Department: **UAMS Institutional Review Board**
Policy Number: **7.3**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
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SUBJECT: Studies Exempt from Review

Research activities involving human subjects that are exempt from the requirement to receive IRB full or expedited review are identified below (45 CFR46.101 (b) (1-6); 38 CFR16.101 (b); 21 CFR56.103-104; 45 CFR).

1. Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

    a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and

    b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

    This exemption does not apply to research involving children unless the research is limited to observation of public behavior when the investigators do not participate in the activities being observed [45 CFR46(d)].

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is **not exempt under paragraph (b) above, if**:

    a. The human subjects are elected or appointed public officials or candidates for public office or

    b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of **existing data documents, records, pathological specimens, or diagnostic specimens**, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

a. To qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins.

b. Under this exemption, an investigator (with proper institutional authorization) may inspect identifiable records, but may only record information in a non-identifiable manner.

Example 1

Investigator A wishes to screen blood samples at a rural hospital for incidence of HIV infection. She does not want to draw specimens specifically for this purpose; rather she proposes to use specimens that were drawn for some other purpose but which remain in the hospital laboratory. If Investigator A proposes to use specimens that had been drawn prior to the initiation of her research and are, for some reason, "on the shelf," the protocol will qualify as exempt, assuming the other requirements are met (i.e., the sources are either publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects). If she proposes to use specimens that will be drawn after the start date of her project for reasons unrelated to her research, the protocol is not exempt from IRB review, even though the specimens will be drawn regardless of her use of the excess blood. The protocol may, however, qualify for expedited review.

Example 2

Suppose Investigator B wishes to examine court records of involuntary commitments to psychological institutions. If he uses court records that were on file before the initiation of his research, the protocol will qualify as exempt. If he proposes to use records filed after the initiation of the project, the protocol is not exempt from IRB review, although it may qualify for expedited review.

5. Research and demonstration projects which are conducted by or subject to the approval of federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

   a. Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs."

      i. The program under study must deliver a public benefit (*e.g.*, financial or medical benefits as provided under the Social Security Act) or service (*e.g.*, social, supportive, or nutrition services as provided under the Older Americans Act)

      ii. The research or demonstration project must be conducted pursuant to specific federal statutory authority.

iii. There must be no statutory requirement that an Institutional Review Board review the project.

iv. The project must not involve significant physical invasions or intrusions upon the privacy of participants.

b. Procedures for obtaining benefits or services under those programs;

c. Possible changes in or alternatives to those programs or procedures;

d. Possible changes in methods or levels of payment for benefits or services under those programs.

6. **Taste and food quality evaluation** and consumer acceptance studies if:

a. wholesome foods without additives are consumed or

b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Children, Prisoners, Fetuses, Pregnant Women, or Human In Vitro Fertilization. These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization [45 CFR46.101(b)]. The 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 (See IRB policy 17.1, and policy 17.8).

The IRB may not create new categories of this exempt research. The IRB may only determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research. The Chair or his or her designee of an appropriate IRB Committee will review requests for exemption.

Results of reviews will be promptly conveyed in a letter by the IRB Office to the investigator. If the proposed research activities do not meet the criteria for exemption, the Chair or IRB Office will promptly convey in a letter outlining any additional information and the proper category for review (e.g., full or expedited) to the investigator.

Continuing Review. Studies receiving exempt status are not required to submit the full continuing review form. They will be required to submit an “Exempt Study Update Report” on an annual basis stating whether the scope of the project has changed and whether the project should remain open.

Request for Changes in Study Design. Any proposed or anticipated changes in an exempt study must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review.