Flex Coalition Luncheon
AAHRPP Conference: Long Beach, CA
April 21, 2016

Introduction

Susan Rose, University of Southern California (USC) welcomed everyone and noted over 150 sites have joined the Flex coalition and please encourage more people to join. Susan acknowledged AAHRPP encouragement and support have been integral in the implementation of flexibility in HRPPs and the development of the flex coalition. Susan she is looking for someone to talk about data security plans/policies. Notes from the speakers follow; Lisa Leventhal (Oregon State University), Megan Kasimatis Singleton (Penn), Sarah Kiskaddon (AAHRPP).

Pursuing Multiple IRB Initiatives and New Flex Policy

Lisa Leventhal, Oregon State University:

Lisa's presentation focuses on the changing landscape at her institution. She described her personal background and the multiple challenges caused by changes in leadership at her institution. Lisa also described the development of the OSU program she led.

OSU IRB initiatives:

- 2009: Advising hours made available for students. Active promotion of ceding or accepting oversight for multi-site projects.
- 2010: Switched from annual reviews of exemptions, to 5-year terminal exemption.
- 2012: Initiated first broad reciprocal agreement with medical center covering collaborative studies conducted by OSU or on university premises or hospital.
- 2013: Initiated second reciprocal agreement and added a second board for the review of student-driven, minimal risk protocols. Also, implemented an in-person review process for exempt determinations and (by popular response) extended to pre-review of PI responses to board stipulations.
- 2014: Developed guidance excluding certain types of revisions to exempt projects from the requirement for review. Proposed a handful of flex initiatives.
- 2015: Initiatives presented in 2014 were approved by the IRB and then ultimately approved in 2016 by the 5th Institutional Official to hold the position in seven years.

Initiatives adapted into OSU policy:

- Added two flex exempt categories
- Expanded approval periods for expedited studies
- Added safeguard standards for pregnant women
- Developed training for staff/students/members:

- Staff required to write three protocols; one for each level of review. They were encouraged to not ask questions of their peers during this process. It has proven to be an incredible learning experience for the new hires and beneficial to the office in general. Mistakes are encouraged and so are fresh perspectives on procedural gaps and things that do or don't work.
- Developed a competency matrix for IRB members that includes knowledge and skills they would like to see in an aspirational member. This is tested annually against a self-assessment.
- Before new members can vote or serve as primary reviewers they are required to attend two orientation sessions with office staff, shadow reviews conducted by at least three different IRB members, complete IRB member training modules online, and attend a minimum of two meetings.
- CE is offered at the start of each meeting and annual retreats are held to provide intensive training, review special topics, and discuss process and policy changes.
- Developed a graduate-level IRB Prep course for students to draft submission-ready application materials (e.g., protocol, consent form, recruitment materials, etc.) for IRB submission. The course has assisted individual students, has helped them get better information into departments, and has improved relationships between the IRB and faculty mentors.

Benefits and drawbacks of OSU initiatives:

1. Things that did not work:
   - Too many initiatives all at once; an overload of ideas submitted at once
   - SOP sections that reference other SOP sections and cannot stand alone
   - Freaking out
2. Things that did work:
   - Limiting the amount of people in the approval process
   - Fostering a safe environment for staff to make mistakes and offer ideas
   - Helping staff to embrace change and chaos
   - Supporting people in finding jobs that are right for them; sometimes that means providing a good reference
   - Being fast to failure; giving new initiatives all the resources they need to succeed and then dropping them as soon as it is clear they don't work
   - Exploiting generosity of peers by capitalizing on policies and practices published by others

Lisa noted Flex Coalition has been an extremely helpful forum for access to many valuable peers and ideas.

Susan commended Lisa for mentioning the importance of not doing everything, and letting go of what doesn't work.

Flexibility with Reviewing Consent Documents

Megan Kasimatis Singleton, UPENN

Megan led an interactive dialogue. She asked the audience to respond to three scenarios by a show of hands:

a) Ready for the change
b) No way
c) I'm' feeling excited about the change but nervous

Scenario 1: Tomorrow you will remove all consent templates from your website, and no longer allow researchers to use them. IRBs will consider reviewing for the protection of human subject populations as opposed to reviewing against a template:

- ✓ The result was mixed, between "no way" to "feeling excited but nervous".

Megan asked to hear from someone willing to get rid of consent templates. Susan said there is strong dislike for long, problematic forms. One person defended consent templates, saying template language is important. However, another said there are limitations though the language is there.

Megan agreed consent forms help communicate certain required language but wondered; is there another way to communicate this in a different, more creative model? Several guests spoke up, noting the consent author's level of expertise matters because a template can guide or limit those that have skills.

Scenario 2: On Monday, you will let your IRB know you will no longer accept marked consent documents. How do you feel?

One person noted many researchers are not aware of IRB edit to their consent. Another person mentioned those who edit consent do it well so there should be no reason to stop that.
There was a split response between those who practice collective reviews using one marked consent document and institutions that have reviewers separately review consent documents.

Megan suggested shared review of one marked consent document because it moves commentaries to a team effort.

Scenario 3: You will propose a new policy that requires IRB members to provide a rationale each time they wish to mandate an optional element of consent be included in a consent document.

Most of the attendees agreed that there are pros and cons; few were entirely in favor or against. An attendee in favor of this change noted it promoted clearer communication between reviewers and increased consistency.

In closing, Megan encouraged everyone to pursue innovative problem solving by:

1. Identifying problem areas
2. Do a sampling of protocols
    a. Observe what is being asked
    b. Ask yourself; where is the root coming from? is it an old practice?
3. Brainstorm new ideas
    a. Are there ways you can adopt slight shifts that could result in total improvement?
4. Evaluate
    a. Measure the success of changes so we can share and follow up with each other.

AAHRPP Standards: Flexibility & Compliance

Sarah Kiskaddon, AAHRPP

Sarah gave a brief summary of the AAHRPP standards/elements that are required for accreditation but do not tie back to federal regulation:

- ✓ I.6.A: The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.
- ✓ I.8.B: In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.
- ✓ I.8.C: When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the organization.
- ✓ I.8.D: Before initiating research, the Organization has a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that Researchers and Sponsors will play in the publication or disclosure of results.
- ✓ II.1.A: The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.
- ✓ II.1.B: The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.

- ✓ II.2.B: The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable laws and regulations. These functions may be delegated to an entity other than the IRB or EC.
- ✓ II.2.C: The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.
- ✓ II.2.H: The IRB or EC has and follows policies and procedures for managing multisite research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.

Sarah provided a link to additional information:
http://www.aahrpp.org/apply/web-document-library/domain-i-organization

Susan concluded the meeting and thanked everyone for coming.