Department: **UAMS Institutional Review Board**
Policy Number: **7.5**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
Revision Date: **June 1, 2005, May 7, 2004**

SUBJECT: Expedited Review

Definitions:

Designee (for this policy only): Shall mean an "Experienced IRB Member"

The Chair may designate one or more IRB members to perform expedited review procedures. In order to qualify as an Experienced IRB Member, one must meet the following criteria:

1. Served on an IRB for a minimum of one year.

2. Demonstrate a consistent and comprehensive pattern of reviewing assigned protocols as a committee member.

3. Willing to devote a set number of hours for expedited reviewing in addition to their regular committee reviewing.

4. Willing to undergo training with the Chair in principles of reviewing and approving expedited protocols.

5. Actual experience with conducting human subject research.

6. Recommendation by Chair and approval by the Executive Committee.

Policy: The IRB Chair/Designee may review certain actions (new, continuing review or modifications) on an expedited basis if they meet the specified criteria as discussed below. All expedited protocols must still be reviewed by the IRB Chair/Designee at least once per year. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply.

An expedited review consists of a review of research involving human subjects by the appropriate IRB Committee Chair or his/her designee. In reviewing the research, the reviewer may exercise all of the authorities of the full Committee except that the reviewer may not decline the research. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.

Expedited Review Requirements:

1. For the initial review of research to qualify for review by the expedited procedure, the research must:

1.1 Present no more than minimal risk to human subjects;

Minimal Risk means that 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.

1.2 Not involve the identification of the subjects and/or responses which would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal;

1.3 Not be classified

1.4 Involve only procedures listed below. Inclusion on the list does not automatically make the research minimal risk. It merely means that the activity is eligible for review provided the circumstances of the specific proposal involve no more than minimal risk to the participants.

1.4.1. **Clinical studies of drugs and medical devices** only when the conditions below are met.

a. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); or

b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

1.4.2. **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, when the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected are considered. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. Children are defined in the federal regulations as "persons who have not attained the legal age for consent to

treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted". In Arkansas, this age is 18 years old.

1.4.3. **Prospective collection of biological specimens for research purposes by noninvasive means**, for example:

a. Hair and nail clippings in a nondisfiguring manner;
b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
c. Permanent teeth if routine patient care indicates a need for extraction;
d. Excreta and external secretions (including sweat);
e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
f. Placenta removed at delivery;
g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
h. Supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
j. Sputum collected after saline mist nebulization.

1.4.4. **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b. Weighing or testing sensory acuity;
c. Magnetic resonance imaging;
d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

f. Collection of data from voice, video, digital, or image recordings made for research purposes.

1.4.5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the requirement that it obtain IRB approval (See IRB Policy 7.3). (This listing refers only to research that is not exempt.)

1.4.6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

1.4.7. **Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the requirement that it obtain IRB approval (See IRB policy 7.3). (This listing refers only to research that is not exempt.)

2. For modifications to previously approved research to qualify for review by the expedited procedure, the research must represent a minor modification

Minor Modifications. A change is considered minor when it does not materially affect an assessment of the risks and benefits of the study; does not substantially change the aims or design of the study and is not directly relevant to the determinations required for approval. Examples of items that generally might be considered appropriate for expedited review and approval: Changes in research personnel or contact information, minor changes to the protocol or consent document in order to clarify or correct earlier information provided there is no change in the evaluated risks or potential for benefit.

3. For the continuing review of research to qualify for review by the expedited procedure, the research must meet one of the following criteria:

3.1 Meet the criteria for initial review by an expedited procedure.

3.2. Be permanently closed to the enrollment of new subjects, where all subjects have completed all research-related interventions; and the research remains active only for long-term follow up of subjects;

3.3. No subjects have been enrolled and no additional risks have been identified

3.4 The remaining research activities are limited to data analysis.

3.5. Meet all of the following criteria

3.5.1 Not be conducted under an investigational new drug application or investigational device exemption

3.5.2 Not otherwise qualify for review by the expedited procedure

3.5.3 The IRB has determined and documented at a full Committee convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Investigator Procedure:

1. **For Initial Review of an Expedited Protocol, Investigator** must:

   1.1 Submit in ARIA all required new application materials as outlined in IRB Policy 7.4 and select the expedited category s/he believes the study to fit.

2. **For Continuing Review under Expedited Procedures:**

   2.1 Submit in ARIA a Continuing Review Report noting on the form which criteria for expedited continuing review the project meets.

3. **For Modifications to be reviewed under Expedited Procedures:**

   3.1 Submit in ARIA a Modification form noting in the section entitled "Description of any significant change in the risk/benefit" that the requested modification does not materially affect an assessment of the risks and benefits of the study; does not substantially change the aims or design of the study and is not directly relevant to the determinations required for approval

IRB Chair/Designee Procedure:

1. **For Initial Review of an Expedited Protocol, IRB Chair/Designee must:**

   1.1 Review materials in sufficient detail in order to determine that the study meets the **criteria for approval** as outlined in IRB Policy 7.1.
   1.2 The Chair or designee must determine that the research meets all criteria outlined in section 1 above allowing review by the expedited procedure.
   1.3 Determine that the research does not involve prisoners as participants. If the study involves prisoners, direct the IRB Staff to place the study on the full board section of the agenda for the next meeting in which the Prisoner Representative can attend.
   1.4 Determine the expedited category into which the study fits and document the category on the Comments section of ARIA.
   1.5 If study as designed does not meet any of the expedited categories, the IRB Chair should request modifications from the Investigator that would allow the research to be expedited. If the Chair and Investigator cannot reach agreement the research will be referred to the convened IRB for review.

1.6 Request approval letter or modification letter outlining any protocol-specific findings and the period for review be prepared for signature and placement on agenda as Expedited Actions Approved by Chair.

2. For Continuing Review under Expedited Procedures IRB Chair/Designee must:

2.1 Follow all elements of IRB Policy 7.6; and
2.2 Document that the research meets one of the criteria outlined above in Expedited Review Requirements, Section 3.

3 For Modifications to be reviewed under Expedited Procedures, IRB Chair/Designee must:

3.1 Determine that the requested modification truly does not materially affect an assessment of the risks and benefits of the study; does not substantially change the aims or design of the study and is not directly relevant to the determinations required for approval.

All items in which the Chair/Designee takes expedited actions on will be reported to the full IRB Committee on each agenda. The Committee will have access through ARIA to all available materials, including the letter of approval which will include a citation to the specific permissible category or categories justifying the expedited review. The Committee members will have an opportunity at each meeting to raise any issues related to expedited items the Chair/Designee acted on.