IRB-HSBS Tips for Student Researchers

Does my research require IRB review?

Projects that meet the regulatory definition of research with human subjects require review and approval by an Institutional Review Board (IRB) BEFORE research (including subject recruitment) can begin. *Research* is defined as: "a systematic investigation… designed to develop or contribute to generalizable knowledge." A *human subject* is "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." See the Human Research Protection Program Operations Manual Part 4, for examples of projects that do not require IRB oversight.

Types of IRB review

- ***Full Board Review*** – Research posing more than minimal risk to subjects or minimal risk projects involving vulnerable subjects or complex protocols. Reviewed by the full IRB membership. Average review time from submission to approval: 4-8 weeks.
- ***Expedited Review*** –No more than minimal risk research meeting one of nine categories of expedited research. Reviewed by a single member of the IRB. Average review time: 2-4 weeks.
- ***Exempt Review*** - Projects meeting one of seven categories of exempt research. Reviewed by a designated individual. Average review time: 1-2 weeks.

How do I apply for IRB review?

1. ***Identify a faculty advisor –*** This is your dissertation chair, masters or undergraduate research advisor. Your advisor will mentor you through the research process and must be included as a study team member on your IRB application.
2. ***Formulate your research question and study design*** –This includes development of survey instruments or interview protocols and identifying your subject population and recruitment strategy.
3. ***Determine how you will obtain informed consent –***See IRB-HSBS homepage for informed consent guidance, templates and sample documents.
4. ***Complete the PEERRS human subjects research training module -*** All UM researchers (including faculty advisors) must complete this training.
5. ***Prepare your IRB application via eResearch –*** You will need the following materials:
   - Research Protocol
   - Performance site information, including site approval letters or IRB approval
   - Informed consent documents (including text for studies using an oral consent process)
   - Recruitment materials (flyers, posters, letters, text of emails or oral recruitment scripts)
   - Survey/interview/focus group questions
6. ***Submit your application for IRB review via eResearch-*** Your advisor and other key study team members will need to review the application and "Accept Role" before submission.
7. ***Monitor your email –*** eResearch notices will be sent to your email when an action on your part is required. Respond promptly to any requested changes to your application or requests for information. Your IRB approval will also be sent via an eResearch email notice.
8. ***Conduct your research as approved by the IRB –*** Any changes to research projects requiring IRB oversight must be approved by the IRB before implementation. Submit an amendment via eResearch system.
9. ***Renew your IRB approval prior to the expiration date –*** Submit a Scheduled Continuing Review application via eResearch at least 30 days prior to expiration.
10. ***Report adverse events or other problems to the IRB –*** Report via an Adverse Event/ORIO report in eResearch.

Key Resources

- ***Institutional Review Board – Health Sciences and Behavioral Sciences,*** University of Michigan, 2800 Plymouth Rd. Building 520, Room 1169; Ann Arbor, MI 48109-2800. Phone: 734-936-0933, Email: irbhsbs@umich.edu

The IRB website includes contact information for IRB staff and the IRB chair; guidance materials, including informed consent templates; a schedule of formal training sessions as well as departmental "IRB-on-the-Road" hours; and the schedule of PI submission due dates and meetings of the full IRB.

- ***eResearch Regulatory Management System (RM),*** http://eresearch.umich.edu.
- ***Program for Education and Evaluation in Responsible Research (PEERRS),*** http://my.research.umich.edu/peerrs/.

The human subjects research module in the PEERRS curriculum is required for IRB approval of research.

- ***Guide for Student Researchers,*** see IRB-HSBS homepage.