
IRB MEETING OCTOBER 28, 2019 AGENDA

- 1) Welcome & Introductions - Record attendance (3 min) – Dr. Dana Leighton, Dr. Joy Goldstein, Dr. Patricia Humphrey, Dr. Jing Chen, Sheila Moore.
- 2) Review & Approval of prior meeting minutes (1 min) –N/A – Angela will review older minutes and prepare to place on website.
- 3) Recruitment (5 min)
 - a) Should we recruit someone from Education? Yes
 - b) Should we recruit alternates: 2 affiliated alternates? 1 unaffiliated alternate? Dr. Leighton is seeking a member of the clergy as a unaffiliated member, as a resource for ethical purposes.
 - c) Should we recruit demographically diverse members?: African-American; Hispanic; Non-cisgender; Non-heterosexual; what else? Dr. Leighton is going to see about obtaining demographics for IRB members from HR and solicit information moving forward with new members.
- 4) Training (40 min)
 - a) HRPP structure
 - b) Overview of the TAMUT review process
 - c) SOPs
 - d) Revised Common Rule changes
 - e) CITI training deadline Jan 15, 2020 – Dr. Leighton encouraged IRB members to complete training over Christmas break.
 - f) IRB Review run-through – Exempt or Expedited? Use case studies from Boot Camp – Dr. Leighton suggested using the SOPs as a checklist, using section 22 in the SOPs.
- 5) BREAK at 50 min (5 min) – no break
- 6) Tasks to delegate to subcommittees/members (30 min)
 - a) Need a “job description” for IRB Members – expectations, workload, time commitment, etc. Put it in the SOPs and on the web site. – Dr. Leighton will take care of this.
 - b) Review of outside research that uses TAMUT affiliated persons as participants? Assign someone to review other IRB and OHRP guidance. Also maybe check with Bruce Whitney. – Dr. Leighton will take care of this.
 - c) IRB Application changes
 - i) Export Control: Are any personnel members of export controlled or working for entities in export controlled countries? Yes, no, if so list the individuals and entities and countries. – Dr. Leighton will take care of this.
 - d) Forms needed
 - i) Progress report form (as specified in SOPs)
 - ii) Informed consent template(s) – Dr. Humphrey, Dr. Chen, and Sheila Moore will work on this as well as a recruitment flyer. A website to reference is <https://irb.unm.edu/library>.
 - e) SOP Changes – will discuss via email.
 - Group 1**
 - i) Change signatories for SOP changes to not list the President as IO - That is usually delegated to a VP. – Preamble, **Process for Revising and Approving SOPs**
 - ii) Add section 1.7 Dept of Energy Requirements
 - iii) 2.2 last sentence of paragraph 2 should say "No research with human subjects conducted by the university or its employees or agents shall take place without the prior approval of the IRB."
 - iv) 3.3 IAA – SOP section 3.3 refers to Appendix L – This should be the new IAA form I created.
 - Group 2**

- v) Establish vice-chair position to fill in for chair in COI or absence – 4.0
- vi) Establish Secretary position to document full meetings – 4.0

Group 3

- vii) Definitions of research and human subjects need to be updated consistent with Revised CR – 8.0
- viii) 16.1 mentions a form at the OGSR website. No such form exists – should we create one or just remove that wording?
- ix) Definition of “others” in the context of adverse or unanticipated problems (SOP 19)
- x) Needs specification of the duration of training certificate validity – 22.12

Group 4

- xi) SOP 24.3 – Is data from behavioral research considered “of value?”
- xii) Section 27.2 refers to a university policy for minimum necessary standard for PHI. I don't think that exists. Remove or find the policy.
- xiii) Need clarification on what constitutes a Case Study and when it is not subject to review. 28.18 provides some, but I think it should apply more broadly than just reports of treatment.
- xiv) Section 29.2 – last point about complaints... check the SOP section numbers referred to. They are wrong.

Group 5 -- Multiple

- xv) Export Control Issues (research projects, collaborators, payments) – Multiple sections
- xvi) Include statement that faculty mentors should be included in all correspondence between IRB and PIs – 2.3 & 28.2

Group 6 -- Throughout

- xvii) Eliminate references to the Dean of Grad Studies and Research. OR - leave it and indicate that in lieu of that person, the VPAA handles it - not sure. - Throughout
- xviii) There have been some changes to the subsections of the federal regulations that need to be reflected in the manual. For example, sections that used to exist do not. See Expedited Category 5 that references 46.101(b)(4) - the new (2018) regs have (b) as “Reserved” - Throughout
- f) Old business (1 min) – N/A
- g) New business (1 min) – N/A
- h) Adjournment – 2:30 p.m.