

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.

17.2. Ethical Assurances

The CHS works closely with SPA to ensure compliance with all regulatory requirements for protection of human research participants. To this end, the senior grants administrators in SPA have access to the HIRBERT database. In this way the grants administrators can confirm that all human research protocols associated with a grant have received CHS approval, and can access details such as CHS approval and renewal dates, involvement of other IRBs, and current CHS certifications for personnel working with human research participants.

The SPA staff is keenly aware of the NIH requirement for certification of training in human subject research for all key personnel on a federal grant who are working with research participants (including participant data and biological specimens). Whenever there is a question of certification, the SPA grant administrators confirm training status on the HIRBERT database, or check with the CHS office if no documentation appears in the database.

In compliance with specific training grant requirements, additional training in the Program in Responsible Conduct of Research is made available to post doctoral fellows and others through the HMS Course on Medical Ethics. The Program in the Practice of Scientific Investigation (PPSI) was established in 1990 by the Division of Medical Ethics to provide education in the responsible conduct of research for post-doctoral research fellows. In 1999, the Dean of the Faculty of Medicine mandated completion of the PPSI for all post-doctoral fellows working in laboratories in the Harvard Medical School Quadrangle, regardless of funding source. The PPSI offers education in the responsible conduct of research to all post-doctoral fellows working in HMS labs. Five sessions for post-doctoral fellows are presented concerning issues such as authorship, data sharing and material transfer agreements, peer review of manuscripts and grants, scientific fraud, and conflicts of interest. The sessions are designed to encourage discussion and to examine the academic policies in place at HMS for the responsible conduct of science.

The SPA and CHS offices are in close proximity to each other allowing effective working relationships and accessibility to files. The Office of Technology Development (OTD) is in the same working area, which similarly allows easy communication and sharing of information. Any issues of potential non-compliance discovered in conjunction with the work of any of these offices are quickly communicated between them, as necessary. The CHS office copies SPA and OTD on official notices when a study has been suspended or terminated. The SPA office or OTD, as appropriate, will notify the funding agency of this occurrence.

17.3. Additional Requirements for Clinical Trials

See Section 12.1.7.

17.4. Requirements for Social/Behavioral Research

Although much of the human studies research taking place at HMS is more social or behavioral in nature, the commitment to the protection of human participants in these studies is no different from that of clinical studies or trials. The funding for these studies may be federal or non-federal,

but the requirements for proper training and the ethical conduct of research in human studies research are the same. Any issues involving non-compliance of non-exempt human studies research will be dealt with in a similar fashion as described above regarding notification of funding entities.

18. Participant Outreach

It is essential that research participants and potential research participants have pertinent information about any research in which they are eligible and wish or agree to take part and that they have information about their rights as a research participant. The Leadership Team will assist in the further development and evaluation of the effectiveness of HRPP participant outreach activities and assess best practices to insure the protection of and information for participants.

18.1. Consent form Requirements

In accordance with regulations at 45 CFR § 46.116 (a)(6-7) and 21 CFR § 50.25 (a)(6-7), each consent form is required to contain:

- Contact information of the Investigator (or his/her staff) for any questions, concerns or problems the participant may have about the research.
- Where to go and whom to contact (and contact information) in the event of a research-related injury when medical interventions or treatments are involved in the research.
- Contact information of the CHS (or other appropriate IRB or ethics committee) for any questions the participant may have about their rights as a participant in research or any complaints or concerns about the research.

18.2. CHS Contact Information and Procedures

The contact for research participants in the CHS office is the ORSP Director (617-432-0651), who handles all calls in a confidential manner. The ORSP Director may take down the caller's name and contact information, or if the caller does not wish to provide that information the call will be treated in the same respectful and serious manner as with an identified caller. The ORSP Director will take notes on the call and will follow-up with the Investigator, especially regarding any complaints or to confirm understanding of the research project (or parts of it, as pertinent to the question of the participant) as it was approved by the CHS.

Depending on the nature of the call, the ORSP Director may advise the participant to call the Investigator or his/her research personnel directly, or may act as the liaison between the two parties. If a serious allegation is made against the Investigator or his/her research personnel, the ORSP Director will treat the allegation in the same manner as noted regarding non-compliance investigations noted in Section 14 of these policies.

18.3. HMS and CHS Websites