

Flexibility Coalition Luncheon
PRIM&R Conference Baltimore, MD
December 5, 2014

Updates from University of Southern California (USC)

- Welcome and introductions
- USC developing booklet about IRB reliance agreements
- USC webpage on reliance agreements
- Conference call will be held in Feb-March focusing on IRB Reliance Agreements
Smaller flexible IRBs, Any new flexibilities with Subparts B, C, and D

USC flex policy modifications:

- 1250 studies have been flexed at USC
- The flex implementation practices between the biomedical and socio-behavioral campuses have become increasingly similar
- USC moved to a three year approval for studies conducting data-analysis-only
- USC Flex Exempt now allows surveys, focus groups, and interviews with minors

Developments in Flexibility Practices:

- Currently there are 210 members of the coalition representing over 75 institutions
- New NIH announcement encourages single IRB review for multi-site research and is currently asking for comments.
- Authors of NPRM may be moving toward including a number of things the flex coalition is doing
- National Academy of Sciences' comments on the ANPRM included recommendations that are same as flex coalition practices
- AAHRPP tip sheets now include flex options

Smaller Flexible IRBs are Proliferating

- Washington University St Louis (Martha Jones) and Children's Hospital Los Angeles (Rebecca Dahl), Wake Forest University (Joseph Andrews) have moved to smaller, flexible IRB model with large number of alternate members. IRB members and staff are cutting review times and like the shorter, more frequent meetings
- Most of the IRBs that have gone to this model have been guided by Huron and all are using Huron toolkits with success.
- Wake Forest University (Brian Moore) acknowledged they have implemented this model without using Huron. Many institutions would like to use the Huron model, but do not have the resources to do so. **The Flex Coalition is soliciting speakers from institutions that have implemented a smaller/flexible IRB model on their own.**

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IRB Reliance Agreements

- Some reliance agreements risk becoming more complicated than individual IRB reviews. Excessive documentation by the relying IRBs appears to be a national problem (the ceded review application for USC is currently 11 pages). The content, local issues and reporting requirements are as varied as the institutions. Improving the IRB reliance process will be a future topic of the Flex Coalition.

Opportunities for Improving IRB Process

- USC is working on implementing a scientific review process that is concurrent with IRB review. Comprehensive Cancer Center funding requires scientific review separate from any review by IRB. Ideal solution would combine scientific review and IRB review into one process.
- IRB approval letters are often excessively long, full of boilerplate text and carbon copies of the minutes. Most sites tell investigators everything the IRB wants them to know in the approval letter and then if something goes wrong, the IRB refers back to the approval letter, which no one reads.
- **Flex Coalition speakers needed on:**
 - how institutions assure community partners meet institution's standards for conduct of research
 - Demonstrable connections between research institutions and the community where research subjects are sought.

The extensive discussion following each presentation is included below.

For additional information about the three presentations see the attached slide sets.



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Transformation of Penn State's HRPP and Embracing Flexibility (Sara Horn)

Penn's HRPP transformation started with the need for a new electronic system. A three part transformation occurred over a few years. The three components of the HRPP transformation included:

- Process, Policies, and Procedures
- Organizational Structure Analysis and Re-Organization
- Implementation of New Electronic System

The transformation process involved tracking metrics such as staff response to change, staff performance, issue handling, earned value, and budget allocation which were all tracked at regular intervals. As far as implementation, decisions on utilizing the Huron HRPP Toolkit, Click IRB software, timelines, and process were made by all governance bodies.

Key to success was the support and governance structure which included an Executive Committee comprised of University Administration, an IRB Advisory Committee comprised of IRB Directors, and an IRB Specific Advisory Committee which included key staff.

Penn State chose the Huron toolkit for development of policies and procedures (SOPs) and to define processes within IRB offices. Penn State implemented Huron Checklists, worksheets and templates and integrated the toolkit into the Click IRB product, which was chosen as their electronic system. The toolkit integrated with the Click product allows for a more efficient accreditation submission process and provides a complete set of tools to meet the regulations and accreditation standards.

The Penn State HRPP program went "Back to the regulations" and enhanced the used of an unchecked box. Sara noted that doing this forced leadership and the staff to take a step back and evaluate current institutional policies and procedures. Penn trained and re-trained staff regarding use of the HRPP Toolkit and interpretation of regulations. Penn State used on-site consulting services through Huron during this process. Sara noted that they developed new protocol and informed consent templates to collect only necessary information.

In addition Penn State decided to get rid of the "turbo tax" type of submission form to allow for flexibility in collaboration on the protocol and transparency of questions. Sara noted that this process was challenging as there were IRB administrators hanging on to old practices and it was difficult trying to shed the gatekeeper tasks that didn't belong to the IRB. Sara shared that there is flexibility built into the Huron toolkit which includes the following:

Exempt Research

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- Exempt Category 2- No limitations on the inclusion of children when research is not conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Environmental Protection Agency (EPA)
- Exempt Category 4- For research conducted, funded, or otherwise subject to regulation by any federal agency “existing” means “existing at the time the research is proposed.” Otherwise, it means “existing at the time the research is proposed or will exist in the future for non-research purposes.”)
- Implemented their Exempt Category 7 and carried this over into the HRPP Toolkit. Exempt Category 7 is for social science research in which participant interaction is limited to providing a response to a non-invasive stimulus. However there are the following exclusions:
 - Federal funding or federal training grants
 - Biomedical procedures
 - Sponsor or other contractual restrictions
 - Clinical interventions (including clinical behavioral interventions)
 - Prisoners as participants
 - Children as participants
 - The use of deception
 - Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data
- No annual review
- Follow up after 5 years only to determine whether study is still active
- Do not accept modifications for things that would not change the exemption determination except:
 - Change to PI or Advisor of Study
 - Change to COI status
 - Change of Funding Source
- No review of ICF (ORP Only)

One attendee asked if Penn State requires informed consent for exempt submissions. Sara responded that they do not require informed consent forms and they do not review them. Sara mentioned that Kathy’s site does require informed consent and ensures that they include the required elements of consent in the document. Judy Birk mentioned that the University of Michigan wrote the shortest possible informed consent template and made it available on their website. However, Michigan does not require that investigators submit an informed consent for exempt research, but advises them that if they are interested they can use the template and model it as they wish. Susan pointed out that it is important to note that informed consent is not required for exempt research per federal regulations.

Susan also asked Sara if they have information available on their website regarding the “toolkit” they used and what prompted University administration to make the transformation. Sara

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responded that the need for a new and user-friendly electronic system drove the transformation. Sara briefly described that a toolkit is a set of policies and procedures, informed consent templates, and checklists that have been tailored to fit the policies and practices of Penn State. The Penn State toolkit is housed within their electronic system but Sara said she would be happy to share if asked; they would just have to authenticate access for guests into their system.

Transformation of Penn State's HRPP and Embracing Flexibility (Kathleen Hay)

Organizational structural changes at Penn State were described. Kathy noted both offices organized existing staff into teams. Each team has a Team Leader (Senior Program Leader) and 2 IRB Analysts. Kathy stated that submissions are assigned to teams based on the Principal Investigator's last name and stay with that team for life of the study. Each team reviews all types of submissions; all team members conduct non-committee reviews, and are also regular/alternate IRB committee members. Each team is assigned to a committee that is responsible for the agenda, minutes and coordination of the meeting.

Kathy noted the Office of Research Protections created a new Assistant Director of HRPP position. The Assistant Director provides leadership to the IRB program and reports to the Director of Research Compliance, which was also a newly created position as of November 2014.

Kathy mentioned that the new electronic system was the biggest impact in the transformation of the HRPP program. Kathy noted that the HRPP Toolkit is integrated into the new electronic system. The new system has an electronic meeting management feature and allows for electronic submissions, e-workflow routing, and review of all types of submissions.

Kathy mentioned the benefits of the electronic system include:

- Clarity in review process
- Ability to directly comment in the system
- Ease of submitting new studies
- Elimination of the need for paper study files

Kathy pointed out that the biggest challenge is the conversion of ongoing studies. Kathy mentioned that conversion is done gradually and requires investigators to submit their study into the new electronic system at the time of continuing review or an amendment.

Kathy noted that since the e-system was implemented in 2013, Penn State has seen significant improvement in review metrics, including drops in review times for all types of review (exempt, expedited, full committee).

They also noted the following results:

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- Decreased use of office supplies, especially paper
- Decreased use of copiers
- Emptying of file cabinets and shelving – freed up space
- Improved clarity and transparency in review process
- Increased morale in IRB Offices
- Positive experiences with submission for researchers

Susan noted that at USC, legacy studies are still a problem. Susan asked Kathy if they hired any new staff. Kathy mentioned that they hired new staff for the management of the IT system.

UC BRAID IRB Reliance Service (UCRS) (Eric Mah)

Eric described a consortium of 5 of the UC Academic Medical Centers (UC BRAID IRB Reliance Service, between UCD, UCSF, UCI, UCLA, UCSD), formed in 2010, with the shared vision to integrate resources and talent across the UCs to accelerate review process. A previous Memorandum of Understanding (MOU) between the IRBs of the UC system written back in 2005/2006 wasn't being utilized as it wasn't clear who had responsibility for what.

Eric explained that the consortium decided to expand the use of the UC MOU to include full board, industry funded, multi-campus clinical research. Eric mentioned that the consortium took a risk- based approach, focusing on the studies were there was the highest risk to subjects (i.e. Phase I and Investigator Initiated). The goals were to increase efficiency, reduce duplicative IRB reviews, and increase earlier access to potential treatments for patients.

Eric noted the following benefits:

For researchers

- Decreased effort
- Decreased time to IRB approval
- Increased efficiency
- Single point of contact and increased customer service

For IRBs

- Eliminates redundant reviews
- Reduces burden on IRB and staff
- Allows IRBs to focus on safety, quality

For sponsors

- Increased accrual
- Decreased time to study activation across sites

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Eric described the UCRS as a concierge service which serves as the central coordination registry and facilitates IRB reciprocity approvals for industry sponsored/industry authored clinical trials.

In the UCRS, when the same protocol is being conducted at more than one campus, the first IRB to review a study serves as the IRB of record. UCRS then facilitates: approvals, post-approval events, standardized documentation, communication and monthly check-ins. Eric noted there is no lead PI in this model and there is independence between the UC PIs.

Rebecca Dahl (Children's Hospital Los Angeles) asked Eric for clarification on how a secondary UC site is made aware of the approval of the study. Eric responded that UCRS is responsible for informing and managing all documentation for the other relying UC sites (the relying IRB will not review the study, but cede completely), and gave the example that the UCRS is taking the commercial IRB model and applying it to academic medical centers.

Michelle Russell-Einhorn (Dana Farber Cancer Institute) mentioned that they have run into problems with the Food and Drug Administration regarding the lead Principal Investigators not having clinical privileges at the other sites, and the FDA requires a plan for when this occurs.

Eric noted that the UCRS was initially funded by the Office of the President for its first two years, and now all campuses support the service through their CTSA funding. Eric gave an update that the UCRS has reviewed 11 studies across the 5 campuses. The system allows for centralized facilitation with templates and standardized documents, check-ins and enhanced support and they have also developed a searchable tool for identifying reliance opportunities called UC TrialQuest.

Eric mentioned that the average approval time is 22.4 days and it takes approximately 1-15 days to add another site. Eric shared that the sample size is small (N=5) and they are learning as they go. However, PIs and research coordinators are thankful for the process which results in cleaner submissions and reduces delays. Susan Rose wondered how much the system costs in staffing time.

Oregon State University Initiatives (Lisa Leventhal)

Three initiatives OSU has undertaken:

- Student IRB
- Data Security Matrix
- In-Office Reviews

Student IRB

Lisa mentioned that the student IRB was an idea from Michael Oaks at the University of Minnesota. The student IRB only reviews student driven projects that are no greater than minimal risk. Lisa noted there is 15-30 minute continuing education at every meeting. The coordinators pick topics based on what members are struggling with and it allows them an

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opportunity to get together to talk about studies. There are also working groups which include IRB and non-IRB members. The working groups identify and address problems such as data security, curriculum, workflow, program evaluations, VO2 max testing, internet research, international research, research in public schools, research involving tribal populations, and establishing exempt submission and review guidance.

Data Security Matrix

Lisa mentioned that their researchers were having problems with what to tell the IRB as far as data encryption and the IRB didn't understand what they were being told. The IRB decided to harmonize with the OSU IT department regarding data security levels. The IRB provides examples regarding the type of data and based on the levels of risk to there are security requirements and recommendations on how best to protect the data.

Student Advising

OSU offers student advising and Lisa provided the following metrics on student advising:

- 6 drop-in hours per week
- 190 appointments per year
- 175 student-driven applications
- 460 student-driven actions per year

In-Office Reviews:

Lisa mentioned that OSU now does in office reviews for the following submissions/determinations:

- Exempt Initial Applications
- Exempt Project Revisions
- Stipulation Notices
- Minor Changes
- Research/Engagement Determinations

Lisa noted that the students must submit their applications the night before and then they meet with the IRB staff the following day and the study is reviewed in the office. Lisa shared that the "branding" of this process was a challenge. The process was branded as "Express Review" and the staff felt this description was demoralizing and minimized the importance of their job; conjuring images of drive thru and concierge services. Lisa said over time it went so well the staff learned to accept it, and now love it. Lisa shared that there were some bumps, but they were able to review most exempt determination in 30 minutes. Lisa shared the following metrics of determinations for in-office exempt reviews:

- 65% exempt determinations
- 23% tabled by PI

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- 10% tabled by Office
- 2% other determinations (NHSR or not engaged)

Lisa also shared the following metrics for determinations of in-office non-exempt determinations:

- 55% sent to reviewers
- 23% approved
- 16% tabled by PI
- 6% Other determinations (more time to review)

Susan asked Lisa if the IRB staff can review and approve exempt research. Lisa responded that most of her staff can, but some new staff are not permitted yet. Lisa mentioned that these initiatives would not be possible without the support of her staff. She mentioned that her staff are creative and approachable and thrive on change and chaos.

Lisa will share her student curriculum package with the coalition.

Closing of Flex Coalition Meeting

Susan thanked everyone for coming and asked the group to please share/send ideas. Susan closed by letting everyone know that notes from the meeting will be shared, there will be a conference call in about 2-3 months and the group will also plan to meet again at the AAHRPP conference in May 2015.