FASHION INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

RECORD KEEPING

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.