The FIT-IRB will prepare and maintain adequate documentation of its activities, including the following:

A) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

B) Minutes of FIT-IRB meetings which will be in sufficient detail to show attendance at meetings; actions taken; the vote on these actions, including the number for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of controverter issues and their resolution.

C) Records of continuing review activities.

D) Copies of correspondence between the FIT-IRB and the investigators.

E) A list of FIT-IRB members, including: names; earned degrees; representative capacity; indications of experience; and any employment or other relationship between the member and the institution.

F) Written procedures which the FIT-IRB will follow: (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually; (3) for ensuring prompt reporting to the FIT-IRB of proposed changes in research activity.

G) The required records will be retained for at least 3 years, and records relating to research which is conducted will be retained for 3 years after completion of the research. All records will be accessible for inspection and copying by authorized representatives of OHRP at reasonable times and in a reasonable manner.