Flexibility Coalition Call Notes 9/17/15

1. Next Flex Meeting, quick note about NPRM discussed by Susan L. Rose

- The Flex Coalitions may have influenced some of the NPRM changes. The NPRM will be discussed at the next Flex lunch during the PRIMR conference.
- RSVP to the Flex Coalition lunch on 11/13 at PRIMR's AER Conference in Boston https://oprs.wufoo.com/forms/flex-coalition-lunch/
- Future Flex Coalition Calls will be conducted via webinar
- All folks are encouraged to share their innovative ideas or useful resources with the group

2. IRBrely discussed by Sabune Winkler and Nichelle Cobb

IRBrely is a national IRB reliance system built in response to fatigue with plethora of IRB-agreements. IRBrely includes a standardized reliance agreement, SOPs and, an informatics tool not confined to a particular area of research or geographic region. It can be used for small projects or large scale studies; including centrals IRBs, phase zero to post-trial marketing. IRBrely is even open to FWA-only institutions that do not have their own IRB.
IRBrely was funded in 2014, by one of 3 CTSA grants, the others being the National EMR "ACT" and the national GCP project. The agreement began among several New England institutions like Harvard and has extended invitations to USC on the west coast, IRBshare out of Vanderbilt, the Ohio CTSI collaborative, UTexas, and University of New Mexico.
IRBrely was designed in a way that would not need to be signed each time it is used. It is not a central IRB but can be used for central IRB studies. It is open to non-CTSA sites. It is not limited to AAHRPP accredited sites. It is not set in stone; it was designed to be adaptive.
The NIH announcement and NPRM have shown that single-IRB review will be widely expected. IRBrely provides sites with an opportunity to try IRB reliance before it becomes mandatory to network with other institutions, and the ability to weigh-in on the project.
A new updated version of the IRBrely agreement will be distributed soon.

To join or learn more about IRBrely contact the project regulator co-leads:

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or

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A commenter noted that projects using IRB reliance are often delayed by ancillary approvals and data use agreements. IRBrely is considering a platform for sites to outline the local issues (such as state laws) that affect the use of IRB reliance arrangements.
Jeff Cooper has a list of issues that should be addressed when a site uses an IRB reliance agreement.

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3. National EMR "ACT" discussed by Vincent D'Itri, ACT Project Manager

Accrual to clinical trials (ACT) is an NCATs funded network that currently includes 22 CTSA sites that have linked their electronic medical records using open-source software (I2B2 and Shrine) to identify patient cohorts for feasibility studies with the goal of being able to enroll those patients later on. One of the goals of ACT is to reach out to patients who would not otherwise know about clinical trials for which they may be eligible.
The coordinating institutions are Harvard, Pitt, UC San Diego, and University of Texas Southwestern. The system will enable investigators to submit a query and obtain de-identified counts of patients at participating sites. The second stage of the project would be engaging the patient to participate in a trial. This would be permitted based on the patients consent associated with the medical record.

For questions about ACT, contact Vincent D'Itri, ACT Project Manager vditri@chartis.com

4. Research Data Security discussed by Katherine Lerner

Many IRBs do not have data security expertise nor the ability to keep up with changes in IT/ Data security. Some IRBS are adding a member with IT expertise. University of Chicago has cultivated a relationship with the institutions data security experts to act as consultants when the IRB is concerned with adequacy of data security in a protocol. Concern is typically focused on studies with data that is sensitive and identifiable. Investigators travel internationally and run the risk of losing a device or having it seized by a foreign government.

Anonymity is easily undermined using modern software and consent documents should reflect the possibility of re-identification. At University of Chicago, the IRB typically has concerns regarding data security if the data is being collected overseas and/or the issues are sensitive such as prison settings, drug use and other illegal activities. Some countries like China have anti-encryption laws therefore researchers must tread very carefully and consult with university IT and legal departments before starting research in those conditions.

Its not enough to tell investigators they need to meet data security standards. They need to be taught step-by-step how to implement data security on their devices. Every institution needs to consider the role of the IRB in verifying that appropriate data security measures have been implemented by researchers. The IRB may be made a nexus point for researchers to be put in touch with the IT experts.

The University of Michigan has a helpful data security checklist at:
http://orsp.umich.edu/sites/default/files/resource-download/checklist_datamanagementsecurity.pdf