

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Progress reports and Continuing Review	Date Effective April 11, 2005	Supersedes P&P dated April 1, 2005

BACKGROUND

Federal regulations require that all approved human subjects research, except that designated as exempt from Federal regulations, be re-reviewed by an IRB at intervals appropriate to the degree of risk associated with the study, but at least once every 12 months. Continuing review is the ongoing monitoring mechanism by which the IRBs ensure the continuing protection of subjects who participate in research.

Continued monitoring of approved research is as important as the initial review and approval. It is only after research has begun that the real risks can be evaluated and the preliminary results used to compute the actual risk/benefit ratio; the IRB can then determine the correctness of its initial judgment. The risk/benefit ratio may also change over time. This may be caused not only by unexpected results or effects of the research project itself, but also by new knowledge resulting from other research. After reassessment, the IRB may approve continuation of the research with few or no changes, or require that the research be modified or even halted. The IRB may also need to impose special protections or relax special requirements it had previously imposed on the research protocol.

JHSPH POLICY AND PROCEDURES

Progress Report

Progress reports continue to be required as long as an approved project remains active or until all data analyses have been completed. Progress reports should be submitted using the CHR [Progress Report Form \(CHR Form B\)](#) following the [Progress Report Instructions/Guidelines](#).

If a study is no longer active and all analyses have been completed, a [Protocol Inactivation Report \(CHR Form C\)](#) should be submitted in place of a Progress Report.

The progress report should provide the following information for the period since the last progress report:

- the number of subjects enrolled (see definition of an “enrolled subject” in [Subject Enrollment and Sample Size](#) .
- a summary of any [unanticipated problems](#) involving risks to subjects or others,

- any subjects who have withdrawn from the research and the reason(s) for their withdrawal,
- any [complaints](#) from subjects or others about the conduct of the research,
- a summary of any relevant recent publications or interim findings that might affect the risk/benefit assessment of the research,
- any amendments or modifications to the research, including changes in investigators, student researchers, or in funding source (submit the relevant grant proposal),
- any multi-center trial reports, if relevant,
- any safety monitoring reports or DSMB reports, if applicable,
- any other relevant information about risks associated with the research,
- updated local IRB approval(s), if applicable,
- one copy of each currently used consent document signed by a subject enrolled in the study or, if CHR approved a waiver of signed consent, one copy of the currently used disclosure letter, telephone script and/or oral consent form. For each document, a back translation should be provided if it is not in English, and
- an updated copy of local IRB approval. Research conducted with collaborating institutions and for which local IRB approval has been obtained, must submit an updated approval from the local IRB. Local IRBs that have an FWA with OHRP and do not conduct continuing review are violating DHHS regulations and the terms of their FWA. JHSPH investigators should alert local IRBs to their obligation to conduct continuing reviews.

Amendments

If a request for amendment is submitted with the progress report it should be provided as a separate set of documents and not incorporated in the current Research Plan. The request for amendment and the progress report will be reviewed separately by CHR. The amendment should be incorporated into the approved research Plan only after it has been reviewed and approved by CHR (see [Changes and Amendments in Approved Research](#)).

Full Committee Review, Expedited Review or Exempt Review

Full committee review

If a study was initially reviewed at a full committee meeting of CHR, continuing review will usually be by the full committee. The study may, however, become eligible for expedited review or classification as exempt if, for example, the only remaining activities will be analysis of existing data.

Expedited review

The study may qualify for expedited review if it meets the following conditions:

- the research is permanently closed to the enrollment of new subjects; and
- all subjects have completed all research-related interventions; and

- the research remains active only for long term follow up of subjects, or
- no subjects have been enrolled and no additional risks have been identified; or
- the only research activity remaining is the analysis of identifiable data.

Review process

The review process for full committee or expedited review, and full committee membership and participation requirements, are the same as those for review of [new research proposals](#). All CHR members will receive the progress report, consent documents, safety monitoring or DSMB reports, the current research plan, any amendments requested with the research plan, and any new information that is relevant to the objectives or procedures of the study. For expedited reviews, the primary reviewer will receive the same materials.

Exempt classification

CHR may move the research to exempt status if the remaining research is limited to data analysis and the investigator has recorded the data in such a way that the data are not identifiable and cannot be re-linked to personal identifiers. Research that is determined by CHR to be exempt does not require annual progress reports or continuing review.

Period of Re-approval

The period of re-approval may not exceed 12 months. CHR may, however, re-approve for a shorter period if it believes that doing so would reduce possible risk to study subjects. This might be considered if the risks or benefits associated with the research are thought likely to change, if new information is expected that is directly relevant to the question being studied, or for other reasons. The period of re-approval will be indicated on the Progress Report Form that is signed by a CHR Co-Chair and returned to the Principal Investigator.

Meeting the Renewal Deadline

As a courtesy, notice that a progress report is due is mailed to the Principal Investigator from the ORS approximately 16 weeks prior to each project's expiration date. A second notice is sent 12 weeks prior to expiration and a third, and final, reminder is sent 8 weeks prior to expiration.

Progress reports must be submitted to CHR at least eight weeks prior to a project's expiration date. This is the minimum time required to process and review a report. It is the Principal Investigator's responsibility to ensure that a complete progress report is submitted on time irrespective of whether a notice has been received from ORS.

Federal regulations require that if a progress report is not reviewed and re-approved before a study's expiration date, CHR approval automatically expires and all research activity in the study must stop, unless CHR finds that it is in the best interest of individual subjects to continue in the research interventions or interactions. If investigators believe this to be the case, they must apply for and

receive written approval from CHR to continue the research with individual subjects beyond the expiration date. The request should be submitted to CHR as a memorandum. Such expiration of CHR approval does not need to be reported to OHRP as a suspension of CHR approval.

If the study is stopped because approval has expired, CHR may require that it be formally terminated, with notification to the Office of Research Administration. In that case, if the investigators wish to resume the research, a new research application must be submitted for review and approval by CHR. Alternatively, CHR may choose not to terminate the study, but to complete its review of the late progress report and, if it is approved, allow the study to resume. In either event, the research may not be resumed until CHR has provided formal written notice of approval.

DEFINITIONS

RESOURCES & REFERENCES

OHRP Requirement _____
FDA Requirement _____
AAHRPP Element _____