Operations and Procedures Manual (OPM) of the Institutional Review Board for the Protection of Human Subjects

Arkansas State University-Jonesboro

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This Operations and Procedures Manual (OPM) represents the most current A-State operations and procedures of the Institutional Review Board (IRB). This OPM provides A-State's standard approach to the interpretation of federal regulations, best practice standards, state and local law, and internal practices. The OPM serves as a reference for the IRB membership, Research & Technology Transfer (RTT) staff, and A-State researchers. Regulations and their interpretation can evolve over time. For questions and assistance please contact the A-State Institutional Review Board through the RTT office at 870-972-2694.

I. BACKGROUND

i. Institutional Review Board

Arkansas State University (A-State) endeavors to support researchers in the use of safe, ethical practices when human subjects are involved in research. In accordance with Federal Regulations (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), A-State has an Institutional Review board (IRB) that oversees Human Subjects Research (HSR). The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB. A-State researchers must acquire IRB approval prior to conducting any research activity.

The IRB is not a shared governance committee. Policy decisions are forwarded to the Vice Provost for Research & Technology Transfer. Membership consists of one community representative, a representative from the Office of Research and Technology Transfer, and nine faculty representatives appointed to staggered three-year terms by the Provost and Executive Vice Chancellor for Academic Affairs & Research. Note: Guidelines require some faculty familiar with human subjects research, some faculty members familiar with the social/psychological dimensions of research, and at least one faculty member from a non-scientific area. The Provost and Executive Vice Chancellor for Academic Affairs & Research must make appointments consistent with guidelines. The committee elects a chair at the beginning of each year.

ii. Federal Regulations

The National Research Act of 1974, recognizing the need for safeguard regulations concerning the use of human subjects in biomedical, social science, and behavioral research, requires institutional review, letters of assurance, and documentation thereof for such research. The Federal Policy for the Protection of Human Subjects, known as the revised Common Rule and published on January 19, 2017 and effective as of July 19, 2018 represents the latest Federal regulations for protection of human subjects. See, Revised Common Rule. The US Department of Health and Human Services (HHS) and 15 other Federal departments and agencies have adopted these regulations. The Office for Human Research Protections (OHRP) within the HHS retains general jurisdiction over these matters.

Under the regulations, all institutions receiving funds from any of these departments/agencies are required to establish institutional review boards to review and monitor all funded research involving humans. Institutions are further required to submit to the Federal government periodic letters of assurance that they are complying with the regulations. Arkansas State University has such a letter on file with HHS, which letter commits the university to abide by the provisions of title 45 CFR, part 46, subparts A-D of the HHS regulations concerning

protection of human subjects. It is the policy of this university to apply the regulations to all research and research-related activities which involve humans, funded or not.

Infractions of the regulations could have very serious consequences: not only could grant or contract support be withdrawn from a single offending project, but the host institution could lose all Federal funding. Consequently, A-State takes the protection of human subjects very seriously for both fiscal and ethical reasons.

iii. CITI

Prior to submitting an IRB study application, researchers will need to complete one or more research ethics training courses. A-State uses an online portal called the Collaborative Institutional Training Initiative (CITI). Individuals must set up a personal account through the CITI site: https://www.citiprogram.org/. The site will ask a series of questions about the type of research to be conducted, as well as the researcher's status (faculty, student, etc). The answers will determine the number and type of modules required for the human subjects research ethics training. At a minimum the researcher should complete the most relevant "Responsible Conduct of Research" (RCR) and "Human Subjects Research" (HSR) courses. Each of these courses consists of multiple modules which may take several days to complete. Upon completion of the assigned course(s) the researcher will be sent a training certificate that is valid for 3 years. Researchers should ensure the RCR and HSR certifications are valid throughout the proposed time period of their IRB-approved research studies.

iv. Cayuse IRB

A-State uses the Cayuse protocol management software for IRB submissions. Cayuse uses response-driven web forms for electronically preparing, submitting, and routing studies for approval. New Cayuse users, or those who have forgotten log-in credentials, should send a *Request for Cayuse Log-In Credentials* to CayuseIRB@astate.edu. Faculty and staff should provide their name, A-State email address, department, department phone, and post office box. Students should provide their name, A-State email address, personal phone number, department, and department post office box.

II. DEFINITION OF TERMS

i. Human Subjects

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Thus, the scope of "human subject" is interpreted broadly. See, 45 CFR 46.102(e) at CFR 46.102

ii. Research

Scientific research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Similarly, human research is defined as any systematic activity involving the collection and/or analysis of data on human subjects for the purpose of advancing generalizable knowledge, unless this activity is specifically exempted by current federal regulations. See, 45 CFR 46.102(l) at CFR 46.102.

Not all data gathering is necessarily research. For instance, activities in oral history, journalism, biography, literary criticism, legal research, and historical scholarship, are not considered research. Nor are public health surveillance activities, or information collected for criminal justice purposes, among other. See, 45 CFR 46.102(l1-4) at CFR 46.102(l1-4).

Still, any activity that may eventually lead to publication of the findings, or presentation of the findings at a professional meeting, typically would be considered human research, if it has the potential to contribute to generalizable knowledge. Field studies, master's theses, and special problems studies conducted by students would also typically be considered human research. Coursework assigned to students for the sole purpose of demonstrating established methodologies typically would not be considered human research. However, any study involving a vulnerable subject population, sensitive behaviors, or greater than minimal risk always will be considered human research. If after reviewing the federal guidelines, it is unclear whether your project meets the definition of research, please consult with the Director of Research Compliance before submitting your application.

Research done outside of the United States is subject to the same considerations and review as work within the USA. The Federal government feels very strongly on this point, particularly because some underdeveloped nations are of the opinion that some of their citizens have been used as guinea pigs in studies which would not be permitted in the USA. The investigator also must abide by the laws and values of other countries.

iii. Risk

The IRB, with assistance from the PI, must decide what degree of risk is involved. Risk can be social or psychological as well as physical.

The IRB realizes that risks are an inevitable and accepted part of life, but the committee's task is to ascertain if the proposed research increases risks beyond this normal level. To do so, the PI should adequately address three questions:

1. Is the risk minimal? Minimal risk is defined as the level of risk, considering both magnitude and probability, encountered in the course of normal daily living, including routine physical exercise or psychological examination or tests. Because people often try to avoid situations in their daily lives that produce strong negative emotional states (e.g., anxiety, guilt, depression), research on topics likely to evoke such reactions in some people (e.g., death and dying) may involve more than minimal risk. See, 45 CFR 46.102(j) at CFR 46.102.
2. Could the research objective be attained through procedures bearing less risk? For example, could an aversive electric shock be given by batteries rather than by a transformer plugged into a 110-volt wall socket? Could anonymous numbers be used instead of names? Such risk-reducing options would be suggested to the investigator.
3. If the risk cannot be avoided, is the value of the research sufficient to justify it? This is the thorny "risk/benefit ratio" which poses a perpetual problem. Although the regulations to not ordinarily require institutional review boards to concern themselves with the merit of the proposed research, when anything more than minimal risk is involved, the institutional review board must judge merit in order to evaluate the

risk/benefit ratio. The benefit, if any, may be to the subject directly, to science, or to society in general.

4. The IRB recognizes that the time of subjects is a valuable resource. And in cases of both minimal risk and more than minimal risk, the proposed research project must ensure that a benefit is provided to the participants, the professional knowledge base, or society more generally.

III. INFORMED CONSENT

Besides concerning itself with risk, the IRB must consider the subject's consent to participate in the research project. To be valid, consent must be "informed," which means that the subject must have a reasonable comprehension of that to which they are consenting. The investigator must use language appropriate to the subject's ability to comprehend. Nondisclosure of information to subjects must not be used simply to assure their participation in the research. It is desirable, but not mandatory, that the investigator, rather than an assistant, obtain the consent.

To obtain informed consent, the investigator must provide a document that includes the information listed on the Sample Informed Consent, included in the Appendix. The sample reflects both requirements of the Federal regulations and customary language adopted by the IRB. Use of the sample will facilitate IRB review. For the general requirements of informed consent, see 45 CFR 46.116 at Part 46.

Key information, representing concise and focused information that is most likely to assist an individual in understanding the reasons why or why not to participate in the study, should be presented at the beginning of the consent form, see Key Information.

i. Who is to give consent?

Any legally competent adult can give consent; but said adult cannot give valid consent if they are under the influence of alcohol or drugs, or if the consent is obtained under duress. This latter point is important in academic circumstances because it is easy for an instructor to call upon students to volunteer as subjects. It must be made clear that the decision to participate will have no effect on their academic career, including grades or other evaluations.

ii. Vulnerable populations

A vulnerable population is a group vulnerable to coercion or undue influence. Subjects selected from vulnerable populations may include children, prisoners, individuals with impaired decision-making capacities or from economically or educationally disadvantaged groups. Specific concerns for vulnerable populations are discussed below. Also see Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research at Part 46.204.

a. **Minors:** Persons aged 18 and older may consent to being research subjects and parental permission is not required. However, the consent of at least one parent or legally authorized representative (LAR) is almost always required for subjects aged 17 and under. In addition, the aims and general nature of the project must be described in language a child can comprehend, and the child's assent obtained. If the child is

between ages 7-17 then written assent is requested, children under age 7 of speaking ability may give verbal assent.

Children who are wards of the state must meet additional criteria to be included as subjects in research. See Part 46.409.

To obtain informed assent, the investigator must provide a document that includes the information listed on the Sample Informed Assent, included in the Appendix. The sample reflects both requirements of the Federal regulations and customary language adopted by the IRB. Use of the sample will facilitate IRB review. For the general requirements of informed assent, see 45 CFR 46.408 at Part 46.408.

b. Individuals with Impaired Decision-Making Capacities: Depending upon the severity of their impairment, individuals with impaired decision-making capacities may not be able to give consent. If a person is capable of understanding the nature of the project, consent should be obtained from both the subject and a parent or LAR. With older participants who are cognitively impaired and have an LAR, the LAR should provide consent. If the impairment is very severe, such that assent is not possible, consent by the parent or LAR is sufficient.

c. Prisoners: The use of prisoners as subjects is limited because such subjects' ability to consent voluntarily is limited by the "coercive nature of the environment." Prisoner means any person involuntarily confined or detained in a penal institution. The term also includes persons detained in other facilities (e.g., group homes, work release centers) by statute or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as persons detained pending arraignment, trial, or sentencing. See Subpart C.

Funded research involving prisoners must be approved by both the local IRB and the department/agency head. The research must be limited to (a) 'minimal risk' studies of criminal behavior and incarceration, penal institutions, and prisoners as a social class; (b) research on conditions affecting prisoners - including social and psychological problems - only if approved by the department/agency head after expert consultation; and (c) therapeutic research, with control groups also requiring the department/agency head's approval.

Any researcher planning research involving prisoners is encouraged to review the current regulations for other requirements before submitting the IRB application for review.

iii. Broad Consent

Broad consent is prospective consent for unspecified future research. For some research, broad consent may be used as an alternative to informed consent for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens. Broad consent is unlikely to be used in the social and behavioral sciences, humanities and education. As noted in the regulations, broad consent requires basic elements, see Subpart A 46.116d.

Researchers seeking broad consent should first consult with the Director of Research Compliance.

iv. Deception, Concealment/Incomplete Disclosure

Deception involves intentionally telling the subjects something untrue regarding the nature or purposes of the research. Concealment/incomplete disclosure occur when investigators do not reveal relevant details of the protocol to the participants, often to prevent biasing the results. By some definitions (e.g., within CITI modules), concealment and incomplete disclosure are considered deception.

Such practices should be employed only when there are no viable alternative procedures because they impede on a participant's ability to provide informed consent.

For the IRB to review a study that involves deception or concealment/incomplete disclosure, the investigator will need to convey reasons for such within their application. The information should include why alternative procedures cannot be employed, how the potential benefits of the research justify the use of deception or concealment/incomplete disclosure, the debriefing plan, and a debriefing script.

Deception or concealment/incomplete disclosure may be part of a study, but it is urged that preliminary consent be obtained, even though the investigator informs the subject that the study cannot be described fully in advance. After the study, the subject should be informed of the practice. We recognize that there are rare instances in which no consent can be obtained or advance briefing done (e.g., if the researcher pretended to lie unconscious on a sidewalk and noted how many and what sorts of persons stopped, attempted assistance, or simply hurried past). A debriefing plan should be submitted with the IRB application. Further, the faculty mentor should either conduct the debriefing or at least be present during debriefing procedures for any student project that involves deception in a face-to-face study. If it is not possible for the faculty mentor to be present at a debriefing, then a script should be prepared with assistance from the faculty mentor and adhered to by the student.

IV. EXEMPT RESEARCH

Under the Federal regulations certain types of research are exempt from these rulings. It is the A-State Committee's practice to encourage but not require *signed* informed consent statements from subjects in exempt research projects. The A-State IRB does, however, generally require that information about the research be given to subjects in either oral, written, or electronic form. Some exempt studies may qualify for waivers of documentation of informed consent, as provided by federal law, CFR 46.117, see Subpart A 46.117. For instance, when certain conditions are met, as outlined in CFR 46.117, a study conducted online may have participants opt in by clicking on consent statements or by typing their name electronically, but the participant might not actually sign or receive a copy of the informed consent.

V. CLASS ASSIGNMENT VS. RESEARCH

Class assignments primarily intended for educational purposes (e.g., to demonstrate how research is conducted) are not subject to IRB review so long as such assignments do not involve placing human subjects at more than minimal risk. However, student research projects involving vulnerable populations (e.g., pregnant women, fetuses, prisoners, individuals with impaired decision-making capacities, minors, economically or educationally disadvantaged persons) will require IRB approval. Instructors or the Research Compliance Director are responsible for making the initial determination as to whether IRB review is required. Also see, X. STUDENT-LED RESEARCH, p. 14.

VI. RESPONSIBILITIES OF RESEARCHERS

1. Researchers are responsible for maintaining high ethical standards in their treatment of human subjects. All research procedures must be consistent with University policy and with any ethical standards established by the researcher's academic discipline.
2. Researchers are responsible for following current IRB guidelines for ethical review of human subjects. Researchers should seek clarification from the IRB when questioning the need for IRB approval.
3. Researchers are responsible for using only those procedures approved by the IRB. Researchers must suspend data collection and seek IRB approval whenever there is a significant modification to the project or unanticipated risks to human subjects become evident. IRB approval is also needed when suspending a treatment could be harmful to the subject. Also see XVI. PROTOCOL DEVIATIONS, p 18.
4. Upon completion of a study researchers should close the study within Cayuse IRB. Administrative check-in will occur 1 year after approval of a study requiring Convened Review and after 3 years for studies categorized as Exempt or Expedited. If the studies are continuing beyond these timeframes, the researcher is responsible for notifying the IRB that the approved procedures are still being employed through a 'Request for Continuing Review' in Cayuse IRB. Expired studies, or those not closed by the researcher, within Cayuse IRB will be archived by an IRB administrator.
5. Researchers who are not directly affiliated with A-State, but who wish to conduct human subjects research on the campus subject populations must identify an A-State contact who is also named on the IRB application. They must also complete and submit the requisite CITI courses.
6. If a project includes students who are currently enrolled in the researcher's classes, the researcher should be forthcoming and cognizant of potential conflicts. Students may feel pressure to participate in their own instructor's studies, particularly when the instructor announces that they need to increase their sample size or if students are receiving credit as part of a course requirement. In such cases, alternatives to research participation should be presented, when possible. To mitigate any perceived or unintentional coercion to participate, it is recommended that a faculty collaborator or well-trained student research assistant engage in the subject recruitment and data collection processes, and that data be de-identified prior to analysis by the instructor.

VII. OPERATIONS AND PROCEDURES OF THE A-STATE IRB

i. Meetings

The Committee meets regularly to discuss and review projects, September through May, and in summer as necessary. Procedures for the Committee's meetings are governed to the extent possible by federal regulations and institutional practices. To review proposed studies, a quorum must be present in convened meetings. In most cases, meetings are only open to members, alternates, consultants and invited guests. See, IRB Meeting Guidance.

ii. Submission of application via Cayuse IRB

Requests for approval to use human subjects for research should be submitted through Cayuse IRB. Investigators should allow the maximum time of 30 days for review prior to the beginning date of the project. Projects are considered by the Committee at regular intervals through the Cayuse IRB portal and at the IRB committee meetings. To ensure review during a given month, requests should be submitted one full week before a scheduled meeting. However, many proposals will meet criteria that allow for a rolling review process conducted via Cayuse IRB and will not require convened committee review.

Under the Federal regulations, proposals which appear to be Exempt may be reviewed by the Director of Research Compliance, the IRB chair or some other person designated by the Director of Research Compliance or IRB chair, rather than by the convened committee. Proposals that are Exempt but fall under-Limited IRB Review or Expedited may be reviewed by the IRB chair or some other person designated by the Director of Research Compliance or IRB chair, rather than by the convened committee. Proposals categorized as Full Board or Convened Review must be reviewed by a quorum of voting IRB members during a convened meeting. No proposal will be disapproved without convened Committee review.

iii. Approval Processes

In its review of protocols, the Committee determines that the following requirements have been satisfied:

a. **Equitable selection of subjects.** No individual or group should be asked unfairly to assume the burden of research participation. When risk is involved, the potential benefits that justify this risk should be generally described to the subjects selected for the study. Members of vulnerable populations should not be used as subjects unless this population is the specific focus of the investigation.

b. **Voluntary, informed consent.** Unless the IRB waives one or more aspects of informed consent, human subjects must voluntarily give their full informed consent prior to their research participation. Minors should give an equivalent informed assent. No aspect of informed consent will be waived unless there is no more than minimal risk involved and the study could not be practically carried out without the waiver. If deception or concealment/incomplete disclosure is involved, full disclosure through debriefing must be provided at the earliest reasonable opportunity.

   When members of a vulnerable subject group are used as subjects, these persons should be allowed to give their informed consent to the extent that they are able.

However, full informed consent should also be obtained from appropriate persons who are responsible for the subjects' welfare.

Researchers must have subjects sign a written informed consent statement if the research involves more than minimal risk, or if subjects will receive therapy and/or drugs. Researchers may be required to obtain signed informed consent statements from LARs from vulnerable populations. When data are collected using questionnaires, informed consent information can be included as part of the instructions for completing the questionnaire. Oral informed consent can be obtained in most other types of research.

No informed consent statements may include exculpatory language through which subjects waive or appear to waive any of their legal rights. In addition, informed consent statements may not include language that releases the researcher or the institution from liability due to negligence.

When the study involves more than minimal risk the IRB may require researchers to provide a copy of the signed informed consent statement to subjects or their guardians.

c. **Minimization of acceptable risk.** If subjects are to be exposed to more than minimal risk, researchers must demonstrate that (a) alternative procedures involving only minimal risk are not available, (b) the risk is justified by the anticipated benefits of the research, (c) every effort has been made to reduce the level of possible risk, and (d) reasonable efforts will be made to remove any injury or harm incurred by subjects.

When greater than minimal risk exists, the IRB may require researchers to report on the status of the research more often than annually, and may also require independent verification that the approved procedures are being followed.

iv. Confidentiality and anonymity of data

If it is possible for data collected from human subjects to be anonymous, this is preferred as it minimizes the chances of linking responses directly to individuals. However, all data collected from human subjects must be kept confidential. Only persons actively involved in conducting the research project should have access to information that would allow identification of individual subjects or their responses. If appropriate, the IRB may approve having subjects voluntarily sign a statement waiving their rights to confidentiality. The waiver statement must inform subjects of the circumstances under which their identity could be revealed and the purpose of doing so. Information must be released in such a way that it can be used only under the specific conditions to which the subjects have agreed.

If data are collected by the researcher in a manner by which the identity of the participant can readily be ascertained, directly or through identifiers linked to the subjects, the study will undergo Limited IRB Review. Limited IRB Review may be conducted by one or more experienced IRB Committee members, but not solely by the Director of Research Compliance.

For studies collecting identifiable information, the informed consent must now include a statement about use of data for future research studies. Per 45 CFR 46.116(b)(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; *or*

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

v. Common problems with approvals

Rarely are protocols disapproved by the Committee. However, many studies require additional information for adequate review. Occasionally, the Committee requests investigators to revise their procedures. Examples of common problems causing delays in the review and approval process are the following:

1. Failure to complete or inadequate completion of the appropriate forms (e.g., lack of details in responses, inconsistencies within the protocol or between protocol and informed consent, etc.).
2. Inadequate informed consent statement.
3. Inability of committee to ascertain risk without consulting experts.
4. Lack of clarity in how confidentiality or anonymity will be protected.
5. Unacceptable risk involved. (These are generally few in number and, typically, can be modified to meet concerns of the Committee.)

vi. Approval notification

When the approval is granted, the principal investigator, and in certain cases the faculty mentor, will be notified via Cayuse IRB of approval. If notification of approval is required for external funding, the Office of Research Compliance will send a copy of the signed Documentation of Review and Approval for forwarding to the appropriate agency.

Exempt and Expedited protocols with minimal risk do not require continuing review, as long as certain conditions are met (e.g. no modifications are made to the approved studies), see Subpart A 46.109. For studies requiring convened review, approval is granted for one year. Studies which undergo convened review that are continuing for more than one year must apply for continuation of review to receive approval each year the study is active. If the initial application indicates a multi-year study, the investigator will be notified by through Cayuse IRB when it is time to apply for this approval.

Investigators frequently ask whether or not a proposal needs to be reviewed. If the study is a research project (a systematic investigation designed to develop or contribute to generalizable knowledge), the results of which are to be published or made public in some other manner, and humans are/were involved now, in the future, or in the past, then the study most likely needs to be reviewed by the IRB.

vii. Records

The Committee maintains the following files through the Office of Research Compliance:

1. Federal regulations and communications, as well as University memoranda and letters of assurance.
2. Minutes of the meetings.
3. Original protocols and copies of memoranda sent to, and received from, investigators.
4. Protocols not as yet reviewed.
5. Protocols from which approval has been withheld and suitable remedial action not yet taken.
6. Correspondence.

IRB files are maintained by the Office of Research Compliance (ORC). All protocols shall be kept for at least three years after completion of the research.

viii. Confidentiality

IRB committee members are expected to keep information, discussions, and documentation related to the IRB review process confidential. Committee members will not, without appropriate authorization, release confidential review information to anyone outside of the review process either within or outside the institution, nor will they use such information for unauthorized purposes. The confidentiality requirements related to IRB review continue indefinitely for current and former Committee members.

VIII. DEPARTMENTAL COOPERATION

Departments, institutes, or centers whose faculty or students do research with human subjects may wish to establish screening committees which examine all faculty and student research prior to submission to the IRB. If a department, institute, or center generates so few research projects using human subjects that a standing committee is not justified, the head of such a unit could appoint ad hoc committees as needed. Regardless, all applications in which students are the principal investigators must have a faculty mentor associated with a unit at Arkansas State University, and mentors must approve the student application prior to review by the IRB Committee.

Cooperation with the IRB by both faculty and students is essential if we are to comply with Federal and university regulations. We recognize that the Federal regulations and our interpretations of the regulations can be daunting to an investigator on first encounter. The IRB will provide whatever assistance it can to investigators or departments to explain our procedures and to secure compliance with a minimum of delay or disruption of research.

IX. PROCEDURES FOR SUBMITTING AND REVIEWING RESEARCH PROJECTS

Researchers must follow the submission procedures described in this section whenever they are required to (a) obtain a letter of exemption or (b) obtain formal ethical approval from the IRB. All requests for IRB action are submitted via Cayuse IRB to the Office of Research & Technology Transfer.

Upon completion of the requisite CITI courses and after establishing Cayuse IRB credentials, the researcher will enter the Cayuse IRB portal and add a New Study, give it a descriptive title, and indicate it is an Initial submission. Cayuse IRB will then request additional information about the investigator and the project. Responses will place the Review Level as Exempt, Expedited, or

Convened Review. Exempt research involves no more than minimal risk AND meets one or more categorizations listed on the Exempt section of the application. If research does not fall into the Exempt review level, applicants must select either Expedited or Convened Review, along with respective categorizations listed under each of these levels. If a researcher is uncertain which review level or category to select, then the Director of Research Compliance or IRB Chair can help to determine which review level and category are most suitable.

i. **Letters of exemption.** When the Office of Research Compliance or a member of the IRB determines that the research is Exempt, researchers will be sent a letter of exemption via Cayuse IRB. If the Office of Research Administration or a reviewer from IRB committee believes the research is not exempt, additional reviewers may be consulted. If the IRB then determines the research is not exempted, researchers will be required to submit the proposed research for ethical approval following the procedures for either expedited or convened review. In some circumstances a study submitted to IRB may be designated as NO ENGAGEMENT IN RESEARCH. This designation can be made by the Compliance Officer or one or more members of the IRB.

ii. **Formal ethical approval (Expedited or Convened Review).** After reviewing the proposed research, the IRB will take one of the following determinations:
    a. **Approved.** Researchers may proceed with the research.
    b. **Approve with conditions.** Researchers may proceed with the research only after making non-substantive (minor) revisions which may be approved by the administrator.
    c. **Revisions required.** Researchers may not proceed with the research until certain information or issues are provided or dealt with by the researcher, this often requires submission of a revised application that is then re-reviewed by the IRB.
    d. **Denied.** Researchers may not proceed with the research.

Cayuse IRB offers a menu of options for documenting decisions by reviewers that do not directly align with the determinations above. Options include Approved, Deferred, Disapproved, Exempt, Minor Stipulations, No Engagement in Research, No Human Subjects Research, Not Reviewed, Rely on External IRB, Rely on NCI-RB, Return to PI. With any of the preceding designations a letter of notification will be sent and/or access to comments and requests from the IRB.

When the research project is denied by the IRB, or when the IRB grants conditional approval, the Office of Research Compliance will notify the researcher in writing of the reasons for this action. Researchers who believe this action is inappropriate can have the IRB reconsider its decision by writing the IRB Chair or ORC requesting a second review and detailing the reasons the researcher believes the decision of the IRB is in error. The researcher may also request to appear before the IRB in person to explain his or her position. The decision of the IRB following the second review is final.

X. STUDENT-LED RESEARCH

As defined in CFR Title 45, Part 46 (Department of Health and Human Services policy for Protection of Human Research Subjects), "research" is a "systematic investigation designed to develop or contribute to generalizable knowledge," and "human subject" is " a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or

interaction with the individual, or (2) identifiable private information." Since class assignments are usually not intended to, or likely to lead to generalizable results, the IRB would not normally include these projects under its operational definition of research. Rather, they are viewed as practicum resources of teaching.

A. Research led by students, including classroom and independent study projects, theses and dissertations, that may place the subjects at more than minimal risk, are subject to IRB review. In clinical courses, subjects will be considered to be at risk if the procedures used and/or the questions asked do not fall under what is construed as being ordinary practice. Consideration should be given to the research setting when assessing risk.

B. Projects involving special populations, including minors, pregnant women, fetuses, abortuses, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged, are subject to IRB review.

The following procedures are to be followed for all research projects conducted by students:

1. Faculty mentors and instructors should review and endorse research projects conducted by students and make the initial determination as to whether the project may fall in the category of research as described above, thus requiring IRB review.
2. If an instructor determines that a project conducted by a student qualifies as research the same procedures for submitting and reviewing research projects outlined in section IX. of this manual will be applied.
3. If there is any doubt as to whether the project should be reviewed by the IRB, the IRB Chair or the Research Compliance Officer is to be contacted for assistance. If the IRB Chair or the Research Compliance Officer believes that a particular project is subject to regular IRB review, the proposed project must receive IRB review.
4. In the event IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Instructors and students are reminded of the substantial penalties and risk of liability for failure to comply with federal policy governing the use of human subjects in research. Consequently, the researchers should adhere to ethical standards and use informed consent where appropriate.
5. If there is reasonable expectation on the part of the instructor and the student that the study will be funded (regardless of source) and/or published or offered for public performance, regular IRB guidelines should be followed.
6. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that, under our guidelines, IRB approval is required, the instructor shall present for Committee approval one application setting forth the parameters of the research being conducted by the students. The instructor would describe the types of research to be undertaken by the students, the nature of the subjects to be used, and the kinds of procedures to be used in the research projects. This means that individual forms would not be filled out by each student. Still, the students in the course and the instructor should all complete the CITI training course(s). Also,
    a. individual student projects should be reviewed by the instructor/faculty member;
    b. students must draw their participants from the A-State student population;

c. if extra credit points are awarded to subjects, then the instructor/faculty member will need to determine whether the points awarded are appropriate and demonstrate in the application that the amount of extra credit will not coerce participation;
d. student projects cannot involve personal, sensitive, or incriminating topics or questions that could place participants at risk;
e. student projects should not manipulate behavior of the participants in any way beyond the range of normal classroom activity or college life;
f. student projects cannot involve physically or psychologically invasive contact with the participants;
g. the faculty mentor/instructor should have access to the original, raw data at all times, further,
h. student projects that are conducted to fulfill requirements of a thesis (Honors or Masters) or a dissertation are not suitable for blanket approval. A separate application will need to be submitted for these types of studies.

Any research not within the described parameters would require separate approval. All research conducted by students must include the instructor's approval and must identify the students conducting the study.

XI. RESEARCH CONDUCTED ONLINE

If a study, an instrument, or interview will be administered online, investigators should provide details of the collector (Qualtrics, SurveyMonkey, Facebook, Twitter, etc) and tell of the settings used to protect the data, the confidentiality of responses, and what steps they will take to permanently remove the information from these accounts once the project is completed. If confidentiality or anonymity cannot be guaranteed, which is often the case with online data collectors, then this should be made clear to any prospective participants in the process of obtaining informed consent.

In most cases, investigators should enable the SSL encryption feature and IP addresses should be masked. Also instruments should be designed to allow for a “no response” or “prefer not to respond” and participants should be allowed the option to withdraw at any time without penalty. For more information on Qualtrics’ survey protections, see: Qualtrics Survey Protections. For SurveyMonkey’s IRB guidelines, see: SurveyMonkey IRB Guidelines.

Social media sites such as, but not limited to, Facebook and Twitter may use the data collected through them and participants should be informed of this possibility as part of the consent process. See Facebook’s Data Use Policy and Twitter’s Privacy Policy.

XII. SITE PERMISSION

Site permission is written approval from a representative of the school, university, clinic, organization or other venue which permits an Arkansas State University investigator to conduct research off of Arkansas State University property.

Though not an all-inclusive list, the following sites are examples of locations off Arkansas State University property from which the IRB would generally require site permission. Site permissions from venues not listed below may be requested at the discretion of the committee.

- Schools (e.g., other universities, public/private schools, including Independent School Districts),
- Businesses/Corporations,
- Festivals, Carnivals, Athletic events,
- Conference/Concert Venues,
- Doctor's office/clinics, medical centers
- List serves,
- Professional organizations,
- Non-profit organizations,
- State/City government agencies.

Site permission should be in the form of a letter printed on organizational letterhead, with the printed name and title and personal signature of the representative who gives authorization. In the event letterhead is unavailable, then permission granted through electronic communication will suffice as long as the name and title for the representative, along with contact information are included, and the correspondence is sent through a professional, rather than personal, email system. The letter or correspondence should be scanned and attached in the appropriate section of the Cayuse IRB portal.

A sample site permission letter is available within the Operations and Procedures Manual posted within Cayuse IRB. In general, the letter should include:

- The investigator's name and title,
- The title of the research protocol,
- A brief purpose statement to confirm understanding of the study,
- What the site has agreed to allow the investigator to do, including any restrictions or limitations and what responsibilities, if any, they are assuming,
- Who the participants will be and whether they are adults, minors, or both,
- The time frame involved or any time restrictions.

XIII. REPORTING CONCERNS

Concerns over the conduct of research involving human subjects on the university campus or by university investigators should be addressed to the IRB Chair, and/or the Director of Research Compliance. Confidentiality requests will be honored to the extent allowed by the laws of the State of Arkansas and university policies. Individuals who have concerns about their rights as participants should contact the Director of Research Compliance or a researcher identified in the participant informed consent document.

XIV. ALTERNATE IRB MEMBERSHIP

If a regular member is unavailable for an IRB meeting, an IRB alternate who has comparable expertise may be called upon to review protocol materials and attend the IRB meeting in the regular member's place. There is no pre-determined schedule for this, and sometimes the IRB has little advance notice that a substitute is needed.

The time commitment for an alternate may vary and will depend on the demand for the specific area of expertise and the availability of the IRB member with whom the alternate is paired. It is possible an alternate could go an extended period without being asked to conduct a review.

IRB alternates may also intermittently serve as an Expedited Reviewer and/or Exemption Reviewer, conducted through Cayuse IRB. In advance of assigning reviews to alternate members, additional training will be provided to enable such members to become proficient in these review processes. Like regular members, alternate IRB members will be required to complete the relevant IRB member training courses.

For more information about becoming an alternate IRB member, contact the Director of Research Compliance at 870-972-2694.

XV. CASE REPORTS

Retrospective analysis of no more than three case reports will fail to meet the definition of "research" as it does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically, and also because findings are reported uniquely to an individual, not extrapolated to a population. However, when researchers explicitly seek out an individual with a particular condition or medical anomaly, and the intent of the publication is to generalize the outcomes, test explicit hypotheses, and/or evaluate the condition in a planned, systematic manner, these activities may meet criteria for research that requires IRB oversight. Under these circumstances, the researcher should submit a protocol to the IRB before embarking on additional data collection or analyses.

For case reports, IRB review is not required if <u>all</u> of the following conditions are met:

- the report involves only retrospective analysis of one, two, or three clinical cases,
- the individual(s) is not meant to be a representative sample (not drawing conclusions), and
- results are reported/published without attempting to draw broader conclusions.

IRB review is required if <u>any</u> of the following conditions are met:

- report involves prospective research,
- report involves only retrospective analysis of four or more cases,
- researchers draws conclusions about a broader population based on the reported cases (even if not statistically significant; e.g. pilot studies can be "research"), or
- results are reported/published in a way that suggests broad findings or recommendations.

Researchers should understand the difference between a single case report and a case-control study, which is a type of observational study that meets the definition of human subjects research and requires prospective IRB review and approval.

XVI. HUMAN RESEARCH INVOLVING NYITCOM

A-State researchers collaborating on projects with the New York Institute of Technology's College of Osteopathic Medicine (NYITCOM) should seek IRB approval from NYITCOM. This is part of A-State's overall agreement with NYITCOM. After the NYITCOM researcher has IRB approval, A-State's RTT should be notified along with a request to process an institutional authorization agreement (IAA)

between the institutions that will cover A-State researchers as part of the study approved by NYITCOM's IRB. This policy applies to any protocol involving an employee of NYITCOM, it is not limited to the PI being part of NYITCOM.

XVII. PROTOCOL DEVIATIONS

Policy on IRB Review of Protocol Deviations and Noncompliance for Non-exempt Research

Background

Principal investigators (PIs) are responsible for ensuring their research is conducted in accordance with the protocol approved by the Arkansas State University Institutional Review Board (IRB) and with applicable University policies and non-University regulatory requirements. Failure to do so can have a negative effect on research participants— deviations from the approved protocol can jeopardize the safety, rights, and welfare of participants. Additionally, these deviations can place the University at risk of federal sanctions, up to and including losing the right to receive federal funding for human subjects research.

The A-State IRB recognizes that deviations from the approved protocol may occur during the course of a research study. Deviations must be promptly reported to the IRB. This policy outlines the responsibilities for reporting deviations and the process by which these deviations will be reviewed.

Any modification to a protocol, survey instrument, or informed consent forms, should be submitted to IRB for approval before implementation. The only exceptions are the ones delineated for minor noncompliance changes in Exempt research. Any other changes not submitted and approved by IRB would be considered a deviation.

Scope

Because exempt research reflects a different level of review (as stated in the Federal guidelines), one policy is for exempt research. A second policy is applicable to non-exempt research involving human subjects.

Exempt Research

For exempt research, minor changes in the research protocol are allowed without IRB notification. Examples would include the following:

Minor noncompliance: Minor noncompliance typically involves administrative oversights, non-substantive changes, etc. Any noncompliance that does, or reasonably may, adversely affect the rights, safety, or welfare of research subjects is **not** minor, even if no actual harm has occurred. Examples of minor noncompliance include:

- Implementing non-substantive changes to approved procedures without IRB approval, such as:
    - Re-wording or correcting survey or interview questions where the meaning and

scope of the question do not change;

- Wording changes in recruitment materials or consent documents that do not change the meaning of the information provided or result in excluding any required element(s) of consent;
- Changing the order in which study conditions are administered, as long as a specific order is not necessary to minimize risk;
- Enrolling subjects who do not meet the inclusion or exclusion criteria, except in the circumstances described as serious noncompliance below.
- Adding additional trained, CITI-compliant researchers to a study as co-investigators (not as principal investigators).

- Exceeding the approved number of subjects in a study

Serious noncompliance needs to be reported to the IRB, and modifications related to the following conditions need to be reported in advance of their implementation:

Serious noncompliance: Noncompliance that compromises the safeguarding of the rights, safety or welfare of human research subjects, or that does or may reasonably adversely affect the rights, safety, or welfare of human research subjects, even if no actual harm occurred. Acts that are determined by the IRB to be a flagrant or intentional violation of IRB requirements may also constitute serious noncompliance. The IRB will consider the circumstances surrounding the case when making a decision related to serious noncompliance. In general, examples of serious noncompliance include:

- Failure to obtain IRB approval prior to initiating research activities with human subjects;
- Allowing unqualified or untrained individuals to perform research procedures or monitor subject safety;
- Failure to provide participants with all information necessary to constitute meaningful "informed consent" unless a waiver has been granted by the IRB;
- Enrolling a child in a research study without the informed consent of a parent or legal guardian unless parental consent was waived by the IRB;
- Enrolling subjects from a vulnerable population (i.e., children, prisoners, cognitively impaired individuals, etc.) when their inclusion is not described in the IRB-approved protocol and appropriate protections are not in place;
- Enrolling subjects who do not meet the approved eligibility criteria when doing so compromises the safety or well-being of the subjects;
- Failure to follow approved measures for protecting privacy and confidentiality when the failure presents any risk of harm to the research subject (such as harm to their reputation, social or psychological harm, risks of legal or civil liability, embarrassment, harm to workplace or family relationships, etc.);

- Implementation of changes to data collection procedures, without prior IRB approval, that increase risks to participants or adversely affect their rights, safety, or welfare (e.g., adding survey questions that collect sensitive information, substantially increasing the duration or intensity of exercise activities, adding plans to collect data from private records without subject consent, changes to confidentiality protections, etc.);
- Failure to report serious adverse events or unanticipated problems involving risks to subjects or others as required by IRB policy;
- Instructing or knowingly allowing subordinates (e.g., research assistants, employees, etc.) to engage in activities that are contrary to IRB or institutional policies or regulatory requirements;
- Providing false or intentionally misleading information to the IRB;
- Multiple protocol deviations suggesting a lack of oversight, inaction, or negligence such that research subjects' rights, safety, or welfare could be adversely affected.

Non-Exempt Research

Definitions

Principal investigator (PI): The individual responsible for the conduct of the research who is named as Principal Investigator on the IRB application. In cases where a co-PI/faculty supervisor is named per the policy on PI eligibility (e.g., student projects), the term "PI" also includes the individual listed as co-PI or Faculty Supervisor.

Protocol or approved protocol: The information included in the final approved IRB application, including any attachments, addenda, or appendices. Subsequent modifications and applications for continuing review are included in this definition. A copy of the approved protocol is provided to the PI along with an IRB approval letter when IRB review is complete.

Protocol deviation: Any departure from the IRB-approved protocol. Protocol deviations may involve changes deemed necessary to eliminate apparent immediate hazards or risks to research subjects. Protocol deviations may be intentional or unintentional/unavoidable. The researcher's failure to take reasonable steps to prevent protocol deviations may be considered intentional. Examples of intentional protocol deviations include:

- Enrolling subjects who do not meet the eligibility criteria specified in the IRB approved protocol;
- Exceeding the number of subjects approved for enrollment, except where enrollment is outside of the control of the investigator (see examples of Unintentional/Unavoidable Deviations below);
- Changes to the approved recruitment or informed consent processes (e.g., failing to obtain signed consent, if signed consent was required; changing from an in-person to an online consent process; failing to obtain parental consent prior to enrolling children; etc.)

- Altering the wording in the approved informed consent document (beyond correction of typographical or grammatical errors, or attempts for greater clarification for participants);
- Changes or additions to survey or interview questions (beyond correction of typographical or grammatical errors, or attempts of greater clarification for participants);
- Removing survey or interview questions if the questions are designed to assess eligibility or otherwise relate to reducing risk;
- Adding procedures to the approved protocol (e.g., adding a condition, increasing the amount of blood to be drawn, or adding a blood draw, etc.);
- Removing or failing to perform protocol-required procedures when the change adversely affects risk to participants (e.g., failing to assess eligibility, failing to follow confidentiality measures, etc.).
- Changing the timing or order of procedures if timing or order are important for reducing risk to subjects, ensuring adequate time for informed consent, etc.;
- Providing compensation in a manner that differs from that in the approved protocol;
- Engagement of new study personnel in research activities prior to IRB approval of a personnel modification.

Unintentional or unavoidable protocol deviations are those that are largely outside of the reasonable control of the researcher(s). Examples of unintentional/unavoidable protocol deviations include:

- A subject cannot attend an appointment which results in a change in timing of study procedures (when timing of procedures is part of the approved protocol, and the change does not adversely affect risk to subjects);
- An ineligible subject is enrolled in the study due to misinformation provided to the researcher;
- Exceeding the number of subjects in a study in limited circumstances when enrollment is outside the control of the researcher, (e.g., responses to a recruitment flyer with a link to an online survey exceed the number expected; in this case, the researcher cannot control who sees the flyer, how many individuals choose to respond, etc.).

Noncompliance: Failure to adhere to federal regulations or IRB and/or University requirements for human subjects research, including intentional protocol deviations, unless such deviations are necessary to eliminate apparent immediate hazards or risks to research subjects. Noncompliance can be minor, serious, and/or continuing as defined below.

Minor noncompliance: Minor noncompliance typically involves administrative oversights, non-substantive changes, etc. Any noncompliance that does, or reasonably may, adversely affect the rights, safety, or welfare of research subjects is **not** minor, even if no actual harm has occurred.

Examples of minor noncompliance include:

- Implementing non-substantive changes to approved procedures without IRB approval, such as:
    - Re-wording survey or interview questions where the meaning and scope of the question does not change;
    - Wording changes in recruitment materials or consent documents that do not change the meaning of the information provided or result in excluding any required element(s) of consent;
    - Changing the order in which study conditions are administered, as long as a specific order is not necessary to minimize risk;
    - Enrolling subjects who do not meet the inclusion or exclusion criteria, except in the circumstances described as serious noncompliance below.
- Exceeding the approved number of subjects in a study

Serious noncompliance: Noncompliance that compromises the safeguarding of the rights, safety or welfare of human research subjects, or that does or may reasonably adversely affect the rights, safety, or welfare of human research subjects, even if no actual harm occurred. Acts that are determined by the IRB to be a flagrant or intentional violation of IRB requirements may also constitute serious noncompliance. The IRB will consider the circumstances surrounding the case when making a decision related to serious noncompliance. In general, examples of serious noncompliance include:

- Failure to obtain IRB approval prior to initiating research activities with human subjects;
- Allowing unqualified or untrained individuals to perform research procedures or monitor subject safety;
- Failure to provide participants with all information necessary to constitute meaningful "informed consent" unless a waiver has been granted by the IRB;
- Enrolling a child in a research study without the informed consent of a parent or legal guardian unless parental consent was waived by the IRB;
- Enrolling subjects from a vulnerable population (i.e., children, prisoners, cognitively impaired individuals, etc.) when their inclusion is not described in the IRB-approved protocol and appropriate protections are not in place;
- Enrolling subjects who do not meet the approved eligibility criteria when doing so compromises the safety or well-being of the subjects;
- Failure to follow approved measures for protecting privacy and confidentiality when the failure presents any risk of harm to the research subject (such as harm to their reputation, social or psychological harm, risks of legal or civil liability, embarrassment, harm to

workplace or family relationships, etc.);

- Implementation of changes to data collection procedures, without prior IRB approval, that increase risks to participants or adversely affect their rights, safety, or welfare (e.g., adding survey questions that collect sensitive information, substantially increasing the duration or intensity of exercise activities, adding plans to collect data from private records without subject consent, changes to confidentiality protections, etc.);
- Failure to report serious adverse events or unanticipated problems involving risks to subjects or others as required by IRB policy;
- Instructing or knowingly allowing subordinates (e.g., research assistants, employees, etc.) to engage in activities that are contrary to IRB or institutional policies or regulatory requirements;
- Providing false or intentionally misleading information to the IRB;
- Multiple protocol deviations suggesting a lack of oversight, inaction, or negligence such that research subjects' rights, safety, or welfare could be adversely affected.

Continuing noncompliance: Repeated acts of noncompliance in the conduct of human subjects research suggesting a pattern indicative of a lack of understanding or attention to adequate safeguarding of the rights, safety, or welfare of human subjects or of University policies and/or non-University regulatory requirements for the conduct of human subjects research. Continuing noncompliance is characterized by the frequency rather than the magnitude of the noncompliance. Examples of continuing noncompliance include:

- Repeated failure to obtain IRB approval prior to initiating human subjects research activities;
- Continually late submissions of continuing review applications resulting in repeated lapses in approval;
- Multiple instances of serious or minor noncompliance; this includes multiple incidents within a single project or multiple incidents by a single investigator across more than one project.

Policy

All protocol deviations and instances of noncompliance must be promptly reported to the IRB chair(s) or ORTT staff. Written reports are preferred, although reports by telephone are acceptable. Instances involving actual or imminent harm to research subjects or others must be reported immediately.

Reports of protocol deviations and/or noncompliance may come from many sources. The PI may self-report such instances and is encouraged to do so. Self-reporting will be looked upon favorably during assignment of corrective actions. In other cases, a research subject may submit a complaint, a member of the research team may report an incident, or an incident may be

discovered during IRB review or post-approval monitoring. Research staff who become aware of protocol deviations or noncompliance should notify the PI as soon as possible. In cases where research staff prefer not to notify the PI, reports can be submitted to IRB@astate.edu. Alternately, any individual may report concerns to A-State's Director of Research Compliance .

Instances discovered during IRB review or via post-approval monitoring will be reported by the Director of Research Compliance or IRB staff to the Vice Provost for Research & Technology Transfer (VPRTT), after confirmation that a protocol deviation or noncompliance event has occurred. Immediate reporting is required in cases where evidence suggests human subjects may be at risk.

A PI may also be required to report incidents to his/her department or the study sponsor; PIs are responsible for knowing reporting requirements that may exist beyond those specified by the IRB and for following those requirements.

IRB Review Process

Upon receipt of a report of a protocol deviation or noncompliance, IRB staff will forward the information to the Director of Research Compliance and the IRB Chair as needed to ensure that both parties are informed of the incident. In cases involving serious harm to subjects or where immediate action is needed to prevent such harm, other responsible parties should be consulted if the IRB Chair and/or Director of Research Compliance are unavailable. These individuals may include the VPRTT who serves as Institutional Official (IO), and/or the IRB Vice-Chair.

Initial review

The Director of Research Compliance, will, in consultation with the IRB Chair and/or Vice-Chair, determine the initial course of action. Initial action includes a preliminary evaluation of the allegations/concerns to determine whether the allegations are based in fact. If the Director of Research Compliance, in conjunction with the IRB Chair and/or Vice-Chair, deem an allegation/concern unsubstantiated, it may be decided that no additional action is needed, that further inquiry is necessary, or that the issue should be presented to the convened IRB.

If, upon initial review, the Director of Research Compliance, in consultation with the IRB Chair and/or Vice-Chair, determine that the alleged incident is based in fact, a preliminary assessment is made related to whether the issue involves a protocol deviation or noncompliance. When needed, additional information will be gathered at this stage by the Director of Research Compliance, IRB Chair(s), or IRB staff. The VPRTT may be consulted when necessary (e.g., additional resources are needed to adequately complete the investigation, the incident may also involve academic misconduct, etc.). Temporary suspension of IRB approval may be enacted by the parties involved in the initial review if deemed necessary to prevent harm to subjects.

Sub-committee review

Review of the incident is referred to a subcommittee consisting of the Director of Research Compliance, IRB Chair, Vice-Chair, and a member of the IRB committee selected by the VPRTT who

review the allegations and related materials during a subcommittee meeting to determine whether an incident constitutes noncompliance. If an incident is determined to constitute minor noncompliance, corrective actions will be imposed to resolve the noncompliance during this initial subcommittee review. Such actions may include:

- Acknowledgement of the report with no further action needed;
- A warning or reminder to the PI with instructions on how to avoid future incidents, clarifications regarding requirements and rules, etc.;
- Requiring additional training regarding human subjects research;
- Requiring submission of a modification application or report of an adverse event/unanticipated problem;
- Requiring the PI to submit a corrective action plan;
- Directing post-approval monitoring visits or compliance audits.

If the PI complies with these actions, additional review by the convened IRB is not required. A report summarizing these incidents and the outcomes will be provided to the convened IRB but will not require IRB action. If the IRB disagrees with the determination of minor noncompliance, it may request additional information or further review by the convened IRB.

Committee review

Review of the incident will be referred to the convened IRB review in the following circumstances: (1) if it is determined during the initial review that the incident involves serious or continuing noncompliance; (2) if there is uncertainty or disagreement by the initial reviewers about the level of noncompliance; (3) if the investigator fails to cooperate with the actions required to correct minor noncompliance; or (4) if the IRB disagrees with the determinations made during the initial review.

A report describing the potential noncompliance, along with relevant materials, will be shared with the IRB to allow the committee to review and assess the case. The PI will be informed of the committee review and invited to attend the meeting and discuss the report with the IRB. Reasonable efforts will be made to accommodate scheduling needs of the PI. Actions by the IRB will include a formal determination of the type of noncompliance (i.e., serious and/or continuing). If the IRB determines that neither serious nor continuing noncompliance has occurred, the IRB may dismiss the allegations or determine the noncompliance is minor and delegate handling of corrective actions to the DORR.

In cases where the IRB determines that serious and/or continuing noncompliance has occurred, the IRB will recommend corrective actions to be considered for implementation by the VPRTT or the Provost and Executive Vice Chancellor for Academic Affairs & Research (Provost). When appropriate, a reasonable timeframe for implementation of these actions should also be established. Such actions may include:

- A warning or reminder to the PI with instructions on how to avoid future incidents, clarifications regarding requirements and rules, etc.
- Requiring additional training regarding human subjects research
- Requiring the investigator to submit a corrective action plan
- Disallowing use of the data collected as a result of the non-compliant actions
- Directing post-approval monitoring visits or compliance audits
- Restrictions on serving as an investigator on human subjects protocols (e.g., requiring a supervising co-PI, barring future eligibility as PI, etc.)
- Notification of study participants
- Requirement that participants re-consent to participation

The IRB may also require modifications to the protocol or informed consent process, more frequent review, or that all future submissions be reviewed by the convened IRB. The IRB may also suspend or terminate approval of protocols found to be noncompliant if deemed necessary to protect human subjects. The welfare of currently enrolled subjects will be taken into account when considering suspension or termination of approval.

The IRB may refer the issue to other organizational entities, such as legal counsel, risk management, etc., in lieu of or in addition to the recommended corrective actions.

Principal investigators are encouraged to play an active role in the noncompliance review process. The PI will be provided with an opportunity to review and comment on reports provided to the IRB for consideration. Such comments must be received by the deadline established by the Director of Research Compliance. The PI will be invited to address the IRB during the meeting where the noncompliance review occurs. A report summarizing the IRB's determinations and recommended corrective actions will be provided to the PI for review and comment prior to submission to the VPRTT or Provost for consideration of corrective actions. Comments must be provided by the deadline established by the Director of Research Compliance. The PI's comments will be forwarded to the IRB for reconsideration if the comments reveal new factual information or other circumstances that are reasonably likely to affect the IRB's determinations or recommendations.

Institutional Official review

In cases of serious or continuing noncompliance, the Provost will receive a final report documenting the noncompliance review process, the IRB's recommendations, and any response to these recommendations by the PI. The Provost may accept, revise, add to, or reject any or all of the IRB's recommended corrective actions but may not change the IRB's determinations related to the level of noncompliance or overturn the IRB's decision to suspend or terminate IRB approval, to require modifications to the approved protocol, or to require more frequent or higher level IRB review. The final report documenting the Institutional Official's actions will be provided to the PI, the PI's department chair/head, supervising faculty (if applicable), the IRB Chair(s), and for the IRB file.

Other internal and external reporting requirements are outlined below.

Other review

There may be instances where noncompliance rises to the level of academic misconduct. Academic misconduct charges are processed in accordance with A-State policy.

Follow-Up

Investigators are responsible for ensuring the corrective actions outlined in the final noncompliance report are implemented by the timeframes established in the report. The appointed IRB committee member will oversee the progress of implementation with the assistance of the Director of Research Compliance and IRB Chair as needed. Failure to meet the conditions established in the report will result in additional review by the IRB and possibly termination or suspension of IRB approval.

Internal reporting

The PI's department chair will be provided with a copy of the finalized report in cases determined to be serious or continuing noncompliance. Other A-State offices will be informed of the IRB's noncompliance review as necessary to conduct the review or meet reporting requirements. For example, the Office of Sponsored Programs may be contacted for advice on requirements for sponsored research related to reporting noncompliance.

External reporting

When applicable, incidents of serious or continuing noncompliance must be reported to the Office of Human Research Protections per the requirements set forth in 45 CFR 46.103(b)(5) and the funding agency or sponsor in accordance with their requirements. Similarly, reports of serious or continuing noncompliance must be provided to the Food and Drug Administration for FDA-regulated research in accordance with 21 CFR 56.108(b), 21 CFR 56.113, 21 CFR 812.150. When appropriate, preliminary reports may be filed pending final resolution of the case.

This Operations and Procedures Manual (OPM) represents the most current A-State operations and procedures of the Institutional Review Board (IRB). This OPM provides A-State's standard approach to the interpretation of federal regulations, best practice standards, state and local law, and internal practices. The OPM serves as a reference for the IRB membership, Research & Technology Transfer (RTT) staff, and A-State researchers. Regulations and their interpretation can evolve over time. For questions and assistance please contact the A-State Institutional Review Board through the RTT office at 870-972-2694.

Sample Informed Consent

Consent to Participate in *(Brief Title of Study)*

The following information is provided to inform you of the research project that will be conducted by _____ of the Department/School/College of _____at Arkansas State University, *under the tutelage of* _____. You were selected to participate in this study because _____.

1. ***Describe the purpose of the study and present key information in this section.*** This study is being conducted to better understand *(research topic).* This research will help *(who?)* to better understand how *(issue being investigated). The reasons why or why not to participant in the study are,*

2. ***Describe the anonymity or confidentiality of survey results/responses and limits to these assurances. One of two statements should be made here:*** *1) Either no personally identifiable information will be collected and the steps that will be taken to ensure that identities are not discerned; or 2) personal information will be coded using the following safeguards. Also, any remote possibility of a security breach should be identified. 3) Your responses to interviews/questions are only available to (interviewer/researcher/faculty supervisor).* [If collecting information in a manner in which identify can be directly or indirectly ascertained then a statement must be included on whether this information may or will not be used in future studies.]

3. ***Describe the procedures to be followed and approximate duration of the study****.* Participants in the research will participate in *(describe data collection process)* which will focus on *(research topic).* This *(data collection process)* will last approximately *(length of time)* and your responses will be combined with approximately _____ other participants.

4. ***Describe the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study****. Note: "no risk" is not an acceptable designation, so please do not state this. Use "minimal" or "no known risks outside of everyday life", if risks are not expected.*

5. ***Describe the anticipated benefits resulting from this study****.*

   A. The potential benefits to you from participating in the study are *(describe benefits*). The study may be helpful to increase your understanding of *(issue being investigated).*

   B. The potential benefits to science and humanity that may result from this study are *(describe benefits).* This study will provide information to *(intended audience of research results)* to help them *(intended outcomes of the research results).*

6. ***Describe any alternative procedures****.* If alternative procedures exist, please describe them here. Otherwise, include a statement that says: There are no alternative procedures to participation in the interview.

7. ***Provide contact information****.* If you have any questions about this study, you can contact the person(s) below:

Name of Principal Investigator	Name of Supervisor (if PI is a student)
Department/School	Department/School
Address	Address
City/State/Zip	City/State/Zip
Office telephone numbers	A-State telephone numbers
A-State e-mail addresses	A-State e-mail addresses

This study has been reviewed and approved by Arkansas State University's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Advisor. If you have any questions regarding your rights as a research subject, please contact the Director of Research Compliance at 870-972-2694.

8. ***Describe the rights as a volunteer***. By agreeing to participate in the study, you do not waive any rights that you may have regarding access to and disclosure of your records. Your participation in this study is completely voluntary. If you choose to participate, your responses will be held in confidence. You are free to withdraw at any time without penalty. If the results of this study were to be written for publication, no identifying information will be used.

STATEMENT BY PERSON/PARENT AGREEING TO PARTICIPATE IN THIS PROJECT

Please check each box then sign and write in today's date.

[ ] I certify that I am 18 years of age or older.

[ ] I have read this consent form, and all of my questions have been answered. I freely and voluntarily choose to participate in this study, and I understand that I am entitled to receive a signed copy of this form.

[ ] The information contained in this consent form has been adequately explained to me. All my questions have been answered and I freely and voluntarily choose to participate. I understand that I may withdraw my consent at any time.

_____ _____

Date Signature

Consent obtained by (signature): _____

Print name and title: _____

Informed Assent Form

My name is *[insert researcher name].* I am trying to learn about *[insert topic of study in simple language]* because *[explain research purpose in age-appropriate language].* If you would like, you can be in my study.

If you decide you want to be in my study, you will *[explain all tasks and procedures clearly and simply].*

[Explain the risks and benefits in clear, simple child-friendly language. The benefits must outweigh the risks.]

Other people will not know if you are in my study. I will put things I learn about you together with things I learn about other *[children, teens]*, so no one can tell what things came from you. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop at any time.

My telephone number is *[researcher's work (not personal) telephone number].* You can call me if you have questions about the study or if you decide you don't want to be in the study any more.

If you'd like I will give you a copy of this form in case you want to ask questions later.

Agreement

I have decided to be in the study even though I know that I don't have to do it. *[Name of researcher]* has answered all my questions.

_____ _____

Signature of Study Participant Date

_____ _____

Signature of Researcher Date

SAMPLE SCHOOL/SITE PERMISSION LETTER
[Place on letter head]

Date

Arkansas State University
Research and Technology Transfer/ Institutional Review Board
PO Box 2760
State University, AR 72467

To Whom It May Concern:

Researchers at the Arkansas State University Department of (*insert Department*) have requested permission to conduct the research project named below on site at (*insert School/Institution/Clinic Name*) during the period of *(insert beginning and end dates).*

This letter notifies you that I/we grant permission to research staff members of the Arkansas State University Department of (*insert Department*) to conduct this research at the location listed below. We understand the purpose of this study will be to (*insert description*) and that it will include participants from *(insert participant description and whether the study will include adults, minors, or both).*

Research Project Title:

Principal Investigator(s):

Study Site Location: (Name)

(Address)

Permission granted by:

_____
Name of Individual (print) and Title

_____ _____
Name of Individual (Signature) Date