

Is Your Project Human Subjects Research?

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Human Subjects Research

Research Projects involving human subjects require review and approval by the Institutional Review Board (IRB) before the research can commence.

An IRB is an ethics committee composed of Keene State College faculty from each school who serve as advocates for human subjects involved in research and ensure compliance with federal regulations imposed by the [Office of Human Research Protections](#).

The IRB's guiding principles, in order of importance, are:

1. Protection of Human Subjects
2. Facilitation of Research

The first question a researcher/scholar should consider with respect to IRB review is whether the research project fits the definition of human subjects research. In light of the mission to protect human subjects, and the potential regulatory consequences of not obtaining IRB review and approval, *the investigator should choose to err on the side of caution and consult with the IRB when uncertain about whether the study is human subjects research or not.*

Defining Research

Federal Regulations define research as **"a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"**¹ (45CFR46.102(l)).

As described in the Belmont Report² "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that

sets forth an objective and a set of procedures to reach that objective."

"Research" generally does not include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. It generally does not include journalism or political polls. *However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.*

Defining Human Subjects

A human subject is defined by Federal Regulations as "a living individual about whom an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." (45 CFR 46.102(e)(1)(i)(ii))

"Living individual" – The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects.

"About whom" – a human subject research project requires the data received from the living individual to be about the person.

"Intervention" – includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

"Interaction" - includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as other modes of communication.

"Private information"³ – "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place," (such as a public restroom) "and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (or example a medical record)." (45 CFR 46.102(e)(4)). **"Identifiable private information"** means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual.

human subjects research by the U.S. Department of Health, Education, and Welfare.

³ Researchers must take caution since disclosure of private information may place the subjects at risk of criminal or civil liability and/or damage their financial standing, employability, or reputation.

¹ **"Generalizable knowledge"** is information where the intended use of the research findings can be applied to populations or situations beyond that studied.

² The Belmont Report is a statement of ethical principles (including beneficence, justice, and autonomy) for

“Identifiable biospecimen” is a biospecimen for which the identify of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

Studies based on data that are individually identifiable but are also publicly available *might* not constitute human subjects research. However, the term “publicly available” is intended to refer to record sets that are truly readily available to the broad public, such as census data, or federal health, labor, or educational statistics. An investigator should not assume information qualifies as “publicly available” merely because it has been posted on an electronic website and can be accessed without authorization.

Types of Review

Federal regulations allow institutions to use a variety of types of review processes, designed to match the level of scrutiny with the risks posed. Each protocol will be screened upon submission to determine which type of review is most appropriate for a given project; investigators may not make that determination themselves under current federal regulations. Many of the activities conducted by researchers at Keene State College fall under the two lesser levels of review (Exempt or Expedited).

Exempt Review

Exempt reviews are handled on a rolling basis. During screening, your protocol may be determined by the IRB to be **exempt from further IRB review** if it poses only minimal risk⁴ to participants AND the ONLY activities proposed fall into one of eight exempt categories described in [45 CFR Part 46](#). A protocol form must be submitted by the investigator, containing enough information to allow the IRB to determine eligibility for an exemption.

The primary benefit of an exemption is that the project is reviewed only once, at the outset, and is not subject to annual continuing review. However, if the nature of the activities changes in the future in a way that could impact the exempt determination, the researcher must bring this to the IRB’s attention for verification of continued exempt status.

The federal Office of Human Research Protections recommends that investigators NOT be given the authority to make an independent determination that

their own human subject research is exempt because of the potential for conflict of interest.

Expedited Review

Expedited reviews are handled on a rolling basis. In order to qualify for expedited review, the activities must place participants at no more than minimal risk and fall under one of nine [expedited review categories](#) described by OHRP.

Full Board Review

Protocols that present more than minimal risk to participants will undergo review by the full IRB committee at a convened meeting. The deadlines for convened meetings (and deadlines for submitting materials) are listed on the [OSPR](#) Webpage.

Course-Based Research

Faculty incorporating research projects into their courses may seek one blanket approval for the class by submitting an IRB Course Approval form. The faculty member does not need to specify the exact projects the students would undertake in the course (as this will often be unknown in advance), but must be able to specify the general types of activities that will or will not be allowed to be undertaken by the students.

Projects considered for course review should not exceed minimal risk, target special populations, and/or include sensitive subject matter.

Course-based protocols are handled on a rolling basis—but please submit well in advance of the start of term.

psychological examinations or tests. Researchers are reminded that physical, psychological, emotional, legal and social/reputational risks must all be considered.

⁴ *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or