Coronavirus and Partners Human Subject Research

March 11, 2020

The Partners IRB is committed to protecting the safety and welfare of our research participants and the research community during the global outbreak of the coronavirus. Our goal is to help our research teams plan for how they can best accommodate any disruptions to the conduct of their research studies while maintaining key protections for our research participants. We want to emphasize the priority must always be the safety and protection of the research participants and our research staff. The IRB and IRB staff are available to answer questions and support any necessary changes to facilitate responses to the quickly changing conditions.

This document provides important information that reflects our best recommendations and plans for research disruptions at this time. We will continue to update this document as new information becomes available:

Changes to the protocol which DO NOT require prior IRB review and approval

- **Implementing mandatory COVID-19 screening of research participants prior to planned study visits.** All study teams should immediately implement the COVID-19 procedures to screen research participants before any interaction and incorporate mandatory telephone screening prior to planned study visits. Bothe MGH and BWH have provided specific procedures to conduct this mandatory screening. If you are at a facility that has not provided this information, please follow the procedures at these links:
    - MGH Research Patient Telephone Screening
    - BWH Advance Telephone Screening for Research Subjects.

- **Changes to protocols to prevent an immediate hazard to research participants.** The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and wellbeing of the participant. If there is a need, the PI may make the change without first obtaining IRB approval. Note this option is only available for changes that would impact

participants already enrolled in the study. It is not appropriate to make such a change in order to enroll a new participant (for example exceptions to inclusion/exclusion criteria.) We know we can rely on your flexibility and judgment in a making these decisions in this challenging environment.

Follow the steps below if a change is made to prevent immediate hazard without IRB approval:

- Submit an "Other Event Form" to the IRB via Insight within 5 working days of the change.
- The change and rationale for making it should be clearly documented in your research records (e.g. in a note to file.)
- This change may apply to one subject or a group/all subjects in the research study.

- **Minor protocol deviations which do not have the potential to negatively impact participant safety or integrity of study data (ability to draw conclusions from the study data), or affect subject's willingness to participate in the study.** Minor protocols deviations could include conducting a study visit virtually (by remote means) or outside of window, omitting a specific research procedure or collecting questionnaire/assessment data over the phone instead of in person. Minor protocol deviations are reported to Partners IRB at time of Continuing Review through submission of the Minor Deviation Log.

Changes to the protocol which DO require prior IRB review and approval

- **Changes to the protocol and requests for protocol exceptions that may impact participant safety or the integrity of the study data.** This may include dispensing study drug without performing a key safety lab or procedure, or failure to capture endpoint assessment data. PI and study teams submitting Amendments or Protocol Exceptions (via Other Event Form) related to COVID-19 may email the IRB helpdesk to request a priority review: **IRB@partners.org. We also ask that Amendments and Other Events clearly reference COVID-19 in the Amendment or Protocol Exception description.**

Contingency Planning

PI and study teams should begin planning now for potential disruptions of supplies, study visit schedules, temporary reduction in research staff etc. Closely monitor clinical advice from the hospitals and Partners to assess how disruptions in research could impact safety and welfare of research participants.

- **Investigational Drugs**: If research participants are on investigational drugs, work with the research pharmacy and your sponsor (as applicable) to determine what the plan would be if the investigational drug could not be dispensed to the research participants. If the investigational drugs cannot be dispensed to the research participants, the PI should make plans to transition

research participants back onto their most appropriate clinically available treatments. This transition should include consultations with the investigational drug service, research sponsor(s) and the clinical team caring for the research participants.

- **Research Procedures:** PIs need to assess whether any reduction in staff makes it unsafe to complete the planned research procedures. Specimen collection may not be safe if the study does not have appropriately trained staff to conduct the specimen collection.

- **Review of research data:** If research team members are not available, completion of research-required procedures such as reviewing lab results in a timely manner might not be possible and will require special attention under the direction of the study PI.

- **Conference Call/Video Conference**: If medically appropriate, PI and study teams should consider alternative study visit options to allow participants who cannot or do not want to come to the hospital to complete study visits.

If you have specific questions on research contingency planning, please contact the Partners IRB helpdesk: **IRB@partners.org.**

Home Visits

The IRB is aware that some protocols are currently approved to conduct home visits. The PI must ensure that the activity can continue to be conducted safely within the home and that the study team implement the mandatory screening questions prior to the planned study visit.

Any additional requests to conduct a study visit or portion of a study visit as a home visit must be submitted to the IRB as amendment request for review and approval. Sending staff to patients' homes is not something to be undertaken lightly. There are numerous practical clinical and employment issues to be considered, and is not generally recommended, especially if staff are not clinically credentialed and trained to do this.

Requesting priority review for novel coronavirus research

Some Partners researchers have already started conducting novel coronavirus research. We expect that many more studies are being planned. Such research needs to consider exposures to staff and clinical needs, and we suggest you may wish to consult with infection control before crafting your protocol. Due to expected shortages in PPE, and to avoid exposure of staff, clinical care visits to infected patients may be limited or "bundled." In order for us to prioritize the review and consult on the regulatory and ethical issues we ask that the PI provide the following information by email (**IRB@partners.org**):

- PI Name
- Protocol No.

- Protocol Title
- Funding (if any)
- 1-2 sentence summary on the proposed work
- Identify any local agencies working on the study

FAQs

1. Do I have to submit an amendment to change an in-person visit to one conducted virtually or by remote means?

   It depends.
   If the approved procedures to be conducted at that visit can be done remotely without compromising the safety of the research participant or the scientific validity of the study, this would be considered minor deviation and would not require prior approval by the IRB. However, if there are procedures that cannot be conducted because an in-person visit cannot occur AND those procedures impact the safety of the participant or the scientific validity of the study, this should be submitted to IRB for approval as described above.

2. Should consent forms be revised to include the risk of contracting coronavirus at the hospital or during a study visit?

   No.
   Research teams should carefully consider the risks of participants attending study visits in light of the factors discussed in this document.

3. Do I need to report risk of contracting coronavirus at time of continuing review in response to the question "Since the last continuing (or initial) review, have the risks to subjects changed"?

   No.
   The PI should not include the risk of contracting coronavirus in the continuing review progress report form.

4. Do I need to report to the IRB if a subject or member of the research tests positive for COVID-19?

   No.
   The PI and research teams should follow applicable hospital policy for reporting all new COVID-19 infections. The IRB does not require Other Event reporting for COVID-19 infections or deaths unless determined to be unexpected and related to the protocol.

5. Do I need to report to the IRB if a participant is hospitalized or dies due to COVID-19?

   No.
   Unless the hospitalization or death is determined to be unexpected and related to the

research protocol.

6. How can I flag my Amendment or Protocol Exception related to COVID-19 for priority review?

   Email the IRB helpdesk (IRB@partners.org) AND include COVID-19 in the description field in the Amendment form and in the description of the protocol exception field in the Other Event form.

7. Should we suspend recruitment activities?

   Each reach team should carefully consider whether they can appropriately conduct screening and recruitment activities, as well as meet protocol requirements for the conduct of the research. Teams should assess whether they will have sufficient number of trained staff and supplies, support services, and "treatments" (drug, devices, agents) to continue the research without interruption.

8. The PI has decided to suspend the study temporarily due to COVID-19, do I need to notify the IRB?

   It depends.
   If this is a Minimal Risk study (expedited study) where the temporary suspension would not impact the safety or welfare of research participants, this would be considered a minor deviation and would not require prior approval by the IRB. If the study is More than Minimal Risk (Full Board study), submission of an Amendment is required to the IRB and should contain information on contingency planning related to interruption or changes in investigational product and/or safety monitoring.