 Joint Commission International Accreditation Standards for Hospitals, 5th Edition
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#### 6.0 ATTACHMENTS:

6.1 Overview of Process – Specimen Handling – Appendix 1
Overview – Specimen Handling

RSAC approves study involving biospecimen collection/handling

PI ensures conduct of study in compliance with IRB, ICH GCP, SCH, and regulatory requirements

PI ensures data associated with biospecimens are managed according to HMC Policy Data Ownership, Stewardship & Security of Health Information