Research Policy Committee Minutes
Tuesday, January 25, 2019
2:30-4pm
Topic: **IRB-HSBS and IRBMed**
Fleming 4006
Chaired by Francine Dolins

Members present: Jake Carlson, Irene St. Charles, Yi-Su Chen, William Close, Mimi Dalaly, Francine Dolins, Kate Eaton, Nick Harris, Tim Guetterman, Albert Liang, Jinghyun (Jessie) Lee Nocona Sanders, Adam Van Deusen
Absent: Niccolo Biltramo, Marisa Conte, Austin Glass

I. Guest Speakers:

[Please also see powerpoint slides provided by Cindy and Judy, and uploaded to shared RPC MBox folder.]

A. **Ms. Judith Birk, Director,** IRBMed

1. Campus IRB - Significant changes:

Consolidated UM-AA IRB with UM-D.

2. The University of Michigan currently has thousands of active studies that are reviewed by staff in IRB-Med and IRB-HSBS.

IRB Med has 5098 (78%) staff = 30
IRB-HSBS 1283 (20%) Staff = 9
UM-D and UM-F about 60 studies in total.

3. Policy and regulation changes for human research

i. OHRP Regulations
Common Rule – Jan 21 2019
Single IRB (sIRB) – Jan 20, 2019

ii. NIH Policy
Single IRB (sIRB) – Jan 25 2018
NIH Certificate of Confidentiality – Oct 1, 2017

Requirement for federally multiple-collaborative sites with sponsored research will be reviewed as one unit; became effective recently. Presents challenges for IRBs.

4. Common Rule Key Changes - 2019

- Eliminates continuing review for most minimal risk research
- Expands exemption categories and changes the review processes
- Reframes informed consent info and adds required elements

5. IRB "Pilot Project"

- Last June, the IRBs released the revised eResearch application and implemented some of the new Common Rule burden-reducing provisions as a pilot for non-federally-sponsored projects
- Key elements of the pilot
    - Elimination of continuing review for qualifying studies
    - Implementation of new exemption categories
    - Testing of exempt studies reviews

6. Changes to Continuing Review

- Continuing review is eliminated for studies reviewed via expedited review
    - The IRB can require continuing review for a study if there is cause
- Also eliminated for more than minimal risk projects once subject interaction is completed
- Amendments and Adverse (ORIOS) – process changed

7. Changes to Exemption Interaction/Intervention Exemptions

New Processes

- System-generation exempt determination process- researchers can generate own exempt status
- Submit to IRB –
    - Exemption with "limited IRB Review" (new regulatory category]
        - For projects collecting sensitive, identifiable data, the IRB will review privacy/confidentiality [review by an IRB member]
    - Standard exempt review by IRB staff member for certain types of exemptions or by investigator choice

8. New Application Type – Secondary Analysis of Data or Biospecimens

- All data/specimen-only projects now use one application type (rather than requiring the investigator to select the correct application type up-front)
- Questions designed to route application to the correct IRB determination (not regulated, exempt, comprehensive IRB review)
- Includes expanded exemption 4

9. Informed Consent Changes

- Provide a "concise and focused presentation of key information" up front (an executive summary)
    - Key info

        - Voluntary participation
        - Summary of research procedures
        - Risks
        - Benefits
    - IRBMed added key info sections to its template
    - IRB-HSHS consents do not require adjustment for most research
        - Consents are shorter and it would be redundant to include the key info.

10. New Informed Consent Elements

- New required consent element
    - De-identified data or biospecimens may be shared for future research (or not)
- New Consent elements (if applicable)
    - Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
        - IRBMed will require this language in its standard consent template and other relevant consent templates
    - Clinically relevant results will be returned (or not)
    - Research will involve whole genome sequencing

11. Other Consent-Related Changes

- New required determination for waiver of informed consent (for secondary use of data)
    - Must validate why use of identified data is necessary to the research
    - Waiver is no longer required for screening of subjects but HIPAA requirements still apply (medical record screening)
- → For federally-sponsored clinical trials, a copy of the consent form must be posted on a "Federal Web site that will be established as a repository for such informed consent forms."

12. NIH Certificates of Confidentiality

- NIH Policy
    - Certificates are automatically issued as part of terms and conditions of NIH award
    - Protects "identifiable, sensitive" information from compelled disclosure
    - NIH's broad definition means that all identifiable human subject's data biospecimens, individual human genomic data or other research data are covered
- NIH will continue to issue CoCs by application for other health-related research. Protects data from "compel" disclosure.

ClinicalTrials.gov Registration

13. Registration is required:

- When conducting an NIH funded Clinical Trial
- When conducting an Applicable Clinical Trial (ACT) per FDAAA
    - For example, clinical trials involving drugs and devices
- Due to other contractual obligations

- For publication

14. Other NIH Clinical Trials and Procedures

Controversy: applying clinical trial definition to fundamental research/basic science
Should fundamental research projects defined as a clinical trial by NIH be required to register and report results on ClinicalTrials.gov?

- Definition of fundamental research
- Key consideration – is project really "clinical"?

15. IRBMed Structure (30 FTEs)

- Staffing and leadership
- Number of reporting lines
- IRB Med office
- Regulatory Office and Affairs
- IRBMed chairs
- IRBMed admin

16. IRBMed is heavily audited by federal government.

Every 4 years inspected by FDA.
IRBMed and IRBHSHS continually audited by Office of Research Compliance Review – ongoing quality assurance reviews.

17. IRBMed of approved studies: breakdown

Approximately 67% are Clinical

18. Single IRB Review (sIRB) in Multi-Site Research:

Maintain own ancillary committee reviews and local oversight
RISK:

- Some PIs are not prepared to be the lead site in multi-site research
- Institution must become comfortable with risk if IRBMed makes an error during review
- Risk to institution of a participating site experiencing a negative event related to the protocol

19. eResearch

i. Regulatory Oversight

ii. Budget & Resources

iii. What are the benefits and opportunities to refer studies to Commercial IRBs?

Select best IRB for multi-site review.

iv. Costs can be very high; NIH will not always cover all costs of IRB oversight.

v. Adjust staffing levels/expertise to meet TAT expectations
vi. Redesign workflows to place an appropriate emphasis on expedited reviews
vii. Identify additional faculty reviewers
viii. Develop sIRB program
- Define/refine scope (balance)
- Staffing

B. **Ms. Cynthia Shindledecker,** Director, Health Sciences & Behavioral Sciences IRB

1. UM-Dearborn is working as a pilot with goals to:
- Eliminate administrative overhead operating a separate IRB
- Capitalize on existing strong relationship between UM-D and IRB-HSBS teams and similarities between research portfolios
- Harmonize regulatory compliance across two campuses
- IRB application and review process will be virtually unchanged for UM-D Faculty

2. IRB-HSBS top depts it works with:

School of public health
Psychology
ISR
School of Information
School of Nursing
UMTRI

3. Federal Sponsorship

Approx. 25% 336 studies federally funded

IRB – HSBS under UMOR – Lois Brako Asst VP

IRB – HSBS: 9 FTEs

4. Turnaround times: much less for exempt and expedited but can be up to 8 weeks or longer for full review.

5. Challenges – Administrative/Regulatory
- Preparing for expansion of sIRB requirements to all federally funded research
- Continuing to update policies and procedures as feral guidance is provided on Common Rule
- Ensuring investigators/IRB members/IRB staff are mindful of special federal requirements that apply to only a small number of HSBS projects

- Evaluating research

6. Ethical and regulatory issues associated with
- Social media
- Big data
- Autonomous vehicles
- Clinical trials in real life settings
- Etc.

7. Opportunities
- Increase number of self-exempt studies

C. Question & Answers:

1). Can we as a committee write a letter to suggest that more funding go to staff in both IRBs to assist and make the reviews faster and more efficient to support faculty research.
We can, as a committee, write a letter about staffing in IRBs and also in the Library (e.g., Deep Blue) to better support these initiatives that supports and enhances research.

2). Sharing Data – focus different these days to allow data sharing rather than destroying data after a specified time.

3). Some information that can be collected is not regulated by the regulators (e.g., when a person is more of an informant than a participant).

II. Meeting adjourned at 4pm.