"Beyond Flexibility"

Flex Coalition Luncheon
AAHRPP Conference: April 24, 2014
(Notes by Kristin Craun, Director USC IRB)

Susan Rose, University of Southern California (USC) welcomed everyone and stated there will be a flex coalition lunch at every PRIM&R and AAHRPP conference and also a conference call in June 2014 to engage those who couldn't attend. This will keep the initiative moving forward. Susan provided two handouts:

1) Creative Flexibility: List of elements needed to implement a formal flex policy/List of optional flex initiatives afforded in the regulations
2) Flexibility Redefined: Creative Approaches to Human Subject Protections

Susan acknowledged and thanked Sarah Kiskaddon (AAHRPP) for enabling flex coalition meeting and supporting the initiative.

Susan noted the National Academy of Sciences' comments on the ANPRM are in sync with the mission of the flex coalition and have the same view as the coalition on flexibility.

Susan noted that at prior flex coalition meetings, a representative from OHRP was not included, per AAHRPP's request. Since one of the goals of the coalition is to let the federal government know what the flex coalition is doing and accomplishing as a statement of the community, federal representatives are welcome to attend.

Susan noted several institutions that would or could not "uncheck the box" wanted to be involved in flex efforts so there are now two communities: institutions with a checked box and those without. In response to this, the flex coalition is going to change course and language to move toward creativity/innovation and workflow processes that may or may not need an unchecked box.

Susan mentioned the handouts, which included a comprehensive list of all flex ideas thus far. She asked everyone to share any unique flex ideas from their home institution. Susan noted she understands not every institution can implement every flex initiative but hopes to at least bring the ideas to everyone's attention. Susan reminded everyone that there will be a conference call in June 2014 with speakers focusing on novel work flow ideas.

John Heldens, UCSF: Streamlining IRB Review of Chart Review Studies:

John introduced himself and mentioned that he is not speaking as a UCSF representative, but speaking for himself, as he has decided to leave the UCSF IRB and pursue other opportunities. John mentioned the UCSF had a CTSI pilot award to simplify retrospective chart review research. UCSF chose to go directly to novice researchers to acquire input and feedback to develop the application, intentionally bypassing IRB members in order to avoid creating an application with too much regulatory wording and background. The application was developed

based on the investigator feedback and piloted with real research studies. The types of questions in the application included the following:

- What do you hope to accomplish with this study?
- Describe the population being studied.
- List the study period (dates of records being used).
- List the variables collected from records.
- What is the approximate number of records you will review/analyze?

Free-text v. check boxes

UCSF followed up with a survey to twenty random PIs who had utilized the pilot application. John noted that UCSF chose to minimize the use of check boxes in the chart review application (excepting the sections identifying vulnerable populations and HIPAA issues), with the intention of trying to eliminate the back and forth between the PI and the IRB. UCSF also chose to have PIs sign a simple attestation of privacy practices that met UCSF's minimum security standards. Susan asked the group what their thoughts were on the use of check boxes versus free text.

Jeff Cooper (WIRB-Copernicus Group) recommended that IRBs never ask a PI a question in the IRB application that the IRB staff already know the answer to. John agreed completely, noting that the check boxes in their application are used to trigger branching of the application or smart-form checklists.

Another attendee noted that their institution moved in the opposite direction and created an IRB application similar to a Turbo Tax application, noting the IRB staff understands the checkboxes but the investigators do not. John asked the group if any of their institutions allow the IRB to correct the application.

Karen Hale (Ohio State University) responded that they do allow the IRB staff to correct the application and then notify the PI that the application has been changed and to contact the IRB if the changes are not accurate.

Judy Birk (University of Michigan) shared that their IRB staff have edit rights limited to correcting certain check boxes (and prohibiting staff from changing open text). Susan asked Judy how the PI sees where the changes were made. Judy responded that they are notified via email through the electronic system and a list of each section that was changed is shared with the PI.

UCSF Pilot -- Expedited Categor 5, Expedited Category 7 for Social-behavioral research

John mentioned that there is also a CTSI pilot award for expedited category 5 research, and that a pilot application for expedited category 7 for social-behavioral research is underway. Susan

asked John how we will find out the results. John mentioned that Lisa Denney (UCSF), lisa.denney@ucsf.edu, 415-514-2152 will be able to share what the future roll-outs look like. Jeff asked John how many chart review studies involved PIs using data from their own patients. John noted that he didn't think any of the studies used in the pilot project were CQI studies. John noted that UCSF adopted the University of Michigan's CQI policy.

Susan mentioned that a future topic of discussion will focus on quality assurance/improvement activities versus research. John closed by referencing the plenary talk by Dr. Briggs Morrison who stressed the importance of getting people involved. John mentioned that UCSF developed a culture where the IRB and research staff came together as one team with common goals.

Jeff Cooper, WIRB-Copernicus Group: Limiting IRB meeting discussion to the approval criteria

Jeff's talk covered limiting IRB meeting discussion to the approval criteria 45 CFR 46.111/21 CFR 56.111. Jeff gave scenarios on how IRB meeting discussion can quickly get off topic. For example, IRB members going on consistent tangents about power analysis, collecting social security numbers or IRB reporting requirements for payment that would never come up if those members were not present at a meeting. Jeff recommended that that IRB consider if these issues fall under the approval criteria, and try to avoid situations where members come to a meeting with their own criteria or pet peeves. Jeff mentioned that one way of streamlining IRB meetings is to organize them around the approval criteria. Jeff noted IRBs do two things:

- Discovery of the protocol – IRB is trying to get information about the protocol (i.e. risks, benefits, etc.)
- Ethical review –easy for scientists to get involved in the ethical review and easy for non-scientists to get lost.

Jeff recommends teaching IRBs the following:

1) Discovery – having both scientists and non-scientists do the ethical review. Jeff recommended the primary reviewer focusing on approval criteria, and leading a discussion about the surrounding issues. Jeff mentioned that this may take some time in the beginning of implementation, but over time, it will become quicker and easier.
2) Effective IRB leadership –The job of the IRB Chair is to keep personal opinions/pet peeves off the table, and redirect any biases that members bring up to discussion on the regulatory criteria. The IRB Chair needs to be consistent and set the same bar at every meeting, keeping all discussion limited to the regulatory criteria.

Jeff noted that it is hard in an IRB meeting when a personal suggestion is made, not affecting the approval criteria, but members feel pressured to go with the consensus. In situations like this, Jeff recommended that the Chair leads an open discussion about how that suggestion affects the regulatory criteria and not have a discussion about the suggestion itself. In order to

maintain the focus and consistency of IRB meetings, empower non-scientists, and keep the IRB away from mission creep, any suggestions that do not affect regulatory criteria should be kept off the table. One attendee asked Jeff for advice on consent forms: For example when an IRB member wants the consent to "ask" rather than "invite" the subject to participate. Jeff responded that the member should be asked what regulatory criteria is affected and does this difference in wording affect the consent process or documentation of consent. Jeff noted that he likes the idea of reviewer checklists and any revisions having to fit in one of the categories of approval. Jeff also mentioned that minutes document changes requested by the IRB and the basis for the change needs to relate back to the approval criteria. Susan asked Jeff if this process works. Jeff responded that it works in practice, but may take a while. Jeff noted that you need the support of the Institutional Official and effective leadership at IRB meetings. Jeff mentioned that most IRB members get it immediately, and the process avoids catering to the person who yells the most. Jeff recommended that when an IRB member feels their issue does affect the approval criteria, the IRB Chair should stop the meeting and take a vote on whether the members agree, and then drop the issue once the board has spoken. Susan mentioned that USC solved the problem by having one year term limits for IRB members and removing problematic members. Jeff concurred and noted that IRBs should have a systematic process involving yearly evaluations that would determine whether an IRB member is invited back. An attendee mentioned that their IRB is doing exactly what Jeff is recommending with noting the approval criteria, but their non-scientists feel like their comments/concerns are invalidated when they are asked about what regulatory criteria are being affected. Jeff responded that IRBs need good, supportive leadership to do this effectively, and that asking which regulatory criteria is affected should be used as a teachable moment that involves all IRB members. Jeff found it helpful to talk to the non-scientist members and describe how IRB decisions are analogous to buying a car, where every member brings different values to the discussion. Jeff noted that when some members believe one way and the rest believe another, there should be a split vote and those in the minority should not be able to vote to approve the protocol. Jeff mentioned it is a tyranny of consensus, but there are worst things that can go on at an IRB meeting. Susan noted that there are teachable moments everywhere.

David Clark, Medical College of Wisconsin: Models for ceded and collaborative IRB review when different E-Systems are involved.

David mentioned that the idea behind ceded/collaborative agreements is to build trust between groups of institutions so they will feel comfortable doing IRB reviews for one another. David mentioned that these collaborative agreements are best done regionally, when the institutions know one another and have opportunities for face-time. David also mentioned that their collaborations in Wisconsin are limited to institutions that are AAHRPP accredited (or in the process of seeking accreditation). David noted that as far as documentation, there is an IRB **master reliance agreement** deferring to one IRB for lead IRB review. David noted that more

collaborative research is being done through the CTSA model of consortium networks. David mentioned the following collaboration agreements that his institution is involved with:

- Wisconsin created an all-state IRB consortium agreement which has been nailed down.
- Under Wisconsin's CTSA, there are eight institutions with a model similar to that of Harvard Catalyst.
- There is a one city/one IRB model in which over 30 IRBs in the city of Milwaukee are engaged.
- There is the CTSI model, which is close to being finalized, that is regional and involves two or more IRBs all agreeing to a single IRB review.
- Greater Plains Consortium, which involves Nebraska, Kansas, and Texas schools with lots of business collaboration, is still negotiating who should do IRB review.

David mentioned it is important to have a screening mechanism to find out if a single IRB review is appropriate. There are then phone calls, emails and discussion about which IRB should take the lead. The lead IRB is typically chosen based on the institution that received the primary grant or the institution with the specific expertise to review the study. David noted that the institutions involved in the collaborative agreements try to take turns serving as the lead IRB. As part of their agreements, the lead IRB's forms/submission system is used and the lead IRB maintains all documents and has to agree to provide the other institutions access to all study records within 24 hours of a request. David mentioned that there are detailed procedures in the agreements for communicating critical details and sharing records. David noted that in the Wisconsin IRB Consortium (WIC), there are multiple local processes wired into IRB review and each IRB needs to decide what is managed locally. In this model, the lead IRB maintains all study records and then the local sites manage a shell application with minimal information, which allows for local context issues to be addressed. Susan asked David if he could talk about the local context worksheet they use in their system. David mentioned that each group of IRBs gets together, and if an institution does not want to accept or defer IRB review, they can always pull a study out. If an institution deems any study is sensitive or feels that it raises concerns for the institution locally, it can address those issues at the start. Susan asked David if the local context worksheets at each institution have similar data elements (e.g. HIPAA, Conflict of Interest [COI]). David responded that the local IRB can decide if the local or lead IRB will be responsible for reviewing HIPAA and COI. Emily Sheffer (Vanderbilt) asked if they have overlapping members in the consortium. David responded that yes they do. Emily also asked if there are separate applications for each group. David responded that there are no central electronic systems, or central documents on a central web location. All IRB records are the property of the lead/reviewing IRB and the IRB application is submitted within the lead IRB's system, but all involved institutions can be provided access to those records within 24 hours upon request. Susan asked David if it was instant access and in what format? David responded that all records are provided via flash drive or paper in a readable format. Susan asked how do

you figure out which site is doing what? David responded that if it is a single protocol with the same procedures being done at all five sites, it is pretty straight forward. David mentioned that it becomes more difficult when there are different responsibilities at each site. There is then a discussion on determining which sites are engaged, what activities are being done where, and who should serve as the lead IRB. Susan mentioned that in collaboration agreements with USC, the lead IRB is typically where the highest risk to subjects will occur.

Ohio State University – "the HUB"

Karen Hale (Ohio State University) mentioned that Ohio has a state-wide IRB Authorization agreement for institutions in Ohio with a CTSA. This includes a central electronic platform (the "HUB") that the Cleveland Institution developed off of the Click/Huron system. The lead IRB is chosen based on the PI on the study. All approval documents are shared and the "HUB" is used to communicate with everyone. The agreement can be used by any of the institutions as a single agreement (one institution reviews for another institution) or can be used by all (one IRB reviews for all institutions). Karen mentioned that there is talk by the Ohio Governor to expand the initiative particularly for clinical research (although she noted that institutions doing clinical research are already using independent IRBs so she is unsure of the utility for the expansion of clinical research within the consortium). Karen also pointed out that there is a limitation, which is that the agreement excludes smaller institutions that may not be able to share IRB review. Susan asked Karen if the Governor's office paid for the HUB. Karen noted that there was no direct support yet, but the Cleveland Institution did get money for the development of the electronic platform.

Audit of Ceded Studies

Susan asked if anyone started on audits or monitoring and if so, who is doing them. David noted that the agreements should spell out who has the audit responsibility for ceded studies. David noted they have a variety of travel budget ideas for audits when deferring to another IRB review; the QA/QI team has an audit algorithm every year. Susan mentioned that QA/QI process/staffing/travel is expensive and has to be supported. Susan asked the group how many institutions have dedicated QA/QI teams. Approximately 10-12 institutions raised their hands.

Eifaang Li, Cedars-Sinai Medical Center (CSMC): IRBs working with Research Coordinators: Education, Support

Susan mentioned that USC has gotten involved with Research Coordinators job descriptions and financial support for certification and training. Susan introduced Eifaang Li and noted that Cedars Sinai Medical Center (CSMC) is two years ahead of USC on this process. Susan asked Eifaang to share what Cedars has done to legitimize research coordinator positions. Eifaang began with providing the number of studies/researchers at Cedars in 2013: 400 new studies,

800 continuing reviews, 200 unique PIs and approximately 1500 certified study personnel. Eifaang mentioned that when they were accredited in 2004, part of the CQI efforts were to cut down on IRB review times. Eifaang shared with Cedars' leadership that part of the problem was the IRB submissions were poor and incomplete, and that they could benefit from training research personnel. Eifaang shared that one Vice President took her input seriously and launched the "Research Personnel Remapping Initiative" in 2011. Eifaang detailed that Human Resources held a focus group with research coordinators, study coordinators, and investigators regarding job requirements and minimal qualifications, in order to review all the job descriptions of research positions for job responsibilities. The one-year investigation concluded that CSMC had grown their HRPP very quickly, but were not providing adequate support to their researchers, and therefore were not seeing equivalent growth among research coordinators. The Initiative came up with five categories of research personnel:

- Clinical Research Coordinator
- Clinical Research Budget Coordinator
- Clinical Research Specialist
- Clinical Research Associate
- Clinical Research Data Specialist

The initiative was implemented in 2012. Phase I involved updating research coordinator support staff job descriptions and Phase II addressed compensation. Eifaang mentioned that CSMC has seen some improvements and are currently in the process of implementing five new initiatives:

1) HRPP reaches out to any new research groups before they come to CSMC to introduce the staff and provide guidance on IRB submissions.
2) CSMC created an "IRB101" workshop geared towards new study staff that aims to help study personnel understand the IRB process/policies.
3) CSMC instituted an online IRB chat room as part of the on-line submission system, which is staffed from 9am-5pm and allows any research coordinator to log in and receive responses to their questions immediately. The program automatically develops transcripts, which allows the IRB to trend for problems or FAQs.
4) CSMC has partnered with various departments (Cancer, Pathology and Surgery) to develop a Protocol Review Outreach Program (PROP), which targets high volume submitters to identify common issues and works with them to create template responses. These studies are then monitored for the number of rounds of pre-review correspondence. Ideally, there is no pre-review correspondence, but the goal is to reduce the number of rounds of pre-review correspondence and the time to approval.
5) The Research Operations Group manages an institution-wide New Employee Orientation, a mandatory, full-day orientation for all new personnel.

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Susan asked Eifaang if she could share the new orientation syllabus. Eifaang mentioned that it is not specific to human subjects, but that it covers animal research, basic research, human subjects and more. An attendee asked Eifaang what she did so we don't have to reinvent the wheel. Eifaang responded that she did not give up. Susan noted that there is a difference between USC and Cedars; USC translates every issue into money and CSMC supports issues with money and adequate staff. An attendee mentioned to get Risk Management involved and scare them; they will get on your side to help. Susan also mentioned that USC is building a nurse coordinator into their job descriptions/qualifications, although the salary discrepancy is a problem.

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 June 2014, and the group will also plan to meet again at the PRIM&R conference in December 2014.