

events and/or activities, the CHS may contact the reviewing IRB to coordinate actions to be taken, or review minutes of meetings when the events were discussed. If ceding review is no longer appropriate, the Administrator will notify the Investigator (with a copy to the reviewing IRB) of the reasons for this determination and the need to complete a Continuing Renewal application, inclusive of the amendment request (see Sections 5 and 6, respectively).

The Leadership Team may be asked to evaluate the effectiveness of ceding review to a particular institution. Additionally the management of procedures for ceding review will be evaluated regularly to assess best practices for the HRPP to insure protection of participants while decreasing unnecessary redundancies in oversight.

#### **7.4.4. File Closure**

Studies that have been ceded to another institution's IRB may be closed with the CHS office (even if there is continuing IRB approval at the reviewing institution), assuming one or more of the following conditions:

- i. When there is no more funding for the research activities awarded through the Faculty of Medicine;
- ii. When the funding is transferred to another institution and there is continuing review at that institution; or
- iii. When the study is closed by the Institution providing review responsibilities and research activities are no longer taking place. Note: if the study is closed at the reviewing institution, but there is data analysis being performed by a Faculty of Medicine Investigator, then the CHS will review the study.

To request file closure, the Investigator must complete the CHS File Closure form (Appendix 34) and submit it with the closure confirmation of the reviewing IRB and other documentation noted on the form, as appropriate. CHS file closure is confirmed with a letter to the Investigator (Appendix 41) that is copied to the reviewing IRB and the Faculty of Medicine's SPA representative, as appropriate.

## **8. Multi-Site Studies**

Faculty of Medicine Investigators often participate in collaborative research projects that involve multiple research sites.

### **8.1. Where the Faculty of Medicine is the recipient of the primary funding award (regardless of the source), and the research is conducted at HMS or HSDM (with additional sites coordinated by the HMS/HSDM Investigator)**

- i. The CHS is responsible for the initial and continuing reviews of the main study, the grant, all research materials and activities, and participant safety.
- ii. The CHS is responsible for receiving copies of IRB approvals, approved consent documents and research materials (including language translations) from all sites and, for

DHHS sponsored research, assuring that research is taking place at institutions holding a current FWA.

- iii. The CHS will review plans for circulating approved protocols and data collection instruments to the sites, for communicating changes to the protocol to those sites, and for data distribution from those sites back to the Investigator and/or between sites.
- iv. The CHS is responsible for reviewing unanticipated and adverse events (unless there is a DSMB) and for ensuring an adequate plan of informing additional sites of these issues in a timely manner.
- v. The CHS is responsible for reviewing requests for changes to the protocol and the Investigator's plan to disseminate information about approved changes to the additional sites, and also is responsible for receiving amendment approvals (and approvals of any revised documents) from the IRBs at those sites.
- vi. The CHS is responsible for reviewing any protocol deviations or issues of non-compliance with federal regulations at the HMS/HSDM site, and for reviewing any such reports to/from the additional site's IRBs. The CHS will review the Investigator's plans for reporting such issues to the other sites and will itself report such issues to the other site IRBs.
- vii. The CHS will collaborate and communicate with other IRBs reviewing or ceding review of the research, as necessary.

**8.2. Where the Faculty of Medicine is the recipient of a primary funding award and the Principal Investigator is an HMS/HSDM faculty member who is based at a Harvard-affiliated institution where the research will be taking place**

- i. The CHS will either confirm its use of a Cooperative Agreement (CA) or Reliance Agreement (RA) with the Institution or will ordinarily enter into an IRB Authorization Agreement (IAA) with the IRB of the Harvard-affiliated institution.
- ii. If the CHS is unable to enter into an IAA with the IRB of the Harvard-affiliated institution, then the CHS remains responsible for the items in Section 8.1, above.
- iii. The CHS will collaborate and communicate with other IRBs reviewing or ceding review of the research, or to whom it is ceding review, as necessary.

**8.3. Where the Faculty of Medicine is the recipient of a subcontract funding award and the research is taking place at HMS or HSDM**

- i. The CHS is responsible for the initial and continuing reviews of the research indicated in the subcontract for the research taking place at HMS/HSDM, and for participant safety at the HMS or HSDM sites.
- ii. The CHS is responsible for ensuring that the Investigator enters into a material transfer agreement (MTA; Appendix 42) or a clinical trial agreement (CTA; Appendix 43), as appropriate, before the research begins. The CHS is responsible for reviewing the CTA with the Office of Technology Development (OTD).
- iii. The CHS is responsible for receiving a copy of the approval document from the IRB of the institution receiving the primary funding award.

- iv. The CHS is responsible for reviewing unanticipated and adverse events (unless there is a DSMB) and the plan for (i) reporting events to the main/overall Investigator, and (ii) receiving information on events from the other research sites, and/or the DSMB.
- v. The CHS is responsible for reviewing requests for changes to a protocol at the Faculty of Medicine site.
- vi. The CHS is responsible for reviewing any reports of protocol deviations and/or non-compliance with federal regulations at the HMS/HSDM site.
- vii. The CHS will collaborate and communicate with other IRBs reviewing or ceding review of the research, or to whom it is ceding review, as necessary.

**8.4. Where an HMS/HSDM Investigator who is based at a Harvard-affiliated institution is the recipient of a subcontract funding award from the Faculty of Medicine and the research is taking place at the Harvard-affiliated institution**

- i. The CHS will either confirm its use of a CA or RA with the Institution or will ordinarily enter into an IAA with the IRB of the Harvard-affiliated institution.
- ii. If the CHS is unable to enter into an IAA with the IRB of the Harvard-affiliated institution, then the CHS remains responsible for the items in Section 8.3, above.
- iii. The CHS will collaborate and communicate with other IRBs reviewing or ceding review of the research, or to whom it is ceding review, as necessary.

**8.5. Where there is no external funding to the Faculty of Medicine and the HMS/HSDM Investigator is the Principal Investigator and additional sites are coordinated by the Investigator**

See Section 8.1, above.

**8.6. Where an HMS/HSDM Investigator who is based at a Harvard-affiliated institution receives no external funding through the Faculty of Medicine and the research is taking place at the Harvard-affiliated institution**

The research should be approved by the IRB of the Harvard-affiliated institution.

**8.7. Where the primary research funds are awarded to the Faculty of Medicine and may or may not include a subcontract to the Institution where the research is taking place and where the HMS/HSDM Investigator has no affiliation**

See Section 8.2, above.

**8.8. Where the subcontract research funds are awarded to Faculty of Medicine and the research is taking place at an Institution where the Investigator has no affiliation**

See Section 8.4, above.

The Leadership Team may be asked to evaluate the effectiveness of these policies to assess best practices for the HRPP to insure protection of human participants while decreasing unnecessary redundancies in oversight.