# NHGRI IRB Checklist: Expedited Continuing and Triennial Reviews

(Include 1 copy of checklist with submission)

Principal Investigator: _____

Protocol Number: _____ Title: _____

**To request an expedited continuing or triennial review of your protocol, please indicate which of the criteria apply:** *(see http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)*

**I. This protocol involves one of the following (check *one*):**

- ❑ *The research is permanently closed to enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow up of subjects*
- ❑ *No subjects have been enrolled and no additional risks have been identified*
- ❑ *Remaining research activities are limited to data analysis*

**OR**

**II. This protocol presents no more than minimal risk to human subjects and involves *only* one or more of the following procedures (check *all* that apply):**

- ❑ *Research on drugs/devices not involving an IND/IDE*
- ❑ *Collection of blood samples (see limits at*
- ❑ *Prospective collection of biological specimens for research by noninvasive means*
- ❑ *Collection of data through noninvasive procedures used in routine clinical practice (not radiation)*
- ❑ *Research involving previously collected materials (data, documents, records, specimens), or materials to be collected solely for nonresearch purposes*
- ❑ *Collection of data from voice, video, digital, or image recordings made for research purposes*
- ❑ *Research on individual or group characteristics or behavior and/or research using e.g., surveys, interviews, oral histories, or focus groups.*

**If one of these categories applies, please submit the following (*original + 3 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) protocol progress and key findings (include publication citations); b) adverse events and protocol deviations over the past year; c) any "yes" responses to questions on 1195-1; d) amendments made within the last year; e) reason(s) for continuing the study; and f) a statement that research subjects will no longer be accrued
- ❑ SRC review, if applicable (note: protocols must go through SRC at triennial review, even if expeditable)
- ❑ Research Participant Enrollment Report

***If protocol involves ongoing enrollment of subjects, also include the following:***

- ❑ Table of contents listing protocol and any appendices, recruitment materials, and consent forms
- ❑ Up-to-date protocol
- ❑ Up-to-date consent form(s)
- ❑ Previous year's IRB minutes for protocol

*Please submit materials to Victoria Willits, Bldg. 10, CRC/6-3340, by noon on the due date. (See NHGRI IRB Calendar).*

***For questions regarding the checklist or submissions, please contact:***

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