WHAT IS THE IRB AND HSD?

IRB stands for Institutional Review Board. HSD is the Human Subjects Division at the University of Washington.

DOES MY RESEARCH NEED REVIEW?

If you are conducting regulated research that involves human subjects, you will need to submit your research to HSD so that they can determine the appropriate level of review.

HOW DO I FIND OUT MORE ABOUT SPECIFIC IRB ISSUES OR TOPICS?

HSD has a wealth of information about the latest forms, the Zipline electronic IRB system, federal regulations, and how the University of Washington's HSD interprets these regulations via their documentation of policies, procedures and guidance. You can find out more information at the HSD website.

DO YOU HAVE ANY EXAMPLES OF IRB APPLICATIONS?

Yes! Here is an example of an exempt application along with our information statement and consent form that we provided to our subjects. Note that for the exempt application, these materials did not have to be submitted with the application, but could be created after approval. The elements of consent are highlighted for the purposes of this FAQ.

Sometimes you have to modify expedited studies. Here is an example of a modification application for a minimal risk study. This form was to add a case study procedure to our research design. Note that modification forms are only applicable for minimal risk or full committee IRB approved studies. With our modification application, we submitted our consent and recruitment materials, including an information statement, a recruitment email, an oral recruitment script and a supplemental waiver requesting to use oral consent. These materials were all highlighted within the modification application itself so that the reviewer would know when these materials would be used in our recruitment and consent protocols.

NOTE!!! On November 1st, 2016, we will be submitting our IRB applications using the HSD Zipline electronic system. Once this is in place, all applications will be online and new zipline forms will be required. However, these examples of previously approved IRB applications will give you some guidance in how to explain your study, what materials you will need to submit, and how to write about how your subjects will experience the study and what recruitment and consent protocols you will use.

HOW DO I PLAN RECRUITMENT AND CONSENT?

Consent is a process: it begins with your first interactions or recruitment of subjects and ends after the study is complete. You are responsible for ensuring that subjects are well informed about what they are participating in and allowing them the option to opt out of the study at any time. Think about what your subjects may expect: who are they? Where will you be meeting or first encountering subjects? What information will they want to know? Is signed consent appropriate and feasible or not appropriate and feasible? Is your study an experiment and requires that you withhold some information, such as the study's purpose? If so, how will you inform subjects after they have participated about what the study was truly about?

In complex studies where you may have multiple subject groups with multiple pathways of consent and recruitment, can be helpful to develop a flowchart that you can share with your research team and the IRB reviewer. Below is an example of a recent flowchart submitted with an exempt application. Our group of subjects would undergo observations and multiple interviews before and after their time participating in a course. Follow the flowchart to see how recruitment and consent (as well as coding and analysis) were planned with this group.