

## **9. Research by Faculty of Medicine Students**

HMS and HSDM pre-doctoral students conduct independent research projects, and thus the CHS allows these students to serve as Principal Investigators on their own studies. Student research must meet minimal risk exemption or expedited review criteria (though, as stated in Section 4.10.2, some minimal risk studies may require full CHS review depending on the research topic, activities, population and/or location). HMS and HSDM students are subject to the same policies, guidelines and regulations as the Faculty of Medicine, as documented in this Policy and Procedures manual, as well as additional requirements outlined in this section.

### **9.1. Mentors**

Each student must have at least one faculty mentor or faculty advisor and one mentor at the site where the research is taking place. The faculty mentor should be available to assist the student in developing his/her protocol, CHS application and study materials. The site mentor should be available to assist the student with any local/institutional approvals, and be available while the study is being conducted, in the event that problems or questions arise.

#### **9.1.1. Mentor Letters/Letters of Support**

##### **9.1.1.1. HMS and HSDM Faculty Letters**

Students are required to have a letter from their faculty mentor or advisor. This letter must accompany the CHS application and should include the following information:

- The mentor is assisting the student in the development of the research proposal, CHS application and research materials.
- The mentor will be available throughout the conduct of the research to answer any of the student's questions and help the student deal with any problems that may arise.
- The mentor is familiar with the ethical conduct of research and has taken a human subjects protection course or training (documentation of the mentor's current certificate should accompany the student's CHS application).
- Any knowledge the mentor has of the site/location where the student will be working, or with whom they will be working (i.e. on-site mentor or organization).

##### **9.1.1.2. On-Site Mentor Letters/Letters of Support**

Students performing research at institutions, organizations, or clinics not at HMS/HSDM, domestic or international, are required to also have an on-site mentor (i.e. a mentor at the institution, organization or clinic where the research will be taking place). Site mentor letters should include the following:

- The site mentor will be available to help the student set up his/her research project.
- The site mentor will be available to help the student with any questions/problems that arise with the research/materials.

- The site mentor is familiar with the ethical conduct of research and confidentiality/privacy issues.
- The site mentor is familiar with local customs, language, laws (or can assist the student in seeking such legal counsel), standards of care and practice where the research is taking place.

### **9.1.2. HSDM Faculty Advisors**

The HSDM Office of Research assigns students to Faculty Advisors who are responsible for working with students to ensure they are meeting their research requirements, selecting appropriate projects and mentors, and offering guidance as needed throughout their program. The HSDM Office of Research has a database of mentors that have worked with HSDM students in the past and will keep this resource on file. There is a HSDM Pre-Doctorate Advisory Committee which oversees the research advisor program.

## **9.2. Funding for Student Research**

### **9.2.1. Faculty of Medicine Office of Enrichment Programs (OEP)**

The OEP serves as a resource for Faculty of Medicine students interested in applying for Harvard University and other domestic or international traveling fellowships for study, community service, or research. These fellowships include, for example, the Fulbright Scholars Program, the Zuckerman Fellowships, the Howard Hughes Medical Institute fellowships, the Doris Duke/Pasteur fellowships, the Fogarty Ellison Overseas Fellowships in Global Health and Clinical Research, and the traveling fellowships available through the Harvard University Committee on General Scholarships.

The OEP and CHS offices work closely together to ensure that all student research projects have been reviewed and approved by each office/Committee before research activities commence. Students who have submitted funding applications to OEP must submit the complete OEP application with their CHS application to the CHS office. No funding may be released by OEP to the student until the CHS office confirms with OEP that the student is actively engaged in the CHS approval process or that CHS approval has been documented.

### **9.2.2. Fellowship Monies**

If a student will be receiving fellowship monies from the Faculty of Medicine to support his/her research project and the fellowship includes living expenses, the funding can be released with the following conditions: (a) the student may not expend any of the fellowship monies for research purposes until CHS approval has been documented, and (b) no research activities can take place until CHS approval has been documented. However, if the fellowship is only for research purposes, no money may be released until CHS approval has been documented. CHS approval is documented in the form of a ROA or exemption letter (see Sections 4.8, 4.9, 4.10).

### **9.2.3. Extramural Funding**

Students receiving grants or contracts from outside the Faculty of Medicine must submit the entire grant application, along with the CHS application and all applicable materials outlined in Section 4, for CHS review and approval. No research monies will be released until CHS approval is documented in the form of a ROA or exemption letter (see Sections 4.8, 4.9, 4.10).

### **9.3. CHS Student Submission Requirements**

Student submissions of independent research projects to the CHS should include:

- Cover letter
- CHS Application signed by student and mentor.
- A copy of the grant, contract, and/or OEP or research fellowship application.
- Informed consent forms or request for waiver (also HIPAA authorization or request for waiver of same, if applicable).
- Research materials (such as recruitment fliers, survey instruments, questionnaires, telephone scripts, and focus group questions)
- Evidence of HETHR training (or equivalent training certificate) for student and mentor.
- IRB approvals from other institutions/sites.
- Mentor letters (HMS/HSDM faculty *and* on-site supervisor).

Students who wish to work on an already existing or a soon to be approved research project (as a research assistant/associate) and who are receiving funding from the Faculty of Medicine must submit:

- A cover letter explaining the student's role in the research project.
- A copy of the complete OEP application.
- Evidence of HETHR training (or equivalent training certificate)
- A copy of the IRB approved research application or protocol that includes the student as research personnel, or an amendment documenting the addition of the student to the study roster, and current IRB approval documentation.
- If the student will be performing additional research activities involving human participants not included in the original IRB application, then the student and/or Investigator must submit an amendment to the appropriate IRB to include this work. Documentation of the amendment and the IRB approval must be submitted to the CHS office.

### **9.4. Communication**

To provide all-around support for the student and information about his/her intended research project, all communications from the CHS office to the student are copied to: (a) OEP (if the student is receiving OEP funding); (b) the faculty mentor; (c) the on-site mentor, as appropriate; and (d) any other appropriate entity (such as additional IRB/ethics committee, facility manager or advisor).

### **9.5. Institutional Approvals**

Students are required to obtain **all** appropriate institutional and site approvals before commencing research activities.

### **9.5.1. CHS Approval**

CHS approval must be documented with an ROA or letter of exemption (or a letter of participation; Appendix 44, if the student is receiving funding from the Faculty of Medicine and joining a study as research personnel) before any research activities may commence. Approval documentation will additionally be copied to: (a) OEP (if the student is receiving OEP funding); (b) the faculty mentor; (c) the on-site mentor, as appropriate; and (d) any other appropriate entity (such as additional IRB/ethics committee, facility manager, or advisor). Final approvals for research to be undertaken at external sites may be held until formal approval documentation from that site is forwarded to the CHS.

### **9.5.2. Research Site Approvals**

As noted in Section 4.13 of this policy document, the CHS is required to have knowledge of the local research context (whether the research site is a domestic or international research site) in order to provide a thorough review, to understand particular risks and benefits of the study population, and the relevance, customs and cultural significance of study procedures and outcomes to the community in which the research is taking place. In addition, while the CHS provides institutional approval for the student (which is required), it cannot and does not cover the responsibility or replace the need of the student to receive approval from the local reviewing authority at the site where the research will be taking place. Site approvals are required in all circumstances.

### **9.5.3. Ceded Review of Student Research**

Review and approval of independent student research projects ordinarily are not ceded to another institution. However if the research activities would require review by another Harvard IRB or the IRB of one of Harvard's affiliated institutions, a request to cede may be granted if approved by all involved/engaged IRBs. Affiliated and other institutions, however, may cede review of student projects (where appropriate) to the CHS.

## **10. Policies and Criteria for IRB Approval**

### **10.1. Participation Review**

The mission of the CHS is to ensure that all participants are protected from any unnecessary risk when enrolled in a research study; to ensure participants make an informed decision to participate, and when possible, ensure that participant and/or society at large benefits from the knowledge gained from the research study. The CHS reviews the participation of humans in research, in accordance with applicable federal regulation (45 CFR § 46.111(a) and (b)), the Belmont Report, and University and CHS policy, as documented in the following section.

#### **10.1.1. Equitable Selection of Participants**