

15.2. Notification of CHS Determinations to Investigator, Institutional Officials, and Regulatory Agencies

Whenever the CHS suspends or terminates the approval of a study due to serious or continuing non-compliance or an unanticipated problem involving risks to participants or others, the ORSP Director will draft a report of the suspension/termination. The report will include the circumstances surrounding the suspension or termination, the findings of the CHS in making the determination to suspend or terminate the research, any necessary steps to be taken to ensure the safety, welfare and rights of past or present study participants (e.g., drug tapers, continuation of treatment, notification to participants, etc.), and any corrective actions for the Investigator. The report is reviewed and approved by the CHS Chair (and other CHS members, as the Chair determines) prior to distribution.

The following individuals and entities receive a copy of the suspension or termination report, ordinarily the next business day (and not later than 5 business days) after the CHS determination to suspend or terminate the research, by the ORSP Director:

- The Investigator and Co-Investigator;
- The Investigator's Faculty of Medicine Department Head (and any additional Department Heads where the Investigator holds multiple professional appointments)
- The Faculty of Medicine Institutional Official. The IO will contact any additional institutional authorities, such as the Dean of the Faculty of Medicine, the President of the University, the Associate Provost for Research, the representative from the Office of the General Council, and Risk Management and Audit Services;
- The Sponsored Research Administration representative (where grants are supporting the research), and the Office of Technology Development (where corporate/company contracts are supporting the research). SPA or OTD will notify the study sponsor.
- Any additional University departments involved in the conduct of the research;
- Any additional IRBs and institutions involved in the research (for multi-site studies, subcontracts, IRBs and institutions relying on CHS review);
- FDA, when the research is FDA-regulated;
- Any additional federal agencies involved when the research is subject to those agencies; and
- OHRP, as appropriate.

Investigators shall have the opportunity to respond to the suspension or termination and offer new procedures or a new research plan to protect the rights and welfare of the participants.

16. CHS Records

The CHS maintains the following documentation in its office: (1) discussions and decisions of reviews by the convened CHS; (2) discussions and decisions that take place by an expedited review procedure; (3) discussions and decisions that take place by an exempt review procedure; (4) communications between CHS members or CHS staff and Investigators and/or their staff; (5) study files; (6) CHS Membership Rosters; and (7) Policies and Procedures of the CHS.

The CHS' record-keeping practices comply with 45 CFR § 46.115, which are as follows:

- (a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:
 - (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
 - (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
 - (3) Records of continuing review activities.
 - (4) Copies of all correspondence between the IRB and the investigators.
 - (5) A list of IRB members in the same detail as described in § 46.103(b)(3).
 - (6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).
 - (7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).
- (b) The records required by this policy shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

The CHS records also contain the following documentation:

- Copies of the DHHS-approved sample consent documents.
- The description of action taken by the Reviewer
- The specific permissible categories for expedited and exempt reviews.
- The frequency of reviews for full CHS and expedited studies.
- Documentation of determinations required by the regulations along with protocol-specific findings justifying those determinations.

16.1. Active Study Files

Study files are kept in the CHS office for all active studies requiring full CHS and expedited reviews. The files are organized such that the CHS or others could construct a complete history of the study and all CHS actions pertaining to the review and approval of the study.

CHS study files contain the following documentation, as appropriate:

- CHS applications (new and continuing), signed by the Investigator and Department Head (or mentor, if student).
- Complete protocol, if not embedded within the application.

- Complete grant applications, subcontracts and contracts (including budget pages and appendices).
- All study materials (such as recruitment letters/emails/phone scripts, surveys, questionnaires, other data collection instruments, and payment forms).
- Approved consent documents (see Section 10.3), containing the CHS stamp. Please note – where another IRB has already stamped a consent form, the CHS will not additionally stamp the form, unless it is requested.
- DHHS-approved sample consent documents.
- Yearly progress reports, including any significant new findings that have been reported to study participants.
- All unanticipated problems, adverse event forms, and DSMB reports, as well as resolutions and/or acknowledgement of review by the convened CHS, or CHS Chair, as appropriate.
- All completed reviewer sheets noting any additional findings and safeguards for research involving populations protected under subparts B, C and D of 45 CFR § 46 and other vulnerable populations as noted elsewhere in these policies.
- Any additional scientific or consultant reviews.
- Communications between the CHS staff or CHS members with the Investigator (or designated research personnel).
- All approvals from additional IRBs reviewing the project, and at times, complete applications and materials approved (such as consent forms, recruitment and data collection tools) from additional IRBs.
- The ROA for each CHS review (including initial, continuing, and amendments).

Study materials are organized in reverse chronological order, with the first approved record last in the file, and the last approved record (or most recent), first. All records pertaining to a study are kept together in the file cabinet until the study is closed. Convened CHS meeting minutes are stored separately.

Exempt studies and studies not meeting the definition of research or research with human subjects are scanned in their entirety, made into a .pdf document, and kept on the CHS shared-drive (listed by Investigator last name and protocol number). The original paper copies are sent to the Depository.

16.2. Study Record Retention Policy

16.2.1. Investigator's Study Records

In accordance with the Faculty of Medicine policy on retention of research records (Appendix 53), Investigators should keep all records pertaining to clinical studies for a minimum of five years after the study is complete. The CHS recommends this retention policy for all studies, regardless of risk or type of CHS review. At a minimum standard set by DHHS (45 CFR § 46.115(b) and the FDA (21 CFR § 56.115(b)), Investigators must keep complete study records for three years. Records must be kept in a secure location that allows for maintaining participant confidentiality. The study records must be available for inspection by the CHS, DHHS, FDA, or the funding source, as applicable, and if requested.

16.2.2. CHS Study Records

The CHS maintains all study records (containing the above noted materials, as appropriate to the study) at the Harvard Depository. The records stored at the Depository are saved for a minimum of 7 years from when the study is complete (note: this differs from OHRP policy requiring records to be maintained for a minimum of 3 years), and may be held indefinitely, depending on the study. Records are also maintained for studies that were cancelled without participant enrollment for a minimum of 3 years.

Records may be recalled from the Depository when needed, however only the CHS Administrator, ORSP Director, and CHS Staff Assistant have the authority to request recall and pick-up of boxes to/from the depository. All records are stored in an archive box and listed in alphabetical order; each box contains a bar code assigned by the Depository.

The CHS Staff Assistant keeps a paper copy of the list of boxes, study records and bar codes for easy recall, and this list is also accessible on the Harvard Depository folder on the CHS shared-drive.

16.2.3. Other Study Records

Some studies either close before any research activities take place or are never completed for various reasons (such as when an Investigator changes institutions or if funding is not awarded). However, any file of a study that received approval from the CHS is organized, maintained and archived in the same manner as other study files noted in this section.

16.2.4. CHS Meeting Packets

In addition to maintaining all study files at the Depository, complete meeting packets of studies that received convened CHS review are stored at the Countway Library, dating back to 2004.

16.3. Minutes of a Convened CHS Meeting

Convened CHS meetings are recorded via tape recorder by CHS staff and each study section is transcribed by the CHS staff responsible for pre-reviewing the study. Tape recordings are destroyed (or taped-over) within a year of the meeting. The CHS Administrator is responsible for transcribing any agenda items that are not study-related, or when responsible CHS staff is unavailable to transcribe his/her section of the minutes. Minutes are entered by CHS staff into the HIRBERT database and then exported into a word document, reviewed and edited by the CHS Administrator.

Minutes of CHS meetings include:

- All members present
- When an alternate replaces a primary member
- All non-members present
- Date of meeting
- Time of meeting commencement and conclusion

- Time of members entering or leaving the room after the meeting has begun
- Documentation of and for each project under review:
 - Members voting for, against or abstaining.
 - The names of the members who absent themselves from the meeting due to a conflict of interest, along with the fact that a conflicting interest is the reason for the absence.
 - Review status (initial, continuing, amendment, adverse/unexpected event, or non-compliance)
 - CHS action (approval, contingent approval, deferral, disapproval)
 - Justification for actions
 - A written summary of the discussion of controverted issues and their resolution
 - Any unresolved questions for the Investigator
 - Any required changes to the study
 - The basis for requiring changes to research
 - Any questions or suggestions for the Investigator that do and do not have bearing on the approval of the study.
 - Degree of risk
 - Determinations required by the regulations and protocol-specific findings justifying those determinations for:
 - Waiver or alteration of the consent process.
 - Research involving pregnant women, human fetuses and neonates.
 - Research involving prisoners
 - Research involving children
 - Special criteria under Massachusetts law
 - The rationale for significant and non-significant risk device determinations.
 - Approval of documents, such as consent forms, recruitment materials, questionnaires, and assessments.
 - Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
 - Confirmation that the CHS reviewed the protocol material in relation to the following: the risks to participants are minimized and reasonable in relation to anticipated benefit to the participants, if any; the importance of the knowledge that may reasonably be expected to result; the selection of participants is equitable; the procedures for securing and documenting informed consent are appropriate; the privacy of the participants and the confidentiality of the data are secured, and when appropriate, data monitoring is performed to ensure the safety of participants.
 - The basis for disapproval of research
 - For approval period for initial and continuing reviews.

The complete/edited minutes are circulated by the CHS Administrator or Staff Assistant to the full CHS via email for approval. The minutes are ordinarily sent to the CHS for review with the meeting packet each month and accepted formally at the next convened meeting (e.g. June minutes are sent with the July meeting packet and accepted at the July meeting).

A copy of the CHS accepted minutes are kept in the 'Minutes' folder on the CHS Office shared-drive, and in the meeting packets sent to Countway for archiving and kept in perpetuity. The meeting packets are archived at the Countway Library at the completion of each year. Additionally, minutes dating back three years are kept in a binder and brought to each CHS meeting.

16.4. Membership Rosters

CHS membership rosters are kept in the 'IRB Membership Lists' folder on the CHS office shared-drive. All changes in membership are approved by the Institutional Official (IO) and submitted by the CHS Administrator to OHRP via their electronic submission system each time a change in membership occurs. Paper copies are also available in the CHS Administrator's office and are distributed to the CHS membership and staff, the IO and Office of General Counsel (OGC) each year and/or each time a change is made.

16.5. Policies and Procedures

Policies and procedures of the CHS are updated as necessary and posted in entirety on the CHS website. Changes to the policies are reviewed and approved by the CHS Leadership Team and the CHS, before being posted. The CHS policies and procedures indicate the date on which they were last updated. The most recent/approved version of the document is available on the CHS website for Investigators, administrators, CHS staff and members, and the general public (**I.3.A**). Changes in regulations, policies or procedures that require immediate action or significant effort on the part of the Investigators (or their staff) are sent via email to the affected parties, are listed in the HMS weekly 'Quad Bulletin' and are noted via banner on the CHS website, as appropriate.

17. Sponsored Research

17.1. Organizational Structure

The HMS Sponsored Programs Administration (SPA) Office provides services to the Faculty of Medicine and oversight and stewardship of sponsored awards. SPA works closely with other offices within the overall research administration infrastructure at Harvard, and has signatory authority for purposes of proposing and accepting awards for the Faculty of Medicine. The funding portfolio at the Faculty of Medicine is comprised largely of federally funded awards for basic science along with a smaller proportion of federal awards for clinical research, non-federal grants, donations, trust or gifts and agreements with pharmaceutical companies.

The proposal review process serves complementary functions of assuring a complete and accurate proposal and compliance with sponsor and institutional policies. The review process is a collaboration between the faculty member, Department Head, Department Administrator, SPA staff and other offices that assure compliance with policies and regulations, including regulations related to human studies research and CHS policies. Each party in the review process assumes an important responsibility to assure that all aspects of the proposal have been thoroughly addressed.