

**NHGRI IRB Checklist: Triennial Review of Protocols**  
**For Full Review at a Convened IRB Meeting\*\***  
*(Include 1 copy with submission)*

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

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

**RENEWAL AFTER THREE YEARS (*original + 25 stapled copies*)**

- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- Protocol Conflict-of-Interest Statement, signed by Deputy Ethics Counselor (DEC)
- Cover memo addressing a) adverse events and protocol deviations over the past year; b) any “yes” responses to questions on 1195-1; c) amendments made within the last year; d) reason(s) for continuing the study; and e) currently proposed changes in protocol or consent form
- Table of contents, listing protocol and any appendices, recruitment materials, and consent forms
- Rewritten protocol:
  - Background section of protocol should address the following: a) protocol progress and key findings (including publication citations); b) changes in the field/new publications that have an impact on future direction; and c) description of new approaches
  - In addition, protocol should be revised/updated in all appropriate sections
  - Please reformat protocol according to *revised* NHGRI Protocol Template available at <http://www.genome.gov/10005807>
- Ongoing Research Participant Enrollment Report
- Up-to-date consent form(s)
- Memo to Branch Chief responding point-by-point to Scientific Review Committee (SRC) review
- SRC review
- Previous year’s IRB minutes for protocol (*please do not submit correspondence, 1195 forms, etc. from previous years*)

\*\* Note: If you believe this submission is eligible for an expedited review, please refer to the Expedited Continuing and Triennial Review Checklist. Expedited Triennial Reviews must still be reviewed by the SRC and the DEC prior to submission to the IRB.

***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:*

**Victoria Willits**  
Email: [vwillits@mail.nih.gov](mailto:vwillits@mail.nih.gov)  
Phone: 301-496-1906

**Sara Chandros Hull Ph.D.**  
Email: [shull@mail.nih.gov](mailto:shull@mail.nih.gov)  
Phone: 301-435-8712

**Fabio Candotti, M.D.**  
Email: [fabio@nhgri.nih.gov](mailto:fabio@nhgri.nih.gov)  
Phone: 301-435-2944

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

Version 8/14/07