

Procedures for Applying for Continuing Research

Federal guidelines mandate that the HSRB assesses risks, potential benefits, informed consent, and safeguards for human subjects both at the initial review and when researchers request continuation. Initial approvals are good for one year. When conducting continuing review, the HSRB needs to determine whether any new information has emerged, either from the research itself or from other sources that could alter the HSRB's previous determinations, particularly with respect to risk to subjects. In addition, any unanticipated problems involving risk to subjects or others that occurred since the previous HSRB review will also be relevant to the HSRB's decision about continued review.

For all types of reviews, the researcher should send the full protocol (shown in the checklist below) to the HSRB chair (hsrb@hope.edu). Answers to Questions 1 through 7 are the *brief proposal for continuation* and may be sent to all HSRB members.

Reviews can be expedited or by the full HSRB depending on the level of risk.

- Minimal risk means the participant is not experiencing any harm beyond that in normal daily activities.
- More than minimal risk means the participant may encounter more risk than that in daily activities.

Expedited Review (done by the HSRB chair or designated HSRB member) can legally be done for the following types of research:

- If your initial study was minimal risk AND
- Your research is permanently closed to the enrollment of new subjects, subjects have completed all research interventions, and the research is active only for long-term follow-up of subjects, OR
- No new subjects are expected and no additional risks are identified, OR
- Continuing research activities are limited to data analysis.

The **full HSRB Board** will review the remaining kinds of research:

- If you plan to **continue running** subjects with a minimal-risk study and no new risks are identified, the HSRB chair will send the *brief proposal* to all members for their decision.
- If your initial procedures were **more-than-minimal risk OR risk issues emerged over the year**, the review will be made by a quorum of the HSRB at a convened HSRB meeting. The researcher is invited to attend this meeting to address questions if he/she wishes.

Check List:

- a. Newly-completed Appendix A (with CITI certification date & signed agreement)
- b. Copy of materials to be used in the study
- c. Debriefing/educational statement
- d. *Brief Proposal – answer these questions:*

1. Number of subjects accrued.
2. Number of future subjects expected and subject selection procedures.
3. Summary of any unanticipated problems and available information regarding adverse events. In many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.
4. Summary of any withdrawal of subjects of research or complaints about the research since last HSRB review. If none, say "none."
5. Summary of any recent research that may be relevant to any changes you are making in the procedure. If none, say "none."
6. Any relevant information, especially if it pertains to related potential risks.
7. A copy of the prior informed consent form and any newly-proposed consent form.