

NHGRI IRB Checklist: Continuing Reviews or Terminations

(Include 1 copy with submission)

Principal Investigator: _____

Protocol Number: _____ Title: _____

Check one:

- Subject accrual ongoing (Complete Section I)
- Subject accrual complete; analysis ongoing (Complete Section II)
- All subject accrual and data analysis complete (Complete Section III)

I. CONTINUING REVIEW FOR FULL IRB REVIEW (original + 25 stapled copies)

- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- Decision memo from DEC regarding NIH employee conflicts of interest
- Cover memo addressing: a) protocol progress and key findings (include publication citations); b) adverse events and protocol deviations over the past year; c) any “yes” responses to questions on 1195-1; d) amendments made within the last year; e) reason(s) for continuing the study; and f) currently proposed changes in protocol or consent form
- Table of contents listing protocol and any appendices, recruitment materials, and consent forms
- Up-to-date protocol
- Ongoing Research Participant Enrollment Report
- Up-to-date consent form(s)
- Previous year’s IRB minutes for protocol

II. EXPEDITED CONTINUING REVIEW (original + 3 stapled copies)

- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- Decision memo from DEC regarding NIH employee conflicts of interest
- Cover memo addressing: a) protocol progress and key findings (include publication citations); b) adverse events and protocol deviations over the past year; c) any “yes” responses to questions on 1195-1; d) amendments made within the last year; e) reason(s) for continuing the study; and f) a statement that research subjects will no longer be accrued
- SRC review, if applicable (note: protocols must go through SRC at triennial review, even if expeditable)
- Research Participant Enrollment Report

III. TERMINATIONS (original + 3 stapled copies)

- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- Cover memo addressing:
 - Why study is being terminated and key findings
 - Adverse events or protocol deviations since the last review
 - List existing samples and data. Who will be responsible for the samples and data? Where at NIH will these be stored? When will they be disposed of or destroyed?
 - Are there identifiers associated with the samples or data that could link them to specific individuals? If identifiable, how will confidentiality be maintained?
- Research Participant Enrollment Report

Materials for full IRB review must be submitted to Peggy McKoy, Bldg. 10, CRC/6-3340, by noon on the due date, or they may be reviewed at a later meeting. (See NHGRI IRB Calendar).

For questions regarding the checklist or submissions, please contact:

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IRB forms and templates can be found at <http://www.genome.gov/10005807>

Version 7/14/06