Department: **UAMS Institutional Review Board**
Policy Number: **7.5**
Section: **Procedures for Study Review**
Effective Date: **July 31, 2002**
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SUBJECT: Expedited Review

Federal regulations allow the IRB to review certain new applications on an expedited basis if they meet the specified criteria discussed below. All expedited protocols must be reviewed by the IRB at least once per year. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply to all IRB approvals regardless of the type of review.

An expedited review consists of a review of research involving human subjects by the appropriate IRB Committee Chairperson 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 disapprove the research. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.

Appropriate Use of Expedited Review Procedures. Federal regulations limit the use of expedited review procedures to specific research categories. Use of expedited review by the IRB must be restricted to those applications that fulfill one of the following nine categories. The categories on the list apply regardless of the age of subjects, except as noted.

1. **Minimal Risk**. Research activities that (i) present no more than minimal risk to human subjects, **and** (ii) involve only procedures listed in one or more of the specific nine categories, may be reviewed by the IRB using the expedited review procedure.

    a. 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.

    b. The nine categories should not be deemed to be of minimal risk simply because they are included on the list.

    c. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The expedited review procedure may not be used where identification of the subjects and/or their responses 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.

Categories of Research Eligible for Expedited Review. The following nine expeditable categories pertain to both initial and continuing IRB review:

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 (21CFR312; 45CFR) 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 (21 CFR812; 45 CFR) 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.

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" [45CFR46.402(a)]. In Arkansas, this age is 18 years old.

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.

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.

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.)

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

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 7.1). (This listing refers only to research that is not exempt.)

8. **Continuing review of research** previously approved by a full IRB Committee as follows:

   a. Where the research is permanently closed to the enrollment of new subjects; Where all subjects have completed all research-related interventions; and Where the research remains active only for long-term follow up of subjects; or

   b. Where no subjects have been enrolled and no additional risks have been identified; or

   c. Where the remaining research activities are limited to data analysis.

9. **Continuing review of research**, not conducted under an investigational new drug application or investigational device exemption where categories b through h do not apply but 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.

Minor Modifications. Minor modifications in previously approved research during the period (of one year or less) for which approval is authorized may be approved using expedited procedures as outlined herein. 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.

Reviewers Must Make Certain Determinations to Approve Application. In conducting the expedited review, the designated reviewers must review materials in sufficient detail to make the following determinations required under federal regulation and IRB Policy 7.5 (21 CFR56.111; 45 CFR):

1. **Risks to Subjects are Minimized** (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to Subjects are Reasonable in relation to Anticipated Benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the reviewers should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies those subjects would receive even if not participating in the research). The reviewers should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. **Selection of Subjects is Equitable**. In making this assessment the reviewers should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Informed Consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulation and institutional policies (See IRB policy 15.3) on Waiver of Informed Consent.

1. **Informed Consent will be appropriately documented**, in accordance with, and to the extent required by federal regulation and institutional policies.

2. **When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

3. **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

4. **Vulnerable Subjects.** Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children,

prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB reviewers must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Materials to be Reviewed. The IRB Chair or one or more experienced reviewers designated by the Chair from among the members of the IRB, reviews the research and may either approve it or refer it to the full IRB for discussion. The following materials should be provided to the reviewer and the Chair for expedited review applications:

1. A completed IRB application with a signature page and conflict of interest statement (See IRB policy 3.3.)
2. Full investigator or sponsor protocol
3. Proposed informed consent document(s) and/or script as appropriate
4. Copies of surveys, questionnaires, or videotapes
5. Copies of letters of assurance or cooperation with research sites
6. Relevant grant applications
7. Investigator's brochure (if one exists)
8. Advertising intended to be seen or heard by potential subjects, including email solicitations
9. Safety Review

Notification of Committee. As a means of notifying the Committee and allowing for comments regarding a review conducted utilizing expedited review procedures, the agenda will reflect all expedited items with the Committee having access through ARIA to all available materials. This documentation must include a citation to the specific permissible category or categories justifying the expedited review.