

The University of Mississippi

Exempt Human Research

Summary/Purpose: Criteria for classifying exempt research; IRB decision-making process

A. Classification Criteria:

All research activities involving human subjects under the jurisdiction of the UM IRB will be reviewed, with the exception of certain QA/QI research (see IRB Policy to Exclude Certain Forms of Quality Assurance and Quality Improvement Research from Review).

Many UM research activities involving human subjects are exempt from the requirement that they receive IRB full or expedited review. The categories of these activities are described in 45 CFR 46.104(d)(1) through (6) and in the IRB's [Screening/Abbreviated Exempt Application](#). The research activities described in categories (7) and (8) will be reviewed as expedited, using the full protocol application form [Application to Conduct Research with Human Subjects](#). The IRB alone determines which activities qualify for exempt review. Investigators are not authorized to make this determination. They must complete the Exempt application and submit it for IRB determination of level of review.

The exemptions provided in 45 CFR 46.104(d)(1) through (6) do NOT apply to research involving prisoners. The exemptions provided in 45 CFR 46.104(d)(1) and (3) will NOT be applied to research involving children.

Research determined to be exempt from IRB full board or expedited review is not exempt from procedures to protect human subjects. The following criteria to protect human subjects must be met for all exempt research involving human subjects:

1. All researchers must be trained in relevant ethical principles, Federal Regulations, and institutional policies governing human subject research using the appropriate CITI course (or approved alternative);
 - a. Exception: A subset of exempt research may require no training (e.g., de-identified data analysis, brief and innocuous surveys or interviews of adults, or other studies as determined by the IRB on a case by case basis).
2. In almost all cases, the investigator must obtain voluntary consent (verbal acknowledgement or simply engaging in study procedures) from the research subjects to participate in the research and inform subjects that the activity involves research and has been approved by the IRB. It may be appropriate to include other information such as a description of procedures, risks and benefits, and IRB and investigator contact information.
3. To the extent that the research involves risks and/or benefits to subjects, the investigator should generally select subjects equitably, so that those risks and benefits are justly distributed.
4. The investigator must submit any changes to the approved protocol for review and approval before initiating those changes.

5. The investigator must promptly inform the IRB of any unexpected or adverse events or any complaints from subjects.
6. The investigator must protect confidentiality and privacy of the subjects and maintain identifiable research data securely to ensure minimal risk to subjects.

B. Decision-Making Process

The following process is used for research that may be exempt from IRB full board or expedited review:

- An IRB Research Compliance Specialist (RCS) receives and screens all applications submitted to the IRB for level of review.
 - If a protocol does not precisely fit exempt category criteria in 45 CFR 46.104(d)(1) through (6),
 - * The RCS consults with a second RCS, the IRB chair or the Director of Research Integrity and Compliance (all maintain IRB membership)
 - * If there's no consensus, the RCS brings the protocol to the entire IRB Executive Committee (RCS, IRB chair, Director of Research Integrity and Compliance) for discussion and majority vote on review classification.
 - The IRB may move a protocol from exempt review to expedited or full board review, even if it meets all relevant exempt review criteria, because of risks, benefits, and other ethical issues.