FREQUENTLY ASKED QUESTIONS FOR MEMBERS

1. **How and when do you receive the materials to review?**

   The agenda and materials related to the human-subjects research and clinical investigations scheduled for review at the PHRC meeting are delivered by courier to members at least five (5) days in advance of the meeting to allow them sufficient time for review. For more information, see PHRC Governance and Operating Procedures.

2. **What regulatory and ethical issues do you consider when reviewing a protocol?**

   The PHRC office has created a "Points to Consider" guidance document for PHRC members, which outlines the Criteria for IRB Approval of Research. This document is included in each PHRC meeting packet and is available on the PHRC website.

3. **How do you evaluate risk and benefit when reviewing a protocol?**

   The PHRC office has created a "Points to Consider" guidance document for PHRC members, which outlines the Criteria for IRB Approval of Research. This document is included in each PHRC meeting packet and is available on the PHRC website. Additionally, a one-page document on Analyzing Risks and Benefits was created to serve as a mini refresher for PHRC members.

4. **Do you use a checklist to remind you of the issues while you review a protocol?**

   The PHRC office has created a Reviewer Worksheet, which outlines the criteria for IRB approval of research and provides members and reviewers with the framework for review. Additionally the "Points to Consider" guidance Criteria for IRB Approval of Research and Requirements for Informed Consent are included in each PHRC meeting packet and are available on the PHRC website.

5. **If you think that additional expertise beyond that available on the committee is needed for the protocol review, whom do you tell?**

   Contact the Chairperson or Administrative Chairperson and let him/her know that you think that additional expertise beyond that available on the Committee is needed. Additionally, when the protocol is discussed at the meeting, the Committee may vote to defer action and require review by an expert in the scientific area or discipline. When additional expertise is needed, the Chairperson is responsible for identifying a consultant and for requesting such consultation. The Chairperson may solicit recommendations from PHRC members and from others in the medical community. Consultants may attend the meeting or provide written comments; however consultants in attendance are not considered voting members and may not vote with the Committee. For more information, see PHRC Governance and Operating Procedures, Use of Consultants.

6. **How do you evaluate investigator financial conflicts of interest?**

   The PHRC has a new policy that requires investigators to complete an investigator financial disclosure form if the research involves any of the following: (1) for profit sponsor or funding source; (2) a marketed drug, device, or other technology, or a drug, device, or other technology in development; or (3) a new technology, software, or therapeutic approach. The PHRC office reviews these forms and refers

disclosures of financial conflicts of interest to Libby Hohmann, the Director and Chair, who will bring any potential financial conflict of interest to the attention of the Committee for consideration. The Financial Conflicts of Interest policy and Investigator Financial Disclosure form are available on the PHRC website.

7. **How do you review the consent form? What elements do you check? Do you use a checklist to remind you of these elements?**

   The PHRC office provides members and reviewers with the guidance document Requirements for Informed Consent in each PHRC meeting packet. Additionally, the PHRC office has developed an Informed Consent Document Checklist and Instructions for Preparing Research Consent Forms, both of which are available on the PHRC website.

8. **What do you consider when you review privacy protections?**

   The PHRC office has created a "Points to Consider" guidance document for PHRC members, which outlines the Criteria for IRB Approval of Research. This guidance document has a section on privacy protections. This document is included in each PHRC meeting packet and is available on the PHRC website. Additionally, a one-page document on Confidentiality Versus Privacy and How it Relates to Human Subjects Protections was created to serve as a mini refresher for PHRC members.

9. **What do you consider when you review confidentiality protections?**

   The PHRC office has created a "Points to Consider" guidance document for PHRC members, which outlines the Criteria for IRB Approval of Research. This guidance document has a section on confidentiality protections. This document is included in each PHRC meeting packet and is available on the PHRC website. Additionally, a one-page document on Confidentiality Versus Privacy and How it Relates to Human Subjects Protections was created to serve as a mini refresher for PHRC members.

10. **How are confidentiality protections different from privacy protections?**

    Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed and disseminated. The evaluation of confidentiality should include storage, handling and sharing of data. Privacy refers to a person's desire to control the access of others to themselves. The evaluation of privacy should include how the investigator will access information from or about participants. Additionally, a one-page document on Confidentiality Versus Privacy and How it Relates to Human Subjects Protections was created to serve as a mini refresher for PHRC members.

11. **How is the duration of approval decided? When do you consider approving studies for less than one year?**

    The duration of approval may not exceed one year from the date at which the protocol was approved (or approved with modifications) at a convened meeting of the PHRC. When determining the duration of approval, the PHRC considers the degree of risk to subjects. Examples of protocols that may be considered for review more frequently than annually include:

    - Phase I studies of a challenging or novel new drug or biologic;
    - Studies involving Category A significant risk devices;

- Studies in which healthy volunteers may undergo anesthesia or medical procedures involving sedation with no direct health benefits;
- Studies for which there is little external oversight or data safety monitoring;
- Studies involving gene transfer or xenotransplantation; or
- Studies involving infectious agents.

For more information, see Initial and Continuing Review of Human-Subjects Research and Proposed Changes in Approved Research at a Convened PHRC Meeting.

12. **Are there special considerations for involvement of children in research?**

Yes. Researchers are required to complete the PHRC form Additional Protections for Children Involved as Subjects in Research that addresses the regulatory requirements for approval of research involving children. The information provided by the researchers in this form assists the PHRC in making the determinations required by regulation about research including children. Additionally, PHRC has a policy on Research Involving Vulnerable Populations.

13. **Are there special considerations for involvement of pregnant women and fetuses in research?**

Yes. Researchers are required to complete the PHRC form Additional Protections for Pregnant Women or Human Fetuses Involved in Research that addresses the regulatory requirements for approval of research involving pregnant women or human fetuses. The information provided by the researchers in this form assists the PHRC in making the determinations required by regulation about research involving pregnant women or human fetuses. Additionally, PHRC has a policy on Research Involving Vulnerable Populations.

14. **Are there special considerations for involvement of prisoners?**

Yes, however because the Partners Human Research Committee (PHRC) does not meet the special membership requirements for review of research involving prisoners, Partners has executed an IRB Authorization Agreement with the Harvard School of Public Health (HSPH) that allows the PHRC to utilize the HSPH IRB for review of research involving prisoners. For more information, refer to the PHRC guidance on Research Involving Prisoners.

15. **Are there special considerations for involvement of decisionally-impaired persons?**

Yes. Researchers are required to complete the PHRC form Additional Protections for Individuals with Impaired Decision-making Capacity and provide the rationale for including subjects who are decisionally impaired in their research. Additionally, Human Research Affairs has developed guidance on Surrogate Consent to Research for Individuals with Impaired Decision-making Capacity (internal link) for researchers and PHRC members. The information provided by the researchers in this form and the guidance document on surrogate consent assists the PHRC in making the determinations about the appropriateness of including individuals with impaired decision-making in the research.

16. **How do you determine whether an IND is needed when an FDA-approved drug is being studied for another indication?**

The FDA has specific criteria for determining when the off-label research use of an approved drug requires an IND. The PHRC has developed a form Research Use of Drugs/Biologics/Dietary Supplements

that requires researchers to provide the PHRC with information related to the FDA status of the drug and its use in the study. This form captures information related to these special criteria and assists the PHRC in its determinations about whether or not off-label use of an approved drug for research requires an IND.

17. **How do you determine whether an IDE is needed when a device is being studied?**

    The PHRC is responsible for reviewing clinical investigations of devices and for determining whether the study is a significant risk or nonsignificant risk device study. When the clinical investigation is being conducted under an IDE, the sponsor and the FDA have already determined that the device is a significant risk device. In the absence of an IDE, the PHRC must make this determination. The PHRC has developed a form Research Related Use of Medical Devices that requires researchers to provide information to assist the PHRC in making the determination about the risk status of the device.

18. **What do you do if you have a conflict of interest with a protocol that is on the agenda of the meeting you plan to attend?**

    Partners has a Conflicts of Interest Policy for IRB Members. PHRC members are required to disclose any conflicts of interest and recuse themselves from participating in the discussion and vote on human-subjects research with which they have a conflict of interest. When meeting materials are delivered, members are reminded by email to review the agenda and notify the Chairperson or Administrative Chair of any conflicts of interest. The Chairperson also reminds members at the beginning of each meeting that they must recuse themselves and leave the room for the discussion and vote on any research with which they have a conflict of interest, except to provide information at the PHRC's request prior to the discussion and vote. Recusals are noted in the minutes of the meeting and do not count towards the quorum requirement for the review. For more information about conflicts of interest, see PHRC Governance and Operating Procedures, Conflicts of Interest.

19. **What do you do if you think that you are being pressured into approving a protocol that you might not otherwise approve?**

    The PHRC must exercise its authority to approve human-subjects research with independence. No one within the institution may overrule the PHRC's decision to disapprove research. In the event that you feel you are being pressured or unduly influenced by someone to provide a specific vote or outcome of a study under review, you should report this to Libby Hohmann or Rosalyn Gray as soon as possible. They will work with the Director of Partners Human Research Affairs (HRA) and the Institutional Officials (IOs), as necessary, to remedy any concern. For more information about the independence of the IRB and undue influence, see PHRC Governance and Operating Procedures, Independence of the IRB and Undue Influence.

20. **When you became an IRB member, did you receive an orientation?**

    The PHRC instituted a formal member orientation program three years ago. New members are now asked to complete the CITI Basic Course and meet with the Administrative Chair of their panel.

21. **As an IRB member, do you receive any routine training and/or educational materials?**

    During PHRC meetings, individual topics are covered through "IRB Education Bites," one-page or short documents that focus on a specific IRB regulatory or policy issue. Topics that have been covered in the past year can be found on the PHRC website under PHRC Member Handbook, Education. Additionally,

the PHRC obtains a subscription for members to "IRB Ethics & Human Research" and "Human Research Report," and also offers members the opportunity to attend PRIM&R conferences.