Experiences with IRB - How are we going to restructure in Phase 2.

Friday 1pm KC room

Hale: very lucky to get things through the site quickly. Worked under assumption that 6 IRBs had already looked at the document and didn't have the level of risk that an Investigator-Initiated study might have. Assigned a staff member to the project, joined the obesity weekly call.

The critical thing was people have to know who people are.

People changed role in the project. Site leads changed at most sites. Sometimes had project managers on the call, sometimes PIs.

Ann: represent both CMH and KUMC. We were told that the main lead in San Antonio would coordinate with IRB at sites. Gap in info that obesity site lead did need to get involved in the IRB. Another issue was getting physician approval for patient populations – it would be a huge burden to get that approval across many people. Is there a way to change interpretation of whatever rule(s) govern this?

Dan: divide out protections for a human subject and protections for the institution. The level of entanglement of these is different at each institution. There was not a coordinated effort put forth for institutional regulations. Led to missed communications. Were able to skip from human subjects processes, but not all institutional process.

State rules seemed to also take effect.

IRB knows there are differences among institutions, but hearing that communications was an issue. Good to know that IRB lead on obesity calls was helpful.

For Phase 2:

- Now working on clarifying the sequencing.
- designated reliance coordinator out of Wisconsin, 30% paid. This person will
    - work with lead PI to ensure governing council has approved the project as GPC study.
    - Gather a submission packet (protocol, consent, names of site PIs and personnel, etc), for the lead IRB.
    - Person would know all the players, all the necessary pieces.
    - That person would then communicate with site IRBs, to determine readiness status. Get the lead IRB moving.

Can this person play a role post-approval? For example, help manage version control, updated consents, etc.?

Typically lead IRB is responsible for dissemination and update of documents.

- Need to help PIs and coordinators understand what reliance means. What does it mean to be the lead PI? What do lead study team and relying study teams do?
- Typically lead IRB will be institution where lead PI is, but there is a decision tree. There are 3 sites not yet willing to be lead IRB.
- Need to be clear on what's IRB and what's not IRB, eg radiation safety, COI, etc. How are not-IRB things addressed. That sort of thing will still need to be addressed/completed.
- Looking at having an IRB portal on the GPC website where approved people can log on to find approved documents, contact names, etc. (modeled after Wisconsin website.)
- Want to have a presence on the main GPC site for education materials that clarify main responsibilities of lead IRB, lead study PI,
- There will still be a local IRB role. There is variability at each site about how to get site approval before it goes to lead IRB

Are there any systematic differences or similarities observed from Phase 1 that can help PIs plan?

- Recruitment. How you get permission to recruit subjects is highly variable. Also how an investigator is able to contact those subjects
- Some state law issues.
- There will always be variability that sites need to be aware of
- Could be useful to compile a list of IRB lessons learned from Phase 1 that the new coordinator position and maintain and circulate.

What value does executing a BAA between two ACM provide?

- None, the DUA addresses that
- Is it PHI? Yes
- PHI is not a GPC product; all the PHI was kept at each site, they provided it post consent
- If you have patient consent you don't need BAA

We think that having the IRB reliance coordinator position front load the work will streamline the approval process. We also want to make sure we're answering needs.

If there are centrally held consent forms, do we need to think about how to share those? Yes, e-consent may play a role here. How are consent forms shared. It will be important to keep this sort of thing in mind in the early phases of research study and design.

Need to be aware and try to bring in the smaller clinics that may be involved in the research and who may be affected by the study and/or IRB.

Another concern is "study exhaustion" – one individual getting many emails about multiple studies. Will really affect illnesses like diabetes or cardiovascular disease.

Might be good to run IRB documents by the project management team for feedback from their perspective.

Would help to have partnership with the lead PIs to help educate them on PCORI and the IRB process.

An issue with GPC is that they're trying to do things on the cheap which makes things more lengthy and difficult. Many sites didn't have a study coordinator and they are the people who get things done.

Lack of funding is also a problem in that this work will be lost if it doesn't continue. A lot of institutional, PCORI, IRB knowledge and work will be lost.

Need education on when IRB is needed and when it is not.

Take aways:

- Communication, Coordination, Education, Understanding institutional differences.
- IRB Website: institutional profile to know contacts, foibles, etc.
- Helpful for sites to get together to know who is working on the project, understand their roles, put names to faces, etc. – study coordinators, PIs, informatics, IRB,