Mass General Brigham

FREQUENTLY ASKED QUESTIONS: RECRUITMENT IN HUMAN SUBJECT RESEARCH

RESEARCH INVITATIONS

1. **What is Research Invitations?**

   Research Invitations is a new opt-out model for recruitment of Mass General Brigham patients to research. Research Invitations allows research recruitment of all Mass General Brigham patients unless they opt-out. Research Invitations include sending recruitment information through Patient Gateway via personalized letters or Targeted Research Announcements or sending a letter via US mail.

2. **What are Targeted Research Announcements?**

   A targeted research announcement is a message that appears on the Patient Gateway Research page for patients who meet specific research eligibility criteria. Each announcement is accompanied by a clickable button that allows the recipient to indicate "I'm interested" (or "No thank you"). Once a research announcement is sent, the Patient Gateway user receives an email notification that includes a link that will take the patient directly to the message after logging in. The announcement is also accessible by clicking on the Main Menu in Patient Gateway and selecting "Research Opportunities."

3. **When can email be used?**

   The use of emails may be permitted in limited circumstances. Research Invitations can be sent via email only if researchers have obtained prior consent from participants to use their email to be contacted for future research opportunities. How this permission was obtained should be described in the study protocol. Researchers cannot obtain email addresses from Epic or Patient Gateway for recruitment purposes. They must have prior permission from patients to use their emails, for example, from interaction as part of previous research participation. Study teams should provide the protocol number(s) where this option for future contact was approved so that IRB staff can verify that the use of email was approved. When email Research Invitations have been approved as described above, follow-up of participants via email is permitted and should be limited to 3 times with a 1-week interval between sending emails.

4. **When can phone be used with the Research Invitations method?**

   Phone follow-up can be permitted only if the optional opt-out language in the Research Invitations letter template (i.e., " If we do not hear back from you within two weeks, we may call

you..") has been included in the initially sent Research Invitation. The IRB does not allow “cold-calling” patients on the phone to recruit them.

5. **When can text messaging be used with the Research Invitations method?**

   Research Invitations via text message are not permitted at this time.

6. **Is the use of research invitations required for both MGB and non-MGB patients?**

   No, Research Invitations is required only to recruit MGB patients using Patient Gateway or mail. Research Invitations, however, cannot be used to contact MGB patients who have opted out.

7. **When is the Research Invitations method required by the IRB?**

   Research Invitations method is required along with the use of Research Invitations templates when researchers recruit MGB patients via Patient Gateway or when sending mailed letters to patients. In-person recruitment in outpatient or inpatient areas do not require the use of Research Invitations if the in-person contact is the initial contact.

8. **When is it acceptable to NOT use Research Invitations?**

   Research Invitations should not be used for in person recruitment or to recruit non-MGB patients. Research Invitations cannot be used to contact MGB patients who have opted out.

9. **If patients opt-out of receiving Research Invitations, can the study team send letters to them with their provider's permission?**

   No. A patient’s provider cannot “override” the patient’s decision.

10. **What if patients are only interested in hearing about a specific type of study, but not all studies?**

    Currently, the Research Invitation opt-out is all or nothing. Patients cannot select to opt in or out of specific types of studies. The Rally website does have functionality that allows people to apply filters to the types of studies they want to see.

11. **Will the opt-out process apply to pediatric patients as well?**

    Initially the opt-out process will only apply to Research Invitations sent to adults. The IRB would not normally approve invitations being sent directly to children or minors. Typically, a letter to recruit minors would be sent to the parent. If the parent has opted out of receiving Research Invitations, then they should not be sent Invitations for themselves or their children.

12. What should researchers describe in the IRB submission about the use of the above methods?

Study teams must revise the "Recruitment Procedures" section of the Site Addendum or Detailed Protocol to reflect the Research Invitations procedures. State in the Site Addendum or Detailed Protocol that Research Invitations will be used for direct recruitment of any eligible subjects who have not opted out of receiving Research Invitations. Specify that patients who opted out will be filtered out of the recruitment list (e.g., from RPDR, Epic) and they will not be sent the Research Invitation. Also specify that the PI will conduct ongoing monitoring of patient responses to ensure that your selection criteria are identifying the right patients and that complaints about this method of recruitment will be submitted to the IRB as an Other Event. Remove the outdated recruitment letters from the Attachments tab in Insight and upload new recruitment letters using the Research Invitations templates included in the link provided below.

13. Where are the Research Invitation templates?

The Research Invitations templates can be found at this link: Pages - IRB Forms and Templates (sharepoint.com).

Additional information about the Research Invitations recruitment method can be found in the above link (under the header Research Invitations, #1).

14. Can the Research Invitations templates be modified?

No, the templates cannot be modified except in the designated areas.

15. Can investigators send a co-signed (e.g., co-signed by primary care provider or medical treater) personalized recruitment letter to their patients?

No, this would not be permitted. Investigators must use the Research Invitations approved templates. The Research Invitations can be signed by the PI or co-investigators.

16. If mailing recruitment letters (e.g., for a single survey study), can a hard copy of the survey and fact sheet be mailed with it?

Yes, a copy of the survey and information sheet can be mailed along with the Research Invitation.

17. **Can consent language be included in the Research Invitations template?**

    No, consent or information sheet language cannot be included in the letter template. A copy of the survey or information sheet can be included as an attachment.

18. **Can a link to a prescreening survey be included in the Research Invitations letter (e.g., If you are interested in this study, please complete a brief pre- screening survey to help us determine your eligibility through: https://...)?**

    A survey link can be included in the 'To learn more about this study' section of the letter.

19. **Can a lay title be used in the Research Invitations letter? Rally allows for the use of more participant friendly study titles. Can something similar be done with Research Invitations?**

    Yes, a lay title can be used and it should be related to the study.

    If participants contact the Research Navigator Office with questions about the study, the navigators need some way to identify the study in Insight. The title that is used should be reasonable and related to the study.

20. **Can a QR code be included in the Research Invitation templates?**

    Yes, a QR code can be used for Research Invitations. The code can link to a flyer or survey.

21. **How many times can the Research Invitations letter be sent to potential participants?**

    The use of the Research Invitations letter should be limited to a maximum of three times, and the plan for the use of this method should be described in the Detailed Protocol or Site Addendum (e.g., a second letter will be sent to participants if we do not receive a response after 1 week).

    As described in #3 above, when email has been approved for Research Invitations use, follow-up of participants via email is permitted and should be limited to 3 times with a 1-week interval between sending emails.

22. **Can Research Invitations be used for studies reviewed by an external IRB?**

    Yes, but you must follow the Mass General Brigham policies for using the contact approach. If your study is already approved, you should update your recruitment documents to the new templates for the new opt-out process and submit an amendment to your external IRB for approval.

23. **If we are currently recruiting using the RODY opt-in process, do we need to revise our IRB application?**

    Yes. If you are currently sending invitations using Patient Gateway or mailed letters under the old RODY system and you need to continue recruiting, you will need to submit an amendment to update to the new templates and revise your recruitment description to use of the new Opt-Out process. Review #12 above for more information.

OTHER FAQs

1. **For patients in RPDR that do not have Patient Gateway, is it appropriate for researchers to contact these patients directly via mail or other options?**

   Yes, it is acceptable to contact patients using mail. Research Invitations template should be used to contact patients via mail. The IRB does not allow "cold-calling" patients on the phone to recruit them. Phone follow up to a mailed Research Invitations letter is permissible per #4 above.

2. **Can I recruit through PCP/treatment provider referrals?**

   PCPs or treatment providers can notify their patients about research studies and refer them to study teams to obtain information about a study. This can be done in person or in the course of routine medical care or by providing a flyer or other IRB-approved written recruitment materials to patients.

   If information, including contact information, about the patient needs to be shared by a Mass General Brigham provider with a Mass General Brigham research team for recruitment purposes, the Authorization to Release Contact Information for Recruitment document must be completed. This Authorization must be obtained from the patient prior to sharing patient information with the study team to initiate contact. This Authorization is not needed if the potential participant is provided with information about the study and they are asked to initiate contact with the study team. This Authorization does not need to be submitted to the IRB, but the recruitment section of the protocol must describe how this Authorization will be used to recruit potential participants. The signed Authorization should be maintained in the study records to document compliance with recruitment procedures. It is the research team's responsibility to obtain the completed Authorization from the Referring Provider, not the participants.

3. **I have a list of subjects who have agreed to be contacted by email about future research studies. Can I email them a recruitment letter?**

Yes, the recruitment letter must be on the Research Invitations template. See #3 under Research Invitations above.

4. **I have a list of subjects who have agreed to be contacted by phone about future research studies. Can I email them a recruitment letter?**

   No, subjects must be contacted using the method for which they agreed to be contacted. Texting is not permitted.

5. **Can I take email addresses out of Epic to contact patients for recruitment?**

   No, you cannot obtain email addresses from Epic without prior permission. See #3 under Research Invitations above.

6. **Can I take phone numbers out of Epic to text patients for recruitment?**

   No, you cannot obtain phone numbers from Epic to call or text patients for research recruitment. The IRB does not allow "cold-calling" patients on the phone to recruit them.

7. **We have identified a potentially eligible subject in Epic who is currently on an inpatient unit. Can we approach this subject about research participation?**

   The study team cannot directly approach the potential subject. Two steps need to occur prior to approaching the patient about research recruitment. Research staff should first discuss this with the primary clinical team to ensure it is clinically appropriate to approach the subject about research participation. If so, a staff member known to the patient from clinical care (i.e., any staff member known to the subject from clinical care (it does not have to be the treating clinician) or administrative staff should ask the patient if they are interested in speaking to research staff prior to research staff direct approach.

8. **We have identified a potentially eligible subject in Epic who will be seen in our outpatient clinic. Can we approach this subject?**

   Study teams should obtain appropriate leadership approval if the study proposes to recruit from outpatient clinics. This documentation should be submitted with the IRB submission, along with a description of the workflow for how recruitment will occur in the outpatient setting. Study teams can directly approach potential subjects in outpatient clinics if the clinic has provided approval. Flyers can be distributed or placed in waiting rooms with appropriate permissions. To protect patient privacy and confidentiality of data, recruitment should always occur in private settings and not in waiting rooms.

9. **Can Patient Gateway be used to contact research participants or as a means to communicate with research participants?**

Patient Gateway cannot be used to communicate with research participants. It can be used only for recruitment purposes using the Research Invitations template described above.

10. **Can Mass HIWay and Care Everywhere be used to obtain external medical records for research purposes?**

    Mass HIway and Care Everywhere cannot be used for research purposes. Researchers should not attempt to obtain patient consent for using either of these methods as the patient consent would not be valid and cannot override institutional agreements in place that restrict use for research. If external medical records are required, the study team must obtain informed consent and HIPAA Authorization from the participant to request medical records from another provider and obtain them through methods other than Mass HIWay or Care Everywhere. Care Everywhere cannot be used by the researcher to request records for a chart review or any other purpose. However, if there is data in MGB Epic that was already brought into the record for clinical purposes, then it can be used.

11. **Research teams from external institutions have asked us to approach MGB patients for research and share their contact information so that the external teams can recruit MGB patients. Is this allowed?**

    MGB investigators are recommended to consult with their department/clinical unit where the recruitment takes place and if applicable, the local institutional research compliance officer. MGB researchers or providers can refer MGB patients to research being conducted at another institution, if approved by their department. Patients could be informed about studies and directed to contact external study teams. If flyers or other external study materials are shared, these documents must be approved by the external institution's IRB. Posting of flyers is at the discretion of department/clinical unit or local research compliance approval, as applicable.

    MGB personnel cannot share any information about patients with another institution for recruitment purposes.

For questions, please contact the MGB IRB Office at partnersirb@partners.org or 857-282-1900.