Department:	**UAMS Institutional Review Board**
Policy Number:	**7.5**
Section:	**Procedures for Study Review**
Effective Date:	**July 31, 2002**
Revision Date:	**May 7, 2004; June 1, 2005; March 13, 2008; July 28, 2008; January 24, 2011; March 6, 2018; August 16, 2021**

SUBJECT: Expedited Review

POLICY

Certain studies may be reviewed using expedited procedures rather than by the convened IRB. The requirements to submit and approve research using expedited procedures are identical to those used to for studies undergoing full board review. All regulatory approval criteria, outlined in IRB Policy 7.1, must be met and all submission forms and requirements are the same. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply.

The expedited review may be conducted by an IRB Chair or Experienced IRB Reviewer as defined below. The reviewer may exercise all of the authorities of the convened IRB except that the reviewer may not decline the research. The reviewer may choose to refer the study to the convened IRB as warranted. The use of "IRB" throughout these policies may mean IRB, IRB Chair or Experienced IRB Reviewer as appropriate to the action described.

All items reviewed by the expedited procedure will be reported on the agenda prepared for the convened IRB. The convened IRB will have access to the complete study file for all studies reviewed by the expedited procedure.

DEFINITIONS

A. **Experienced IRB Reviewer:** In order to serve as an Experienced IRB Reviewer and conduct reviews using the expedited procedure, the following criteria must be met:

   1. At least one year in any of the following roles: Designated Exempt Reviewer; Comprehensive Pre-Reviewer within the UAMS IRB Office; UAMS Human Subject Research Compliance Reviewer; or consistent service as an IRB Reviewer.
   2. Demonstrates a consistent and comprehensive pattern of reviewing assigned protocols as an IRB Reviewer;
   3. Willing to devote the appropriate amount of time to conduct the expedited reviews. This may be in addition to assignments for review with the convened IRB;
   4. Willing to undergo training in principles of reviewing, documenting and approving items using expedited procedures;
   5. Experience conducting, working in, or overseeing human subject research; and
   6. Recommendation by Chair and approval by the IRB Director.

B. **Minor Modifications**. Proposed changes that do not add more than minimal risk to the subjects or substantially change the study's aims or design. If procedures are added, the procedures must fall into one of the first 7 expedited categories below.

PROCEDURES

A. All reviews using expedited procedures shall be conducted as described in this section.

1. Reviews shall be conducted with the same depth and attention to detail as the reviews conducted by the convened IRB. This includes reviewing the same information Assigned Reviewers are expected to review per IRB Policy 7.4.

2. Expedited reviewers may seek input from individuals with relevant expertise, as described in IRB Policy 3.9. Consultants.

3. The criteria for approval of research, as outlined in IRB Policy 7.1, must be used for all expedited reviews.

4. Expedited reviewers may not review a study in which they have a conflict, as described in IRB Policy 3.3.

5. If the research involves prisoners, expedited review procedures may only be used in the limited circumstances described in IRB Policy 17.9 Studies not meeting the criteria for expedited review of research involving prisoners shall be placed on the full board agenda, in accordance with policy 17.9.

6. Actions taken using expedited procedures shall be documented in a letter to the PI through the IRB e-system. The following actions may be taken:
a. Approve
b. Require modifications

B. Review Categories

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.

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.

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 category 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 7.3). (This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) 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 two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Initial Review. For the initial review of research to qualify for review by the expedited procedure, the reviewer must determine that the research:

1. Presents 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;

2. Does 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;

3. Is not classified; and

4. Falls into one or more of the Regulatory Categories that allow review using the expedited procedure. Note that 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 subjects.

The reviewer shall document the category of approval and approval period in the IRB e-system and in the approval letter to the Investigator.

D. Continuing Review.

1. Research initially approved under the 1991 Common Rule and not transitioned to the 2018 Common Rule qualifies for review by the expedited procedure only if the Reviewer determines:

a. The research falls into one or more regulatory categories allowing continuing review using expedited procedures.

b. The current or proposed consent document is accurate and complete.

c. If any review reveals significant new findings that may relate to a subject's willingness to continue participation, the IRB must determine the process to provide that information to the subjects.

d. Whether verification from sources other than the Investigator is needed to ensure that no material changes have occurred since previous review by the IRB. See IRB Policy 7.4 for examples of studies that may warrant outside verification.

e. Whether the research requires review more often than annually.

2. The reviewer should document the category of approval and approval period in the IRB e-system and the approval letter to the Investigator.
3. Continuing review is not required for research that either transitioned to the 2018 Common Rule after initial approval under the 1991 Common Rule; was initially approved either under the 2018 Common Rule or under Equivalent Protections using Flexible IRB Review Procedures; or qualifies for exempt status review. See IRB policies 7.6, Continuing Review; 7.14, Equivalent Protections using Flexible IRB Review Procedures; and 7.3, Exempt Categories of Research.
4. All research subject to FDA oversight must undergo continuing review at least annually.

E. Modifications to previously approved research. Modifications to previously approved research may only be reviewed by the expedited procedure when the change is a Minor Modification. The reviewer must determine that the proposed modification represents a Minor Modification.

F. Responses to Minor Revisions Required. Responses to Minor Revisions Required may be reviewed by the expedited procedure. IRB Policy 9.1 defines Minor Revisions.

REFERENCES
21 CFR 56.109(f)
45 CFR 46.110
AAHRPP Element II.2.F