



## **IRB Q&A for Engaged Learning Fellowship Students**

### **1. What is the IRB at SMU?**

The IRB is the abbreviated name for the Institutional Review Board, a group of SMU faculty and staff researchers who provide ethical oversight of all SMU research that directly or indirectly involves human participants. All human subject research that will be available to the public must undergo IRB scrutiny.

For more information visit <http://www.smu.edu/Research/ResearchResources/Research-Compliance/IRB>

### **2. Why does the IRB exist?**

The IRB protects humans who participate as subjects in research projects.

A little background, any institution that receives federal funding to conduct research with human participants is required to establish an IRB. The U.S. Department of Health and Human Services set the rules and regulations for institutional IRBs in 2001. Under these regulations, the institution's IRB is responsible for the ethical oversight and approval of human subject research conducted within the institution.

In addition, federal regulations state that only the IRB decides if IRB approval is needed for research projects or not. Researchers may not decide if IRB is needed. If IRB approval/waiver is not sought at the institution, there are severe consequences.

Researchers:

- will NOT be allowed to use data collected or received in any public forum, presentation, publication etc. without IRB approval.
- will not receive SMU funding for their project.

SMU:

- is required to notify grant agencies that the project was not reviewed by IRB and grant funding will likely be withdrawn.
- may be penalized, fined and/or lose all of its federal funding including grants and student scholarships and financial aid.

### **3. Do all Engaged Learning Fellowship (ELF) projects need oversight by the IRB?**

YES. All approved ELF projects, whether they are classified as research, service, internships or creative work, are reviewed by SMU Research Compliance upon approval and that office determines if a project is subject to IRB oversight. For any project that includes human participants who are used in any aspect of research (observing, interviewing, surveying, etc.), IRB review will be required. The student and mentor will be notified by SMU Research Compliance to start the process.

The reason for this is that Engaged Learning requires all ELF students to present their work in two public forums – the Engaged Learning Symposium (or similar event) and turning in the final product for possible publication by the university. As ELFs are designed for students to have professional

opportunities to discuss their projects and disseminate data upon fellowship completion (e.g., Engaged Learning Symposia, Research Day, professional conference presentation or publication), IRB oversight is required.

If SMU Research Compliance determines that a project needs to be submitted, this must be done ASAP and **IRB approval granted prior to beginning the project**. IRB cannot grant retroactive approval.

#### **4. Who decides if a project requires IRB approval?**

The director of SMU Research Compliance determines if Engaged Learning Fellowship proposal requires IRB oversight. If so, then the student and mentor work together to complete the IRB application.

#### **5. Who submits the IRB application for an Engaged Learning Fellowship project?**

**THE MENTOR.** Undergraduates cannot submit an application on their own. The mentor is identified as the Principal Investigator (PI) for the project.

The student should add his or her name as a contact on the application so that he or she will be copied on all correspondence between SMU Research Compliance and the PI. It is recommended that the director of Engaged Learning is also added as a contact so that Engaged Learning staff can track the application process and offer support if needed.

If you have questions about IRB, what makes a quality proposal, what forms are needed, etc., your mentor can help you. Mentors are responsible for discussing research ethics and IRB protocol with students prior to beginning their projects.

#### **6. Where are the forms and guidelines for submitting proposals to the IRB?**

<http://www.smu.edu/Research/ResearchResources/Research-Compliance/IRB/SubmissionProcess>

#### **7. How long does the IRB review take?**

The speed of the IRB review is dictated by the quality of the IRB submission:

- If the PI submits a complete application, the review/approval process may take a month or two.
- If the PI submits an incomplete application, the review/approval may take several months or more.

The reality is that most ELF applications are not complete upon the first submission and the PI is asked to address issues or modify data collection protocol or submit missing forms (surveys, interview questions, informed consents, etc.). The length of time it takes to do this is up to the student and the mentor.

Therefore, it takes as long as it takes to get all of the documents correct. The process is valuable though as it dramatically improves the project and the student's experience as a researcher.

Once the review is complete, the PI (and all persons included on the notification contact list) will receive an IRB outcome letter. The outcome letter will either grant final approval or provide information for the next steps required to secure approval.

#### **8. What does the IRB decide?**

**THE PROJECT IS EXEMPT, THE SUBMISSION CAN BE EXPEDITED OR IT NEEDS A FULL BOARD REVIEW.** At the point of submission, SMU Research Compliance will vet the project prior to IRB review and send the PI a pre-review modifications document (if warranted). Once the modifications

are made and the submission package complete, Research Compliance will decide what kind of review is needed. If full board, the PI will be asked to attend the IRB meeting to provide a project overview.

### **9. What kinds of research projects are exempt from IRB review?**

Research in which there is no risk. This may include research involving only anonymous questionnaires, surveys, and educational tests, naturalistic observation in public places when there is no threat to anonymity, or archival research based on publicly available data.

The decision that this type of research is exempt can only be determined by SMU Research compliance. Once a project is tagged as needing IRB oversight, it must be submitted for review. The researcher cannot determine that the research is exempt, they must apply for exempt status.

If the PI or the student may someday want to publicly present or publish the results of a project, IRB approval is required.

### **10. Under what conditions do community-based or service-learning projects need to be reviewed by the IRB?**

If the project involves human participants, the project must be submitted for review. SMU Research Compliance will provide information on planning and implementing the project in accordance with ethical and legal responsibilities that protect the participating individuals.

Know that IRB review **is required** if:

- There is the intent to undertake a systematic investigation, to produce a design or protocol for the research, to sample a population, report findings, etc.
- Data collected within community- or service-based learning experiences will be disseminated to any audience beyond the project through formal presentation (e.g. poster, oral or written, seminar).
- The project may develop into disseminated research.

IRB approval must be obtained immediately. IRB cannot grant retroactive approval.

While IRB approval is generally not required for community-based and service-learning projects except in the cases described above, such activity must still be planned and carried out in consideration of the ethical and legal responsibilities to protect the individuals participating in these activities.

Projects involving special populations as subjects (e.g., youth under age 18; prisoners, individuals with physical or mental disabilities; economically or educationally disadvantaged; institutionalized individuals; pregnant women) require additional safeguards. In these cases, mentors should contact the Director of Research Compliance to determine whether IRB approval is required.

### **11. What if the project gets modified?**

Think of IRB approval as a contract. If a contract is changed, new signatures are needed to make sure everyone knows of the changes. Thus, any changes (e.g., new questions, more or different subjects, recruitment material, etc.) to an approved protocol must be submitted as an amendment and be approved by the IRB.

Information on the amendment process can be found here:

<http://www.smu.edu/Research/ResearchResources/Research-Compliance/IRB/SubmissionProcess>

The PI submits the amendment for approval before modifying the originally approved submission. Approval is needed to be able to use the data with the modified protocol.

**12. What if the project goes in a different direction and the PI or students feels it does not need IRB oversight?**

Think of the IRB process as a commitment. Terminating a commitment requires that the PI emails SMU Research Compliance directly of the change in the proposed activity, attaching the new proposal as a courtesy. This should be done at the time of the change so that the student can be removed from Engaged Learning's list of non-IRB compliant students.

**More IRB Questions? The following links can help you.**

FEDERAL GUIDELINES WEBPAGE <http://www.hhs.gov/ohrp>

SMU RESEARCH COMPLIANCE

WEBSITE <http://www.smu.edu/Research/ResearchResources/Research%20Compliance>

EMAIL [researchcompliance@smu.edu](mailto:researchcompliance@smu.edu)

PHONE 214 768 2029