Exempt Human Research

Summary/Purpose: Criteria for classifying exempt research and decision-making processes for IRB review of exempt research.

Policy: 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 & Quality).

UM’s Assurance with OHRP stipulates that all of our human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule.

Some 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 46.101(b)(1) through (6). Only the IRB may determine which activities qualify for an exempt review. Investigators are not authorized to make this determination and must contact the IRB concerning proposed research or changes in ongoing research.

The exemptions provided in 45 CFR 46.101(b) do NOT apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. Additionally, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does NOT apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

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

1. The investigator must assure that all researchers are trained in the ethical principles, relevant Federal Regulations, and institutional policies governing human subject research using the appropriate CITI course (or approved alternative);

2. The investigator must obtain voluntary consent to participate in the research when appropriate (e.g. surveys, interviews) and will provide subjects with pertinent information, i.e. that the activity involves research and has been approved by the IRB. In addition, it may be appropriate to include other information such as contact information for investigators, a description of the procedures, risks and benefits, and IRB contact information.
3. The investigator must select subjects equitably, so that the risks and benefits of the research 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 participants regarding their risks and benefits; and

6. The investigator must protect confidentiality and privacy of the subjects and maintain research data appropriately to ensure minimal risk to subjects.

**Decision-Making Process**
The following process is used for research that may be exempt from IRB full board or expedited review:

- The IRB Research Compliance Specialist (RCS) screens all applications submitted to the IRB for level of review.
  - When a protocol does not precisely fit into one of the exempt categories of 45 CFR 46.101(b), the RCS consults with the chair of the IRB or the chair’s designate.
  - The IRB may move a protocol from exempt review to expedited or full board review, even if it meets all relevant exempt review criteria, by taking into consideration risks, benefits, and other ethical issues.

- A determination that a protocol is exempt from expedited or full board review requires that the research activity meets the criteria for exempt status as outlined in 45 CFR 46.101(b)(1) through (6) and meets the criteria for protection of research participants in exempt research as stated above.

- Exempt determination is documented on the review checklist and the file log and includes a citation of the specific regulatory category justifying the exemption.

- The IRB staff then issues a letter of exempt designation to the investigator and files a copy.

Approved by the IRB: June 4, 2008