

## Instruction for Modifying a Research Protocol

Follow these instructions if you have decided (independently of HSC instructions or at the direction of the Human Subjects Committee) to make any alterations in your research protocol. Please note that ***all modifications must be approved by the Human Subjects Committee before they may be implemented.*** This includes (but is not limited to) any changes in the wording of consent forms, posters or advertisements to recruit subjects, wordings of questionnaires or interviews, procedures used on human subjects, personnel working on the research project, or data storage.

- Use either the HS-1 or HS-7 proposal form, depending on the nature of your proposed research. Make any changes to the proposal.
- Write a cover letter summarizing the changes you have made.
- Submit the cover letter and revised research proposal to the Human Subjects Committee. Below is the number of copies to be submitted for each modification:
  - **Minor Modifications** requested by HSC requires 1 copies, and will be reviewed by the committee chair.
  - **Major Modifications** requested by HSC require 12 copies, and will be reviewed by the full committee. Consult the meeting schedule and deadlines to have your revised proposal included on a meeting agenda.
  - **Modifications you have decided to make that DO NOT change** the study population or risks to subjects require 1 copies, and will be reviewed by the committee chair.
  - **Modifications you have decided to make that DO change** the study population or the risks to subjects require 12 copies, and will be reviewed by the full committee. Consult the meeting schedule and deadlines to have your revised proposal included on a meeting agenda.
- You will receive a n approval letter telling you whether your modifications are acceptable.
- ***Do not begin research (including enrolling or contacting subjects) until you have approval from the Human Subjects Committee.***