FASHION INSTITUTE OF TECHNOLOGY

INSTITUTIONAL REVIEW BOARD

CONTINUING REVIEW / MODIFICATIONS AFTER INITIAL PROTOCOL APPROVAL

After a protocol has been approved by the IRB, the investigator has several ongoing reporting responsibilities to the IRB.

MAKING MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

All modifications to currently approved research must have IRB review and approval prior to implementation. Investigators should submit a "Request for Modification or Amendment" form and, as appropriate, the revised protocol, consent form, recruitment materials, etc. Investigators should highlight or use bold font to indicate where changes or additions have occurred on the revised documents.

MINOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

A minor modification is defined as a change that (1) would not materially affect an assessment of the risks and benefits of the study or (2) does not substantially change the specific aims or design of the study. Minor changes that do not increase the risk to research subjects may receive an expedited review. Examples of minor modifications include a change in principal investigator or the addition/deletion of qualified investigators, and the addition/the deletion of study sites.

MAJOR MODIFICATIONS TO CURRENTLY APPROVED RESEARCH

A major modification is defined as a change that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Major modifications to approved protocols that may increase the risk to subjects require a full board review.

APPROVAL PERIOD FOR MODIFICATIONS

The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new or annual review takes place on January

1, 2002, the protocol will have an expiration date of January 1, 2010. If a modification is approved during this time, the expiration date still remains January 1, 2011. All modifications, amendments, and when applicable, informed Consent Forms should be incorporated into the renewal application for IRB consideration during the annual review.

CONTINUING REVIEW AFTER INITIAL APPLICATION APPROVAL

The IRB must conduct continuing review of protocols at intervals appropriate to the degree of risk, but not less than once per year. It is the investigator's responsibility to ensure that the research is reviewed on or before expiration of the current approval period, even if the research activity did not begin until sometime after the IRB gave its initial approval. Investigators will be notified by the IRB Office six to eight weeks prior to expiration of their IRB approval. An application for continuing review must be received by the IRB Office in time for review and approval in advance of the expiration date (three to four weeks recommended).

SUBMITTING A RENEWAL APPLICATION

In the renewal application, investigators should incorporate all of the addenda and modifications submitted to and approved by the IRB during the previous approval period. In addition to describing changes in the research design, number of subjects, or changes in Consent Form, the following information should also be included in the renewal request:

- An updated abstract of the study,
- The number of subjects seen since the last renewal, the total number to date, and the number of additional subjects yet to be recruited,
- The study status, if subject enrollment is complete,
- Any adverse events during the past year,
- A determination of whether or not the risk/benefit assessment remains the same,
- A summary of results and publications, and
- Plans for the coming year.
- Consent Forms and other supporting documentation must also be reviewed by the IRB each time the protocol is updated. If the research activity involves a collaborating institution, a copy of the other institution's current IRB approval letter is also required.

UNANTICIPATED PROBLEMS OR NONCOMPLIANCE WITH THE REQUIREMENTS OF THE PROTOCOL

In addition to any modifications after the initial IRB approval, investigators are responsible for reporting to the IRB Chair any unanticipated problems or noncompliance with the requirements of the approved protocol within ten calendar days. The Chair may choose to discuss these matters at a meeting of the full Board.

TERMINATION FOR FAILURE TO OBTAIN CONTINUING APPROVAL

The IRB has the authority to terminate or suspend approval of research that is not being conducted in accordance with regulations and requirements regarding continuing review. When study approval is terminated by the Board due to lack of compliance with continuing review requirements, in addition to stopping all research activities, any subjects currently participating should be notified that the study has been terminated.