

NHGRI Scientific Review Committee (SRC) Checklist: New Submissions or Triennial Review of Protocols

Principal Investigator: _____

Title: _____

**Submit protocol to the SRC through:
Deborah Handon
Office of the Clinical Director, NHGRI
Building 10, CRC/3-2551
301-402-8255**

At time of submission to SRC, Principal Investigators must submit the Protocol Conflict of Interest Statement (http://www.genome.gov/Pages/Research/Intramural/IRB/ProtocolCOIStatement_062507.pdf) to: Barbara Fuller, Deputy Ethics Counselor (DEC), barbaraf@mail.nih.gov

NEW SUBMISSIONS (5 copies)

- Form 1195 signed by PI and Accountable Investigator
- Protocol written according to NHGRI IRB template*
- Appendices including questionnaires, educational materials, investigator's brochure, etc.
- Names/contact information for up to four reviewers at NIH or elsewhere (OPTIONAL)

TRIENNIAL REVIEW (5 copies)

**** Note: If this triennial review is eligible for expedited IRB review, contact Donna Krasnewich (dkras@mail.nih.gov) to determine what materials are necessary for submission to the SRC.**

- Form 1195-1 signed by PI and Accountable Investigator
- 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
- Ongoing Research Participant Enrollment Report

RESPONSE TO SRC COMMENTS (1 copy to Branch Chief)

- Form 1195 or 1195-1
- Memo responding point-by-point to SRC review
- SRC review
- Complete version of revised protocol including appendices, questionnaires, etc.
- Original version of protocol sent to SRC

Branch Chief must verify that modifications requested by the SRC have been appropriately addressed, at which point the Branch Chief signs the 1195 or 1195-1 form, and the protocol may be submitted to IRB.

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

Version 8/14/07