Arkansas Tech University

Procedures for

Use of Human Participants in Research

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Graduate Council IRB Sub-committee

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**ARKANSAS TECH UNIVERSITY POLICY AND PROCEDURES**

**OF THE INSTITUTIONAL REVIEW BOARD**

**The Human Participant Review Process**

All research projects conducted by faculty, staff and students associated with Arkansas Tech University that deal with clinical investigation and/or human participants shall be assessed by the Institutional Review Board (IRB) for risks and benefits of research participation.

**Institutional Review Board Committee Membership**

Membership of the IRB is governed by U.S. Department of Health and Human Services regulation 45 CFR 46.107. The IRB is a standing committee of ATU. The ATU IRB will have representation from each of the academic colleges. Members will be appointed by the Dean of the Graduate College and Research (in consultation with the deans of the colleges) according to federal guidelines and the needs of the university. A good faith effort should be made in the selection of membership to reflect diversity of race, gender, cultural background, and research experience. The IRB Chair will be appointed by the Dean of the Graduate College and Research (in consultation with the deans of the colleges).

**The IRB Review Process**

Proposals shall be submitted using the appropriate application paperwork by the designated deadlines for IRB review. Once the committee determines that benefits outweigh risks, the IRB reviews the consent process to ensure that all potential risks and benefits are clearly identified to prospective participants and those participants participate voluntarily.

After review, the IRB may elect to approve, table, or reject the research application. The IRB may require protocol revisions and resubmission. In the event of requested revisions, the proposal must be resubmitted for IRB review and approval.

To protect human participants, all research projects must be approved by the IRB before investigators begin the research study/project. Investigators cannot begin participant recruitment as recruitment strategies are part of the review process until the study is approved by the IRB. Although there are different levels of review, many projects require “full” committee review.

All IRB actions will be communicated in writing to the principal investigator by the IRB staff. If the investigator is a student, the letter will be addressed to the investigator in care of the faculty sponsor.

For information on the levels of review, see section 4.3.

**Proposal Review Timeline**

IRB applications should be submitted via e-mail to the Office of Research and Sponsored Programs. The application will then be distributed electronically to the IRB committee. Applications that are received within the first week of the month will be responded to by the end of the month. Applicants should allow 2-4 weeks for all protocol reviews. Applicants will be notified via e-mail when their application is approved.

**Recommended Training**

Before you can conduct clinical research on the TECH campus or any affiliated campus, you must complete **Human Participant Protection and HIPAA for Research** training. Go to [**www.citiprogram.org**](http://www.citiprogram.org/) and select Arkansas Tech University.

* Create your own user name and password.
* Fill in your contact information.
* On the Learner Group page, select either Biomedical Research (if your study involves drugs or devices) or Social/ Behavioral Research. You do not have to take any of the other optional courses, but you may find them helpful.
* HIPAA for Research is incorporated into both the Biomedical and the Social/Behavioral courses.
* All modules will require you to score 75% on each quiz. You can take the quizzes as many times as necessary.
* Your certification will be valid for 2 years.
* If you need assistance with this process, call the Office of Research and Sponsored Programs.

**Levels of Review**

Four levels of review:

* Exempt
* Class Assignment
* Expedited
* Full

**EXEMPT REVIEW**

According to the Department of Health and Human Services regulation 45 CFR

46. 101, there are certain classifications of research that are exempt under federal jurisdiction. Exempt research that is conducted to benefit ATU only, does not require submission of an IRB application (see specific classifications listed below). All other exempt research must submit an application to the IRB. The application will be reviewed by the IRB Chair to determine that the research protocol does meet the criteria to qualify as exempt research.

**Exempt Research That Requires IRB Application**

1. The research is conducted in established or commonly accepted educational settings, involving normal education 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. The research involves 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 the human subjects can be identified, directly or through identifiers linked to the subjects; OR,

 b. Any disclosure of this information outside the research could reasonably place the subject at risk of criminal liability or civil liability or be damaging to the subject’s financial standing, employability or reputation.

3. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior when the human subjects are elected or appointed public officials or candidates for public office.

4. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior and federal statutes require without exception that the confidentiality of the personally identifiable information will be managed throughout the research and thereafter.

5. The research involves 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.

**Exempt Research That DOES NOT Require an IRB Application**

There are several classifications of research that may involve human subjects but are exempt from the IRB's policies and jurisdiction. All of the types of research listed below are exempt and do not require IRB applications or approvals.

1. ATU teacher and student evaluations;
2. Program evaluation research to benefit ATU and carried out by ATU administrative officials and/or their designees;
3. Projects designed to enhance or improve curricula offerings;
4. ATU employee performance evaluations;
5. State of Arkansas mandated program evaluations;
6. Marketing research (designed to market the institution as a product).

Except for the examples above, all other research involving human subjects MUST complete an application to be deemed exempt. Exempt categories of research do not require a full IRB hearing, but must be reviewed by the IRB Chair or his/her designee. Funding agencies do not allow investigators to make this determination on their own, nor does Arkansas Tech University.

The IRB Chair must approve any exempt proposal before the proposed research may proceed and the investigator must receive a letter from the Office of Research and Sponsored Programs confirming this decision. There is no such thing as an emergency exemption and no university official other than members of the IRB may designate research as exempt.

**Review Process**

Applicants should allow 2-4 weeks for all protocol reviews. If the proposal is approved by the IRB, the Office of Research and Sponsored Programs will send an email notification and, if desired, an electronic letter of exemption to the principal investigator noting that the research is exempt from the IRB policy. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects’ privacy, or confidentiality of research records), the applicant will receive notification that will outline the concerns that must be addressed in order to continue the review process. It also may indicate that the research does not qualify as exempt and ask the investigator to submit an application for either Expedited or Full Board Review.

**Conditions of Approval**

Once a project is approved as exempt, no further action is needed.

**Changes to the Research Project**

If substantial changes are planned, the investigator should submit a new IRB application. For minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool), the investigator submit a Modification of IRB Approved Research Project form, along with a revised application outlining the modifications in red. Prior to making any changes that will affect the information given on a previously approved exempt application, a member of the IRB must approve changes and the Modification form must be on file with the Office of Research and Sponsored Programs. The Office of Research and Sponsored Programs will contact the investigator upon approval or if the changes outlined are not acceptable.

**CLASS ASSIGNMENTS FOR STUDENTS**

In some instances, students participate in research projects in order to learn about the process of conducting research. These projects do not meet the definition of research as outlined in the IRB policy unless the research is intended to contribute to the generalized body of knowledge in the field. There is a need to ensure that these assignments do not compromise any of the principles outlined in the ATU IRB policy. It also is essential that students be socialized to the ethical and procedural concerns associated with institutional review practices and the need to protect human subjects.

Student projects may be exempt from IRB review if the assignment meets the criteria outlined below.

**Important Note**This procedure does not include honors projects, theses, or dissertations. These types of research require normal review according to the ATU IRB policy.

Faculty members may elect to use the procedure outlined in this section of the policy for student projects that meet ALL of the following criteria:

1. The assignment is part of a class and is conducted under faculty supervision;
2. The purpose of the assignment is for students to learn about the process of engaging in research or applying a pedagogical technique (NOT for research which is intended to be used for publication, formal reports, or presentations at professional conferences);
3. The project is eligible for exempt or expedited review (i.e., no project requiring full board approval may be dealt with under this procedure);
4. The instructor has completed the on-line research ethics training (see section on CITI training) and has filed their certificate of completion with the Office of Research and Sponsored Programs.

Faculty members who wish to use this procedure must submit an Acknowledgement to Proceed with Student Class Projects form and a copy of his or her certificate of completion of research ethics training to irb@atu.edu.

The IRB strongly recommends, but does not require, the following:

1. Require students to complete the online research ethics training and submit their certificate of completion to the instructor.
2. Require students to submit an IRB application for approval by the instructor (instead of the IRB Board); and
3. Review and approve the exempt and expedited review forms submitted by the student to the instructor.

It is recommended that these files be maintained for no less than three years by the faculty member (the length of the approval of a protocol) and that the instructor require students to complete the online training on the IRB process as part of the course work.

**Expedited Review**

Research activities that (1) present not more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review process authorized by 45CFR 46.110 and 21 CFR 56.110.

Expedited review as defined by the federal regulations allows the IRB chairperson or one or more experienced reviewers among members of the IRB to evaluate and approve specific types of research. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When a subcommittee cannot approve the research under expedited review, the study is referred to the full committee for review.

Activities approved in the federal regulations for expedited review are:

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) 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.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/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 participants, 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 children2, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (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 gum base 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 participant or an invasion of

the participant’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.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). 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 HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(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 participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants 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.

**Full Review**

A project that involves greater than minimal risk or does not qualify for exempt/expedited review requires approval for the IRB composed of members qualified to review research in that field.

Research that requires full committee review includes:

* research that involves greater than minimal risk;
* non-exempt research that involves children or other vulnerable populations
* research that involves experimental drugs or devices;
* research that involves invasive procedures; and
* research that involves deception.

Survey research that involves sensitive questions or information about sexual practices or illegal behavior is subject to full review.

All research proposals will be screened IRB Chair/Designee before they are assigned to the IRB. If a proposal is incomplete, it will be returned to the investigator. The IRB only reviews

complete applications. After review, the IRB will act on the application. Possible committee decisions include:

* approved as submitted;
* approved with requests for minor changes
* approved with contingencies (conditions that must be met before final approval is granted)
* deferred pending receipt of additional information or major revisions; or
* disapproved.

All research proposals approved by the IRB will be submitted to the Vice President of Academic Affairs for final review and approval. In the event research is undertaken without the intention of involving human participants, but it is later proposed to involve human participants in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

**Appeal of IRB Determination**

Investigators who have been required to make revisions in their applications or whose applications have been disapproved may request additional information regarding reasons from the IRB or may request reconsideration. Such requests shall be made in writing, addressed to the IRB chairperson to be considered at the next scheduled IRB meeting. At the discretion of the IRB committee, investigators may be invited to meet with the IRB or a subcommittee to collect additional information or to explain reasons for decisions. The IRB will provide the investigators with a written explanation of its reasons or its decision upon reconsideration. The IRB decision will then be final. No additional appeals can be made at that time.

**Preparing the Proposal Application**

The principal investigator must complete the proposal application paperwork at least 4 weeks prior to the start of the research study.

**Designating the Principal Investigator**

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. Qualified faculty must supervise all student research projects.

**Research involving Pregnant Women and Fetuses**

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any

other means, her consent is obtained in accord with the informed consent provisions of subpart A

of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

**THE PROCESS OF CONSENT**

**General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each participant:

 (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

 (2) A description of any reasonably foreseeable risks or discomforts to the participant;

 (3) A description of any benefits to the participant or to others which may reasonably be

 expected from the research;

 (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

 (5) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

 (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

 (7) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and

 (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each participant:

 (1) A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;

 (2) Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;

 (3) Any additional costs to the participant that may result from participation in the research;

 (4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;

 (5) A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and

 (6) The approximate number of participants involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

 (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

 (2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

 (1) The research involves no more than minimal risk to the participants;

 (2) The waiver or alteration will not adversely affect the rights and welfare of the participants;

 (3) The research could not practicably be carried out without the waiver or alteration; and

 (4) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.) [56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

**Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

 (1) A written consent document that embodies the elements of informed consent required by

 §46.116. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or

 (2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

 (1) That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or (2) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

(3) The research includes an online survey where distributing and collecting paper informed consent forms is not appropriate.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.) [56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

**Applications and proposals lacking definite plans for involvement of human participants.**

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that participants may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving participants remain to be selected; and projects in which human participants' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human participants may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

**Research undertaken without the intention of involving human participants.**

In the event research is undertaken without the intention of involving human participants, but it is later proposed to involve human participants in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

**REPORTING UNANTICIPATED PROBLEMS TO THE IRB**

Federal regulations require the Institutional Review Board (IRB) to ensure that investigators promptly report unanticipated problems involving risk to participants or others. These should be reported to the IRB within 10 working days.

**IRB Review of Unanticipated Problems**

The IRB will forward the report to a designated member to evaluate the report and determine if a) no further action is required, b) the principle investigator (PI) is to submit additional information, c) revisions to the informed consent are necessary, d) revisions to the protocol are necessary, e) suspension of the protocol is required upon notification to an agreement of the chairperson, or f) termination of the protocol is required by the IRB.

The reviewer may ask that the report be presented at the next full committee meeting for discussion and further decision. If referred, the IRB may require the PI to notify participants of unanticipated problems. This may require a letter sent to all participants and/or as part of a revised consent form to be signed by returning participants. Depending on the perceived risk to the research, the IRB may require more active monitoring of a research study.

All communications concerning decisions will be conducted via campus inter-office mail, email, and, in addition, perhaps verbally.

**NON-COMPLIANCE**

Non-compliance is defined as conducting research involving human participants in a manner that disregards or violates federal regulations governing such research. This can include, but is not limited to,

1. failure to obtain IRB approval for research involving human participants,
2. inadequate or non-existent procedures for informed consent,
3. inadequate supervision in research involving experimental drugs, devices or procedures,
4. failure to follow recommendations made by the IRB to insure the safety of participants,
5. failure to report unanticipated problems or proposed protocol changes to the IRB, and
6. failure to provide ongoing progress reports.

**Investigation of Allegations of Non-compliance**

According to 45 CFR 46.113, “*An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s actions and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head*.” Given this legal authority, the IRB shall review all allegations of research involving non- compliance with human participants' regulations or unexpected serious harm to human participants. The following policies and procedures will be conducted by the IRB when conducting an inquiry and investigation into allegations of non-compliance and in reviewing incidents of unexpected serious harm to participants.

Appropriate action will be taken by the IRB to insure the safety and welfare of human research participants. Actions may range from corrective or educational measures for the researcher to terminating IRB approval for all active studies of a researcher. In addition, the IRB may suspend approval of research projects at any time during an inquiry or investigation to assure the protection of human participants. Written procedures for reporting actions to appropriate university and federal government officials as required by federal regulations are included in this policy. All research activities of faculty, staff, students and others conducting research involving human participants fall under the jurisdiction of the IRB and are bound to these policies and procedures.

**Reporting Allegations of Non-compliance**

Allegations of non-compliance may be reported to a) the principal investigator; b) the Chair of the IRB; or c) any IRB staff member.

The IRB may initiate a complaint based on available information (e.g., deficiencies noted in IRB

files, media or scholarly reports of research activity subject to IRB jurisdiction).

**Review of Allegations of Non-compliance**

Purpose

In the inquiry stage, factual information is gathered and reviewed to determine if an investigation is necessary. An inquiry is not a formal hearing or an in-depth analysis of the allegations but designed to separate allegations deserving further investigation from those that are frivolous, unjustified or related to minor infractions.

Process

Whenever an allegation or complaint of non-compliance is made, the Chair of the IRB appoints an inquiry panel. Written notice of the allegations is also sent to the researcher and a response is requested within 10 working days. If the complaint raises issues of safety and welfare for research participants that are apparent upon initial review, the researcher is also given notice of an opportunity to address this in his/her response and notified of the possible summary suspension of the researcher’s project(s). The inquiry panel will review the allegation of non-compliance, the response from the principal investigator, and any other information necessary to determine whether an investigation is warranted. The inquiry panel may or may not interview the researcher and others. Securing critical data or materials may be necessary at the outset of an inquiry to protect the integrity of those data, materials, and/or records. The IRB maintains the authority to secure such materials at any time during an inquiry or investigation.

Recommendations and Outcomes

At the conclusion of the inquiry phase, the inquiry panel makes a recommendation to the Chair of the IRB. Recommendations may include: 1) dismissal of the allegation or complaint as unjustified; 2) referral of the matter to another more appropriate system within the university for resolution (e.g., Grievance, Academic Misconduct; Student Conduct Code); 3) resolution through corrective or educational measures where the violation of human participants regulations is minor or inadvertent; and 4) a formal IRB investigation where the allegation or complaint appears founded and is of a serious nature.

The Chair of the IRB acts upon the recommendation of the inquiry panel and notifies the researcher in writing of the outcome of the inquiry phase. This notice includes a statement of the reasons for the decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is completed within thirty working days. The Chair of the IRB may grant an extension of this time frame if warranted.

**Suspension and Reporting**

At any time during the inquiry or investigation process, the IRB may suspend the accrual of research participants or suspend approval of research project(s) to assure the protection of human participants. The authority to suspend research rests with the IRB; both the inquiry and investigation panels may recommend suspension to the IRB. If suspension is warranted, it normally occurs at the end of the inquiry phase. Except in cases of imminent harm to research participants, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance.

When the IRB makes a decision to suspend approval of research, it notifies the Chair of the IRB and other appropriate university officials. These may include the researcher’s department head, dean of the college, and senior administrative officers. The Chair of the IRB, who serves as the authorized institutional official, will send written notice on behalf of the IRB to the following entities, as required under federal regulations:

* the Federal Office for Human Research Protections (OHRP);
* the Federal Food and Drug Administration (FDA) if the suspension of research approval involves an investigation drug or device;
* the OHRP and FDA as applicable, if the matter involves the non-submission of a project which should have been reviewed by the IRB, and the researcher’s failure to do so has resulted in unanticipated risks to human participants or serious or continuing non- compliance with IRB requirements; and
* external and internal sponsors funding a study under suspension. Reports will be filed within five working days of suspension.

In some cases, reporting to professional licensing boards or state agencies may also be required. The Chair of the IRB or other appropriate University officials will make these reports.

**Investigation of Allegations of Non-compliance**

Purpose

The purpose of the investigation is to explore the allegations by assembling and examining pertinent information. The charge of the investigation panel is to write a report that summarizes the information it considered, its conclusions as to whether there was non-compliance with human participants’ regulations, and recommendations for action. During an investigation, additional information may materialize that justifies broadening the range of the investigation beyond the initial allegations. The researcher is informed if new and different allegations are discovered during the course of the investigation.

Process

The investigation is conducted by an ad hoc panel of at least three IRB members established by the Chair of the IRB. One of the panelists is a member of the inquiry panel. All other members are IRB members whose areas of expertise are suited to reviewing the complaint and area of study. The investigation panel may use any and all materials and reports produced during the inquiry phase, but it is not limited by actions or conclusions of the inquiry panel. The researcher under investigation is given an opportunity to submit written comments and appear before the panel on at least one occasion prior to the panel issuing its report. At the conclusion of its investigation, the investigation panel prepares a report summarizing the information it considered and outlining its conclusions and recommended actions. The investigation panel forwards a copy of this preliminary report to the researcher and gives the researcher ten working days in to submit a response to the report. The investigation panel reviews any response received from the researcher and decides based on the response, whether to modify its preliminary report. When finalized, the investigation panel sends the Chair of the IRB its report with any comments received from the researcher. Depending on the case, the investigation phase is expected to be completed within 60 working days. The Chair of the IRB may grant extensions if warranted and may request interim reports.

Outcome

The Chair of the IRB will base her/his decision on the report of the investigation panel and any comments submitted by the researchers. Actions taken may include, but are not limited to the following: a) dismissal of the complaint as unjustified; b) remediation or educational measures; c) increased reporting by the researcher of his/her human participants research activities; d) restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; e) suspension of approval for one or more the researcher’s studies; f) termination of approval for one or more of the researcher’s studies; g) withdrawal or retraction of publications/presentations; and h) referral to other university officials or committees for possible further review and action by those bodies.

**Appeals/Reconsideration**

Purpose

The appeal allows the researcher an opportunity to request reconsideration of the Chair of the IRB decisions under certain limited circumstances. Grounds for appeal are limited to the following: a) new information not reasonably available during the investigation, b) material failure to follow these policies and procedures, and c) restriction exceeds the severity of the violation. No other grounds will be considered.

Process

The appeals panel is comprised of three IRB members who have not served on the inquiry or investigation panels. The appeals panel reviews the written statement of appeal by the researcher and makes a recommendation as to whether the Chair of the IRB should reconsider any aspect of his/her decision based on the reasons outlined above. In realization of this recommendation, the appeals panel may seek a response from the investigation panel. The decision whether or not to grant the appeal is made within 10 working days.

If the appeals panel denies the appeal, the Chair’s prior decision becomes final. If the appeals panel recommends reconsideration, the Chair re-opens the case. When the Chair of the IRB re- opens the case, he/she may choose to reconvene the investigation panel or reconsider the matter on her/his own. The Chair (or the investigation panel, if reconvened) will offer the researcher the opportunity to appear personally to present the appeal.

Upon reconsideration, the Chair determines whether to modify or uphold his/her original decision. This action is final. The reconsideration phase is completed within 30 working days.

**Dissemination of Findings**

At the stage when the Chair’s decision becomes final (i.e., 5 working days after her/his original decision if there is not appeal; upon a decision by the appeals panel to deny the appeal; or upon the Chair’s final determination if the case is forwarded for reconsideration), the findings are released to the researcher and to appropriate University and governmental officials as required under federal regulations. The same guidelines as set forth above for reporting suspensions apply. It may be necessary to inform these same officials of the status of the proceedings while they are pending.

**Coordination with other Investigative Processes**

The IRB will cooperate in the review of allegations of academic misconduct, financial mismanagement, FDA inspections, etc. In cases associated with academic misconduct, the investigation panel may report allegations of such misconduct to appropriate institutional officials. When academic misconduct and IRB investigations are pending against the same researcher, the IRB will participate in a close coordination of processes to avoid duplication of effort and minimize competing use of resources.

**Conflict of Interest/Commitment**

As with all IRB processes, any IRB committee member who has a conflict of interest or commitment relating to the matter under review excuses himself/herself from the proceedings and an alternate is designated by the senior chair. It is permissible to allow substitution of non- IRB members for conflict of interest/commitment concerns at any stage in the establishment of an inquiry or investigative review panels.

**Confidentiality for Complainants and Witnesses**

The researcher under review should have access to the identity of complainant(s) and others who provide information. However, if such individuals are in a status subordinate to the researcher and wish to maintain their anonymity, the IRB makes every effort to protect their identities while at the same time affording the researcher access to the substance of the allegations and information presented against him/her. The IRB cannot guarantee absolute anonymity.

**Retaliation**

Reviewing complaints and allegations of non-compliance is critical to the IRB’s ability to protect human participants. A climate free of sanction is required to foster appropriate reports and ensure a fair review of allegations. Retaliation against persons reporting and/or reviewing complaints and allegations of non-compliance is illegal and is not tolerated at this institution. Persons who report IRB related concerns may utilize other mechanisms at the University for protection from retaliation.

**CONTINUING REVIEW**

The goals of continuing review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard participants are adequate, that the approved protocol is followed, and that the project reflects any changes made in the regulations for human participants’ research since the last approval.

The IRB may require changes in protocol or the consent form if the study's risks were originally underestimated.

**When Continuing Review is Required**

The Department of Health and Human Services (DHHS) regulations 45 CFR 46, require that “an IRB shall conduct continuing review covered by this policy at intervals appropriate to the degree of risk, but not less than once per year...” This continuing review must be substantive and meaningful. Research is renewed up to three times for a total of four years for each project (initial approval plus three renewals). After four years, investigators must submit a new IRB application to continue their research.

A notice for renewal and a continuing review report are sent to the principal investigator approximately 60 days before the review date. The report should be completed and returned to the Chair of the Institutional Review Board by the indicated deadline. The notice for student projects is sent to the faculty sponsor, and this person is responsible for notifying the student and ensuring timely submission of the report. The study expiration date is crucial for the continuation of the study. If the study is allowed to expire, all data collection must cease and no funds may be spent (if funded). Any lapses in approval for the use of human participants must be defended to the IRB and to regulatory or funding agencies. A new application and review is required to reinstate the study if it expires.

If the investigator does not respond, the IRB classifies the study as “inactive.”

The IRB is required to report all federally funded studies inactivated due to lack of response to requests for continuing review to the Office for Human Research Protections (OHRP).

If the study is complete, the investigator is asked to complete several portions of the continuing review report as a “final report” on the project.

**What to Report**

Continuing review requires the researcher to write a Continuing Review Report and attach a current consent form if participants are currently being recruited. The form requires the following information:

* the number of participants enrolled since the last review and the total number of participants enrolled to date; breakdowns of the participant population by gender and other demographics;
* a summary of the results of the research to date, including
* any unanticipated risks or adverse outcomes, and
* any early indication that one of the treatments under study is significantly better or worse than others;
* any difficulties recruiting or retaining participants, an explanation of the difficulties, and the number of participants who withdrew from the study;
* changes in the last year that were approved and the dates they were approved;
* if currently recruiting participants, a copy of the consent form currently in use (as most recently approved by the IRB).

Incomplete reports are returned, which may cause a delay in getting the study on the appropriate committee agenda.

**Making Changes in Research Protocols**

A project approved by the IRB must be executed according to the approved protocol. Any changes in participant population, recruitment, procedures, instruments, study sites, or major research personnel require approval by the IRB. Changes enacted without prior approval constitute a violation in protocol.

Researchers who plan a change must complete the Request for Revision report. The title is that of the approved study and a description of the proposed changes should in lay language. The researcher must explain why the change is needed, describe any implications for participants, and provide the appropriate revised consent documents. All changes are highlighted in the submitted materials.

Absent and Exiting Principal Investigators

If a principal investigator on an approved project goes on sabbatical leave from the university, an interim PI is appointed. The IRB is notified of this person's qualifications, and the new PI provides written notification to the IRB accepting the responsibility for the treatment of participants. If a researcher leaves the university permanently, the IRB is notified both of any interim investigators and of the final replacement. The study is otherwise filed as “inactive.”

How Changes are Reviewed

The Chair or designee reviews all requests for revisions and provides approval if the changes are minor and do not a) alter the risks and benefits to the participants, b) affect the equitable enrollment of participants, or c) modify informed consent protections. If the requested modifications in research represent a significant revision in the approved research or increase the risks to participants, the Chair or designee refers the request for revisions to the full IRB for consideration at a convened meeting unless the amended research would qualify for expedited review.

Investigators are notified in writing of IRB decisions on revisions. If a request for revision is not approved, the IRB provides the reasons for its decisions.

**New Findings**

Adverse Events

Adverse events are unexpected problems of a nature, severity, and frequency not described in the information provided to the IRB or to participants. Unexpected complications in a participant, missteps in the consent documentation, or breaches of confidentiality are examples. Adverse events are reported to the IRB within 10 working days.

A study may be suspended to ensure participants' safety. Reports of events occurring at other sites receive expedited review, but in some cases, the full IRB is involved. All events that occur at Arkansas Tech University are reviewed at a full IRB committee meeting.

Events at Other Institutions in a Multicenter Trial

If the project is a multicenter trial and the event occurred at another institution, the researcher must write to the IRB, describing the nature of the event, its severity, the likelihood that it will occur at the university, and the implications for future participants.

Death of a Research Participant

Researchers should alert the IRB immediately to the death of any study participant, whether the death is believed to be related to the study or not.

New Risk/Benefit Findings

As a study progresses and the risks and/or benefits of participating in the study are better understood, researchers may find that the study must be stopped. Such as in some placebo- controlled trials, preliminary findings may give compelling evidence that a new treatment is efficacious and to continue giving placebos becomes unethical. In such cases, the investigator should write to the IRB, describe the findings and the need to suspend the placebo portion of the study. If the IRB agrees, the researcher should identify all participants who received a placebo and invite those participants to continue in an “open label” study in which all participants receive the study medication.

**Keeping Records**

Researchers should maintain a file of all documents concerning the use of human participants in research for not less than five years after conclusion of the study. The principal investigator's records should mirror the IRB's records: where the IRB holds an original, the principal investigator should hold a copy, and vice versa.

Researchers should have the following documents on file:

Original signed consent forms kept in a secure location separate from correspondence with the IRB but readily available to inspectors. IRB records are subject to inspection by federal authorities. Sanctions include suspension of funding, fines, exclusion from future funding, and suspension of laboratory access.

**SPONSORED PROJECTS: ADDITIONAL REQUIREMENTS**

Most federal and private funding agencies will not award a grant for a research project involving human participants without prior approval of the IRB. However, the University allows for concurrent processing of the human participants review and the management review of a proposal.

**Special Situations**

Funding awarded prior to IRB approval:

A funding sponsor occasionally makes a conditional award before IRB has approved the research project. When this occurs, the funding sponsor specifies a time limit (usually sixty days or less) for IRB approval. The investigator is responsible for notifying the sponsor of IRB approval.

Developmental proposals:

Proposals in the development or concept stage pose a dilemma for investigators, funding sponsors, and the IRB. Funding agencies may be unwilling to consider a proposal without IRB approval, yet given the early stage of the project, the investigator may not be able to provide a complete protocol or consent document. In these situations, the IRB may grant a “conditional approval” that will satisfy the sponsor, yet allow for additional review to protect the participants. The investigator should include an explanation for the deficiencies in the application as well as a statement that research will not begin until the complete project has IRB approval.

Program project grants and training grants:

Program projects are large, multi-project studies designed to produce a coherent body of research from many subprojects. Training grants also may include a variety of subprojects. The initial application to the IRB should include the title of the overall program project, the principal investigator's name and contact information, and a list of the subprojects with the investigators' names and contact information for each. All subprojects in the program grant must be submitted to the IRB separately. It is the responsibility of the principal investigator for the overall project to ensure that the subproject investigators submit their applications in time to allow for review and approval. The IRB will certify its approval of the overall project only after it approves all subprojects.

Additional endorsements:

Funding sponsors occasionally require additional documents of special assurances. If this situation arises, the investigator may contact the Chair of the IRB for additional signatures or forms.

**Changing the Title of a Research Project**

Occasionally an investigator wants to change only the title of a research project to make it more competitive for a particular funding sponsor. The Chair of the IRB may grant such requests; however, any change in the protocol of a research project must be approved by the IRB.

Researchers must file for these changes at least 30 days before the grant submission date. In all cases, investigators must provide a copy of the grant proposal**.**

**Unfunded Proposals**

If a proposal is not funded, the investigator should inform the IRB whether or not the work will be conducted in the absence of external funding.

Information for this policy and procedure was adapted from Lamar University’s Policy and Procedures on Use of Human Participants in Research.

Other resources included information from Western Kentucky University, University of Arkansas Medical School and Northeastern University, and the University of Tennessee at Chattanooga.