

IRB Digest - April 20, 2009

Student Research

Fact: Student research makes up 49% of the research that The University of Arizona Human Subjects Protection Program (HSPP) oversees.

Note: All of the below information assumes that the project involves human subjects as defined by OHRP or the FDA.

When does a student project need to be submitted to the Human Subjects Protection Program?

The Federal regulations under 45 CFR 46.102(d) define research as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” If the project is not a systematic investigation and it is not going to contribute to generalizable knowledge, then it is not human subjects research and does not need to be submitted to our office.

If a project will be part of a thesis or dissertation for The University of Arizona, does the student need to submit it to the Human Subjects Protection Program for approval?

Yes! Theses and dissertations are cataloged in the library and therefore make an individual contribution to generalizable knowledge. These projects must be submitted to the HSPP office for review and approval. Note: This includes undergraduate Honors Theses.

What if the project is to fulfill coursework requirements?

Projects that are done for the SOLE purpose of fulfilling coursework requirements are considered projects for educational purpose only and do NOT require IRB approval. However, if the student intends to extend the purpose of the project to contribute to a thesis/dissertation or publication, then the research may involve human subjects and should be submitted to the HSPP office prior to initiation.

Coursework requirements include any aspect of an educational class that is mandatory in order to pass. This includes presentations and papers that are written into the class curriculum.

What if the student is working on an IRB-approved human subjects research protocol at another institution and is using the experience to fulfill coursework at The University of Arizona?

The purpose of the student’s work for The University of Arizona is to fulfill coursework requirements; therefore, IRB approval by the UA is not required. The student is expected to be listed on the other institution’s IRB-approved project in accordance with their policies.

What if the student wishes to publish their work from a project conducted at another institution under their IRB approval?

The student does not need apply to The University of Arizona HSPP if the student is contributing to a publication under another institution’s IRB approval. If the student will be publishing the work under The University of Arizona, then submission to the UA HSPP office is required.

What if the student's project to fulfill educational requirements involves the testing of a device?

If the project falls under the FDA definition of a clinical investigation as defined in 21 CFR 50.3(c), then submission to the HSPP office is required regardless of the purpose of the project. A *Clinical Investigation* means “any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.”

What if the student wants to participate on an existing IRB-approved project at The University of Arizona and use the information to contribute to their thesis or dissertation?

The gold standard is that the student submits their own project for review and approval. This will assure the Graduate College and the HSPP office that the student is responsible for the project and its conduct. Every student project must have an advisor listed.

What is the role of the Advisor on a student human subjects study?

The advisor is responsible for the mentoring of the student during the course of their research. If the student leaves the institution, the advisor is responsible for the paperwork and conduct of the study.

What if the department will not allow a student to be the PI on a project?

The advisor may be the PI on the project. In these cases, the student should be listed as the Co-PI. A Co-PI has the same authority as a PI to modify the proposed research.

What if the student's project is integral to an ongoing IRB-approved project?

Many existing projects are large grants that allow students to perform cutting edge research within the boundaries of a previously-approved IRB protocol. In these cases where the student's research is within the currently approved study aims and where the information will be used to help fulfill the aims of the grant, then the student can be added to the project as a Co-PI. If this is not feasible, then a *Student PI* designation can be used. The Student PI is a designation created in the spring of 2008 that allows a PI to add graduate students to a project. The boundaries of the Student PI research project are well defined, and the Student PI is then limited oversight of their aspect of the project.

How is a Student PI added to a project?

A Student PI is added by submitting a Request for Amendment Form, a revised Verification of Training Form (VOTF), and an abstract of the student's project (including the title of the project). Any revised documents, if any, including the consenting instruments, recruitment documents, etc. that are affected by the addition of the Student PI should also be submitted for approval. This amendment to the main study is then processed. A separate Project Review Form does not need to be submitted for the student's portion of the project.

What if the aims of the student's project are different from the overall aims of the grant (and IRB-approved project)?

If the aims of the student's project are different from the overall aims of the project, then the student should submit their own project for IRB approval.

Does the Graduate College recognize a Student PI as an appropriate research role for graduation?

Yes, the student should submit a copy of the IRB approval letter classifying them as a Student PI to the Graduate College with their other required paperwork.

Thank you for your continued support of The University of Arizona Human Subjects Protection Program. If you have any questions or comments, please feel free to contact me directly at 626-2979 or wrtate@email.arizona.edu.

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