Human Subjects Research

Top 10 quick(ish) Tips for Research Capstone Projects

From your friendly Research Development Manager, Cortney Leach

1. **Consider completing the online CITI (Collaborative Institutional Training Initiative) training in the Protection of Human Research Subjects.** I recommend completing the Social/Behavioral Course, which takes 3-5 hours to complete. You will you get a great backgrounder on human subjects research regulations and this whole mystical landscape will seem more clear. See: http://www.washington.edu/research/hsd/courses , and definitely follow the instructions sheet rather than pecking around the site. Trust me.

2. **Wait, I didn't need to worry about this when I did research projects in previous classes. What gives?** That's because that while the work you did was valuable, the purpose of your class projects (and practica, internships) was not so much to add to the larger body of general knowledge, but to teach you about research methods and give you the opportunity to practice these skills. Your projects did not meet the federal definition of research that requires review.

3. **So what research <u>does</u> require Human Subjects review?** The federal and University definition of human subjects research is based on a couple of key concepts. One of them is that the project is "designed to develop or contribute to generalizable knowledge." A student needs to submit a Human Subjects Review application for review and approval by the UW Institutional Review Board (IRB) when the work goes beyond practicing skills into actually designing and implementing a research project with *the intent to apply the results more broadly* beyond the individuals studied or beyond a specific time and/or location, such as to other settings, circumstances, or categories. This includes almost all independent undergraduate research projects and honor theses, masters theses, and doctoral dissertations because they are almost always intended to contribute to generalizable knowledge.

4. **Okay, but really, what is the *actual* definition of research that must be reviewed by the UW IRB?** This answer hinges on answering two simple but often challenging questions: Does the project meet the federal definition of <u>research</u> and whether the research <u>involves human subjects</u>.

   "Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

   - Investigation: A searching inquiry for facts, or detailed or careful examination.
   - Systematic: Having or involving a prospectively identified approach to the investigation, based on a system, methods, or plans.
   - Designed: The activity has a predetermined purpose and intent.
   - Develop: To form the basis for a future contribution.
   - Contribute: To result in.
   - Knowledge: Truths, facts, information.

- Generalizable: The data and/or conclusions are intended to apply more broadly beyond the individuals studied or beyond a specific time and/or location, such as to other settings, circumstances, or categories. Publishing or presenting does not necessarily make a project generalizable.

"A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

- Living: means that the subject is alive at the time of the research, according to applicable local and national regulations.
- About whom: means the data or information relates to the person. Asking individuals what they think about something is almost always about the person.
- Intervention: includes both physical procedures by which data are gathered, and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction: includes communication or interpersonal contact between investigator and subject.
- Identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

5. **Plan ahead!** If you're embarking on a <u>research</u> project, that involves <u>people</u> in some way, chances are you're going to need to receive approval from the UW IRB before starting your research activities. And research activities start with your recruitment materials. *The IRB review process can take between 2 and 8 weeks depending on the type of review required.*

6. **There are a few levels of review**…
    a. <u>Not Human Subjects Research</u>: We work with the UW Human Subjects Division (HSD), the administrative arm of the UW IRB, to determine that your project does not meet the federal definition of research involving human subjects. We receive and retain an email to that effect and you're done. *Time estimate = 3 days.*
    b. <u>Exempt Status</u>: Research that poses little to no risk for those human subjects it involves and falls within one or more of six federally-defined categories qualifies for "exempt status." This means that the research is exempt from the federal regulations that govern human subjects research and does not need to undergo review by an Institutional Review Board (IRB). However, a determination does need to be made by HSD that the research qualifies as "exempt." Learn more here: http://www.washington.edu/research/hsd/docs/1206 . Submit Exempt Status Request Form and data collection instruments to iSchool Research Development Manager for review and departmental signature, and then to HSD. *Time estimate = 2 to 3 weeks.*
    c. <u>Expedited/Minimal Risk</u>: Expedited Review is a review process defined by federal regulations. It allows a research study to be reviewed by the IRB committee chair, or by one or more review members designated by the chair rather than the full convened IRB. In addition to meeting the regulatory definition of Minimal Risk, all procedures must fall into one or more of the research categories in this regulatory list: http://www.hhs.gov/ohrp/policy/expedited98.html . If the procedures do not fit into a

category in this list, the study cannot receive expedited review even if it is not more than minimal risk. As defined by the federal regulations, Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Submit a Human Subjects Review Application (Form 13-11); data collection instruments; informed consent forms; recruitment materials; and funding proposal if the project has received extramural funding to iSchool Research Development Manager and then to UW HSD. *Time estimate = 6 to 8 weeks.*

    d. <u>Full Board/Committee (Convened IRB)</u>: If the work does not qualify for Expedited/Minimal Risk review, then it must be reviewed by a full IRB Committee. IRB Committees usually convene twice per month. Submit a Human Subjects Review Application (Form 13-11); data collection instruments; informed consent forms; recruitment materials; and funding proposal if the project has received extramural funding to iSchool Research Development Manager and then to UW HSD. *Time estimate = 6 to 8 weeks.*

7. **Visit The UW Human Subjects Division (HSD) website**: http://www.washington.edu/research/hsd/ HSD is the administrative arm of the IRB.

8. **Pull a fresh form down from the UW Human Subjects Division's website each time you start an application.** The forms change. Often. If you complete and submit an out-of-date form HSD will send it back to you and the review timeline starts over again.

9. **Be very exact with your language when completing IRB applications**. When describing your methods; how potential subjects will be approached; how you will complete the informed consent process with subjects; how you will protect the privacy of your research subjects… be very specific. For example, if you are conducting a semi-structured interview but also want to have subjects perform a task (e.g., look at a prototype, listen to music), then it ceases to be just an interview. This detail will bump you from a 2 to 3 week exempt status review to a 6 to 8 week minimal risk review.

10. **You have resources!** When in doubt, ask your Research Development Manager. No one has to walk this path alone! The best way to start this process is to schedule a quick in-person meeting with your Research Development Manager so we can decide what level of review you will need and to carve a path forward together. The good news is that you're doing research! And research is awesome. And ethical and compliant research is even awesomer.

Questions?

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