FREQUENTLY ASKED QUESTIONS (FAQs)
RELIANCE ON AN INDEPENDENT/COMMERCIAL IRB (iIRB)

WHICH PROTOCOLS ARE ELIGIBLE FOR iIRB REVIEW?

Industry-sponsored Phase III or IV multicenter clinical trials are eligible for review by an independent/commercial IRB at the request of the industry sponsor. The Partners Human Research Office will determine whether a protocol is eligible for iIRB review taking into consideration other factors such as performance sites and qualifications and experience of the PI.

WHICH iIRBs CAN REVIEW A PROTOCOL FOR PARTNERS (BWH/MGH)?

Partners (BWH/MGH) has executed an IRB reliance agreement with Quorum IRB and Chesapeake IRB for review of Phase III or IV multicenter clinical trials and plans to negotiate an IRB reliance agreement with Western IRB (WIRB) over the next few months. IRB reliance agreements may be executed with additional iIRBs in the future.

WILL THERE BE ANY FEES FOR REVIEW OF A PROTOCOL BY AN iIRB?

Yes. There is an iIRB review fee (to be billed to the sponsor by the iIRB). There are also Partners Human Research Office administrative fees and an MCA review fee (to be billed to the sponsor by Partners Research Management).

HOW DO I REQUEST REVIEW OF A PROTOCOL BY AN INDEPENDENT/COMMERCIAL IRB (iIRB)?

To request iIRB review of a protocol by an iIRB, the PI must complete and submit the Partners iIRB Request form to the Partners Human Research Office (a link to the form is below). The Partners Human Research Office will inform the PI whether or not the protocol is eligible for review by an iIRB.

IF A PROTOCOL <u>IS NOT ELIGIBLE</u> FOR iIRB REVIEW, WHAT HAPPENS NEXT?

If the protocol is **<u>not</u>** eligible for iIRB review, the PI will be notified of the decision by the Partners Human Research Office and instructed to submit the protocol to the Partners IRB using Insight/eIRB.

IF A PROTOCOL <u>IS ELIGIBLE</u> FOR iIRB REVIEW, WHAT HAPPENS NEXT?

If the protocol is eligible for iIRB review, the PI will be notified of the decision by the Partners Human Research Office, and sent a memo instructing him/her to complete certain administrative requirements and informing him/her of ancillary committee reviews required **<u>prior</u>** to submission of the protocol to the iIRB.

HOW ARE ANCILLARY COMMITTEE REVIEWS MANAGED?

The Partners Human Research Office will create a protocol record in Insight and upload the Partners iIRB Request form, sponsor's protocol, consent form, and Investigator's Drug Brochure (IDB) for review by the Ancillary Committees. The Partners Human Research Office will send an email to the Ancillary Committees informing them that their review is required for a protocol to be submitted for iIRB review. The Ancillary Committees will notify the Partners Human Research Office and the PI by email of approval or changes required to the protocol and/or consent form. The Partners Human Research Office will provide this information to the

iIRB on the Partners iIRB cover page. The Partners iIRB cover page provides formal documentation that all administrative requirements and ancillary reviews have been completed.

WHEN MAY I SUBMIT THE PROTOCOL TO THE iIRB?

The protocol may be submitted to the iIRB when all administrative requirements and ancillary committee reviews have been completed. The Partners Human Research Office will inform the PI when to submit and will send the completed Partners iIRB cover page to the iIRB. The iIRB will only proceed with their review after receipt of the Partners iIRB cover page.

HOW DO I SUBMIT THE PROTOCOL TO THE iIRB?

The PI submits a request to the iIRB and is given access to the iIRBs online protocol submission system to complete the iIRB's application form. As above, the protocol submission may not be submitted to the iIRB until the Partners Human Research Office has submitted the Partners iIRB cover page verifying that all administrative requirements and ancillary committee reviews have been completed.

HOW WILL I BE NOTIFIED OF iIRB APPROVAL?

The iIRB will notify the PI, Partners Human Research Office, and research pharmacy of approval in writing and will provide any iIRB-approved consent forms and approved recruitment materials through the iIRB research portal.

WILL THE PROTOCOL HAVE AN INSIGHT RECORD?

Yes. The Partners Human Research Office will create a protocol record in Insight and will upload documents, such as the Partners iIRB Request form, sponsor's protocol and IDB, to the Attachments page. Documents will be added and/or versioned in Insight by the Partners Human Research Office when amendments are approved, as applicable.

WILL THE iIRB PROTOCOL SUBMISSION AND iIRB REVIEW LETTERS BE AVAILABLE IN INSIGHT?

No. However, the site-specific iIRB submissions and correspondence will be available in the iIRB's research portal which will be accessible to the PI, Partners Human Research Office, and research pharmacy. Note: The PI is responsible for maintaining the site regulatory binder, which should include all correspondence between the PI and iIRB.

ONCE I RECEIVE NOTIFICATION OF iIRB APPROVAL, WHEN CAN I BEGIN THE STUDY?

The PI can begin recruiting/enrolling subjects only after Pharmacy implementation requirements have been completed, if applicable, and the clinical trial agreement between the company and Partners has been executed.

HOW ARE SPONSOR AMENDMENTS TO THE PROTOCOL SUBMITTED AND REVIEWED BY THE iIRB?

The sponsor submits protocol amendments directly to the iIRB. The iIRB will inform the PI, Partners Human Research Office and research pharmacy of the pending amendment. The Partners Human Research Office will determine if additional ancillary committee review is required and will consult the research pharmacy, as needed, to make the determination. If pharmacy review is needed, review comments, if any, will be

communicated in writing to the iIRB. The Partners Human Research Office will notify the iIRB when the amendment approval may be released for the Partners site.

HOW WILL I BE NOTIFIED OF iIRB APPROVAL OF SPONSOR AMENDMENTS TO THE PROTOCOL?

The iIRB will notify the PI, Partners Human Research Office and research pharmacy of the amendment approval in writing and will provide any iIRB-approved consent forms and approved recruitment materials through the iIRB research portal. iIRB site-specific submissions and correspondence will be available in the iIRB's research portal which is accessible to the PI, Partners Human Research Office, and research pharmacy.

WHAT, IF ANYTHING, DO I NEED TO SUBMIT OR REPORT TO THE iIRB ONCE THE PROTOCOL IS APPROVED BY THE iIRB?

The PI must comply with the requirements of the iIRB for reporting site-specific proposed changes in approved research (amendments) and site-specific unanticipated problems involving risks to subjects or others (UAPs).

HOW WILL I BE NOTIFIED OF iIRB APPROVAL OF SITE SPECIFIC AMENDMENTS OR REVIEW OF UAPS?

The iIRB will notify the PI, Partners Human Research Office, and research pharmacy of approval of any site specific amendments or reviews of unanticipated problems involving risks in writing and will provide any iIRB-approved consent forms and approved recruitment material through the iIRB research portal.

WHAT, IF ANYTHING, DO I NEED TO SUBMIT TO THE PARTNERS HUMAN RESEARCH OFFICE ONCE THE PROTOCOL IS APPROVED BY THE iIRB?

The iIRB only requires information about the PI and does NOT require information about your co-investigators or study staff. Therefore, any changes to co-investigators and study staff, along with financial disclosure forms as applicable, must be submitted to the Partners Human Research Office to track study staff and ensure that they have completed human subject protection training and conflict of interest requirements. The Partners Human Research Office will communicate any conflict of interest issues to the iIRB when applicable and will update the Insight protocol record Staff & Access page.

CONTACT INFORMATION

If you are planning to submit an industry-sponsored multi-site Phase III or IV study and the sponsor has requested to use a commercial IRB, please contact Maria Sundquist, (617) 424-4101 or msundquist@partners.org, to discuss the process.