

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title Inactivation of Research or Withdrawal of CHR Approval	Date Effective 11 March 2005	Supercedes P&P dated

BACKGROUND

Research that has been approved by CHR may be inactivated at the request of the study investigators because it has been completed or for other reasons. Federal regulations also give CHR the authority to withdraw its approval of previously approved research to protect research subjects. This usually happens because the research is not being conducted according to the approved procedures, unanticipated problems have arisen or new information becomes available that cause clinical equipoise between risks and benefits to be lost, or there is serious non-compliance with regulatory requirements. This document describes the procedures involved in the inactivation of a research project or withdrawal of approval of research that was previously approved by CHR.

JHSPH POLICY AND PROCEDURES

Inactivation of a Study by the Investigators

Investigators must notify CHR when an approved study has ended so that CHR approval can be terminated. Some reasons for inactivation of a study are:

- the study has not been initiated and will not be initiated,
- the study is finished, i.e., all analyses have been completed and contact with subjects, their data and/or their specimens is no longer required to achieve the approved study objectives, or
- the study was stopped before completion to protect research subjects; this may happen because the risks increased and/or benefits decreased, causing loss of clinical equipoise, or for other reasons.

Investigators who wish to inactivate their study must complete and submit CHR Form C, the [Protocol Inactivation Report](#), to CHR. If a study is stopped before completion for safety reasons or because it cannot achieve its stated objective, a copy of the DSMB report, other safety monitoring report, or notification from the sponsor, that supports this action should accompany the inactivation report.

CHR will review the *Protocol Inactivation Report* and accompanying documents and, within 4 weeks of their receipt, will provide written confirmation to the investigators that CHR approval has been terminated and the study has been inactivated. The Office of Research

Administration will be provided a copy of the written confirmation and any other correspondence concerning the term of CHR approval, when appropriate.

Withdrawal of Approval by CHR

CHR may elect to withdraw its approval for a study:

- when an [unanticipated problem](#) occurs that increases risk to study subjects or others,
- when new information becomes available that is relevant to the issue being studied and that adversely affects the balance of risks and benefits in the study, or
- when there is serious or continuing [non-compliance](#) by the investigators with Federal, State or local regulations, or other CHR requirements, that increases risk to subjects, e.g., failure to follow CHR-approved study procedures, when this causes increased risk to subjects.

Additionally, and in accord with Federal regulations, CHR approval may be withdrawn when a [Continuing Review](#) Application (Progress Report) is not received at least 8 weeks before, and CHR review and approval cannot be completed by, the study's expiration date.

Whenever CHR withdraws its approval of an ongoing study, the Principal Investigator will be informed in writing within two weeks. The notice will state the reason for withdrawal of approval.

Withdrawal of CHR approval means that all research activities, including ongoing analysis of data or specimens, must be stopped immediately unless the CHR determines that continuing the research is necessary to eliminate immediate hazards to the subjects. A decision that continuation of the study is required is made by the CHR in consultation with the Principal Investigator, who must send a written request to CHR for an exception to continue the research beyond the termination date.

When CHR approval is withdrawn for non-compliance, or because of unanticipated problems that involve risk to subjects or others, CHR will inform the Office for Human Research Protections (OHRP), the funding agency, the JHSPH Office for Research Administration, the JHSPH Institutional Official, the Dean's Office, the relevant Departmental Chairperson and others, as appropriate.