**Section 3. How to Determine if Your Study Requires Full Board, Expedited, or Exempt Review**

**Does my project need IRB review?**

Your project needs to be reviewed by the IRB if it meets **both** of the criteria below

1. The project meets the federal definition of research: systematic investigation intended to produce generalizable knowledge. [45 CFR 46.102(d)]
2. Human participants are involved. Human participants are living individuals about whom you are conducting research and gathering
3. data through intervention or interaction with the individual, or
4. identifiable private information. [45 CFR 46.102(f)]

If your project meets **either** criterion A **or** B, but not both, your project does not need IRB review.  If your project meets **both** criteria, you need IRB approval before beginning your research. Generalizable knowledge refers to the planned dissemination of results in a public forum or academic publication. Classroom projects, for which such dissemination is beyond the scope of the course, are not research according to this definition.

**What are the types of IRB review?**

The federal government has established different levels of review, depending on the method and content of your research.

1. Full Board: must be reviewed by the full committee, requires IRB oversight and follow-up.
2. Exempt: requires no further IRB oversight or follow-up
3. Expedited: may be reviewed by one member on behalf of the full IRB, but requires IRB oversight and follow-up

When you prepare your protocol, you will see that the Puget Sound cover sheet asks you to give your best estimate of the appropriate level of review for your project. However, the final decision about types of review rests with the IRB. In order to determine the level of risk to participants, please refer to the **Level of Risk** document available on the IRB website. You can use the following checklist to estimate the level of review for your project.

**1) Full IRB Review.**

Ifyour project meets **ANY** of the following criteria, then it will require review by the full IRB committee:

\_\_\_\_\_ receives support from non‑university sources that require full IRB approval

\_\_\_\_\_ involves greater than minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants than they would likely encounter every day

\_\_\_\_\_ involves personality tests, inventories or questionnaires of a personal and sensitive nature where participants' identities will not be anonymous to the researcher and/or where the information you collect can be connected back to individual study participants

\_\_\_\_\_ involves sensitive aspects of a participant's behavior that could reasonably place a participant at risk of criminal or civil liability or be damaging to a participant's financial standing or employability

\_\_\_\_\_ involves sensitive aspects of a participant's behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol

\_\_\_\_\_ involves active deception or procedures that are not known to the participant (e.g., the participant will not be fully informed)

\_\_\_\_\_ involves health care procedures that are not conducted for the primary benefit of the participants

\_\_\_\_\_ includes diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

\_\_\_\_\_ involves special populations (e.g., prisoners, pregnant women, or individuals who are mentally or psychologically ill, or incompetent)

\_\_\_\_\_ involves subjects under 18 years of age and involves more than minimal risk

\_\_\_\_\_ involves collection of blood samples or other body fluids in any amount

If any of these apply to your research, your project will need approval from the full Board before you begin your research. Your next step is to prepare a research protocol and submit it to the IRB for review. If none of these apply, then go to (2) below.

**2) Exempt Review.** If your research did not meet **any** of the criteria for full review, it will qualify for either exempt or expedited review. Examples of exempt research may include:

\_\_\_\_\_\_surveys or interviews in which responses will be recorded in such a manner that a participant **CANNOT** be identified directly or through identifiers linked to a participant **AND** any disclosure of participants’ responses outside the research will **NOT** place the participants at risk of civil or criminal liability, or be damaging to the participants’ financial standing, employability, or social standing.

\_\_\_\_\_ investigations of commonly accepted educational practices in established or commonly accepted settings.

\_\_\_\_\_\_observations of public behavior.

\_\_\_\_\_\_collection or study of publicly available existing data, documents, records or specimens.

\_\_\_\_\_\_collection or study of existing data, documents, records or specimens in which information will be recorded in such a manner that a participant cannot be identified directly or through identifiers linked to a participant.

\_\_\_\_\_\_research or demonstration project conducted by or subject to approval of the U. S. Department of Health and Human Services for the purpose of studying procedures, benefits, changes, and payments of entitlement programs.

\_\_\_\_\_\_analysis of information from educational tests that will be recorded in such a manner that participants cannot be identified.

If you checked **any** of the descriptors in (2) above and **no** descriptors from category (1), your research project probably meets the criteria for **Exempt** **Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board and, if it is approved for **Exempt** status, will require *no further oversight or follow-up from the IRB*. If you checked no descriptors in (1) or (2), go to (3) below.

**3) Expedited Review**

The third category allows for expedited review. Does your research project:

\_\_\_\_\_\_ involve only minimal risk (e.g., physical, psychological or emotional, legal, social or economic, etc.) to participants, or only as they would likely encounter every day?

\_\_\_\_\_\_involve participants under 18 years of age with at most minimal risk to subjects

\_\_\_\_\_involve recording data from participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice?

\_\_\_\_\_\_involve analysis of voice recordings made for research purposes?

\_\_\_\_\_\_involve moderate exercise by healthy volunteers?

\_\_\_\_\_\_involve the collection or study of existing data, documents, records or specimens?

\_\_\_\_\_\_involve research on individual or group behavior, or characteristics of individuals, without manipulation of a participant's behavior and in a manner that does not cause stress to participants that is greater than they would encounter in everyday life?

If you checked any of the descriptors above, and none in (1) or (2), your project probably meets the criteria for **Expedited** **Review**. Your next step is to prepare a research protocol and submit it to the IRB for review. Your protocol likely can be reviewed by one IRB member on behalf of the full Board. If it is approved with **Expedited** status, your project will be subject to continued oversight and follow-up with the IRB and you will be required to submit requests for modification to methods, sampling, etc. should the need arise.