



Institutional Review Board
Checklist: Expedited Review

Use For Minor Amendments or
Minor Modifications to Previously Approved Research

NUMBER | HRP-313 a

Expedited submissions are reviewed by a single IRB member.

IRB Number:

Protocol Name:

Investigator:

In accordance with 45 CFR 46.110 and 21 CFR 56.110, an IRB may use the expedited review procedure to review certain kinds of research involving no more than minimal risk to human subjects and one or more procedures listed in Categories 1-9 (on checklist 313), and for minor changes to previously approved research. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by a convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b) and 21 CFR 56.108(c).

1. Additional Criteria for Research Involving Prisoners (Check if "YES" or "N/A")

- The research is minimal risk and the prisoner representative concurs with this determination.
N/A, if there are no prisoners as subjects.

2. Minor Amendments or Minor Modifications to Previously Approved Research
(Check if "YES" or "N/A". All must be checked)

- The modifications do not affect the design of the research
The modifications add no more than Minimal Risk to the subjects
All added procedures fall into categories 1-7 below.
N/A if no added procedures.
The research activities (or remaining research activities) present no more than minimal risk to human subjects
N/A, if the research falls into Category 8
Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will NOT reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.
N/A if the research falls into Category 8
The research is NOT classified. Classified research is generally defined as research subject to a security classification established by a United States government agency.

The research is: (Please check one, and sign/date)

- APPROVED
Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office
Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting
Do Not Recommend approval at this time. List Reasons.
(Convened board must agree by a vote if study is not approved.)

Comments Section:

(Reviewer)

(Date)