Mass General Brigham

Leaning Forward: The Start of Something New at HRA

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Agenda

1. IRB committee and operational changes
2. Human Research QI Program updates
3. New approach to patient recruitment

Lean Forward Project:
IRB & QI Changes

Overall Goals

- Support a culture of *appropriate* protection for human subjects in research
- Conduct reviews in compliance with federal regulations and Mass General Brigham policies
- Create *collaborative* relationship with research community
- Enhance the efficiency, consistency and transparency of the submission and review processes
- Create a sustainable infrastructure for IRB Leadership, IRB Committees, and Human Research Office (HRO).

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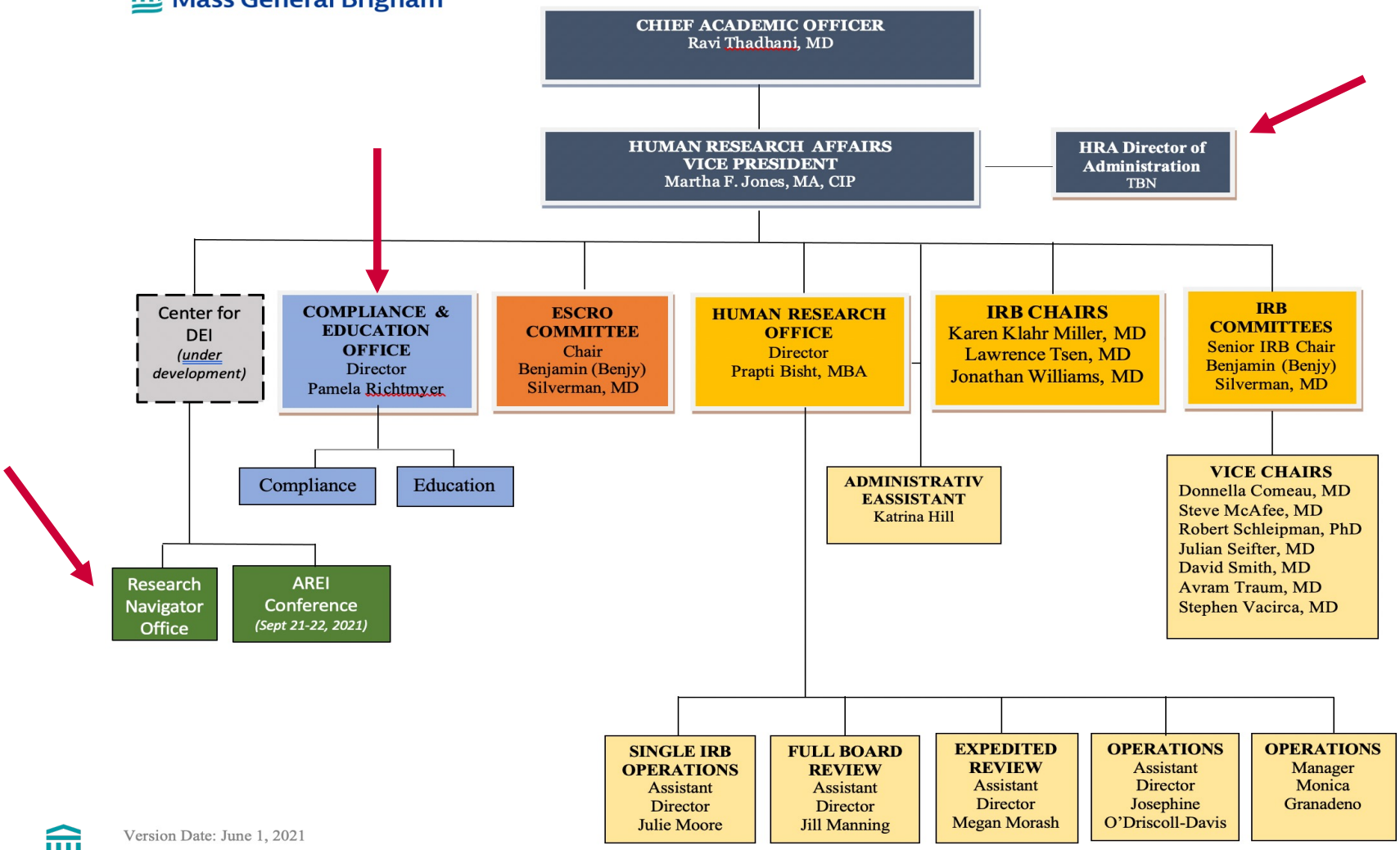


New IRB Structure: 7 IRBS → 2 IRBs

IRB 01

Initial Reviews
Continuing Reviews
Amendments

4 or 5 meetings per week
(extra as needed)

IRB 02

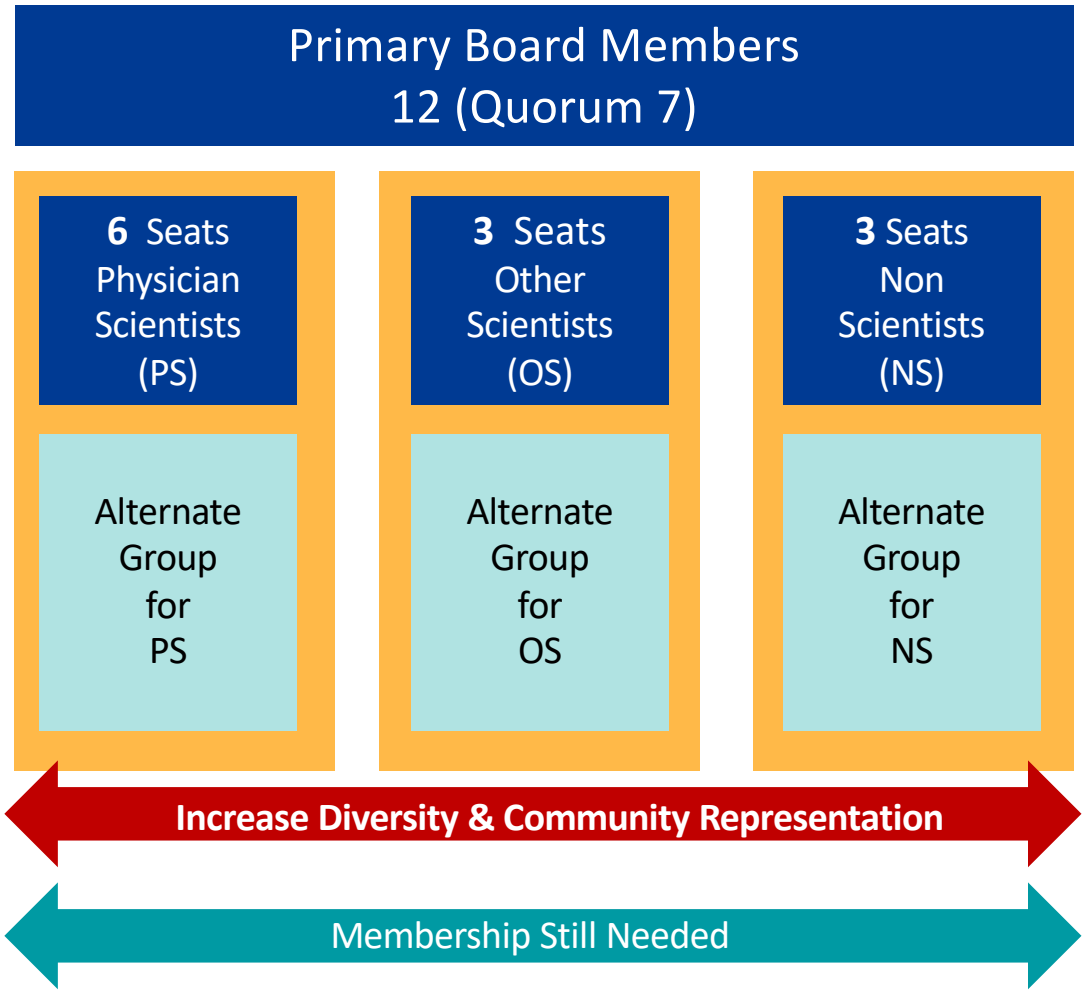
"Other Events"

Noncompliance
Unanticipated Problems

1 meeting per month
(as needed)

New IRB 01 Structure

- All meetings are virtual - zoom
- Flexibility in scheduling
  - Choose 1 meeting out of 16 possible meetings each month
  - Schedule at least one quarter in advance
- Reduced review burden
  - Reduced meeting length (60-90 minutes)
  - Mixture of items on agenda (IR, CR, AME)
- Appreciation & Recognition program
- Regular input/feedback
- Regular assessment of membership needs
- Focus on increasing diversity and community membership



IRB Executive Committee

- New committee to make recommendations to HRA and IRB Leadership on policy, practice, regulatory, and ethical issues.
- Members include IRB Chairs and Human Research Office Director.
- Chaired by Senior IRB Chair.
- Focused on creation of IRB standard operating procedures to ensure objective, consistent, efficient, and prompt review of protocols.
  - Revising old policies and creating new approaches.
  - Grounded in collaboration with and feedback from research community.
- Involved in IRB outreach and educational efforts.
- Committee has additional specific tasks: IRB membership review, oversight of IRB member education, and adjudication of IRB member performance concerns, among others.

Develop a Customer Service Culture

- Goal: Transparency and Consistency
- Problem Statement from PI:

"I will do whatever the IRB wants,
but I don't know what that is,
and it changes every time I submit an application."

- Related: Efficiency and Punctuality

Transparency and Culture of Collaboration

- Direct communication with Expedited Reviewers (not through Protocol Administrators)
- Direct communication with IRB Chairs/Vice Chairs
- Direct communication with any office staff to answer questions
- Entire minutes for the protocol available to the PI as administrative attachments

Transparency and Culture of Collaboration

- HRO Help: phone line/email – Customer service survey

- REDcap Consultation Request (coming soon)
  - Ask a Chair
  - Exception Requests
  - IND/IDE required?

Initiatives Designed to Develop a Collaborative Working Relationship with Research Community

- Foundation of new protocol review model: communication between IRB and study teams
  - Begins with IRB staff conducting pre-reviews and working directly with study staff on IRB applications before assigned to a Board meeting
  - Board Chairs (faculty) and Associate Chairs (IRB staff leads) reach out directly to PIs and study staff before Board meetings to resolve any issues that might result in a deferral (i.e., must be seen at another meeting)
  - IRB reviewer "mandate": *Come to meeting with solutions, not problems*
  - In addition to improving relationships, reduces time to IRB approval
- Publicizing that IRB faculty and staff are available to answer questions

Revised Review Procedures

- Focus on the Criteria for Approval (minimize scientific review), i.e., “stay in our lane”
  - Very brief (1-3 minutes) study summary – everyone has read the materials
  - Identify and discuss only criteria not met
  - Avoid micromanaging items unrelated to approval criteria and that do not enhance protection of human subjects
- PI will be invited to meeting as needed
- Minutes written to clearly identify specific required changes to achieve approval

After Review

- Minor changes (directed by IRB) to consents or recruitment materials may be made by IRB staff and approved/released without returning to research team.
- Concise, directive comments in Insight & Minutes if required modifications or deferred.
- Minutes from the meeting uploaded as administrative attachment.

Transparency:
Be sure to review the complete set of minutes to see the discussion from the IRB and understand context of required modifications.

and

Collaboration:
If the IRB defers the study the IRB Chair/Vice-Chair will reach out directly to the PI after the meeting to discuss issues and clarify the path forward.

Expedited & Full Board Workload
Calendar Year 2019

Review Type	Total	Applications/ week
Full Board	1,536	30
Expedited	20,184	388
Total	21,720	

IRB 01: Time to Approval in Days

	Q2 2020 Mean time to IRB Approval	Q2 2021* Mean time to IRB Approval	Q2 2021* Median time to IRB Approval	# Approved	# Pending	Total
IR	110	54	49	50	29 (37%)	79
AME	55	46	44	25	2 (7%)	27
CR	37	28	26	315	11 (3%)	326

	Q2 2020 Mean time to Release	Q2 2021* Mean time to Release	Q2 2021* Median time to Release	# Released	# Pending	Total
IR	131	62	58	42	37 (47%)	79
AME	57	49	44	24	3 (11%)	27
CR	38	30	29	308	18 (6%)	326

*Submitted on or after 01/01/2021

Lean Forward Project: *Highlights of Workflow Changes*

IRB Application

- Protocol Summary is being retired
  - If sponsor protocol attach: Detailed Protocol & new Site Addendum
  - If investigator protocol attach: Detailed Protocol using new template
- If study requires an IND/IDE, obtain before submission
- If study is seeking funding in order to be conducted, submit upon receipt of JIT – provide JIT documentation
- Don't need to submit AE or Minor Deviations Logs at CR
  - PI still responsible for maintain
  - Expanded review process by HRA Compliance & Education Office – Conducted monthly on approved Continuing Reviews
- All PI, Dept. Chair, and Staff sign-offs must be completed prior to the application being sent to the IRB

Culture Shift:
Please do not submit to the IRB until your study and all documents are fully developed and you are ready to go.

Submitting “to get the review started” only slows the review process for you and all your colleagues.

After Submission

- New single Triage step replaces 2-step HRO1 &HRO2.
- Applications no longer assigned to Protocol Administrators (PAs)
- Full Board: New screening step added prior to scheduling for committee review
  - Thorough screening of application
  - IRB Staff will edit using MS Word “tracked changes” – no more highlight etc.
  - Applications will not be put on a committee agenda for review until all screening issues are resolved.
  - Moving towards requirements for PI to respond within appropriate time window or risk withdrawal of application

PI is in control of the timeline: Complete and clean applications move ahead of others not ready for review.

Additional Changes

- After initial approval, only one application for an approved protocol may be submitted/processed at a time
  - Exceptions:
    - Study Staff amendments
    - Other Events
    - sIRB – multiple “child” site amendments (attachments)
- Removing the +/- 30 day logic at Continuing Review that retains an original expiration date
- Interpreters may be remote (do not have to be in-person)

Lean Forward Project: Just the beginning…

- REDCap forms to ask questions/consult from IRB Chair, exception requests
- Revising Insight forms
- Single IRB processes
- Comments (Bubbles)
- Attachments
- New consent templates
- iSuggest ideas
- Updated/new guidance
- Etc…

New Approach to Recruitment

Replacing RODY *Opt-In* with a New *Opt-Out* Model

After an extensive review both internally and benchmarking against our peer organizations, Mass General Brigham leadership has approved a new **Opt-Out approach** for Research Invitations sent to patients.

New Approach to "Research Invitations"

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

☆ If a patient opts-out, their clinical provider cannot "override" this decision by approving or co-signing Research Invitations

New Opt-Out Model – PI Responsibilities

- Obtain IRB approval using new required templates
- Filter out patients who opt-out from the recruitment lists (RPDR, EDW, Epic) and do NOT send them Research Invitations
- Select criteria so that only those most likely to meet study inclusion criteria are sent invitations.
- Ongoing monitoring of patient responses to ensure the criteria are identifying the correct patients
- Complaints about this method of recruitment must be submitted as an Other Event to the IRB *(change in policy)*

What does this mean for the Researcher?

- By opting out, patients will be choosing not to hear about research opportunities through the method of **Research Invitations** *(only).*
- However, patients may still be approached (with IRB approval)…
  - By other research programs they have previously chosen to join, such as Biobank, Rally, or individual practice or research programs
  - In-person at the hospital or other locations about research opportunities
    - By their clinical care team
    - By others not associated with their clinical care team in collaboration with the clinical team

Timeline & Transition Recap

Date	
Sunday, June 13	Research Invitations: Technical changes to support Patient Gateway/Epic and RPDR being implemented to show patients who have opted out. • Studies currently approved to use RODY preferences must not pull new patients lists until after IRB approval has been obtained (after July 6th)
Friday, June 18	IRB: Insight release of new workflows and processes • New submissions will be processed through the new workflow. • All pending applications will continue to be processed under the old workflow path until released. • No drafts created before June 18 will be accepted
Tuesday, July 6	Research Invitations: IRB will begin accepting Amendments to use new Research Invitations. • Updated templates will be available on Navigator. • Amendments must be submitted with NO OTHER changes (only those related to Opt-Out)

Questions?

Watch for upcoming announcements of:
Research Invitation (opt-out) online training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