

Appendix W: Written Procedures of the Pellissippi State IRB

Written procedures of the Pellissippi State IRB are included throughout this document (for example, see Section 2.0, “Institutional Review Board”). The purpose of this appendix is to provide references to the written procedures that the Pellissippi State IRB follows to comply with the requirements listed in section 103 (b) (numbers 4 and 5) of Federal Regulation 45 CFR 46.

1. Conducting Initial Review of Research

See Section 4.0, “Review Procedures/Steps”

2. Conducting Continuing Review of Research

See Section 8.0, “Continuing Review Report of Human Subjects Research”

3. Reporting IRB Findings and Actions to Investigators and the College

See Section 2.7, “Record Keeping and Reporting Requirements”

4. Determining Which Projects Require Review More Often Than Annually

The Board will determine which projects require review more often than annually for those projects requiring full-board review. Results of discussion on this issue will be recorded in the minutes. The director of Institutional Research, serving as IRB chair, will determine which projects require review more often than annually for research reviewed under expedited procedures. Criteria to consider for this decision include the following:

- a. Studies involving more than minimum risk to participants
- b. Studies involving medical procedures
- c. Studies that report adverse events, unanticipated risks, or protocol changes
- d. Studies managed by investigators whose previous project(s) received an audit finding or report of noncompliance with requirements or determinations of the IRB

5. Determining Which Projects Need Verification from Sources Other Than the Investigators that No Material Changes Have Occurred Since Previous IRB Review

These procedures apply to continuing review of projects. Results of discussion will be recorded in the minutes of the IRB for full-board continuing review or in the report of the director of IR, serving as IRB chair, for continuing review for projects approved under expedited review procedures. Criteria to consider when determining whether outside verification is needed include the following:

- a. Projects that involve partnerships

- b. The same criteria as in item 4, above.
6. Ensuring Prompt Reporting to the IRB of Proposed Changes in a Research Activity and for Ensuring Initiation of Changes Only With IRB Approval

See Section 9.0, “Changes and Other Actions to Approved Projects.” Investigators are required to complete Form D, “Project Status Report: Changes and/or Close Out” and submit it to the director of Institutional Research, who serves as IRB chair. The IRB has the authority to suspend or terminate its approval of the research if these procedures are not followed.

Section 4.1.1 lists the responsibilities of the investigator and states that the “investigator is the responsible official for ensuring that these procedures are followed. The Pellissippi State IRB has the authority to suspend or terminate approval of the project if these procedures are not followed.”

7. Ensuring Prompt Reporting to Appropriate Authorities of Unanticipated Risks, Continuing Noncompliance with IRB Requirements, or Withdrawal of IRB Approval

- a. Reporting for unanticipated problems involving risks: Section 2.7, “Record Keeping and Reporting Requirements,” describes the responsibilities of the Institutional Research office for maintaining IRB records. Any statements of significant new findings developed during the course of the research, such as unanticipated risks or adverse reactions, must be provided to subjects and to the IRB. The director of Institutional Research, serving as IRB chair, will report these problems to College and federal officials (and to the funding agency if applicable).

Section 9.1 provides guidelines and procedures established by the IRB for reporting adverse events.

- b. Reporting of noncompliance: From section 4.1.1: “The Pellissippi State IRB has the authority to suspend or terminate approval of the project if these procedures are not followed. Federal regulations require the IRB to report serious and continuing non-compliance and all suspensions of approval to federal officials (and to the funding agency, if applicable).”

Section 8.0, “Continuing Review of Human Subjects Research,” provides researchers and others with information on how noncompliance is reported to authorities.

- c. Reporting of any suspension or termination of IRB approval: The director of Institutional Research, serving as IRB chair, will report any suspension or termination of IRB approval to the president of the College, OHRP, and the funding agency if the project is supported by outside funding.