

MINUTES

January 23, 2023, 1:30 p.m. | Provost's Conference Room, 200 Derryberry Hall

TENNESSEE TECHNOLOGICAL UNIVERSITY

Institutional Review Board for the Protection of Human Subjects

Present: Michael Clark (Vice chair), Sally Pardue, Michael Adduci, Megan Atkinson, Queen Ogbomo, Chad Rezsnyak, Meral Anitsal, Darek Potter, Ajit Korgaokar

Absent: Carl Pinkert, Steven Seiler, Sue Piras, John Rust, Chris Burgin, Melinda Anderson, Steve Frye, Paula Taylor-Greathouse, Tony Michael

Executive Officer: Carl Pinkert

Recording Secretary: Jill Dicey

- **Welcome**

Call to Order: 1:34 p.m.

- **Approval of the Agenda**

Motion to approve Agenda made by Rezsnyak/seconded by Pardue

Motion CARRIED to Approve Agenda.

- **Approval of Minutes of November 23, 2022**

Motion to approve Minutes made by Pardue/seconded by Adduci

Motion CARRIED to Approve Minutes.

- **Discussion of Expedited Reviews Since the Last Meeting**

Floor was opened for discussion. No discussions were brought forward.

- **Survey Results for Supplementary IRB Training Opportunities**

Michael Clark reviewed the results from a poll inquiring about interest in supplementary IRB training. The results were favorable enough to warrant looking into available training opportunities to bring to IRB board members and Departmental reviewers.

- **Review of Important Elements in Expedited Reviews**

- Risk vs Benefits

- Benefits must outweigh or justify the risk

- Informed Consent

- Document must include all required items for informed consent (listed on IRB website)
 - Language of Informed Consent form must match the reading and understanding level of the person presented with the form
 - It is acceptable when giving feedback to the PI to give them suggestions for the form

- Selection of Subjects
 - Voluntary participation must be assured and documented
 - Procedure for withdrawal from the study must to be carefully documented (how the participant can withdraw and what happens to any data collected)
- Anonymity vs. Confidentiality
 - Anonymity means no one, not even the PI, knows where the data came from
 - Confidentiality means that the personal identification information is known but that information will be safeguarded

Dr. Sally Pardue brought up the issue of certain software identifying the person giving data automatically unless that function is disabled and the importance of the PI being able to demonstrate to the reviewer their knowledge of that and how to turn that feature off if the survey is noted as anonymous.

Dr. Michael Adduci inquired if a study involving high-risk subject population, such as children or prisoners, require a study to be anonymous; do they get extra protection? Michael Clark advised it depends on the study. If all risks can't be eliminated than that is explained in the Informed Consent and the potential participant decides if they want to participate.

Michael Clark also cautioned against collecting multiple characteristics of a person in a small study. The subject might be easily identified by putting several traits together.

- Psychological Risks
 - An example would be a study involving victims and asking them to discuss their experience. There is a possibility of a trigger response so there needs to be a means to deal with that available; some type of counseling easily accessible and on-hand.

- **The Review Process**

Michael Clark advised that the completed, approved application is the official record of the conduct of the study. It's a statement by the PI of how the research is going to be conducted in very clear detail and it's on the record so that if there are ever any deviations or complaints, the committee can go back to that proposal and check to see if the PI deviated from the approved application in any significant way that contributed to the problem. The approval process is forging that document so it must be complete, accurate and it has to be clearly described.

- **Decision and Feedback Form**

It's a helpful tool to assist in evaluating the applications, especially for new reviewers, and helps a lead reviewer organize the notes from the other reviewers to send to the PI. The form follows the format of the application which makes it easy to use. The forms are sent to reviewers upon assignment.

- **Such Other Matters**

Dr. Queen Ogbomo asked if Department reviewers are Co-PI's on an application, who should the application be submitted to? Michael Clark advised those can be submitted directly to the IRB Chairperson.

- **Adjournment**

- Motion to adjourn made by Rezsnyak/seconded by Ogbomo
- Meeting adjourned at 2:27 p.m.

Respectfully submitted,
Jill Dicey, Recording Secretary, Office of Research