Arkansas Tech University

Procedures

for

Use of Human Participants in Research

Prepared by:

Graduate Council IRB Sub-committee

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This draft represents the work of two subcommittees appointed by the Graduate Council.

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Table of Contents

ARKANSAS TECH UNIVERSITY
POLICY AND PROCEDURES ON USE OF
HUMAN PARTICIPANTS IN RESEARCH

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 on the Institutional Review Board Committee (IRB) consists of eight members - one representative from each college appointed by the college deans and a faculty member appointed by the Vice President for Academic Affairs. The function of the IRB is to review requests on research involving human participants. Conduct periodic reviews of human participant policies and procedures.

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. (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117)

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

Proposal Review Timeline

The IRB will meet biannually to review proposals. Meetings dates for the IRB will be set in the summer and posted on the IRB web site. Request must be received by the IRB Chair four weeks prior to the advertised IRB meeting time. Members will be sent a packet of materials for review one week prior to the scheduled meeting. Members are expected to review all materials prior to the meeting.

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** 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 100% 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 (to be determined)

Levels of Review

Three levels of review:

- Exempt review
- Expedited review
- Full Board Review

Exempt Review

Arkansas Tech University requires all human participant research studies meeting, or appearing to meet, one of the "Exempt" criteria to be submitted for review and approval by the IRB. No Investigator or Department on campus shall have the authority to make this decision other than the IRB Chair/Designee.

All research, including that is in the Exempt categories, must meet at a minimum the principles outlined in the Belmont Report. The IRB Chair/Designee may require additional protections to meet these principles, including a level of informed consent appropriate to the research or review by the full committee.

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

Six categories of research are **exempt** from the regulatory requirements, including the following:

- Research conducted in established or commonly accepted **educational settings, involving normal educational practices**, such as (i) research on regular or special education instructional strategies, or (ii) research on the effectiveness of the comparison among instructional techniques curricula, or classroom management methods. --- **45 CFR 46.101(b)(1)**

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), **survey procedures, interview procedures, or observation of public behavior, *unless*:** (i) information obtained is recorded in a manner that human participants can be identified, directly or through identifiers linked to the participants; ***and*** (ii) any disclosure of the human participants' responses outside the research could reasonably **place the participants at risk** of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. --- **45 CFR 46.101(b)(2)**

- Research involving the collection or study of **existing data, documents, records,** pathological specimens, or diagnostic specimens, if these sources are **publicly available *or*** if the information is recorded by the investigator in a manner that **participants cannot be identified,** directly or through identifiers linked to the participants. --- **45 CFR 46.101(b)(4)**

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 children[2], 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

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 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. (http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm, retrieved 3/14/10)

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 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

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.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.119

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. P

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. (See Appendix ___ for Faculty Research Application; Appendix __ for Student Research Application)

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. All student research projects must be supervised by qualified faculty.

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 or not 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.

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 and 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, a) failure to obtain IRB approval for research involving human participants, b) inadequate or non-existent procedures for informed consent, c) inadequate supervision in research involving experimental drugs, devices or procedures, d) failure to follow recommendations made by the IRB to insure the safety of participants, e) failure to report unanticipated problems or proposed protocol changes to the IRB, and f) 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.

Application

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. These reports will be made by the Chair of the IRB or other appropriate University officials.

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.

<u>What to Report</u>

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

All requests for revisions are reviewed by the Chair or designee. The Chair, or designee 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
http://dept.lamar.edu/researchandsponsoredprograms/IRB%20Policy%20and%20Procedure.rtf

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

APPENDIX A

APPLICATION FOR REVIEW OF HUMAN PARTICIPANTS RESEARCH

The following is designed to briefly introduce you to important considerations when answering each item. There is no one "correct" answer for each item, we are simply providing guidance for how to answer or address the issues raised in each item. Please email an IRB member for more information, or to answer any questions you have. Attach application to an email and email to jwarnick@atu.edu (be sure to save a copy of your application).

- Make sure you delete all red type explanations.
- NOTE: Anticipate no action on applications that do not meet the timeline as posted on the IRB web site

- **APPLICATION FOR REVIEW OF HUMAN PARTICIPANTS RESEARCH**

Submit hard copy with signatures to the
Arkansas Tech University, IRB, Jason E. Warnick, Ph.D., Witherspoon Building, Room 350

Email application as an attachment to jwarnick@atu.edu

Principal Investigator(s): *I acknowledge that this represents an accurate and complete description of my research.*

Name of Primary PI	Signature of PI	Date

Additional Researchers' Names

Division

Mailing Address

( )
Telephone Number

Email address (Students email account)

Adviser (complete if PI is a student): I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human participants are properly protected.

Name of Adviser/Chair (typed)	Signature of Adviser/Chair	Date

Adviser's Address	Adviser's Email address	( ) Telephone

Title of Project goes here -- 10-15 words that briefly describe the work

PLEASE NOTE: All applications should be typewritten and edited prior to submission for review. If sufficient space is not provided below for a complete description of the proposed project, please use additional pages as necessary.

Summary of Purpose and Objectives

("See attached protocol" is not acceptable)

Item 1 *Describe the purpose of the research. (Research Question/Hypothesis)*

Provide summary in space below.

The purpose should briefly explain the "reason for the study"—not the expected outcome. Examples: The purpose of this study is to investigate the relationship between….. Or, the purpose of this study is to investigate the factors related to……

Item 2 *Describe the participants of this study, including:*

1) Population to be sampled

1) Population: describe those characteristics that are pertinent to the study: Mentally competent, adults receiving services for…; Adult students in the freshman English class; Full-time employees who work with juvenile offenders.

2) Sampling procedures

2) Sampling procedures need to include exactly how participants will be recruited.

a) how they will be found/selected: All clients currently in the XYZ program at the ABC Agency; Interested students in the English 101 classes; 10 of 50 employees at the ACME Human Service Agency selected using a table of random numbers.

b) How they will be invited to participate (check as many as apply):

___ Mailed a survey

___ E-mailed a survey or request

___ Asked verbally, face-to-face, by researcher

___ Phone solicitation by researcher

___ Asked by caseworker, instructor, administrator (circle appropriate one)

___ Other (please explain)

3) Projected date of data collection:

4) Number of participants expected to participate

4) Number: Approximate number you plan to participate.

5) Relationship to agency/school

5) Relationship: If an agency or school (other than LCSC) is involved, specify your relationship with the agency. Provide a letter of permission from the agency or school on their letterhead **AS AN APPENDIX** (this should be scanned in for electronic submission).

6) How long the participants will be involved

6) Length of involvement: Actual length of time they will be observed tested, questioned. Example: for 30 minutes to fill out consent forms and questionnaire; 30 minutes for pre-test and 30 minutes for post-test occurring 8 weeks apart; for 3 months , once a week, during class time beginning ----, ending ---.

7) Any follow-up procedures planned.

7) Follow-up: Only note if you intend to contact participants after an intervention sometime in the future (i.e., post tests).

8) Include a copy of the script or other mechanisms to be used to solicit participants.

Include what you will say as you approach potential participants BEFORE giving them the consent form. **Provide this as a word-by-word script or outline** AS AN APPENDIX. If there is nothing prior to the consent form (e.g., you mail them a consent form and survey), make that clear here.

Summary of Methodology and Procedures

("See attached protocol" is not acceptable)

Item 3 *Describe each proposed condition, intervention, or manipulation of human participants or their environments. Include a copy of any questionnaires, tests, or other written instruments, instructions, scripts, etc., to be used **AS AN APPENDIX**.*

*Specify if self-created or provide a citation for the source. Include documentation **AS AN APPENDIX** that you have purchased, or have permission to use, the materials.*

Describe exactly what will be expected of the participants: Examples: fill out survey, questionnaire, inventory, or scale; take pre-test, participate in group for 8 weeks, take post-test; undergo physical examination, participate in set of exercises, fill out satisfaction scale.

Risks, Costs and Benefits

Item 4 *What risks to participants are most likely to be encountered (physical or psychological, etc.)?*

If there are no anticipated risks, state "Any risks are considered to be minimal or nonexistent.". If there are minimal risks: list. (some stress, embarrassment, emotional distress OR rapid heart rate, exhaustion, stiffness). Refer to definition of "Minimal risk" in the IRB Guidelines

document on the website.

Item 5 *Will the participants encounter the possibility of stress or psychological, social, physical, or legal risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?*
[ ] Yes [ ] No If Yes, please explain below.

If no—do not explain.

If yes—explain.

Item 6 *Will medical clearance be necessary for participants to participate because of tissue or blood sampling, administration of substances such as food or drugs, or physical exercise conditioning?*
[ ] Yes [ ] No If Yes, please explain how the clearance will be obtained.

Item 7 *Will the participants be deceived or misled in any way?*
[ ] Yes [ ] No If Yes, please explain below.

This may be "NO" because you have explained your intentions in your procedures and your use of the data in the "informed consent". If any deception or withholding of complete information is required, explain why, and explain if, how, when, and by whom participants will be debriefed.

Item 8 *Will information be requested that participants might consider to be personal or sensitive?*
[ ] Yes [ ] No If Yes, please explain below.

Typically this is a "YES" if you are asking them for or observing any of the participants' personal characteristics, attitudes, beliefs, habits, etc.

Item 9 *Will the participants be presented with materials that might be considered to be offensive, threatening, or degrading?*
[ ] Yes [ ] No If Yes, please explain below, including measures planned for intervention if problems occur.

If "NO"—do not justify.

If "YES"—explain what participants might find offensive, threatening, or degrading and what you, as the researcher, will do if participant becomes distressed.

Item 10 *What approach will you use to minimize risks?*

This follows from Items 4-9. If there are no anticipated risks in Items 4-9, check here:____ If there are any anticipated risks in Items 4-9, what will you do to minimize the occurrence of any *psychological, social, physical, or legal risks* presented in Items 4-9?

Item 11 *What are the costs to the participants (monetary, time, etc.)?*

Typically, time to fill out questionnaires, etc. (Example: 30 minutes). However, you need to consider the "cost" of participation in interventions, ie. Transportation, time off work, etc.

Item 12 *Will any inducements be offered to the participants for their participation?*

[ ] Yes [ ] No If Yes, please explain below.

Only explain if "yes".

If extra course credit is offered, describe the alternative means for obtaining additional credit available to those students who do not wish to participate in the research project.

Item 13 *Describe the benefits that might accrue to either the participants or society. Note that 45 CFR 46, Section 46.111(a)(2) requires that the risks to participants be reasonable in relation to the anticipated benefits. The investigator should specifically state the importance of the knowledge that reasonably may be expected to result from this research.*

1) Participants: now or future.

2) Society (community) now or future.

Consenting Process

Item 14 *Where will the research study be conducted (school, hospital, etc.)?*

Actual site(s). List the names of agencies, schools, etc.

Item 15 *How will the research study be explained to the participants?*

Briefly explain whether it will be explained verbally (and by whom) or in written form and (how they will receive this form). This may be during recruitment, in the consent form, after consent or any combination.

Item 16 *In what manner will you present the information for informed consent?*
____Oral ____Written

Please include the consent/assent forms or format for oral consent.

*A suggested format and checklist for the consent form (*click this link for the **Consent Form Guideline**) *may be useful as a guide. Elements of informed consent can be found in 45 CFR 46, Section 116.*

Item 17 *How will the consent form be explained to the participants? (Consider all barriers including culture and language.)*

This is in addition to Item 15 that asks "how the research study" will be explained. Often times the study and request for consent happen at the same time, but not always. Do not include the consent form here, but whether this will be orally or written or both.

> *If there are any possible language barriers involved, state in detail how these will be addressed.*

Explain: typical examples are non-English speaking participants, physically disabled (blind or hearing impaired), cognitively delayed or immature, etc.

Item 18 *How will you make it clear to the participants that their participation is voluntary and they may withdraw from the study at any time they wish to discontinue participation?*

Typically this is stated in the consent, however, there may be situations where it is explained more than once: when and why. Cut and paste the relevant statement **HERE**.

Data Collection

Item 19 *Who will have access to the raw/gathered data? (Investigator, staff, sponsor, LCSC IRB, FDA, etc.)?*

Typically: researcher/s, research advisor if student researcher, and whomever the researcher will share the information. Identify people by name and their relationship to the research.

Item 20 *Will the data be a part of a record that can be identified with the participant?*

[ ] Yes [ ] No *If Yes, please explain how you will protect the confidentiality of participants.*

Typically, do not collect names (anonymous data collection); or remove names from data collected (specify when). You may also need to ensure that other identifying information is also deleted or "hidden" i.e., profession or job title if only one in agency.

Item 21 *What are the plans for retention of raw data?(Note: includes hard copy and raw data computer files)*

1) how will you secure the data for the duration of the research;

2) how long do you intend to keep raw data (Note: anonymous data can be kept forever)

3) how will the data be destroyed and at what point in time? (Typically, raw data is shredded or erased within five years, particularly if identifiers are attached.)

Item 22 *What are the plans for dissemination of results? (check all that apply)*

___ Presentation (paper or poster) at LCSC Research Symposium

___ Submission to Undergraduate Student Research Excellence Journal

___ Possible publication/conference presentation

___ Other (please explain)

Item 23 *If tissue samples or specimens are collected, when will they be destroyed? Will they be used for research other than what is described in the consent?*

Explain in detail.

Item 24 *Will the participant's participation in a specific experiment or study be made a part of any record available to his or her supervisor, teacher, or employer?*
[ ] Yes [ ] No If Yes, please describe below.

Explain if "yes".

THE IRB MUST APPROVE THE RESEARCH PROJECT ***BEFORE*** *THE RESEARCHER(S) MAKE(S)* ***ANY*** *CONTACT WITH PARTICIPANTS.*

CONTINUE BELOW BY CUTTING AND PASTING YOUR RESEARCH MATERIALS

Cut and paste approach script on this page…

Cut and paste survey or other research materials here (this can be more than one page)…

Checklist for application submission:

- ☐ Application (include grant proposal if funded project)
- ☐ Informed consent/assent forms
- ☐ Outline or script to be provided prior to participants' agreement to participate
- ☐ Instrument(s) [questionnaire, survey, testing]

Submit hard copy with signatures to:
Arkansas Tech University
Jason E. Warnick, Ph.D., IRB Chair
Witherspoon Building, Room 350
Russellville, Arkansas 72801

Email application as an attachment to: jwarnick@atu.edu

ANY CHANGES IN THE PROJECT AFTER APPROVAL BY THE IRB MUST BE RESUBMITTED AS A MODIFICATION FOR REVIEW BY THE IRB BEFORE APPROVAL IS GRANTED. MODIFICATIONS DO NOT CHANGE THE PERIOD OF INITIAL APPROVAL.

APPROVAL IS GRANTED FOR ONE-YEAR MAXIMUM AND MAY BE SUBJECT TO REVIEW AT ANY TIME THROUGHOUT THIS PERIOD. ANNUAL REQUESTS MUST BE MADE TO THE IRB FOR CONTINUATION, AS LONG AS THE RESEARCH CONTINUES.

REFERENCES TO 45CFR46 (Code of Federal Regulations) may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html

APPENDIX B

INFORMED CONSENT FORM

The below template for developing an informed consent document to use in your research study is meant to provide structure and guidance to the process, not to serve as your exact informed consent document. Please remember to consult your institution and IRB for specific consent requirements, instructions and templates.

For the purposes of this document, guidelines within the template will be provided in italics. If this document is used to develop your informed consent form, please remember to delete the italicized instructions and insert your specific information.

Informed Consent Document Template and Guidelines

Informed Consent Form

Arkansas Tech University

Title of Project: *(complete title of the project as it appears on the protocol and abstract)*

Principal Investigator: (o*nly one person may be named as principal investigator)*

Other Investigators:

Participant's Printed Name: _____

The Introductory Paragraph

Example Introductory Paragraph:

We invite you to take part in a research study *(title*) at *(location/institution*), which seeks to (purpose of study). Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

Section 1. Purpose of the Research

This section is required in all consent forms. It focuses on explaining to the participant why they were asked to participate in the study and the purpose of the research study.

Example Section 1: Purpose of the Research

You are being offered the opportunity to take part in this research study because *(state why the individual was selected, e.g., condition, age, or healthy volunteer).*

This research study is being done to find out……..

OR

The purpose of this research is to……

OR

The purpose of this research study is to obtain information on the safety and effectiveness of *(name of drug, device, etc.).*

Approximately *(number)* people will take part in this research *(nationwide or worldwide)* and about *(number)* people are expected to take part at *(your institution).*

Section 2. Procedures

This section is required in all consent forms. It outlines the procedures of the study and explains exactly what will happen to the individual should they choose to take part in the study. It should clearly identify what parts of the procedure, if any, are experimental.

Section 3. Time Duration of the Procedures and Study

This section is required in all informed consent forms. The purpose of this section is to clearly outline the time commitment a participant is committing to in choosing to take part in the study.

Example of a Time Duration Section:

If you agree to take part in this study, your involvement will last approximately (*give length of time of participation).*

Section 4. Discomforts and Risks

This section is required in all informed consent forms. For certain research studies, it may suffice to say that there are no know risks associated with the research. However, in most studies, this section will outline in lay terms what risks or discomforts may be associated with each procedures or drug administered. List by regimen the physical and nonphysical risks of participating in the study in percentages and numbers whenever possible. Nonphysical risks may include such things as the inability to work, potential anxiety related to the sensitive nature of the questions asked, etc. List the known human experiences related to the treatment and procedures involved, including bruising or discomfort from blood draws, as well as any relevant animal data. Highlight or otherwise identify side effects that may be irreversible, long-term or life threatening. The use of lists or a table format is recommended.

Example of a Discomforts and Risk Section for a Drug Study:

While on the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person. Drugs will be given to make some of the side effects less serious and uncomfortable. Many side effects go away after the drug is stopped but, in some cases, the side effects may be serious and/or lasting.

Drug XYZ side effects.

More likely:

- Decreased appetite
- Difficulty sleeping
- Headache, dizziness

Less likely:

- Hallucinations or delusions
- Nausea and/or vomiting

(The following text should be added for trials with a placebo arm)

If you are in the treatment group that receives placebo (inactive substance) your symptoms or condition may worsen or not improve.

Other Possible Risks Associated With Participating In This Study

Venipuncture: The risks of drawing blood include temporary discomfort from the needle stick, bruising, bleeding, and rarely, infection.

Subcutaneous Injections: Injections to the skin may be less convenient than some other forms of treatment, such as oral medications. In addition, injections may cause momentary discomfort and other local symptoms, such as bleeding, bruising, and, rarely, infection.

(Also, if applicable, the following should be added)

There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. Your doctor will discuss this with you. You should not breast-feed a baby while on this study.

Section 5. Potential Benefits

This section must be in all informed consent forms. However, the way it is included may vary depending on the type of research. The purpose of this section is to describe the benefits of participating for the participant and for others. The following should be included in this section;

- *This section should address two parts: 1) potential benefits to the participant; and 2) potential benefits to others. The two ideas can be integrated, but for the purposes of the example below, they have been separated into separate paragraphs.*
- *NOTE: Payment given to the participant for participation in the study is not a benefit, it is a compensation for participant's time and any expenses that s/he could incur as a result of participation in the study, and should not be included in this section.*

Example of Possible Benefits Section:

Possible benefits to the participant:

(For clinical research studies where direct benefit is possible) The possible benefit you may experience from the (research drug/device/procedure) described in this research includes (list any benefits that may be reasonably expected). However, there is no guarantee that you will benefit from being in this research.

(For research with no direct benefit) You will not benefit from taking part in this research study.

Possible benefits to others:

(Address potential benefits to others) *The results of this research may guide the future treatment of…*

or

Medical science may gain further understanding of….

Section 6. Statement of Confidentiality

This section is required in all informed consent forms. This section must outline how all confidential information and or materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section.

6a. Privacy and confidentiality measures

Example Statement of Confidentiality:

Your research records that are reviewed, stored, and analyzed at *(your institution)* will be kept in a secured area in (*list where records are stored*). (*Include the following if specimens are collected for research purposes*)Your samples collected for research purposes will be labeled with (*list all that apply: a code number, your initials, etc*.) and will be stored *(list where the samples will be stored and how they are secured).*

(For research records/samples that are sent outside of your institution, describe methods that will be used to ensure confidentiality. If records and specimens are sent to different entities or labeled differently, describe their confidentiality measures separately) For research records *(and specimens)* sent to *(outside entity)*, you will not be identified by name, social security number, address or phone number. The records *(and specimens)* may include (*list all that apply: a code*

number, your initials, date of birth, etc.). The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.

OR

For research records *(and specimens)* sent to *(outside entity)*, you will be identified by *(list all that apply: name, social security number, address, phone number, date of birth, any other direct personal identifier, code number)*. The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.
(Remember to include separate descriptions for records and specimens if they are labeled differently or stored differently or sent to separate entities.)

The following statement is considered mandatory for all research studies:

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

The following statement is for those studies that do not include section 6b.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services *(for drug/device studies, add the U.S. Food and Drug Administration)*
- The (*your institution)* Institutional Review Board *(a committee that reviews and approves research studies)* and
- The *(your institution)* IRB Office
- The National Institutes of Health, the study sponsor

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

6b. The use of private health information:

- *Section 6b is mandatory if the research creates, obtains, uses, and/or discloses <u>identifiable</u> health information about the research participants. The 18 identifiers are listed under HIPAA regulations.*
- *Do not include any part of Section 8b unless the research fits the above criteria.*

Example Statement of Use of Private Health Information:

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the *(your institution)* Privacy Notice. If you have not received this notice, please request a copy from the investigator. At *(your institution)* your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study. *(When specific therapy is only available through the research, include these sentences:* The research-related therapy is investigational; therefore, it is not available unless you allow the use of your health information that is collected during this research study.*)*

(For blinded studies) People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will (*Describe the date or event that will trigger the expiration of this authorization e.g., "expire upon completion of the research study" or "expire when FDA approval of the study drug is obtained" or "will continue for the period of time necessary for the preparation of a related follow-up research study" or "continue indefinitely" or "will continue until the NIA notifies the investigator that the information is no longer needed.").* At that time the research information not already in your medical record will be destroyed (*or "will be retained until ___ in order to ___" or "information identifying you will be removed from such research results at (your institution)").* Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information *(if applicable, add:* and your samples*)* at any time. You must do this in writing. Write to Dr. *(PI)* and let *(him/her)* know that you are withdrawing from the research study. *(His / Her)* mailing address is *(address)*.

If you withdraw your permission:

- We will no longer use or share medical information about you *(if applicable, add the following:* or your samples) for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.

- *(List any and all medical information collected from or about the participant in connection with this research study, e.g. blood and other tissue samples and related tests, your medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc.)*
- *Indicate the span of time from which the records are pulled, e.g., "since your diabetes was diagnosed", "the last five years", "only during the time span of the research study".)*

Representatives of the following people/groups within *(your institution)* may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, ___(*name*)___
- The *(your institution)* Institutional Review Board
- The *(your institution)* Institutional Review Board
- *(If using the Investigational Drug Pharmacy)* The *(your institution)* Pharmacy
- *(If applicable)* The *(your institution)* Financial Analyst for Clinical Research
- *(List every other class of persons or group <u>affiliated with</u> (your institution) (e.g., the research team, the study coordinators, etc.) who might need to use and/or disclose the participant's information in connection with this study.)*

The above people/groups may share your health information with the following people/groups outside *(your institution)* for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original *(your institution)* records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *(List every other class of persons or group <u>NOT affiliated with</u> your institution (e.g. fellow researchers in this study at (list other institutions), outside data analysts appointed for this study, the Data Safety Monitoring Board appointed for this study, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant's information might be disclosed.)*
- *(If the study is international)*Representatives from regulatory agencies in other countries may also review your research record, including research-related medical reports and information, along with the NIA and/or the FDA.

Section 7. Costs for Participation

a. Costs:

- *If there are costs to the participant that may result from participation in the research, include a statement describing any additional costs associated with study participation.*

b. Treatment and compensation for injury:

- *Include your institution's mandatory wording for treatment for injury (see below).*

Example Cost for Participation Section:
(If there is no risk of physical injury to the participant, do not include this section.) Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Add, as a separate paragraph, one of the following statements regarding payment for direct costs of treating research-related injuries.

(If the institution will cover all costs of research-related injuries but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *institution (include the names)* will reimburse the standard charges for the treatment of these complications or injuries. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the investigator institution will cover costs of research-related injuries not covered by the participant's insurance carrier but did not provide consent form wording, include this statement as a separate paragraph) If complications or injuries occur that are the result of a medication, procedure or test required for this study, the *investigator*, *(include the name of institution if appropriate)* will reimburse the standard charges for the treatment of these complications or injuries, provided these charges have not been reimbursed by your non-governmental medical insurance or other third party. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

(If the investigator institution has not agreed to cover costs of research-related injuries, include this statement as a separate paragraph) Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance,

they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay.

(End this section with the following statement) You will not lose any legal rights by signing this form.

Section 8. Compensation for Participation

This section is required in all research studies. It should clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.).

Example of Compensation for Participation Section:

You will be given $__ on each visit to compensate you for time and expenses for participating in this study.

(If participants do not receive any reimbursement for participation) You will not receive any compensation for being in this research study.

Section 9. Research Funding

- *Funding disclosure: Disclose what grantors, institution(s) (e.g., NIA) or companies are involved in the research through funding or grants. If none, say so.*
- *Conflict of Interest: Include information about any consultative or financial relationships the investigators may have with the NIA.*

Example Research Funding Section:

The institution and investigators are receiving a grant from *NIA (list any other grantors)* to support this research.

(For funding disclosure) The institution will be reimbursed by the NIA for use of this site's facilities and for the work the research staff does for this research.

Section 10. Voluntary Participation

Example Voluntary Participation Section:

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include (*Briefly list major responsibilities. NOTE: Do not include this sentence if there are no major responsibilities for the participant).* You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

(Optional, if appropriate) Your investigator may take you out of the research study without your permission. Some possible reasons for this are: *(list possible reasons, for example: you did not follow the study instructions, etc.).* Also, the NIA may end the research study early. If

your participation in the research ends early, you may be asked to visit the investigator for a final visit.

*(Optional, if appropriate) (For clinical studies)*If you will be participating in another clinical trial at [Institution] or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.

(Optional, if appropriate) During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 11. Contact Information for Questions or Concerns

- *Clarify the participant's right to have questions answered.*
- *Indicate whom to contact in case of further questions about the research or to report a research-related injury.*
- *Indicate contact information for questions about participant rights and privacy issues.*

Example Contact Information for Questions or Concerns Section:

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact *(Principal Investigator)* at *(phone number)*. *(If clinical protocol, add the next phrase)* or the *(study)* doctor on 24-hour call at *(phone number).*

(All informed consent forms should include this paragraph). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research *(add the next phrase if using identifiable health information:* or about your privacy and the use of your personal health information*)*, contact the research participants protection advocate in the *(your institution's)* IRB Office at *(phone number)*. You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about the Institutional Review Board (IRB), a group of people who review the research to protect your rights, please visit Arkansas Tech University's *IRB* web site at *(website)*. Included on this web site, under the heading "Participant Info", you can access federal regulations and information about the protection of human research participants. If you do not have access to the internet, copies of these federal regulations are available by calling the *(your institution)* at *(phone number)*.

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

_____	_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

_____

Description of the Legally Authorized Representative's Authority to Act for Participant

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Only approved investigators for this research may explain the research and obtain informed consent.

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.

INSTRUCTIONS: The following applies to optional parts of the research only, e.g., storage of leftover tissue for future research, optional sub-studies, etc.

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part.

(For research involving optional storage of tissue for future research) Optional Tissue Storage for Future Use

As part of this study, we are obtaining (*tissue and/or blood and/or cells)* from you. If you agree, the (*researchers)* would like to store leftover sample(*s)* of your (*tissue and/or blood and/or cells)* so that your (*tissue and/or blood and/or cells)* can be studied in the future after this study is over. *(Add the following statement if storage is optional)* These future studies may provide additional information that will be helpful in understanding [disease/condition], but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither the investigator nor you will receive results of these future research tests, nor will the results be put in your health record. Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(*s)* (*is / are)* used for this kind of research, the results will not be put in your health records. It is possible that your (*tissue and / or blood and/or cells)* might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact (*PI name)* at (*phone number)*.

(For linked samples) Your leftover samples will be labeled with (*list all that apply: "a code number", "your initials", etc.)*. These samples will be stored (*describe how the samples will be secured: "Dr. (PI's name)'s locked laboratory)* at _____. If you consent to the collection of samples of your ___ (*e.g., blood, tissue, bone marrow)* for future research, the period for the use of the samples is unknown. If you agree to allow your (*tissue and/or blood and/or cells)* to be kept for future research, you will be free to change your mind at any time. You should contact (*PI name)* at (*phone number)* and let (*him/her)* know you wish to withdraw your permission for your (*tissue and/or blood and/or cells)* to be used for future research. Any unused (*tissue and/or blood and/or cells)* will be destroyed and not used for future research studies.

(For unlinked samples) Your samples will not be labeled with any of your personal information, such as your name or a code number. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

(Add the following tissue options or variations if storage is optional) You should initial below to indicate your preferences regarding the optional storage of your leftover (*tissue and/or blood and/or cells)* for future research studies.

a. Your sample*(s)* may be stored and used for future research studies to learn about, prevent, treat or cure *(disease/condition)*.

_____ Yes _____ No

b. Your sample[s] may be stored and used for research about other health problems.

_____ Yes _____ No

c. Your sample*(s)* may be shared with other investigator/groups without any identifying information.

_____ Yes _____ No

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

_____	_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

_____

Description of the Legally Authorized Representative's Authority to Act for Participant

Person Explaining the Research: Your signature below means that you have explained the optional part of the research to the participant/participant representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

This document was created using the following resources:
CTN Best Practices ctnbestpractices.org
http://www.fullerseminary.net/sop/travis/humsubj/ic_template.doc

http://www.cancer.gov/clinicaltrials/understanding/NCI-IC-Template-May-2006

Checklist for application submission:

- ☐ IRB/IRB application (include grant proposal if funded project)
- ☐ Informed consent/assent forms
- ☐ Outline or script to be provided prior to participants' agreement to participate
- ☐ Instrument(s) [questionnaire, survey, testing]

Submit one complete hard copy with signatures to the
Arkansas Tech University,
Jason E. Warnick, Ph.D., IRB Chair
Witherspoon Building, Room 350
Russellville, AR 72801

Email application as an attachment to: jwarnick@atu.edu

ANY CHANGES IN THE PROJECT AFTER APPROVAL BY THE IRB/IRB MUST BE RESUBMITTED AS A MODIFICATION FOR REVIEW BY THE IRB BEFORE APPROVAL IS GRANTED. MODIFICATIONS DO NOT CHANGE THE PERIOD OF INITIAL APPROVAL.

APPROVAL IS GRANTED FOR ONE-YEAR MAXIMUM AND MAY BE SUBJECT TO REVIEW AT ANY TIME THROUGHOUT THIS PERIOD. ANNUAL REQUESTS MUST BE MADE TO THE IRB FOR CONTINUATION, AS LONG AS THE RESEARCH CONTINUES.

REFERENCES TO 45CFR46 (Code of Federal Regulations) may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html