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
  o IRBMed added key info sections to its template
  o 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
     o De-identified data or biospecimens may be shared for future research (or not)
   - New Consent elements (if applicable)
     o 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
     o Clinically relevant results will be returned (or not)
     o Research will involve whole genome sequencing

11. Other Consent-Related Changes
   - New required determination for waiver of informed consent (for secondary use of data)
     o Must validate why use of identified data is necessary to the research
     o 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
     o Certificates are automatically issued as part of terms and conditions of NIH award
     o Protects “identifiable, sensitive” information from compelled disclosure
     o 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
     o For example, clinical trials involving drugs and devices
   - Due to other contractual obligations
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 federal 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.