Does my research require review?
If you are a faculty or staff member, or a student at the University of Washington, and your research involves the use of human subjects (either directly or through records or other data such as specimens or autopsy materials), your research requires human subjects review.

1 "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute "research" for the purposes of these regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

2 "Human subjects" are individuals whose physiologic or behavioral characteristics and responses are the object of study in research. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy • 45 CFR 46.102(f)]. In Washington state, individuals who have died are still considered to be human subjects.

Why does the IRB need to review my research?
Federal, state and university regulations require that the use of human subjects in research be reviewed and approved by an Institutional Review Board (IRB). The IRB Committees review the proposed purpose, procedures, and subject populations to be used and determine if the benefits of the activity outweigh the risks to subjects. Issues considered in this analysis include:

- how subjects are approached to participate,
- what measures are used to protect subjects' privacy,
- what physical and psycho-social risks, stresses, and discomforts subjects will be asked to endure.

The scientific merit of the activity is considered only if it has an impact on the risk-benefit analysis. For example, will the number of subjects proposed allow the results obtained to be statistically significant? Is there a less risky way to achieve the same results?

The Committees also evaluate advertisements, approach letters, consent/assent forms or information statements, telephone scripts, and debriefing statements to determine if they are accurate, explanatory, and written in simple, lay language appropriate for the intended subjects.

A Committee may decide that there is insufficient information to approve or disapprove an application. In such a case, the Committee defers consideration and asks the researcher to provide additional information. When the Committee receives the information, the application is reconsidered.

Very rarely, a Committee will determine that the risks of a proposed activity outweigh the benefits and
will withhold approval. Usually, the researcher and the Committee can work out a compromise to reduce the risks and gain permission to carry out the research. If a researcher disagrees with a Committee's disapproval, the decision may be appealed.

**Does all research go through the same review process?**

No. There are three types of research, each of which receives a different level of review.

1. *Exempt Research*
   - Research falling into exempt categories is reviewed by your department. These categories are defined in the Human Subjects Manual and on the back of the Certificate of Exemption form. A Certificate of Exemption must be reviewed and approved by your Chair. Send a copy of the form to the Human Subjects Division and keep a copy for yourself. Approval is valid for five years as of the date of the Chair's signature.

2. *Minimal Risk Research*
   - Research falling into minimal risk categories is reviewed by a subcommittee of the IRB (use form **UW 13-11**). You may also hear the term “expedited review” used in conjunction with the review of minimal risk research; describing the ability of the research to be reviewed by a subcommittee – not that the review process is necessarily faster.

3. *More than Minimal Risk Research*
   - Research falling into categories considered to be of more than minimal risk requires review by the full Committee (use form **UW 13-11**).

**How long does this process take?**

HSD has identified goals for turn-around time from receipt of an application to the time it receives approval by type of application and level of review:

- **Exemptions** – *Goal:* One to two week turn-around at HSD.
- **Minimal Risk** – *Goal:* Four to six week turn-around.
- **Full IRB Review** – *Goal:* Six to eight week turn-around.

Multiple factors can impact the time it takes an application to go from “researcher preparation” to “approved,” including: departmental and other peer review requirements, additional committee reviews (i.e., Radiation), and time in revision and/or clarification.

Each new application is screened by HSD staff for completeness when it is received. If the application is complete, it will be assigned to a Committee. Each IRB Committee meets every two weeks and the agenda is sent to Committee members one week before the meeting. This means that an application and all related materials must be received at least two weeks prior to a meeting date to have the potential for review at a particular meeting. However, receipt of materials at least two weeks in advance does not guarantee review at a specific meeting. Due to the high volume of application submissions, applications can wait longer before they are able to be assigned to a meeting agenda. The absence of necessary information can also significantly delay the processing of an application.

You can expect to receive a letter from the Committee after the meeting at which the application is reviewed, requesting any additional information and consent form revisions necessary before full approval can be given. Once a full response to the Committee's requests has been received by HSD, you can typically expect approval unless further questions arise.