Mass General Brigham

Leaning Forward: What's Next for IRB Improvements?

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IRB Update

IRB 01 Update – January 1, 2021 to mid November

- Completed 160 meetings including
  - 9 MGH Cancer Center Phase 1 Meetings
  - 1 EFIC Panel Meeting
- Meeting length:
  - Average 55 minutes (Range 23 to 94 minutes)
    - Past month: 52 minutes (Median 45)
- 4 deferred protocols

Processing Times from Submission (Goal 45 days)

Applications submitted on or after 1/1/2021

	IR (169)			AME (125)			CR (623)		
	To Meeting	To IRB Approval	To Completion	To Meeting	To IRB Approval	To Completion	To Meeting	To IRB Approval	To Completion
Mean	52	72	86	48	56	61	28	33	34
Median	30	49	63	42	50	53	25	30	32

Processing Times from Submission: Submitted on or after 1/1/2021

	IR (169)				
	To FB Screening	To Scheduling	To Meeting	To IRB Approval	To Completion
Mean	9	40	52	72	86
Median	1	22	30	49	63

What's Next:

- Additional Metrics
  - Break workflow steps down further to count time at each step
  - Identify time with PI vs time with IRB and ancillaries
- Fill Staffing Vacancies
  - Expedited Reviewers
  - Full Board Specialist
  - Continue Staff Training
- Insight Forms Redesign
- Additional focus on expedited review process
- Possible expansion of Phase I fast-track program

Insight Form Updates

Detailed Protocol & Site Addendum Reminders

Study Details Form

- Detailed Protocol required for all intervention/interaction studies.
- If the study has a protocol that is not Investigator-Initiated (e.g. an industry sponsored protocol):
  - Attach the protocol as the Detailed Protocol and
  - Include a Site Addendum
- If the study is Investigator-Initiated:
  - Attach the Detailed Protocol only (no Site Addendum Needed)
- Site addendum will eventually be built into Insight.

What's Next

- Insight form Changes
  - Continuing Review Intervention/Interaction Form
  - Minor Deviation Logs: Removing the requirement to submit a blank document.
  - Have there been any AEs including expected, non-serious or unrelated events since the study was initiated?
    - AE Attestation document required
    - Reminder: you should NOT attach an AE Log

- **The PI is still responsible for maintaining BOTH an Adverse Event log and a Minor Deviation Log.**

Policy Change: Who May Obtain Consent from Research Participants?

Informed Consent Policy Changes

- Updated policy and guidance are posted on Research Navigator.
  - https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/MGB%20IRB-Policy-and-Guidance.aspx
- Updates to match current scope of practice of advanced practice practitioners.
- Changes to improve consistency of IRB review and to minimize need for exception requests.
- The PI is responsible for providing training and oversight of research staff involved in the consent process according to the IRB-approved protocol and institutional policies.

Who Can Obtain Informed Consent by Role:

Role on Study Staff	Can Consent for Which Types of Research Study?	Backup Needed?
➢ Licensed Physician Principal Investigators and co-Investigators ➢ Licensed Doctoral-level Nursing Principal Investigators and co-investigators	➢ More than minimal risk ➢ IND/IDE ➢ Minimal risk	➢ None
➢ Principal Investigators who are: ▪ Licensed Clinical Pharmacists ▪ Licensed Psychologists ▪ Other clinically licensed faculty members ▪ Other IND/IDE holders	➢ More than minimal risk ➢ IND/IDE ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Principal Investigators who are non-licensed or non-clinical faculty including: ▪ Non-licensed Physicians ▪ Statisticians ▪ Physicists ▪ Epidemiologist ▪ Other doctoral-level scientists	➢ More than minimal risk ➢ Limited Investigational Device studies: Only Non-significant risk or IDE exempt ➢ Limited Investigational Drug studies: IND exempt ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Other licensed advanced practice provider co-investigators including: ▪ Licensed Nurse Practitioners ▪ Licensed Physician Assistants	➢ More than minimal risk ➢ IND/IDE studies ➢ Minimal risk	➢ Licensed physician investigator listed on study staff
➢ Other study staff including: ▪ Study Nurses ▪ Research Coordinators	➢ Minimal risk* *Consent for minimal risk studies involving drugs or investigational devices should be obtained by clinically licensed staff, including study nurses, co-investigators, and PIs.	➢ Principal Investigator/Co-Investigators listed on study staff

Who Can Obtain Informed Consent by Type of Study:

Type of Study	Who Can Obtain Consent?	Backup Needed?
➢ Investigational drugs and devices, including under IND/IDE ➢ More than minimal risk	➢ Licensed Physician Investigators (PI and co-Investigators) ➢ Licensed Doctoral-level Nursing Investigators (PI and co-investigators)	➢ None
➢ Investigational drugs and devices, including under IND/IDE ➢ More than minimal risk	➢ Principal Investigators who are: ▪ Licensed Clinical Pharmacists ▪ Licensed Psychologists ▪ Other clinically licensed faculty members ▪ Other IND/IDE holders ➢ Other licensed advanced practice provider co-investigators including: ▪ Licensed Nurse Practitioners ▪ Licensed Physician Assistants	➢ Licensed physician investigator listed on study staff
➢ Limited Investigational Device studies: Only Non-significant risk or IDE exempt ➢ Limited Investigational Drug studies: IND exempt ➢ More than minimal risk	➢ Principal Investigators who are non-licensed or non-clinical faculty including: ▪ Non-licensed Physicians ▪ Statisticians ▪ Physicists ▪ Epidemiologist ▪ Other doctoral-level scientists	➢ Licensed physician investigator listed on study staff
➢ Minimal risk studies involving drugs or investigational devices	➢ Clinically licensed study staff including study nurses, co-investigators, and PIs.	➢ Principal Investigator/Co-Investigators listed on study staff
➢ Other minimal risk studies, including those involving non-invasive approved medical devices (e.g., standard MRI, EEG, EKG, etc)	➢ Study staff including research coordinators/assistants	➢ Principal Investigator/Co-Investigators listed on study staff

A New Process to Obtain Consultation from the IRB

IRB REDCap Consultation Request

- Redcap.link/mgbirbconsult
- Going Live this month!

Consultation Request Details

Please indicate the type of consultation requested (Select all that apply).

* must provide value

- [ ] Pre-IRB Submission Consultation
- [ ] Question about Existing/Approved IRB Protocol
- [ ] Do I need an IND/IDE for my study?
- [ ] Request to Submit Protocol for IRB Review Prior to IND/IDE Determination from FDA
- [ ] Request to Submit Protocol for IRB Review Prior to JIT/Funding Awarded
- [ ] Request for Other MGB IRB Policy Exception
- [ ] Do I submit my study to DFCI IRB or Mass General Brigham IRB for review?
- [ ] Other Single IRB or Cede IRB Question
- [ ] Question Regarding Single Patient Use of Investigational Drugs or Devices
- [ ] Request for Institutional Certifications for dbGaP or Other Repositories
- [ ] Request for Not Human Subject Research Determination
- [ ] Which Staff can obtain Informed Consent for my study?
- [ ] Other (Described in Text Below)

If applicable, please indicate any topic areas you would like to cover in the consultation (Select all that apply).

- [ ] Research involving Deception
- [ ] Research involving AI/Machine Learning Algorithms, Mobile Applications, or Software as a Medical Device
- [ ] Research involving Clinical Decision Support Tools
- [ ] Informed Consent
- [ ] International Research
- [ ] Educational Research
- [ ] Quality Improvement/Quality Assurance Projects
- [ ] Data/Tissue Repository Creation or Operation
- [ ] Data/Tissue Sharing (including Genetic Information)
- [ ] Vulnerable Populations
- [ ] Return of Research Results
- [ ] Recruitment Policies and Procedures
- [ ] Subject Remuneration
- [ ] Electronic Informed Consent Policies and Procedures
- [ ] Guidance on Blood Draw Volumes
- [ ] Research Involving Radiation

Please provide a brief description of what you would like to discuss with the IRB and/or any other additional information pertaining to this request.

* must provide value

Expand

Update on Clinical Trials.gov Process

When to Register

- CT.gov is now set up as an “ancillary” in Insight
  - May submit with NCT# pending
    - Complete registration as soon as receive Insight Protocol#
  - IRB approval can occur in parallel
  - NCT# must be submitted prior to release (complete)

Research Invitations & Opt-Out Updates

Giving all Patients an Opportunity to Hear about Research

Starting in July 2021, Mass General Brigham initiated a new approach to enable more of our patients and our community to be informed of research studies that might be of interest to them.

Research Invitations include:

- Sending recruitment information through Patient Gateway
  - ✓ Personalized Letters
  - ✓ Targeted Research Announcements
- Sending information through the mail (US, FedEx, UPS, etc.)
- Emails (limited circumstances)
- Texts (limited circumstances)

New Opt-Out Model

- In the new opt-out model, **all** Mass General Brigham patients may be recruited through Research Invitations to participate in research studies *unless they opt-out*.

☆ Researchers do not go through the patient's clinician unless the IRB requires them to do so.

  - The IRB must approve use of this method and the criteria used to identify patients for recruitment
  - Research Invitations require the use of specific REQUIRED TEMPLATES

Results So Far…

Number of Patients:

Sent a letter/notice from 1 study	243,684
Sent multiple letters from multiple studies	39,461
Number who have Opted-Out	697
	<0.3%

What's Next

- Translation of Research Invitations into 6 standard languages (February 2022)
  - Researchers will need to demonstrate they can support conduct of the study in other languages – not just recruitment
    - Consent translated
    - Interpretation for study visits
    - Other participant-facing materials translated/interpreted.

The Research Navigator Office (RNO)

Support for Patients | The Research Navigator Office

- Answer general questions about research
- Answer questions about specific research studies
- Help patients who want to opt-out of receiving research invitations
- Liaise with research studies that are recruiting patients
- Provide support to clinicians or their patients with questions about research studies

Staffing

Experienced research staff serve as **Research Navigators** and are available to all of our patients across Mass General Brigham and the broader community:

- There are currently 5 Navigators supporting the Research Navigator Office
- All Navigators have worked as Clinical Research Coordinators, with experience ranging from 6 to 29 years

RNO Contact Data

Request to Opt-Out	
Yes	12
No	95
N/A	17
Total	124

Contact Method	
Email	16
Phone	73
Phone Message	33
Referral from Rally	1
Unknown	1
Total	124

MGB Entity	
BWH/Faulkner	19
DFCI	1
McLean	2
MGB	38
MGH	47
Spaulding	4
Unknown	13
Total	124

Category	
General Research Info	5
Internal	9
Looking for a study	22
Opt-Out Info	11
Patient Stipend	3
Rally	2
Received Research Invitation	46
Specific Study	15
Other	11
Total	124

Those who Received a Research Invitation

- Called RNO instead of study contact
- Called study contact
  - No return call
  - Voicemail full
- Filled out online questionnaire, no response

Operations

Hours: 8:00 AM – 5:00 PM Monday-Friday

Phone: 857-282-5370
Email for internal use by researchers/clinicians: askresearch@partners.org

- All calls are be logged
  - Analyzed for trends
  - Development of FAQs
  - Monitor acceptance of Opt-Out program

What's Next

- Continue to grow staff – goal to include multi-cultural/multiple languages support
- Develop resources/templates/education for researchers and their staff related to recruitment

What's Next: Miscellaneous

What's Next:

- Fill Staffing Vacancies
  - Expedited Reviewers
  - Full Board Specialists
  - Continue Staff Training
- Insight Forms Redesign – likely launch in 2023
- Redesign of Consent Forms

What's Next

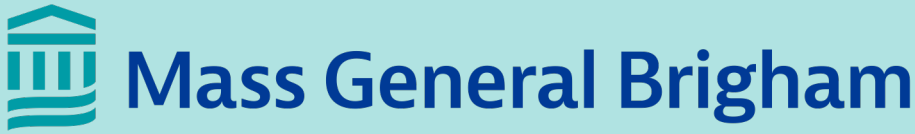
- Ancillary Updates
  - RISO
    - Committee working on reassessment of all security risks and how best to manage (RISO, contract terms, policy etc.)
    - How best to integrate with Biomed Eng or other associated review
    - Develop new data collection form to replace Digital Health Form
    - Develop template of information when working with sponsors/outside vendors
  - Pharmacy – initiating quarterly meetings of all pharmacy reviewers
  - Radiology
    - Potential revision to pregnancy testing policy
    - Consent language updates

What's Next

- Update on use of contracted research staff
- Revision to CITI
  - Compliance & Education Office – Assistant Director, Education
  - Develop internal human subjects training and stop use of CITI
  - Consider integrating GCP
- Finalizing Research Virtual Visit information
- Metrics Dashboard

What's Next

- DEI in Research
  - IRB DEI Committee
  - May 23-24 – Inaugural national conference
  - Launch of broader system-level initiative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