

## Institutional Review Board

## Does evaluation require IRB review?

Research studies involving human subjects require IRB review. Evaluative studies and activities do not. It is not always easy to distinguish between these two types of projects and projects frequently have elements of both. Therefore, the decision about whether review is required should be made in concert with the IRB.

If you think that your project is limited to evaluative activities and therefore not subject to IRB oversight, please submit a <u>Determination Form</u> for review. If you have an approved protocol with the IRB and would like the Board to examine the protocol for potential reclassification, please email the office at

## IRB@oregonstate.edu.

Research studies are defined by Federal Regulation as:

Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

## Evaluative studies are defined as:

Systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program (or processes, products, systems, organizations, personnel, or policies), improve effectiveness, and/or inform decisions about future program development.

Below are elements that are common to evaluation and research projects. This list is not intended to be comprehensive and not all elements are required in order for a project to be considered research or evaluation. Rather, this list of elements can be used to assist faculty in determining whether an activity involves research requiring IRB review.

Common Elements	
Evaluation	Research
Determines merit, worth, or value	Strives to be value-free
Assessment of how well a process, product, or program is working	Aims to produce new knowledge within a field (designed to develop or contribute)
Focus on process, product, or program	Focus on population (Inuman subjects)
Designed to improve a process, product, or program and may include:	May be descriptive, relational, or causal
-needs assessment	
-process, outcome, or impact evaluation	
-cost-benefit or cost-effectiveness analyses	
Designed to assess effectiveness or a process, product, or program	Designed to be generalized to a population beyond those participating in the study or contribute broadly to knowledge or theory in a field of study (designed to develop or contribute to generalizable knowledge)
Assessment of program or product as it would exist regardless of the evaluation	May include an experimental or non-standard intervention
Rarely subject to peer review	Frequently submitted for peer review
Activity will rarely alter the timing or frequency of standard procedures	Standard procedures or normal activities may be altered by an experimental intervention
Frequently, the entity in which the	May have external funding
activity is taking place will also be the funding source	-
Conducted within a setting of changing actors, priorities, resources, and timelines	Controlled setting (interaction or intervention) or natural setting (observation which may or may not include interaction or intervention)