Institutional Review Board

Minutes

December 6, 2019

Present: Renee Houston, Hajung Lee, Mark Reinitz, Brad Richards, Alexa Tullis, Andreas Udbye, Ann Wilson

Minutes: The minutes from the meeting of 11-15-2019 were approved.

Protocols reviewed and approved since 11-15-2019

1920-027
1920-028
1920-029
1920-030
1920-032
1920-034
1920-036
1920-037
1920-038
1920-040

Addition of a standing charge to the IRB: Reinitz submitted the following proposed text for an additional self-charge *"To monitor requirements of relevant Federal programs, such as the Federal wide Assurance program and to ensure that IRB policies and procedures are in compliance and remain current."* to Sarah Moore, Faculty Senate Liaison to the IRB. Given that this is a new standing charge, it must be vetted by the entire faculty senate.
ACTION: Reinitz will add/imbed this language into the current charges and forward to Sarah Moore who will then navigate the vetting process through the Faculty Senate.

Presentation of Student Research Projects in a Public Forum: Reinitz sought feedback from Lisa Ferrari regarding the amount of latitude given to student research projects that are later presented in a public forum. Ferrari's recommendation was that having students gain approval for such class projects will give them the option for future presentation/dissemination. The board members present concurred with this.
ACTION: Reinitz will reply to Andrew Gardner who was approached by a student researcher with a question about this and have Gardner let the student know what was decided.

MACH Form to Submit Protocols: The MACH form to submit protocols is now on the website.
ACTION: Nakamura had agreed previously to draft language for notification of expiration of protocol approvals and will submit that to the IRB for approval. Tullis will upload a "test" protocol to make sure that the system is working properly and will inform Jimmy McMichael of any problems.

Progress on Federal Wide Assurance (FWA) Application: Houston reported that the FWA application has been submitted to the Department of Health and Human Services. The agency will send an auto reply once the application is approved and when approved, the approval will be good for five years. In reviewing materials to assure compliance with FWA guidelines, Houston noted that the guiding principles pertaining to research with human subjects is currently included in the IRB Handbook but she wondered

if it would be useful to add the principles to the website so that they are move evident. The board members present concurred.

CITI Training for Faculty: Houston reported that she had received verification from CITI Support Services that a course consisting of the requisite training modules for Faculty Researchers and Faculty Advisors of Student Research had been added to the CITI website. The next step is to notify the faculty that this requirement will be effective January 21, 2020.
ACTIONS: 1) Tullis will trial accessing the training modules for the faculty course to ensure it is operating correctly. 2) Since the requirement for faculty researchers/student research advisors originated with a charge from the Faculty Senate, Reinitz will send draft language of an email intended for faculty to Sarah Moore, Senate Liaison to the IRB, for review. If she concurs with the language, the email will be sent to Jimmy McMichael for distribution to the faculty. 3) Reinitz will send the instructions for accessing the training course (see Appendix I) to Jimmy McMichael so that it can be added to the webpage.

The meeting was adjourned at 4:55 pm.

Respectfully submitted,

Ann Wilson

APPENDIX I

Attention Faculty Researchers and Faculty Advisors of Student Research!

Beginning **January 21, 2020**, all IRB protocols must be submitted with a certificate of completion from the **CITI program**, indicating that the Faculty Advisor or Faculty Researcher(s) have passed the Puget Sound CITI course for Faculty. Note that student researchers are still required to complete their own CITI training.

Please read all instructions thoroughly before proceeding with the training.

Here's what you do:

1. Go to citiprogram.org and set up an account for yourself. Detailed instructions on how to set up your account appropriately are found here .

2. Once you have set up your account, complete the five REQUIRED modules under the "**Faculty**" course:
   - Belmont Report and CITI Course Introduction (ID 1127)
   - Informed Consent (ID 504)
   - Cultural Competence in Research (ID 15166)
   - Assessing Risk (ID 503)
   - Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID 14928)

   If the study involves any of the specific types of research listed below, Faculty Advisors of Student Research or Faculty Researchers must also complete the relevant module(s):
   - Internet-based research (ID 510)
   - International Research (ID 509)
   - Research with Prisoners (ID 506)
   - Research with Children (ID 507)
   - Research in Public Elementary and Secondary Schools (ID 508)
   - Research Involving Pregnant Women, Fetuses, and Neonates (ID 10)

   Course modules will become available only after you click the link **Complete the Integrity Assurance Statement before beginning the course** and complete the statement.

   Take the quiz at the end of the course.

3. Download your certificate of completion for the course and attach it to the IRB protocol before submitting. Your certificate is valid for three years from the date of completion.

Questions or problems? Please contact Jimmy McMichael at irb@pugetsound.edu or (253) 879-2656.