

**SUBMISSIONS RECEIVED WITHOUT APPROPRIATE DOCUMENTATION WILL BE RETURNED TO THE
PRINCIPAL INVESTIGATOR WITHOUT ACTION**

National Cancer Institute

Branch Protocol Coordinator's Initials: _____

Protocol Submission Checklist (10/2004)

Please indicate the type of material enclosed and check the appropriate boxes below:

- New Protocol (PRMC) New Protocol (IRB) Response to Stips (PRMC/IRB) Amendment Continuing Review/Termination

I. PROTOCOL OR CONCEPT FOR PRMC REVIEW:

IN 25 COLLATED COPIES, THE FOLLOWING: (bound w/clips, not staples, please)

- Cover memo signed by PI AND Branch Chief
 Protocol OR concept sheet (**DO NOT SUBMIT CONSENT**) (use CCR format; see <http://home.ccr.cancer.gov/irb/>)
 Email containing all files (**DO NOT SUBMIT CONSENT**) to nciprmcadmin@mail.nih.gov

II. EXPEDITED RESPONSE TO PRMC STIPULATIONS: (P# _____)

Original only; no additional copies required (bound w/clips, not staples, please)

- Cover memo, signed by the PI and Branch Chief, responding point-by-point to stipulations/recommendations
 Revised pages, showing additions as underlined text, and deletions as ~~strike-through text~~
 Clean, revised protocol and appendices (do not submit consent)
 E-mail containing all files (to include appendices, etc) to nciprmcadmin@mail.nih.gov

III. FULL BOARD RESPONSE TO PRMC STIPULATIONS: (P# _____)

In 25 COLLATED COPIES, THE FOLLOWING: (bound w/clips, not staples, please)

- Cover memo, signed by the PI and Branch Chief, responding point-by-point to stipulations/recommendations
 Revised pages, showing additions as underlined text, and deletions as ~~strike-through text~~
 Clean, entire revised protocol (do not submit consent)
 E-mail containing all files (to include appendices, etc) to nciprmcadmin@mail.nih.gov

IV. NEW PROTOCOL FOR IRB REVIEW: (P# _____)

In 30 COLLATED COPIES, THE FOLLOWING: (bound w/clips, not staples, please)

- Form 1195 signed by PI, Accountable Investigator, Branch Chief, and initialed by ALL AIs
 PRMC minutes, PI response, and PRMC approval memo
 Protocol, Consent, Appendices, and any patient recruitment materials
 E-mail containing entire Protocol (to include appendices, etc), Consent (Microsoft Word), and CTEP PSW (if applicable) to nciirbadmin@mail.nih.gov

AND 1 COPY ONLY OF THE FOLLOWING:

- Data Collection Forms
 CTEP Protocol Submission Worksheet (PSW) (found at <http://ctep.info.nih.gov/InfoForms/default.htm>) (if CTEP monitored)
 Investigators' Drug Brochure (if applicable)
 Form 1572 (if applicable) signed by PI
 CV of PI and Protocol Chairperson
 Contact persons (2) (for patient recruitment purposes) with address, phone number, and E-mail

Name of person completing the form

Phone No.

Date:

- V. FULL BOARD RESPONSE TO IRB STIPULATIONS: (P# _____)**
IN 30 COLLATED COPIES, THE FOLLOWING: (bound w/clips, not staples, please)
- Cover memo, signed by PI and Branch Chief, responding point-by-point to stipulations/recommendations (use standard format) see <http://home.ccr.cancer.gov/irb/>
 - Form 1195 showing revisions (if applicable)
 - Revised pages, showing additions as underlined text, and deletions as ~~strike through text~~
 - Clean, entire revised protocol, appendices, and consent
 - E-mail containing cover memo, underlined changed pages, and entire Protocol, Appendices, and Consent to nciirbadmin@mail.nih.gov.
- VI. EXPEDITED RESPONSE TO IRB STIPULATIONS: (P# _____)**
Original only; no additional copies required (bound w/clips, not staples, please)
- Cover memo, signed by the PI and Branch Chief, responding point-by-point to stipulations/recommendations (use standard format) see <http://home.ccr.cancer.gov/irb/>
 - Revised pages, showing additions as underlined text, and deletions as ~~strike through text~~
 - Entire revised protocol, appendices, and consent
 - E-mail containing cover memo, underlined changed pages, and entire Protocol, Appendices, and Consent to nciirbadmin@mail.nih.gov.
- VII. EXPEDITED AMENDMENTS: (C# _____) (bound w/clips, not staples, please)**
- Original + 1 copy of cover memo, signed by PI and Branch Chief, outlining changes in a point-by-point fashion
 - Original + 1 copy of the amended pages, showing additions as underlined text, and deletions as ~~strike through text~~
 - Original + 1 copy of the entire revised protocol, appendices, and consent
 - E-mail containing cover memo, underlined changed pages, and entire Protocol, Appendices, and Consent to nciirbadmin@mail.nih.gov.
- VIII. AMENDMENTS FOR FULL BOARD REVIEW: (C# _____)**
IN 30 COLLATED COPIES, THE FOLLOWING: (bound w/clips, not staples, please)
- Cover memo, signed by the PI and Branch Chief, outlining changes in a point-by-point fashion
 - Revised pages, showing additions as underlined text, and deletions as ~~strike through text~~
 - Clean, revised protocol, appendices, and consent
 - E-mail containing cover memo, underlined changed pages, and entire Protocol, Appendices, and Consent to nciirbadmin@mail.nih.gov.
- IX. CONTINUING REVIEWS (C# _____):**
IN 30 COLLATED COPIES, THE FOLLOWING (staples are acceptable):
- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief, **AND** Clinical Director
 - Cover memo, signed by PI and Branch Chief, using the standard NCI template (see <http://home.ccr.cancer.gov/irb/>)
 - Updated title page of protocol to include any investigator changes
 - Current consent document (for open studies only) **printed from the Web**
 - Email containing cover memo to nciirbadmin@mail.nih.gov
 - Pertinent publications (1 copy only) (if none, please state "NONE")
- X. TERMINATIONS (C# _____):**
IN 30 COLLATED COPIES, THE FOLLOWING (staples are preferred):
- Form 1195-1 signed by PI, Accountable Investigator, Branch Chief, **AND** Clinical Director
 - Cover memo, signed by PI and Branch Chief, using the standard NCI template (see <http://home.ccr.cancer.gov/irb/>)
 - Verification from Central Registration of off-study dates for all subjects

**THIS CHECKLIST MUST ACCOMPANY ALL PROTOCOL ACTIONS.
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 PRINCIPAL INVESTIGATOR WITHOUT ACTION.**