

NHGRI IRB: Checklist for Renewal of Protocol After Three Years

(Include 1 copy with submission)

Principal Investigator: _____

Protocol Number: _____ Title: _____

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

- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- Cover memo addressing any amendments made within the last year, any currently proposed changes in protocol or consent, any changes in the protocol that would require a new consent form to be signed by currently enrolled subjects, any study publications, and any departures/withdrawals, adverse events, protocol violations, or other protocol variations.
- Table of contents, listing protocol and any appendices, recruitment materials, and consent forms.
- Rewritten protocol, including Ongoing Research Participant Enrollment Report.
 - √ Background section of protocol should address the following:
 - a) A concise statement regarding protocol progress to date and key findings.
 - b) Any "Yes" responses to questions on 1195-1 (e.g., slower than expected accrual, Complications/side effects, withdrawals, etc).
 - c) Changes in the field that have an impact on future direction, including publications.
 - d) Reason(s) for continuing the study and description of new approaches.
 - √ In addition, protocol should be revised/updated in all appropriate sections.
- Up-to-date consent form.
- SRC review and cover memo to IRB Chair and branch chief with PI response (if any).
- A copy of IRB stipulations/recommendations from previous year.

II. RESPONSES TO STIPULATIONS FOR CONDITIONALLY APPROVED PROTOCOLS

- ***original + 25 stapled copies if full IRB review required***
- ***original + 6 stapled copies if IRB Subcommittee review required***
- ***original + 3 stapled copies if NHGRI IRB Chair review required***
- Cover memo responding point-by-point to stipulations.
- Revised pages of protocol and consent, with the additions and ~~deletions~~, so noted.
- Copy of IRB Meeting Minute Stipulations.
- Clean copies of entire revised protocol and consent form.
- Diskette or e-mail containing clean, final copy of consent form.

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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