

# **Institutional Review Board & Human Subjects Office**

# **Back to School Reminder**



As student investigators return to classes this spring semester, the <u>Human Subjects Office (HSO)</u> would like to offer a friendly reminder to those conducting <u>human subjects research</u> to start the <u>HawkIRB</u> application submission process sooner rather than later. It is important for students and faculty members conducting human subjects research, particularly time sensitive or semester projects, to submit applications to the HSO/IRB and

any materials to the <u>applicable UI committees and programs</u> that review research involving human subjects as soon as possible. Faculty members assigning semester or class projects are strongly encouraged to contact and/or meet with HSO staff if the entire class will be conducting a human subjects research project. The HSO is available to provide guidance to help ensure class research projects are conducted in an ethical manner in accordance with the UI IRB's Course-Related Student Projects Policy.

## **Course-Related Student Projects**

For course-related research projects, students <u>conducting human subjects research as part of a course requirement</u>, or faculty members/class instructors <u>assigning these projects</u> should refer to the <u>Course-Related Student Projects Policy</u> to help determine if the project will require IRB review and approval.

## **Faculty Advisor Responsibilities**

The Faculty Advisor listed on a HawkIRB application is considered the responsible party for the legal and ethical performance of a student investigator's project. To ensure compliance with federal regulations and institutional policies for the protection of human subjects, Faculty Advisors should refer to the supplemental handout provided by the HSO highlighting important oversight responsibilities and assurances.

## Is it Human Subjects Research?

Those who are unsure as to whether a proposed project requires IRB review should submit a <a href="Human Subjects Research Determination">Human Subjects Research Determination (HSRD)</a> form in HawkIRB to receive a documented determination from an IRB Chair. The HSRD is a short form, consisting of four sections, that allows an IRB Chair to determine if the project described by the investigator constitutes <a href="human subjects research">human subjects research</a>. Keep in mind that the submission of an HSRD form does not grant the investigator permission to start the research. Investigators typically receive a determination via HawkIRB within 24-48 hours after submission. For projects determined to meet the definition of human subjects research, investigators will need submit a New Project Application in HawkIRB to review IRB review and approval prior to beginning the research.

## **Allow for Enough Time**



Investigators should plan for IRB review to take approximately 6-8 weeks for a new study, regardless of whether it receives expedited or full board review. Allowing for a sufficient amount of time to receive IRB review is particularly important for researchers who need to make travel arrangements to conduct international research. Submitting a HawkIRB application 1-2 weeks before a scheduled international research trip with an expectation of receiving quick IRB approval is not advised. Also keep in mind that the IRB-02 Full Board (the board



which reviews social and behavioral research projects that are more than minimal risk to participants) meets once per month to review and approve projects. Investigators should allow themselves ample time to discuss their research plans with their faculty advisor or class instructor, visit <a href="HSO">HSO</a> Office Hours or contact the HSO to ask questions and receive guidance on submitting the application. Starting the review process as early as

possible helps ensure that the study is approved with plenty of time to complete the research, but also allows time for the investigator to consider and/or correct any issues that may delay the research.

### **International Research**

This reminder is especially important for students conducting international research, which requires additional documentation (e.g. translated consent documents, documented permission from the site where research procedures will occur, etc.). Also keep in mind that the country's ethical review committee, if one



exists, will require time to review and approve the project. If the country does not have a local ethical review committee, the UI IRB requires the submission of a completed Local Context Review Form. This form (the template can be found in the Miscellaneous section on the attachments page of your HawkIRB application) requires the investigator to identify a local expert. This individual should be someone who is familiar with conducting human subjects research in the country of interest to review the research plan and provide written responses to questions reviewed by the IRB. Certain funding entities may also require additional documentation. For example, <a href="International Programs">International Programs</a> has specific requirements for <a href="Stanley Undergraduate Award">Stanley Undergraduate Award</a> recipients that may necessitate additional planning on the part of the student investigator and their faculty advisor.

#### **Research in Public Schools**



Investigators planning to conduct research in public schools may want to consult with the <u>Cooperating Schools Program (CSP)</u> to receive assistance in obtaining and documenting permission to conduct research in lowa schools and school districts. Investigators will also want to consider the time of year they wish to conduct the research and account for the availability of teachers, school administrators, and students during holidays and school breaks. Conducting research with minors may also require written parental consent. Investigators need to allow for enough time in their projects to obtain parental

consent and take into account delays in obtaining documented consent and allowing for enough time to answers parents' questions about their child's participation in the study.