

# NHGRI IRB: Protocol Amendment, Adverse Event, or Termination Checklist

(Include 1 copy with submission)

Principal Investigator: \_\_\_\_\_

Protocol Number: \_\_\_\_\_ Title: \_\_\_\_\_

## I. AMENDMENTS *Call Sara Hull (301-435-8712) to determine type.*

### ***Expedited amendments (original + 6 stapled copies)***

- Cover memo explaining changes.
- Amended pages, with the additions and ~~deletions~~, so noted.
- Complete, clean protocol and consent form.
- CD or e-mail attachment containing consent form electronic file IF changes to consent are involved.

### **OR**

- "Previously Collected Human Biological Materials/Data" Amendment Form.

### ***Full board review (original + 25 stapled copies)***

- Cover memo explaining changes.
- Amended pages, with the additions and ~~deletions~~, so noted.
- Complete, clean protocol and consent form.
- Diskette or e-mail containing consent form IF changes to consent are involved.

## II. SERIOUS ADVERSE EVENT REPORTING

### ***Full Board review (original + 25 copies for Serious Adverse events)***

- Memorandum to IRB Chair (with copy to the clinical director) describing adverse events
- Serious Adverse Event Report Form

## III. TERMINATIONS: Original and 3 copies

- Cover memo addressing:
  - Why the study was terminated and the key findings
  - Any protocol violations or adverse events 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?
- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief.
- NHGRI Enrollment Table

Materials for full IRB review must be submitted to Peggy McKoy Bldg 49, Room 4A14 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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