



# **HMC IRB Report**

**Period Covered: 22 Oct 17 – 22 Apr 18**

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**Academic Research Associate**

# IRB Statistics

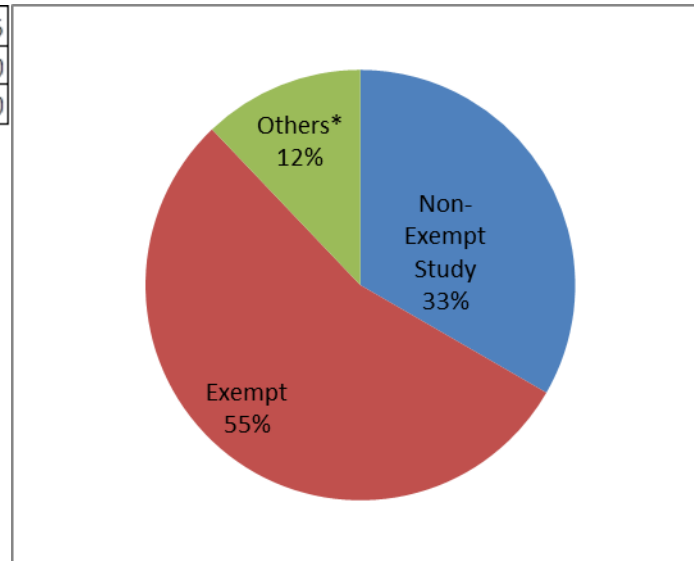
- IRB Roster: **25 Members** (6 Core members, 18 Alternate members and 1 Non-Voting member)
- Number of Full Board Meetings: **10 Meetings**
- Number of 1:1 Meetings with PI: **21 Meetings**
- Number of Studies Monitored since September 2017: **6**
- Average Process Duration from receiving by IRB office to approval: **25 days** (if the application is valid and ready for IRB review, not including translation time)

# IRB Statistics

- We have currently **292 Ongoing Non-Exempt Studies**
- Number of Expired Studies: **49** (MRC is following up with the PIs)
- Total studies on Abhath submitted to the IRB since beginning of Abhath: **127** (out of which 35 Non-Exempt studies)
  - Completed: 104
  - Under Review: 23 (at different Levels: some pending with PI, some with technical issues, some under IRB review)

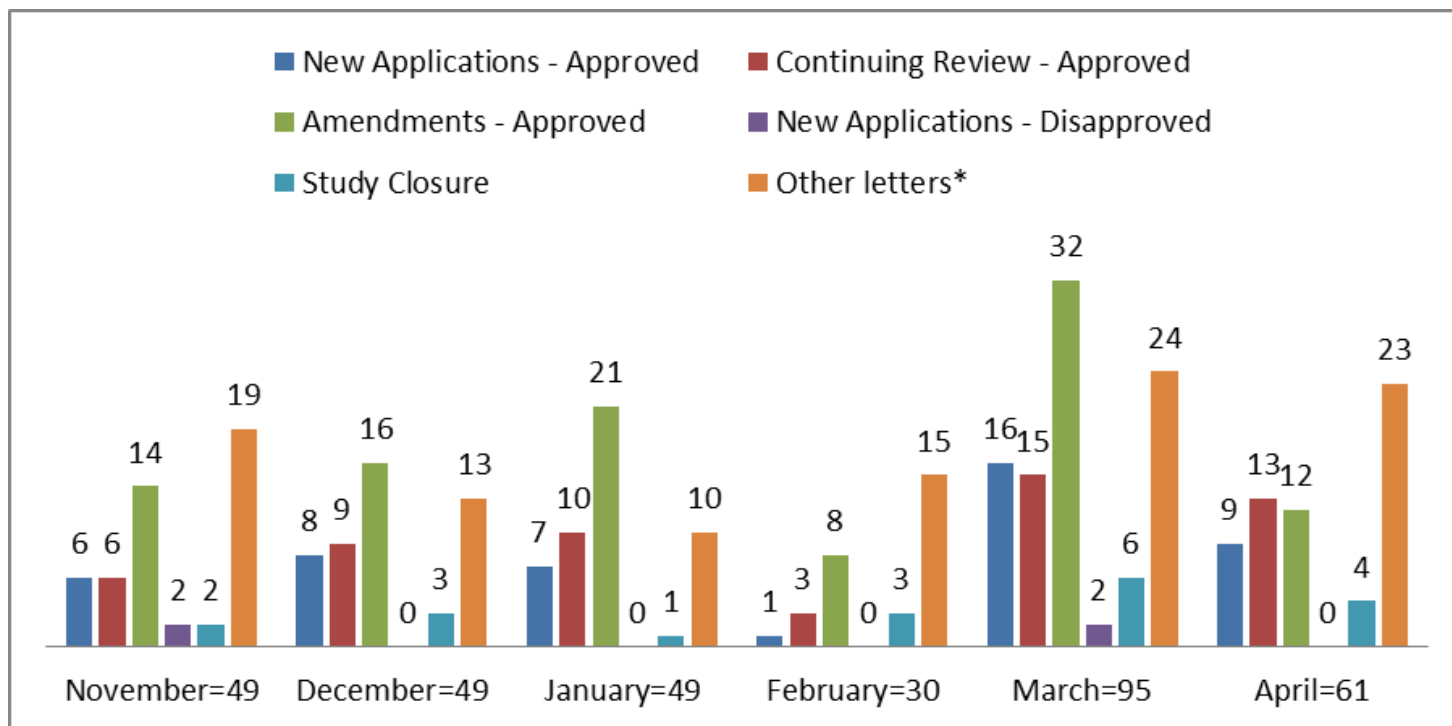
# Applications Received by the IRB Office

Non-Exempt Study	55
Exempt	90
Others	20



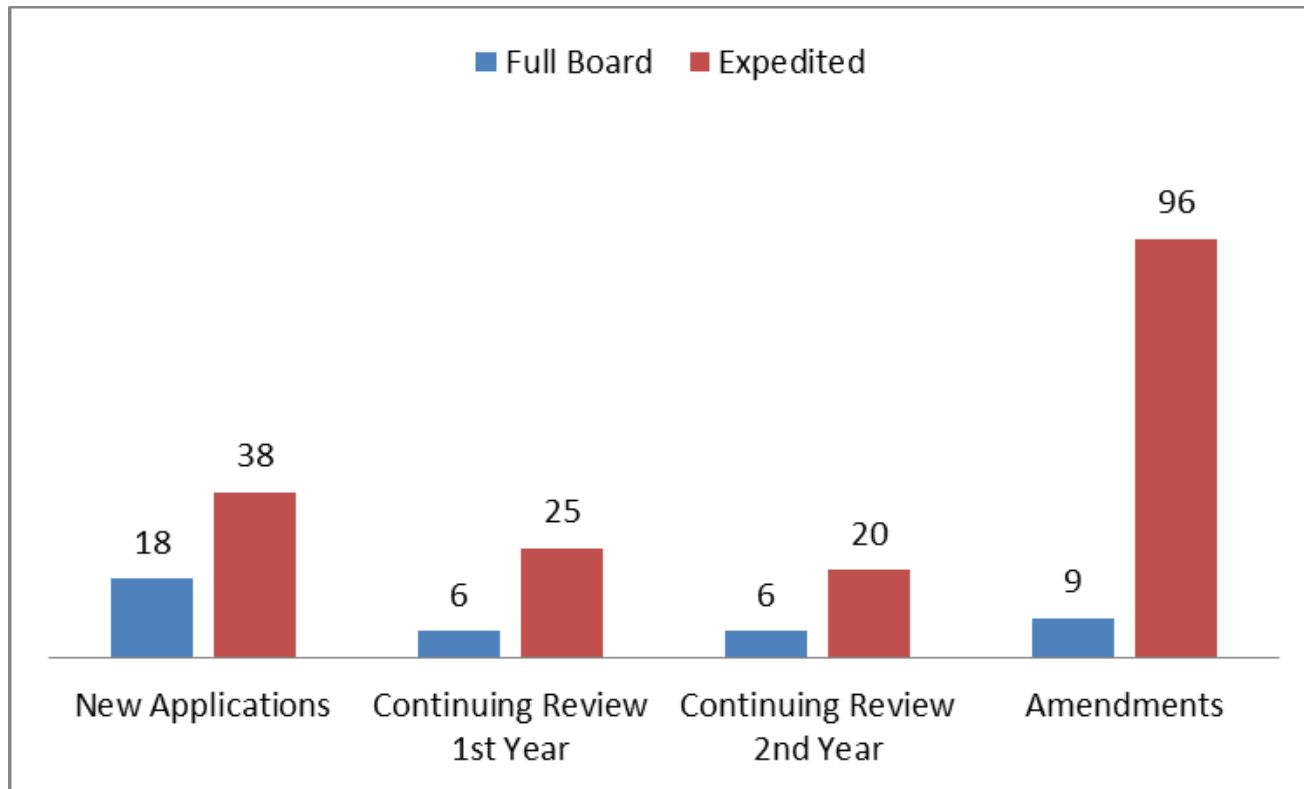
\*Others: Quality Improvements, Audits, Non-Human Subject Research

# Reviewed Applications by the IRB per month (some studies has been reviewed more than once until approval is obtained)



\*Other letters Issued: Deferral, Modifications Requested, Corrective Action Letters, acknowledgement of Receipt letters, etc...

# Level of Review – Expedited or Full Board – Approved and Disapproved Studies



# Details per each Application Type

The Below Table Reflects all applications received by the IRB since July 2015

Row Labels	Count of MRC number
Approve	315
Approve with conditions	12
Case Report	1
Closed	81
Deferred	6
Disapprove	8
Modifications Requested	4
MRC	2
NA	72
Non-Human Subject Research	5
Non-Research Registry	1
Quality Improvement	2
Withdrawn	7
(blank)	13
<b>Grand Total</b>	<b>529</b>

Blank: Under IRB Review or PI not responding

NA: not applicable for IRB review for different reasons (e.g. completed), related study files are closed

## Details per each Application Type (Blanks Means still Under Review)

The Below Table Reflects Studies that went through 1st continuing Review

Row Labels	Count of MRC number
Approve	136
Approve with conditions	3
Close	43
NA	184
(blank)	161
Deferred	2
<b>Grand Total</b>	<b>529</b>

Blank: Under IRB Review or PI not responding or not due for continuing review yet

NA: not applicable for IRB review for different reasons (e.g. completed), related study files are closed



## Details per each Application Type (Blanks Means still Under Review)

The Below Table Reflects Studies that went through 2<sup>nd</sup> continuing Review

Row Labels	Count of MRC number
Approve	32
Approve with conditions	2
Close	7
NA	230
(blank)	257
Deferred	1
<b>Grand Total</b>	<b>529</b>

Blank: Under IRB Review or PI not responding or not due for continuing review yet

NA: not applicable for IRB review for different reasons (e.g. completed), related study files are closed

# Other Tasks Done by IRB Office

- Issued Guidance for Consent Process and Documentation
- Issued Guidelines for Cerner Documentation
- Doing Lectures in Research Methodology Courses (coordinated by MRC and Medical Education)
- Participating in Research Forums and QF Annual Research Conference
- Coordinating with Medical Records Department for uploading the consent
- Working on the general consent to use medical information
- Working with MoPH for the review of clinical trials and IRB registration and membership
- Meeting with JCI consultant regarding HRP policies
- Working on Reliance Agreements with legal department and other institutions
- Working on IRB Organization Chart and Job Descriptions
- Working on Abhath IRB Workflow to fix all the issues

**Thank you**