Tulane University Human Research Protection Program

Types of IRB Review

Exempt Review

The federal government has identified certain categories of research involving human subjects that qualify for exemption from federal regulations. Tulane University is authorized by the federal government to determine whether studies thought by the principal investigator (PI) to be exempt from federal regulations actually qualify for exemption. Such determination is made on behalf of the Tulane University HRPO. Only the Tulane University HRPO has authority to make a determination that a research study is exempt from federal regulations. When the IRB notifies a PI that a research project is EXEMPT, it also notifies the PI that the research is approved for initiation.

In order to qualify for exemption, a research study must fall entirely within one or more of the six categories for exemption and it cannot place the subjects at greater than minimal risk. If the research involves prisoners, then it does not qualify for exemption from federal regulations.

What Exemption Means: “Exemption” as used in this document means exemption from the requirements set forth in Regulations for the Protection of Human Subjects (Title 45 Part 46 of the Code of Federal Regulations), such as the requirement for a written informed consent document. At Tulane University, determinations of exemptions are made by the HRPO.

What Exemption Does Not Mean: “Exemption” does not mean that the research activity is exempt from the laws of the State of Louisiana, and it does not mean that the research need not conform to the canons sound research ethics.

For additional information regarding Exempt Review Categories, see OHRP Decision Charts #2-7 for Exempt Categories. Also, see more on the 6 Exempt Categories in the Guidance Document entitled, “Criteria for Exempt Determination.”

Expedited Review

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. A list of categories has been established in the Federal Register that may be reviewed by the IRB through an expedited review procedure. An IRB may use the expedited review procedure to review either or both of the following:

Some or all of the research appearing on the list of categories of research (established in the Federal Register) and are found by the reviewer(s) to involve no more than minimal risk.

Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Criteria: The following criteria must be met in order to be considered for expedited review:

The research activities must present no more than minimal risk to human subjects. 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.

All of the research activities involve only procedures listed in one or more of the research categories established in the Federal Register. The categories in this list apply regardless of the age of subjects, except as noted. Categories 1-7 pertain to initial and continuing review. For additional information regarding expedited review categories, see OHRP Decision Chart #8 and see more on the 9 expedited categories within the Guidance Document entitled, “Criteria for Expedited Determination.”

**Full Board Review**

If the study does not meet the criteria for Exempt or Expedited review, then it must be submitted for full review by a convened meeting.

Although a PI may apply for a specific type of IRB review, the Tulane University IRB reserves the right to require a more stringent review of any study as deemed appropriate.