Flex Coalition Luncheon
PRIM&R Conference: Boston, MA
November 13, 2015

Welcome

Susan Rose,
Office for the Protection of Research Subjects
University of Southern California (USC)

Introductions:

- Speakers:
  - Jeff Cooper – Does the NPRM Coopt All Flexibilities?
  - Michelle Feige– AAHRPP 2.0
  - Emily Sheffer– Update on IRBChoice

- Plans for the next Flex Coalition Conference Call and an invitation to participate on the call will be forthcoming.

Updates:

- Comments from Council on Governmental Relations (COGR) mention Flex Coalition's positive influence on NPRM.
- COGR advocates removing continuing review of minimal risk research studies.
- COGR recommends NPRM follow the Flex Coalition approach to cutting down continuing review, thus creating less work for IRB Staff.
- Flex Coalition has attracted OHRP's attention, which is good, until they clamp down on what Flex Coalition has been doing. NPRM is moving in wrong direction. Flexibilities (for which we have excellent data) should be extended from non-federally funded sector into federally funded sector.
- Future Flex Coalition discussion will address:
  - Flexing more studies under Subparts B, C,D
  - Taking engagement off the table for non-federally funded collaborations between institutions.

"Does the NPRM Coopt All Flexibilities?"

Jeffrey A. Cooper
Vice President for Process and Strategic Improvement
WIRB-Copernicus Group

- NPRM does not coopt all flexibilities.
- Jeff Cooper conducted an exercise on coming into compliance with the NPRM changes; specifically identified necessary changes to minimum 25 of 97 documents (policies, SOPs, checklist, worksheets, and forms); with major changes to 6:
  - HRP-300 CHECKLIST: Waiver of Consent HHS
  - HRP-303 CHECKLIST: Waiver of Documentation of Consent
  - HRP-421 WORKSHEET: Definition of Human Research

  - HRP-423 WORKSHEET: Exclusion and Exemption
  - HRP-400 WORKSHEET: Criteria for Approval
  - HRP-415 WORKSHEET: Waiver of Consent Recruitment

- Many IRBs apply the regs incorrectly. The more complex regulations introduced by the NPRM is partly a response to IRBs that set unnecessary hurdles for minimal risk research such as over interpretation of "research", "human subject" or "minimal risk", and insufficient use of exemptions or expedited procedures.

Benefits and drawbacks of the NPRM

Exclusions

The NPRM exclusions are defined by intent, which is helpful for those that over-interpret research.

- Activities excluded because they are deemed not to be research:
  - Oral history, journalism, biography, and history
  - Program monitoring
  - Quality improvement
  - Public health
  - Criminal justice
  - Surveillance for national security
- Activities excluded because they are considered to be low-risk human subjects research:
  - Current exempt 2 (plus Subpart D restriction)
  - Current exempt 4 not involving bio-specimens
- Low risk exclusions:
  - Research that falls into current exempt 2 or 4 is low risk
  - Exempt 2 cannot include interventions
  - Exempt 2 involves "no influence by investigators" (meaning is unclear)

Concerns related to low risk exclusions:

- Current exempt 2, in regards to surveys and interview procedures:
  - Interventions are defined as "physical procedures by which data are gathered and manipulations of the subject or the subject's environment."
  - Jeff's personally defines a survey or interview as "limited to communication, whether by writing or internet." (Per Jeff, surveys are communications, not interventions.)
- New exclusion for interviews, surveys and observations of public behavior that are "uninfluenced by the investigators" (meaning is unclear).
- The following new exclusion for bio-specimens is too vague, it reads:

"The following activities are excluded because they are considered to be low-risk human subjects research activities that do not meaningfully diminish subject autonomy: The research use of a non-identified bio-specimen designed only to generate information about an individual that already is known."

- NPRM eliminates flexibility for a few large categories of research. The NPRM states that all clinical trials* not subject to FDA are subject to OHRP, regardless of support.
  * Presume new NIH definition of clinical trials applies.

- New process for exemption/exclusion determinations will be more complex/time consuming than currently exists.

Advantages of NPRM:

- Any new federal guidance shall be issued only after consultation with other federal departments and agencies that have adopted Common Rule.
- More research exempt/excluded from IRB review
- Some exemptions reflect flex coalition innovations
  - Old exempt 4 applied to prospective record review
- Privacy board review of records protected by HIPAA will offload many chart reviews from further review
- Promised exemption tool could greatly reduce workload
  - Will OHRP take responsibility?
  - Will OHRP defer to institution?
  - Misinformed investigators might complete paperwork incorrectly. There is too much responsibility for PI. Most investigators lack experience to determine exclusions, or reliably identify FDA research.
- Exemption categories for secondary use of specimens, biobank creation and biobank
- "Broad consent" sanctioned by OHRP for unspecified future research but required template not yet provided.

New concepts in NPRM:

- For excluded and exempt research investigators are responsible for acting ethically without IRB oversight.
  - Will AAHRPP buy in? Will sites buy in?
  - Expanded definition of human subject adds bio-specimens
    - Obtaining, Using, Studying, Analyzing
    - Documentation of consent is required

Reminder: make comments that push the deal in the direction we want to go!

Flex Coalition Luncheon
PRIM&R Conference: Boston, MA
November 13, 2015

New burdens on biospecimen research:

- Broad consent required for use of tissues (similar to notice of privacy practices)
- Tracking who said no
- Implementing new data security practices (not yet provided) although this should not be a problem for HIPAA compliant institutions

Deidentified biospecimen research is done all the time without consent per OHRP data specimen guidance. Most people see research as good and want to help, so we are really placating the <1%.

Elimination of continuing reviews for certain research

- According to Jeff, this includes research eligible for expedited review, research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data, and tissue specimen research.
- Annual confirmation is still required. According to NPRM, the IRB must receive confirmation on an annual basis that the research is still ongoing and that no changes have been made to the research that would require the IRB to conduct continuing review.
    - The requirement should be removed or altered.
    - What if a PI does not submit annual confirmation?

"Expanded" waiver of consent

Is permitted for: "obtaining identifiable private information without individuals' informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects of research."

"Expanded" waiver of written documentation is unnecessary and redundant because documentation is not required under current regulation's recruitment provisions and IRBs are already doing this.

New data security requirements

More information is needed about the new data security requirements.
The new requirements could simplify review of confidentiality issues and limit IRB variability or make it more cumbersome.

- Will the requirements be appropriate for all research?
- Will the burden be on the institution or the IRB to enforce compliance?

Flex Coalition Luncheon
PRIM&R Conference: Boston, MA
November 13, 2015

AAHRPP 2.0

Michelle Feige, Executive Vice-President, AAHRPP

- AAHRPP supports and advocates flexibility among accredited organizations.
- No changes will be made to AAHRPP standards until (or if) there is a final rule.
- Any input from the flexibility members is appreciated, especially with suggestions on how to approach the implementation of these changes.
- For members that are accredited, feedback satisfaction surveys will be released, with the hopes to reduce some of the accreditation burdens that are experienced.
- All in all, AAHRPP hopes to relieve some of the burden, support one another through this process and become more consistent.
- AAHRPP will still allow organizations to not apply federal regulations to unfunded research, but will require equivalent protections for activities that are not subject to regulations.

Update on IRBChoice (formerly IRBshare)

Emily Sheffer, MPA
IRBshare Project Manager
Vanderbilt Institute for Clinical and Translational Research (VICTR)

The IRBchoice Master Agreement has been expanded. Institutions can now choose a shared or ceded model and use it on a study by study basis. The Master Agreement was released 11/12/15 and is open to all institutions with an FWA. More information is available on their website: https://www.irbchoice.org/p/

Meeting adjourned

- **Lunch meeting notes to be provided**
- **Flex Coalition phone call to be announced**
- **Flex Lunch at AAHRPP conference 2016**