PARTNERS HUMAN RESEARCH COMMITTEE
PATIENT CENTERED OUTCOME RESEARCH (PCOR) AND IRB POINTS TO CONSIDER

PCOR projects are received by the IRB with increasing frequency. We are familiar with the concepts and requirements of patient engagement, learning health systems, funding mechanisms for PCOR, CER and PCTs.

There is little formal guidance from PCOR, NIH, OHRP and others on how institutions and IRBs should review engagement of patients, large-scale data uses and new technologies. We will work with you on these issues. This page is a *work in progress*, and offered as guidance – points to consider for investigators to provide information for IRB review – it may change and be updated frequently.

See: http://www.pcori.org/, see also Sugarman and Califf, JAMA 311(23), 2014.

Planning

Because there are strict time limits from "Letters of Intent" to funding, to "deliverables" for PCOR- funded projects, careful planning by experienced study staff is required for the best outcomes and to be sure grant budgets adequately cover institutional resources needed. Investigators who are "clinical trialists" may need to seek assistance from social scientists and health services researchers in advance.

There may be a need for:

- Time for discussion of ethical and legal aspects of study design and logistics such as valid consent methods
- Office of the General Counsel (OGC)/legal input
- Consideration of requests to use a centralized IRB
- Reliance agreements between institutions
- Discussions between IRBs at different institutions, and coping with variation across IRBs when reviewing social/behavioral and CER research.
- Privacy office review
- Research Computing/Information Technology review/risk assessment
- Agreement from Institutional Officials or leaders of clinics or departments
- Human Resources/Volunteer Office
- Addition of study staff or consultation with researchers with expertise in social/behavioral or health services research methods and uses of new technologies
- IRB reviews, including in some cases full panel review

Issues for IRB submissions and reviews

It is important to demonstrate in your IRB submission that you have considered the following issues:

Standard Care vs. Research interventions

This is especially relevant in cluster randomized interventional and related research studies.

- Clearly differentiate between what is ALREADY part of standard care at the study site(s), what will be implemented as "improved" standard care for all individuals at sites going forward. Explain how the study interventions change the environment, treatment, costs, or time involved for both patients and clinic or hospital staff. These issues have broad implications for informed consent. For example, in some cluster-randomized trials, where a site (and not an individual) is randomized to an intervention, informed consent may not always be required. Notification of staff and patients may be all that is

needed, and in some cases a waiver of informed consent may apply. These are complex and nuanced issues and providing complete, thoughtful, scientifically and ethically supported reasons for your plans for recruitment and consent are required to facilitate review.

- Consider when the data collected are to be used in care and therefore placed in the medical record, and when data are used for research only and NOT placed in the medical record. Sensitive or actionable data such as suicidality, child abuse/neglect, or illicit behavior may require special consideration and legal advice.
- Clearly state who will see which data, and when. When health information (with or without identifiers) will be collected from subjects and shared with other subjects or sites, data sharing "pathways" need to be clearly described.
- If your study involves multiple sites or states, legal issues related to provider licensure, scope of practice, and mandated reporting need to be considered. Laws and responsibilities will differ by state. Distant sites may need to seek legal advice in their state.

Advertisements

IRBs are required by federal regulations to review and approve advertisements, including the text and the visual and verbal messages. PCOR studies often have nonspecific general plans to recruit subjects using multiple methods and media outlets, sometimes engaging marketing firms to assist in reaching millions of individuals over short periods of time. We recognize the difficulties this raises, but we are unable to simply approve an "advertising campaign;" the IRB is required to review specific advertisements and texts. Some flexibility is allowed; for example, we do not need to see every "tweet" or Facebook post that is used, especially if these brief messages are simply ways to link to more complete IRB-approved texts and recruitment materials. You may submit a list of sample tweets you would use. A screenshot of a Facebook page, along with a description of privacy settings and the name of the study staff who is in charge of the page can be submitted. Please see guidance GUIDELINES FOR ADVERTISEMENTS FOR RECRUITING SUBJECTS, http://healthcare.partners.org/phsirb/advert.htm.

Informed Consent

Alternative methods for obtaining informed consent may be considered for minimal risk research. Please note that many social/behavioral research methods allow for a Waiver of Documentation of Informed Consent. In many cases, we discourage the use of a written consent form on the PHS template, and instead suggest use of a Fact Sheet or accompanying/introductory text that includes the elements of informed consent as applicable. Consent is implied via return of a survey, or collected verbally and documented in the research record, and in some cases may be provided online.

HIPAA

The HIPAA regulations still apply to PCOR research. Subjects must be made aware of, and agree to how their information will be stored and shared. The IRB will consider when an authorization or an alteration to required authorization is appropriate.

New Technologies

If a protocol is using a new electronic platform or technology (i.e., one NOT previously vetted by PHS Research Computing such as Vidyo, REDCap, etc.), additional review is required by Partners Research Computing, and a data security risk assessment will need to be performed. It is best to have this done prior to or concurrently with submission of your IRB application. Technology used might include: development of new apps that collect data or provide an intervention, use of smartphone/text interventions, novel internet based data collection

methods, internet-based interventions with video, telemedicine (across state lines), use of social media, etc. Please see: http://healthcare.partners.org/phsirb/Guidance/Survey_Research_Using_Web-based_Tools.5.10.pdf and http://rc.partners.org/

Patient Participation

Involving patients in the research process is a crucial and mandatory element for PCOR research, allowing for neglected viewpoints to be considered. Ethical and practical issues need to be considered; this is new territory for IRBs and researchers. Inviting your patients to participate in research planning and/or conduct can create dual roles for patients. Clear understanding and communication about their roles within their health care system is needed. It is important to clarify how this participation is different from care and to educate the patient about research, so that participants understand roles, their boundaries, their responsibilities, and how taking on a role may affect their relationship with their health care providers. Federal requirements for oversight of the patient's activities may vary. Are they a researcher or a research subject, or perhaps both? The responsibility that a Principal Investigator gives to patients when they become part of your study staff is significant, and careful consideration is needed as with any study staff you involve in your research (please see: http://healthcare.partners.org/phsirb/PI_Responsibilities.htm).

The role of the patient in the PCOR project needs to be outlined in detail. We recommend that you provide this detail in the Protocol Summary in a section with the heading, "PCOR PATIENT ENGAGEMENT", including:

- How the patient is asked to take on this role, specifically how, when, where and by whom they are identified and approached.
- How they will be screened for appropriateness and qualifications for the role.
- What specific activities they will perform.
- How they will be educated and trained to perform these activities (PCOR requirement for "Co-learning").
- Whether they will be compensated for their work (PCOR requirement for "Partnership").
- How you will communicate with each other and establish trust and transparency (PCOR requirement for "Trust, Transparency, Honesty").

Sometimes the role the patient/stakeholder assumes will make them part of the research staff, and their engagement will require specific IRB review and approval. Below we provide some general guidance on patient activities in research. If you have questions, please contact us to discuss the planned role.

Roles which probably DO NOT require IRB review as ADVISORY to the project

If a patient is asked to do the following, they would not be considered engaged in human subjects research and would not be listed as study staff:

- Participate in a research planning committee to formulate research questions
- Participate in a preparatory focus group that informs research questions
- Review and advise on protocol development or study endpoints
- Participate in a stakeholder meeting
- Advise or participate in grant writing, or survey development
- Participate in a patient advisory panel to a research project

Roles which likely WILL need IRB review as STUDY STAFF

Patients taking on these roles likely need to meet Human Resources, COI and CITI requirements:

- Be a member of a committee reviewing identifiable health data
- Serve as a co-investigator

- Being involved in scientific aspects of study design
- Recruit other patients based on those patients' private health information
- Collect data from other research participants
- Obtain informed consent or agreement to participate from other individuals
- Participate in analysis of identifiable data
- Serve as off-site study coordinators/research assistants
- Participate in a focus group that is part of the research activities and answers research questions
- Participate as subjects in the PCOR research interventions

Recruitment of participants

PCOR can vary widely in terms of target populations. Recruitment on a large scale, with the use of social media or "marketing campaigns" for study recruitment can raise some complex issues in the current regulatory environment. Whenever possible, based on recent experience, before launching wide-scale contact of groups based on any private information, we strongly recommend piloting the recruitment with a smaller group, or releasing recruitment efforts in stages. Privacy and respect considerations are important when contacting individuals based on PHI, and this cannot be ignored for reasons of expediency. Initial contact methods should be described in detail. In general, if one is contacted based on their private information or private health information, acceptable methods will entail the use of a clinician or appropriate administrative leader to co-sign a letter or call patients directly. When recruiting patients to participate in other non-human-subjects aspects of the research such as an interest panel, explain why approaching specific patients is appropriate, and describe measures you will undertake to ensure that: 1) patients do not feel obligated to participate and 2) neither participation nor refusal will affect their care. Clarify why the patients chosen are both qualified to serve and representative of the population of interest.

It may be possible to create internet-based presence such as an educational website, social media site that can be done outside of the research study, which can link to research sites that house specific study recruitment materials or online consent when appropriate. These potential arrangements would need to be discussed with the IRB on a case-by-case basis.

For questions about the guidance above, contact: Melissa Abraham PhD, IRB Chair. mabraham2@partners.org

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