Department: **UAMS Institutional Review Board**
Policy Number: **7.3**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
Revision Dates: **June 1, 2005; February 8, 2005; May 7, 2004**

SUBJECT: Exempt Categories of Research

Purpose: The purpose of this policy and procedure is to set out the criteria for studies classified as Exempt under the Federal Regulations

Policy: UAMS requires all human subject research studies meeting, or appearing to meet, one of the Exempt criteria to be submitted through ARIA for review and approval by the IRB. No Investigator or Department on campus shall have the authority to make this decision other than the IRB Chair/Designee. All research, including that in the Exempt categories, must meet at a minimum the principles outlined in the Belmont Report. The IRB Chair/Designee may require additional protections to meet these principles, including a level of informed consent appropriate to the research or review by the full committee.

Studies receiving an Exempt classification by the IRB Chair/Designee will be required to submit a one page Study Update each year in order to keep the study open. The IRB shall be made aware of any changes in the study scope or design prior to implementation of the changes to insure that the study continues to meet the Exempt Criteria.

FDA allows two categories of clinical investigations to be considered exempt from IRB review. However, the IRB requires review of both categories. The FDA emergency use of a test article process can be found at IRB Policy and Procedure 18.3 and 18.4. The other allowable FDA exempt category is listed below as #6.

No research involving, or potentially involving, prisoners, as participants may be classified under the Exempt Categories listed below.

Exempt Categories:

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.

   NOTE: This category may be applied to research involving children.

   NOTE: This category may not be applied to FDA regulated research.

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.

    NOTE: The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

    NOTE: This category may not be applied to FDA regulated research.

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.

    NOTE: This category may not be applied to FDA regulated research.

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. Investigator must describe where the information exists.

    b. Under this exemption, an investigator (with proper institutional authorization) may inspect identifiable records, but may only record information in a non-identifiable manner. Investigator must describe how information will be obtained, what data elements will be recorded, and whether any links to identifiers will be recorded.

NOTE: Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation and requires additional IRB review.

NOTE: This category may not be applied to FDA regulated research.

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.

    e. Before invoking this exemption, the IRB will obtain concurrence of the funding agency that this exemption can be applied.

    NOTE: This category may not be applied to FDA regulated research.

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.

NOTE: This category may be applied to children.

NOTE: This category may be applied to FDA regulated research.

Procedure:

1. The Investigator will:

1.1 Submit a protocol and application through ARIA, including all surveys, questionnaires or other instruments to be used.
1.2 Provide any additionally requested information.
1.3 Submit any proposed or anticipated changes to the IRB, through ARIA Modifications, prior to implementation.
1.4 On an annual basis, submit an Exempt Study Update Form if desiring to keep study open.

2. The IRB Director or Designee will:

2.1 Review all requests for exemption.
2.2 Request additional information as necessary.
2.3 Document in the Office Notes section of ARIA whether the study appears to qualify for requested category.
2.4 Draft Approval letter for Chair/Designee signature, or notify Investigator that the study will need to be reviewed by either Expedited or Full procedures.
2.5 Place on Agenda under Exempt Studies Approved by the Chair/Designee.

3. The IRB Chair/Designee will:

3.1 Review submitted documents and Office Notes.
3.2 Request additional information as necessary.
3.3 Determine that the research meets the organization's ethical standards.
3.4 Determine that the research does not involve prisoners as participants.
3.5 Determine the category of the exemption and document the category on the Comments section of ARIA.
3.6 If the research falls into one or more categories of exemption, and meets the organization's ethical standard, grant a determination that the research is exempt and document that determination on the Comments section of ARIA.
3.7 If the IRB Chair/Designee cannot grant an exemption, the IRB Chair/Designee should request modifications from the Investigator that would allow the research to be exempt. If the Chair/Designee and Investigator cannot reach agreement the research will be referred to the convened IRB for review.
3.8 Request approval letter or modification letter be prepared for signature and placement on agenda as Exempt Studies Approved by Chair/Designee.