

## Which projects/studies must be reviewed by the IRB?

The Oblate School of Theology's Institutional Review Board (IRB) has assured federal regulatory agencies that the institution will review and approve all research that meets the federal definition of human subjects research.

Ascertaining whether your project meets the federal definition of human subjects research is a two-step process. You must first decide if the project meets the federal definition of research and, if so, does it include human subjects. We hope the following information might help you know whether IRB review is required.

### Step one — Is it Research?

The Federal Policy for the Protection of Human Subjects (Common Rule) defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge...”

#### Systematic investigation

*Systematic Investigation* is commonly a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory. Systematic investigations include observational studies, interview or survey studies, group comparison studies, test development, and interventional research.

*Projects that are not systematic investigations* include oral histories, journalism, phenomenological activities.

*Gray areas:* Case studies prepared and disseminated for educational purposes are not systematic investigations and therefore, are not considered research. If you are unable to prepare the case study report without disclosing information that would make it possible to identify the informant(s), you must obtain permission from the person before using their data. Please note the important difference between a case study that is not research and an experimental research study, with an “n of 1,” (a research study with only one subject) that is human subjects research. Program evaluation may also fall into or out of this definition based on design and intent.

#### Generalizable knowledge

Developing or *contributing to generalizable knowledge* means that intent or purpose of the systematic investigation is the dissemination of findings. Common ways of disseminating results include publishing or presenting. Thus a doctoral dissertation, thesis, or published doctoral project fit into the “contributes to generalizable knowledge” category.

To help determine *the intent or purpose of the activity* ask this question: would this project be conducted as proposed if the researcher knew that he or she would never receive any form of academic recognition for the project including publication of results in a peer-reviewed journal or presentation of the project at an academic meeting? If the project would remain exactly the same, the activity is likely *not* research.

*Gray areas:* Quality Improvement (QI) is not considered research if the primary intent of the QI is to inform or improve a local process. However, if your primary intent is to generalize the results outside of your local area, the activity is research.

*Submission of an EXEMPT Application for IRB review is required if your project does not match the definition of research.* You need only submit an *Exempt Application*. If your project matches the definition of research, go to Step Two below.

### Step two — Does it involve human subjects?

The Federal Policy for the Protection of Human Subjects (Common Rule) defines human subjects as “...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.”

Notice that the definition of human subject focuses on what information or material is obtained from people. If either of the following is true, your research activity involves human subjects.

Data about living individuals through intervention or interaction

*An intervention* may be physical procedures (e.g., massage) or manipulations of living individuals or the living individuals' environments.

**or**

*An interaction* may be communication or interpersonal contact between the investigator (or research team) and the living individual. Examples include interviews, questionnaires, surveys, observations, manipulations of subject behavior, diet, or environment.

*Why "about whom" is key*

Consider if the project focuses on the person or if the focus is on policies, practices, or procedures about which the person is knowledgeable. Projects which collect information about policies, practices, or procedures – even if the person who provided that information is identified – do not constitute human subject research.

Identifiable private information about living individuals

*Identifiable* means if 1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information.

*Private Information* is information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g., medical record, or student records).

*Examples of identifiable, private information* include the subject's name, address, phone number, social security number, student or employee identification number, or in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age, and gender may not individually identify a subject, but when combined, could in certain cases, identify a specific individual.

*What is NOT considered identifiable, private information:* If the information cannot be linked to a living individual, or is considered public or is given with the expectation that it will be made public and that it will be linked to the individual (e.g., biography or news story), then it would not be considered private identifiable information. For example, use of a publicly available data set that does not contain identifiers or codes linked to individuals does not involve human subjects research. However, use of a publicly available data set that contains identifiers linked to individuals does involve human subject research.

If you obtain/purchase/are given data that has already been collected by someone else for some other purpose, and the data are not linked to any identifiers that would make reasonably possible to identify an individual, the activity is not considered research with human subjects.

If your activity is research but *does not* involve human subjects as defined in the regulations, your activity does not fall under the purview of the IRB. You submit only an Exempt Application.

If you have determined that your research *does* meet the federal definition for human subjects research, you will need to apply for IRB review and approval *before you begin* collecting any data (the IRB will not review projects retrospectively).