

Tip Sheet

Exempt and Expedited Reviews of Human Subjects Research

Research Eligible for Exemption:

There are activities that **do** meet the definition of research with human subjects but are **not** covered by the provisions of the [Common Rule](#). Thus they do not require review as described in the Rule. They are, however, subject to the ethical principles adopted by USC. (For example, the Belmont Report requires a consent process for **all** research).

While these studies do not require review in accordance with the Common Rule, some procedure is necessary to make the determination that they are eligible for exemption. Institutional procedures vary, but the common element is that the institution must make the determination, not the investigator.

Research may be eligible for exemption if **all** the activities associated with the research fall into one of six categories. Of the six categories, three are frequently used by social and behavioral scientists. They are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices
2. Research involving survey procedures, interview procedures, or observation of public behavior providing that any disclosure of identifiable information outside the research setting would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

NOTE: If [Subpart D](#) applies (**this subpart applies to all research involving children as subjects**), either by sponsor requirement or institutional choice, interviews with children and participant observation with children cannot be exempt.

3. Research involving the collection or study of existing data (collected prior to the research for purposes other than the research) if the data is publicly available or recorded by the investigator in such a manner that the subjects cannot be identified

A complete list of eligible activities is provide at [45 CFR 46.101](#).

Research Eligible for Expedited Review:

To be eligible for expedited review research must meet two criteria:

1. Pose no more than minimal risk to subjects. "No more than 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 psychological examinations or tests."
2. Consist of one or more research activities specified in the regulations (46 Part 46).

Eligible activities are similar to those for exempt research (some surveys, interviews, and data analysis) with the addition of some minor and non-invasive medical procedures, such as blood pressure readings, occasionally used by social and behavioral sciences. The preamble to the list of activities notes that if the primary risk to subjects is a breach of confidentiality and that risk can be managed to no more than minimal, the research may be reviewed with through expedited process.

Subject population and institutional policy may require review by a convened IRB even for a study with no more than minimal risk, such as a study of decisionally-impaired individuals. If research involves more than minimal risk and/or does not fall into one of the categories of activity eligible for expedited review, it must be reviewed by a convened IRB. This review involves consideration by a larger, more diverse group, thus bringing more perspectives and more experience to the review.