Learning Enrichment Conference Breakout Session 2

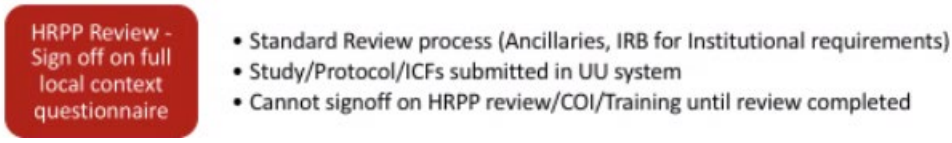
Project/Team Name: IRB | **Date:** October 21, 2021

Location: Virtual Meeting | **Time:** 11:00 a.m.

- **Sarah Mumford – Session Leader**

- **Frustration about HRPP Process at different institutions**
  - Cannot tell institutions what they have to do, but would be useful to understand where we are all at now, changes we have made, how things are going.
  - What are our processes, what is required, what are we seeing, etc.
  - Providing an HRPP toolkit?
  - Where are the differences

- **Chart of activities**
  - Reliance Request regardless of sources
  - Call, meeting, consultation
  - Agree to Rely – SMART letter of acknowledgement (we can sign off since counsel has already signed master agreement)
  - Addendum to LOA (I don't like these because we have to take it to general counsel and it restates what is in the agreement)
  - With the reliance invitation in the system, we will agree to rely.
  - At this point, Reviewing Institution needs information about you, i.e., Institutional profile. Site questionnaire, generic information that doesn't change. Then they start to ask questions I can't answer yet because there isn't a final protocol. So, I have to provide answers like "If LARs are to be used, state law limits who is permitted as an LAR". So we are in the beginning of the process and I sign off with general answers because it is premature.



  - Until HRPP Review is complete, we can't provide language to go into the consent form, training, or COI.
  - Goes into a pending state until sIRB approval goes through.
  - PI submits consent form and sIRB approval.
  - HRPP confirms all requirements have been met and site activation letter.
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- Name
  - Where to sign

- **Jarrod Feld – Iowa IRB**
  - Issue with completing COI before it is in their system. We can give an "agree to rely" at the very end when Ancillary committees approve and then funds are released.
  - It is more like "it looks like a good fit" – not "agree to rely".
  - When we are the reviewing IRB, we are not going to…The issue we are not going to review the site, consent forms, if they are not going to participate. We are bit more informal (i.e., email) if that they want to do. We put burden on team to work with relying sites.
  - Do you have activation letter? Our electronic system issues
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- **Kimberly Hawkins, UTSW**
  - Initial approval before inviting relying sites in IREx? Sarah will check with others in her office about Drafts.
  - Kathy Jurius – There are so many people that don't use IREx; On one of our forms, we have a box that says, "would you prefer to your Institutional Profile".
  - IREx is easier to use than it used to be.

- **Meyad Baghezza – UTHSC SA**
  - I initiate agreement, flexible terms, get the study up and running during an amendment. Not usually large studies – but I have one coming up.

- **Letter or document as relying site**
  - Janelle Greening (MU) – Yes, populates who we are relying on and responsibilities. They get 2 formal letters. (Lori Wilcox) We do that for non-reliance as well.
  - Are you charging fees that need to be part of the grant budget? Yes, it is part of the budget.

  - Kathy Jurius (KUMC): Letter saying we agree to rely and a final release letter
  - Kyle Stephens (KUMC): Letter with Budget, Approval letter for each site, Letter for initial study approval.
  - Kimberly Hawkins (UTSW): 2 letters (Approved other approvals Pending,

- **Beth - MCW**
  - We need to know that our site is approved. If the sIRB is granting a HIPAA Waiver.
  - Would you accept…
  - If you added us 6 months months ago when the study was approved 8 months ago, do you have proof that we were specifically added to the HIPAA Waiver?
  - We've accepted a screen shot of the application

- **Sandy from Marshfield**
  - I submit to the IRB and they want everything. They want PI, entity to whom we are deferring, contacts for the IRB, a lot of information they want. Approval of the protocol from the lead site, application from the lead site.
  - What type, funder, what each site will be doing, names of contacts, consent forms
  - IRB sends a formal letter to the PI and study team may send to lead site saying deferral has been approved

- **?**
  - Issue an institutional activation letter, if any components pending, then site activation will be held.
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