Exempt Human Research

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

A. 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 and Quality Improvement Research from Review).

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 should complete the Exempt application and submit it for the IRB’s final determination.

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, or research conducted in established or commonly accepted educational settings, involving normal educational practices. [See exceptions for certain research below in C.]

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);
   a. Exception: A subset of exempt protocols may require no training (e.g., de-identified data analysis, innocuous surveys or interviews of adults, or other studies as determined by the IRB).

2. The investigator must obtain voluntary consent from the research subjects 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; and

6. The investigator must protect confidentiality and privacy of the subjects and maintain research data appropriately 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:

- 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, because of 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. [See additional categories for certain research below in C.]

C. Additional Exempt Categories for Certain Research not Funded by a Federal Agency or Federal Department

Background and rationale. As allowed by federal policy, UM limits the contractual applicability of its Federalwide Assurance (FWA) to federally funded human subjects research. Although the IRB has always applied all federal regulations to all human subjects research regardless of funding, this allows the IRB to adjust application of the regulations for those human subjects studies that are not funded by federal agencies and departments.

In order to focus human subject protection resources on studies that pose risks for human subjects, the IRB adds Category 7 and Category 8 to the six categories of studies that can be considered exempt from the federal regulations. These additions also serve to reduce administrative burden for PIs, which will foster PI compliance with federal regulations and IRB policy and will promote human subject research at UM.

Low risk required. The federal regulations at 45CFR46.102(i) define ‘minimal risk’ as when “…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.” Daily life is often
highly stressful, physical examinations are often painful or embarrassing, and psychological
tests often increase anxiety. Procedures of studies included under Category 7 and Category 8
must be below the regulatory threshold of “no greater than minimal risk:” their anticipated
risks must approach zero, with extremely low magnitude and probability of risk.

- When questions of applicability arise, studies will be reviewed on a case by case basis.
  Inclusion/exclusion of any research project will be at the discretion of the IRB Executive
  Committee.

- These projects will be reviewed using a process identical to that used for exempt research
categories 1-6 under 45 CFR 46.101(b).

1. Additional UM exempt categories

   Category 7: Studies of adults employing behavioral task performance methods or
   behavioral games, such as computerized economics, business, and accounting simulations of
   real-world transactions and innocuous online or in-person surveys that employ experimental
   manipulations (e.g., exposure to different written or video scenarios)

   Category 8: Studies that include minors as subjects and do not collect sensitive
   information: 1) online surveys, 2) in-person focus groups, and 3) surveys conducted in a
   group setting

2. Exclusions from additional exempt categories 7 and 8

   - Research funded by a federal agency or federal department
   - No cost extensions for research funded by a federal agency or federal department
   - Student projects with faculty sponsor-received federal funding
   - Federal sponsorship, including federal training grants
   - Studies conducted in a laboratory entirely federally funded and/or part of a federally funded
     program project grant
   - Studies with FDA regulated components
   - Studies with contractual obligations or restrictions precluding this amendment
   - Studies using prisoners as subjects
   - Studies seeking or obtaining Certificates of Confidentiality

3. Monitoring

   Subsets of studies approved under exempt categories 7 and 8 will be audited to ensure risks
   remain as low as estimated during review with particular attention to any untoward responses
   from child subjects in category 8 research. Audits will be conducted by emails to
   investigators and will be more frequent following implementation of this policy change.