NHGRI IRB Checklist: Protocol Amendments or Adverse Events

(Include 1 copy of checklist with submission)

Principal Investigator: _____

Protocol Number: _____ Title: _____

I. AMENDMENTS *Contact Sara Hull to determine whether amendment is eligible for expedited review.*

Expedited amendments (original + 3 stapled copies)

- ❑ Cover memo explaining changes
- ❑ Amended pages of protocol and/or consent form(s), with the additions and ~~deletions~~ so noted
- ❑ Revised, clean protocol (if revisions are substantial) and/or consent form(s)
- ❑ Protocol Conflict-of-Interest Statement, signed by Deputy Ethics Counselor (DEC) (if amendment involves adding new investigators who are NIH employees)
- ❑ Electronic version of consent form (diskette, CD, or e-mail attachment)

OR

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

Full board review (original + 25 stapled copies)

- ❑ Cover memo explaining changes
- ❑ Amended pages of protocol and consent form(s), with the additions and ~~deletions~~ so noted
- ❑ Revised, clean protocol and consent form(s)
- ❑ Protocol Conflict-of-Interest Statement, signed by Deputy Ethics Counselor (DEC) (if amendment involves adding new investigators who are NIH employees)
- ❑ Electronic version of consent form (diskette, CD, or e-mail attachment)

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

Materials for full IRB review must be submitted to Victoria Willits, 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