

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Preparing and Submitting New or Continuing Research Applications and Amendment Requests	Date Effective 1/03/05	Supersedes P&P dated 12/14/04

BACKGROUND

Federal regulations lay out specific criteria for IRB review and approval of new and continuing human subjects research. To assist researchers, and to facilitate the review process, CHR has developed guidance on the preparation and submission of research applications, including forms, instructions and checklists, that help to ensure that applications provide all of the information and documentation required for review.

JHSPH POLICIES AND PROCEDURES

Instructions for preparing and submitting new and continuing research applications and requests for amendments to approved research projects should be followed carefully. Required checklists should be completed and attached with the application. Required documentation should be provided. Submissions that are incomplete will be returned to the Principal Investigator for completion and the review process will stop until a completed proposal is received.

Researchers who have questions concerning any aspect of the application and review process are encouraged to discuss them with staff of the Office for Research Subjects.

New Research Applications

Applications for new research projects that involve human subjects should be submitted using [CHR Form N](#) or [CHR Form A](#).

[CHR Form N](#) (*Certification of Exempt Status*) is used for human subjects research that an investigator believes qualifies as exempt from Federal regulations. See [Exempt Review](#) for definitions of the types of research that qualify for exempt status. The Office for Research Subjects has final responsibility for determining whether a study meets the exemption criteria.

All human subjects research that does *not* qualify for exempt status must be submitted using [CHR Form A](#). Detailed instructions for preparing a new application submission, including a listing of all required supporting documents, are found at the [CHR website](#). The

website also provides guidance on [preparing the research plan](#) that must be submitted with the new research application.

Guidance on developing consent forms is also available on the CHR website (see [Informed Consent Process](#)).

Continuing Review Applications (Progress reports)

CHR must review and approve the progress of each active research project at least annually. See [Progress Reports and Continuing Review](#). Applications for continuing review should be submitted using [CHR Form B \(Progress Report\)](#). See also [Progress Report Instructions/Guidelines](#).

Requests for Amendments

All changes and amendments to previously approved studies must be reviewed and approved by CHR *before* they are initiated, except when a change is necessary to eliminate immediate hazard to subjects. CHR review is initiated by submitting an [Amendment Request Form](#) describing the planned change to CHR. See [Changes and Amendments to Approved Research](#).

Supporting Documents and Checklists

Other forms and checklists that may be required for new or continuing research applications are located on the CHR website at [Applications and Forms](#). Those most frequently required are:

[Certification of Translation](#)

[Checklist for Consent Forms](#)

[Checklist: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#)

[Checklist: Decisionally Impaired Subjects](#)

[Drug Data Sheet Form](#)

[HIPAA Forms](#)

[New Application Submission Checklist](#)

[Prisoner Checklist](#)

[Research Involving Children Checklist](#) (Form M)

[Research Projects Involving Ionizing Radiation Forms](#)

[CHR Form J](#) Request for Use of Ionizing Radiation in Human Research

[CHR Form K](#) Worksheet for Radionuclide (Internal) Radiation Exposure

[CHR Form L](#) Worksheet for External Exposure

[Sample Child Assent Form](#)

[Sample Memo to Request Planning Phase Review](#)

When and Where to Submit

Research proposals that include human subjects research do not require CHR approval before they are submitted to sponsoring Federal agencies for review. Federal regulations require, however, that CHR approves, or certifies as exempt, all proposals that involve human subjects research *before the studies are initiated*. For this reason, funds awarded by the sponsors will not be released by JHSPH until CHR has reviewed and approved the protocol. To avoid a delay in funding, investigators who are notified that their proposal will be funded or that a grant application has received a score that appears to be in a “fundable range” should submit the proposal promptly to CHR for review.

Applications for exempt research using Form N should be submitted at least 30 days before the research will begin.

Applications for new research using Form A should be submitted at least 60 days before the research will begin.

As a courtesy to investigators, notification that continuing review applications (progress reports) are due are sent from the Office for Research Subjects 120 days before CHR approval is due to expire. Reminders are sent 90 and 60 days before the date of expiry. Reports should be submitted at least 30 days before the date of expiry in order to avoid passing that deadline. It is the responsibility of the Principal Investigator to ensure that continuing review applications are submitted in time to permit review by CHR before approval expires.

All research applications and supporting documentation should be submitted to:

Office for Research Subjects
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Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
Baltimore, MD 21205-2179
Tel. 410-955-3193