

The use of human subjects in research is extremely important to the development of new knowledge in many areas. However, careful attention must be given to questions of ethics and human dignity whenever human subjects participate in research.

All research involving human subjects (*including course projects, capstone projects, master's theses, and independent student research*) **must** be formally reviewed and approved before any data are collected.

External Researchers and Organizations Seeking IRB Approval – Thank you for your interest in including ALCORN students and employees in your research. We value human subjects research on this campus and encourage collaboration with our academic professionals and staff members. Please send us a copy of the IRB approval letter from your institution along with all the other necessary documents you submitted to your IRB (this should include your proposal, consent documents, applications, material, interview questions, surveys etc.) This information will be used as part of our internal review by our IRB. You may submit your information electronically to IRB@alcorn.edu.

The regularly scheduled IRB meeting is the fourth Thursday of each month. Applications should be in at least one week prior to the meeting date to be reviewed, otherwise the researcher application will be reviewed at the next scheduled meeting.

Required Training for Investigators

ALL investigators, students, and research staff conducting research with human subjects must complete training and education requirements every 3 years. Research will not be approved until the training requirements are met. Documentation of training must be provided to the IRB Office with all new applications or renewals.

Alcorn State University IRB Policy and Procedures

Policies and Procedures: Human Subjects in Research

Introduction

Alcorn State University Institutional Review Board (IRB) operates under policies and procedures mandated by the U.S. Department of Health and Human Services and the Office for Human Research Protections. These policies are available for review at www.hhs.gov/ohrp/. This document is meant to serve both as a policy statement for the IRB at Alcorn, and as a handbook for investigators involving human subjects in their research.

Questions regarding this document or submission of materials should be directed to:

Alfred L. Galtney, J.D.
Director, Research and Sponsored programs
agaltney@alcorn.edu
601-877-3965

IRB Policy

Alcorn State University fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the campus. Actions taken in the review and conduct of human subjects research by Alcorn will be guided by the principles of respect for persons and justice that are set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979) and with other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (U.S. Department of Health and Human Services (HHS) policies and regulations at 45 CFR 46, which are known as the Common Rule). Any project that represents a systematic investigation designed to contribute to generalizable knowledge and that involves the collection of data through interaction or intervention with individual humans or the gathering of identifiable private information about individual humans is considered human subjects research under Alcorn policy. This policy covers all human subjects research conducted by Alcorn employees and students, as well as research conducted by individuals

external to Alcorn when their research involves the collection of data from Alcorn employees or students, or the gathering of identifiable private information about Alcorn employees or students from records. Human subjects research is not defined in terms of particular research methods, whether qualitative or quantitative in type. Research covered by this policy includes both sponsored and unsponsored projects, data gathering for institutional research purposes, sharing of data across institutions, and student research conducted in a course or supervised tutorial context. Human subjects research conducted by a Alcorn student or by an individual that is not a Alcorn employee or student must be supervised by a Alcorn employee, who will be designated the Responsible Research Supervisor. Under this policy, research conducted or supported by any federal department or agency that has adopted the Common Rule constitutes a special category of research. Whenever Alcorn becomes engaged in human subjects research (i.e., whenever any Alcorn employees or students engage in any form of data collection through interaction or intervention with individual humans or the gathering of identifiable private information about individual humans from existing documentation, or any Alcorn employees or students are the subjects' of data collection, for the purposes of contributing to generalizable knowledge) that is conducted or supported by any federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt according to Alcorn Policies and Procedures for Human Research Protection, actions taken will be in accordance with the terms of the Federalwide Assurance (FWA) for institutions within the U.S.A. In order to ensure the responsible conduct of research with human subjects, Alcorn maintains an Institutional Review Board for the Protection of Human Subjects of Research (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects'. It is the function of the IRB to (a) determine and certify that all projects reviewed by the IRB conform to the policies and procedures in this document and all applicable regulations regarding the health, welfare, safety, rights, and privileges of human subjects; and (b) assist the investigator in complying with federal, state, and Alcorn State University regulations.

All institutional and non-institutional performance sites for Alcorn, domestic or foreign, will be obligated by Alcorn to conform to ethical principles that are at least equivalent to those of this institution. This policy and these procedures shall be operative as of the date they are approved by a quorum of the Alcorn IRB and accepted by the Alcorn Provost/Executive Vice President. Policy and procedures shall be reviewed yearly and revised as necessary. Revisions in statement of policy require approval of the Alcorn Provost/Executive Vice President.

The ALCORN IRB has jurisdiction over all human subject research (as defined above) conducted under the auspices of the institution. Research under the auspices of the institution includes research conducted at this institution, conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involving the use of this institution's non-public information to identify or contact human subjects.

Principles Governing IRB Review of Research

It is the duty of the Alcorn IRB to review and make decisions on all protocols for research involving human subjects. The IRB is guided in its decision-making by ethical principles, and federal, state, and University regulations regarding research with human subjects. The Primary responsibility of the IRB is the protection of research subjects from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of three principles, which are the touchstones of ethical research: (1) voluntary participation by the subjects', indicated by free and informed consent, must be assured; (2) an appropriate balance must exist between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and (3) the selection of research subjects must be the result of fair procedures and outcomes. These principles are summarized as respect for persons, beneficence, and justice, each of which is discussed below. Researchers should be especially cognizant of the need to provide a substantive and cogent rationale for proposed research with subject groups drawn from vulnerable populations. For example: federal guidelines explicitly recognize as vulnerable populations, in a broader context, subject vulnerability is always a relevant consideration for researchers, and it is the responsibility of researchers and IRB members to consider the context of specific research purposes and methods (i.e., to consider what information and actions are required of whom, under what conditions, and for what purposes).

Respect for Persons: Voluntary Participation and Informed Consent One of the most important elements in any research involving human research subjects is the assurance of voluntary informed consent. Any person who is to be a research subject, whether the research is designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what they will be asked to do as a research participant and what the potential risks and benefits of their participation are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB at Alcorn strives to ensure voluntary informed consent of research subjects through careful review of the recruitment and consent process, and of the consent form or

information sheet to be used with subjects'. The informed consent concept is extended to those studies in which the subjects' are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the research subjects well-being (e.g., parents or legal guardians of children). The IRB's concern is to verify that the consent process and document are likely to assist these persons to make an informed decision, which is in the best interest of the research subject. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects'. The IRB must exercise special care when considering subjects' whose ability to give free and informed consent may be compromised in any way.

Beneficence: The Risk-Benefit Ratio The IRB is charged with deciding, for any proposed activity that falls under its jurisdiction, whether: "The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept [those] risks" (Federal Register, May 30, 1974). The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and document. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research subject at risk, however minimal. Thus, the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

Justice: The Fair Election of Research Subjects Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects' should avoid bias for or against particular social, racial, sexual, or ethnic groups. **Sharing Research Risks.** The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a protocol that carries elevated levels of risk might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g. institutionalized

people or prisoners; patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate. An undue share of research risks should not also burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the populations who might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bears some direct relationship to the conditions or circumstances of the research subject population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations.

Assurance of Compliance Alcorn holds Federalwide Assurance (FWA 00004663). The FWA is an assurance of compliance with the federal regulations for the protection of human subjects in research that is federally funded. The FWA is also approved by OHRP for federal-wide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support. In its FWA, ALCORN has opted to apply the Common Rule to human subjects research that is federally funded. This includes pass-through funding for which the original source of support is a federal agency. The subparts of 45 CFR 46 only apply to research funded by HHS. However, regardless of funding source, the Alcorn IRB routinely relies on the principles and guidelines of the Common Rule in making determinations regarding the protection of human subjects of research and the level of review required for approval of research protocols.

ALCORN Institutional Review Board The ALCORN 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 this institution. There is one campuswide IRB. The ALCORN IRB reports directly to the Director of Research and Sponsored Programs (who also serves as the Institutional Official).

Authority of the IRB. The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all the research documents and activities that bear directly on the rights and welfare of the subjects' of proposed research. The application or protocol, the consent/assent document(s), tests, surveys, questionnaires and similar measures, and recruiting documents are examples of documents that the IRB reviews. Before any human subject is involved in research in relationship to this institution, the IRB will give proper consideration to (a) the risks to the subjects'; (b) the anticipated benefits to the subjects' and others; (c) the importance of the knowledge that may reasonably be expected to

result; and (d) the informed consent process to be employed. The IRB has the authority to suspend, place restrictions on, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with serious harm to subjects'. By its recommendations to the Provost/Executive Vice President, the IRB can effect action that withholds or withdraws financial or approved support from projects involving human subjects that are not in compliance with University policies or federal regulations. The IRB has the authority to observe or have a third party observe the consent process and the research if the IRB determines such steps are indicated for the protection of human subjects of the research. Alcorn administrators (departmental chairs, deans, directors, division heads) should remind prospective investigators of IRB requirements whenever a proposed activity involves human subjects.

Jurisdiction of the IRB. The IRB jurisdiction extends to all research (funded and not funded) involving human subjects conducted at Alcorn, as well as research conducted elsewhere by Alcorn faculty, staff, and students, except research where the only involvement of human subjects is in one or more exempt categories. If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the Alcorn Ethics Officer(Dr. Martha Ravola). The official receiving the report will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

IRB Relationships to Other Entities The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, independently determines whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects, which includes but is not limited to research conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects regulations. Research that has been reviewed and approved by the 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.

Relationships with Other Institutions Alcorn may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for Alcorn to provide this oversight, a formal relationship must be established between the campus and the other institution through a Memorandum of Agreement. This relationship must be formalized before the campus will accept any human research proposals from the other institution. In the conduct of cooperative research projects, Alcorn acknowledges that each institution is responsible for safeguarding the rights and welfare of human

subjects and for complying with applicable federal regulations. When a cooperative agreement exists, Alcorn may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. • When Alcorn relies on another IRB, the Chair or designee of the Alcorn IRB will review the policies and procedures of the external IRB to ensure that they meet Alcorn standards. • When Alcorn reviews research conducted at another institution, the particular characteristics of each institution's local research context must be considered, either (a) through knowledge of its local research context by the Alcorn IRB or (b) through subsequent review by appropriate designated institutional officials. •

Roles and Responsibilities. Chairperson of the IRB The task of making the IRB a respected part of the institutional community is shared equally by all members of the IRB; however, the IRB Chair has special responsibility for ensuring that the IRB processes and decision-making follow the principles and established guidelines for the responsible conduct of research and that IRB decision-making is fair, impartial, and immune to any perceived pressure from sources of competing interest. The IRB Chair should be a highly respected individual, from within the campus, capable of managing the IRB, and the matters brought before it with fairness and impartiality. The IRB Chair advises the Director of Research and Sponsored Programs about IRB member performance and competence.

Vice-Chair of the IRB In consultation with the IRB members, the Chair of the IRB may appoint a Vice Chair to serve for a renewable two-year term. Any change in appointment, including reappointment or removal, requires written notification. The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair.

Resources for the IRB. The Director of Research and Sponsored Programs provides reasonable resources to the IRB, including adequate meeting and office space, and staff for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources provided for the IRB will be reviewed during the annual budget review process.

Conduct of Quality Assurance To allow for quality assurance determinations, researchers will maintain research files for no fewer than three years. It is understood that Researchers may be subject to professional, legal, or other regulatory requirement to maintain research records for longer periods of time. As provided in University policy, investigations and audits of ongoing research or records will be conducted when the IRB directs an audit be conducted or a complaint or allegation of non-compliance is received. In addition, the staff will conduct "for cause" and "not for cause" audits of research. University reviews may focus on any of the following elements as described in written documents

and as implemented in practice: • Institutional and IRB policies and procedures for protecting human subjects • Organizational issues affecting systemic protections for human subjects • IRB documentation and records-keeping practices • Adequacy of IRB forms and templates • Standards and practices for initial and continuing IRB review • Standards and practices for obtaining and documenting informed consent • Standards and practices for monitoring compliance with IRB determinations • Standards and practices for monitoring unanticipated problems and adverse events • Methods and effectiveness of communication between the IRBs and research investigators • Training of IRB members, investigators, research personnel, and administrative staff. All recommendations for improvement in the human research protections program will be considered by the Director of Research and Sponsored Programs, Human Research Ethics Officer. Changes in the program will be presented to the IRB for review prior to implementation.

IRB Membership IRB members are selected from the faculty and from the community-at-large to ensure representation of professional expertise and community attitudes. The Director of Research and Sponsored programs will notify OHRP each time there is a change in membership.

Composition of the IRB The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB will be sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall not consist entirely of members of one profession. Reasonable efforts will be made to ensure that IRB membership represents diversity in race/ethnicity, gender, and academic discipline, and exercises sensitivity to community attitudes. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. One member may satisfy more than one membership category. If the IRB regularly reviews research that involves a vulnerable category of subjects' (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons) consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects'. The Chair of the IRB is a voting member.

Appointment of Members to the IRB. The Director of Research and Sponsored Programs identifies a need for a new or replacement member, or an alternate member, and solicits nominations from IRB members, deans, department chairs,

or others, as appropriate. Nominations are reviewed by the Director for Research and Sponsored Programs, and Humans Research Ethics Officer, and the names of recommended candidates are forwarded to the Provost. The final decision in selecting a new member is made by the Provost. Appointments are made for a renewable two-year period of service. There is no limit on the number of terms any individual may serve. Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the Provost. On an annual basis, the Director for Research and Sponsored Programs and Human Research Ethics Officer review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

Alternate members The IRB has the option of appointing alternate members. The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

Duties of IRB Members The agenda, protocols, submission materials, proposed informed consent forms, and other appropriate documents are distributed to members prior to the convened meetings at which the research is scheduled to be discussed. Members review the materials before each meeting, in order to participate fully in the review of each proposed research project. Research proposals, protocols, and supporting data will be treated as confidential information, and should be disposed of appropriately.

Attendance Requirements Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the Director for ORSP. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Director. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate, the alternate can serve during the primary member's absence, provided the IRB has been notified in advance.

Training / Ongoing Education of IRB Members in Regulations and Procedures A vital component of a comprehensive human research protection program is an education program for the IRB members. Alcorn is committed to providing training and an ongoing educational process, related to ethical concerns and regulatory and institutional requirements for the protection of human subjects, for the IRB members.

Records Retention Requirements All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner. The above detailed IRB records must be stored securely and must be retained for at least three years. Records are maintained in locked file cabinets and/or locked offices within the Director of Research and Sponsored Programs Office and are available only to authorized staff and IRB members. If a protocol is cancelled without subject enrollment, IRB records will be maintained for at least three years after cancellation.

Written Procedures and Guidelines The Alcorn Operating Policies and Procedures for Human Research Protection detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the Alcorn IRB. The policies and procedures present the most current information for reference by potential investigators and their staff; however, this is not a static document. The policies and procedures are reviewed at least once every three years and revised by the Director, ORSP and the IRB. The Provost will approve all revisions of the policies and procedures. The Director, ORSP will keep the Alcorn research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. The policies and procedures will be available on the Alcorn IRB website.

Investigator Responsibilities Responsible Principal Investigators are ultimately responsible for the conduct of research and have primary responsibility for protecting the rights and welfare of human subjects. Principal Investigators are responsible for complying with all applicable provisions of Alcorn State University's FWA, federal and state laws and regulations, and the University's policies and procedures. Principal Investigators may delegate research responsibility; however, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

- develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
- develop a research plan that is scientifically sound and minimizes risk to the subjects';
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have sufficient resources necessary to protect human subjects, including: • access to a population that would allow recruitment of the required number of subjects' • sufficient time to conduct and complete the research • adequate numbers of qualified staff • adequate facilities • a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions • medical or psychological resources available that subjects' might require as a consequence of the research; • protect the rights and welfare of prospective subjects'; • have plans to monitor the data collected for the safety of research subjects; • have a procedure to receive complaints or requests for additional information from subjects' and respond appropriately; • ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff; • obtain and document informed consent as required by the IRB and ensure that no human subject is involved in the research prior to obtaining consent; • ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research; • comply with all IRB decisions, conditions, and requirements; • ensure that protocols receive timely continuing IRB review and approval; • report unexpected or serious adverse events problems that require prompt reporting to the IRB (see Section 8.9 Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events below); • obtain IRB review and approval in writing before changes are made to approved protocols or consent forms; and • seek IRB assistance when in doubt about whether proposed research requires IRB review. Only faculty or staff members with University-paid appointments may serve as the Responsible Principal Investigator or as the faculty sponsor on a research project involving human subjects. Adjunct faculty of Alcorn State University and any investigator whose status is considered to be "in training" (i.e. students and medical residents) may not serve as a Principal Investigator but may serve as a coinvestigator. The IRB recognizes one Responsible Principal Investigator (RPI) for each study. The RPI has ultimate responsibility for the research activities. Protocols that require skills beyond those held by the Responsible Principal Investigator must be modified to meet the investigator's skills or have one or more additional qualified faculty as Co-Investigator(s). Students must have a faculty sponsor who will serve as the RPI for the research.

Changes to Approved Research Investigators must seek IRB approval before making any changes in approved research--even when the changes are planned for the period for which IRB approval has already been given--unless the change is necessary to eliminate an immediate hazard to subjects' (in which case the IRB must then be notified at once). Minor changes (i.e., changes that do not involve increased risk or discomfort) may be authorized by the Director, ORSP or IRB Chair or his/her designee. A letter specifying the changes requested, a revised consent form (if applicable), and a copy of the approved protocol with the

proposed changes highlighted, should be sent to the Director, ORSP. The Director, ORSP or IRB Chair must provide written approval. [NOTE: IRB-approved amendments to ongoing research do not extend the original approval expiration date.]

Continuing Review after Protocol Approval Ongoing research studies must be reviewed by the IRB at least annually, or more often if the IRB finds that the degree of risk to subjects' warrants more frequent review. This renewal must occur before the expiration date noted on the approved protocol; otherwise, subject recruitment/enrollment must be suspended and, if the research is HHS sponsored, the Agency must be notified. When investigators are notified of their protocol approval, they are informed that, should they have a need for continuing their study beyond the original approval period, they must submit a continuation request at least 45 days in advance of approval expiration.

Unanticipated Problems Responsible Principal Investigators must report to the IRB as soon as possible, but in all cases within 5 working days of any:

- adverse events which in the opinion of the Principal Investigator are both unexpected and related;
- an unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk;
- information that indicates a change to the risks or potential benefits of the research. Examples include:

- an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- a paper published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- a breach of confidentiality.
- incarceration of a participant in a protocol not approved to enroll prisoners;
- change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant;
- complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team;
- a protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm;
- an event that requires prompt reporting to the sponsor; or
- a sponsor imposed suspension for risk.

Complaints, Non-compliance and Protocol Deviations Investigators must report all complaints and concerns from subjects', non-compliance by research staff, and any protocol deviations to the IRB within ten (10) working days. Investigators must report all non-compliance by research staff to the IRB within ten (10) working days.

Progress Reports Investigators must report the progress of the research to the IRB in the manner and frequency prescribed by the IRB, but no less than once a

year. Once data collection has been completed and the research is closed at either the Alcorn State University or other sites, the Principal Investigator is not required to submit any further reports of the research to the IRB.

Conflict of Interest – Investigators All Investigators and key research personnel must follow Alcorn Conflict of Interest Policy. Key research personnel are those individuals who (a) recruit human subjects; (b) obtain consent from human subjects; (c) collect data from human subjects; or (d) evaluate the response of human subjects. Where a conflict of interest exists, with a protocol involving human subjects, the RPI must develop and submit a conflict management plan, for the IRB to consider along with the proposed protocol. The Director, ORSP or IRB Chair (or designee) will review the conflict management plan to determine if the conflict will adversely affect the protection of human subjects and if the management plan is adequate. A copy of the final, approved conflict management plan will be filed in the Office of the Provost. The IRB application asks protocol-specific questions regarding conflict of interest for the investigators and key personnel. As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human subjects. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human subjects in the protocol is in place. If the conflict of interest status of an investigator changes during the course of a study, the individual is required to notify the IRB Office within ten working days of the change. The IRB will review the change as a modification to the protocol. At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

ALCORN Students and Employees as Subjects When Alcorn students and/or employees are being recruited as potential subjects', researchers must ensure that there are additional safeguards for these research participants. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects' that neither their academic status nor grades, or their employment, will be affected by their participation decision. To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in procedures which are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit subjects' through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own. When entering a classroom to recruit students and conduct research (e.g., administer a survey), investigators must do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

Student Research Given that student-researchers conduct research as part of degree- or course-requirements, a faculty member ultimately shares responsibility for the protection of the subjects', even if the student is the primary researcher and actually directs the project. However, student-researchers are responsible for adhering to IRB policy and following research protocol as approved by the IRB. Student-researchers should immediately report any protocol deviations, or problems with the research process, to their Responsible Research Supervisor. Accordingly, undergraduate and graduate students must have a faculty sponsor who will serve as the Responsible Research Supervisor on the study. Faculty or staff research supervisor assume the responsibility for students engaged in independent research under their supervision, and instructors are responsible for research that is conducted as part of a course

Course Projects Involving Research with Human Subjects Learning how to conduct ethical human subjects' research is an important part of a student's educational experience. Research activities that are designed as part of a course requirement for the purposes of learning experience only and that are not designed to develop or contribute to generalizable knowledge may not require IRB review and approval if all of the following conditions are true: • results of the research are viewed only by the course instructor for teaching purposes and are discussed within the classroom for teaching and learning purposes; • results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.); • research procedures involve no more than minimal risk; • vulnerable populations (e.g., children under age 18, prisoners, persons who are cognitively impaired, etc.) are not targeted for participation as research subjects; • data collected are recorded in such a manner that the subjects' are not identifiable*; and • when appropriate, an informed consent process is in place. [*NOTE: images in videotapes, photographs, and voices on audiotape are identifiable, so such procedures require IRB review.]

Responsibility of the Course Instructor The course instructor serves as the Responsible Research Supervisor (RRS) and is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including ensuring that a process is in place for obtaining voluntary informed consent from research subjects' when appropriate), and for monitoring the students' progress. When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should: • understand the elements of informed consent; • develop appropriate consent documents; • plan appropriate strategies for recruiting subjects'; • identify and minimize potential risks to subjects • assess the risk-benefit ratio for the project; •

establish and maintain strict guidelines for protecting confidentiality; and • allow sufficient time for IRB review (if necessary) and completion of the project. In making a determination of whether or not a class research project requires IRB review, the instructor is encouraged to err on the side of caution and to contact the IRB for assistance

Exempt Research All research using human subjects must be approved by the institution. Certain categories of research (i.e., exempt research) do not require full IRB committee review and approval. Exempt research is subject to institutional review and must be determined and approved by the IRB. Research with specific populations does not qualify for exemption. All exemptions must include a termination date. The period of exemption expires on that date and may not exceed three years. If the research extends beyond the termination date, the researcher must resubmit the protocol for review.

Categories of Research Permissible for Exemption The categories of research permissible for Exemption are described on the IRB Application for Exemption.

Expedited Review of Research An IRB may use the expedited review procedure to review either or both of the following: • some or all of the research appearing on the list of research eligible for expedited review and found by the reviewer(s) to involve no more than minimal risk ; and • minor changes in research previously approved by the full IRB during the period (of one year or less) for which approval is authorized. A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (a) the level of risks to subjects'; (b) the research design or methodology (c) the number of subjects' enrolled in the research; (d) the qualifications of the research team; or (e) the facilities available to support safe conduct of the research. Adding procedures that are not eligible for expedited review would not be considered a minor change. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among members of the IRB. IRB members who serve as designees to the IRB Chair for expedited review will be selected based on the relevance of their field of expertise for the study under review. When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), should receive and review all documentation that would normally be submitted for a full-board review, including the complete protocol, a Renewal Form when appropriate, notes from the pre-screening conducted by the IRB Office staff, and current consent documentation. When a protocol is reviewed by the expedited procedure, reviewers are provided with and are expected to review all information that the full IRB meeting IRB would have received. For expedited review protocols, any IRB member can also request to review the full protocol by contacting the IRB Office

Quorum Requirements A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. The IRB Chair, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible for ensuring that the meetings remain appropriately convened. Votes may only occur when a quorum is present. If a quorum is not maintained, the proposal must be tabled or the meeting must be terminated. All members present at a full IRB meeting have full voting rights, except in the case of a conflict of interest. In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. It is strongly recommended that IRB members be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

IRB Member Conflicts of Interest IRB members will not participate in any IRB action taken, including the initial and continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member of the IRB member:

- is the project director, or other member of the research team;
- has a financial interest in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research;
- has a financial interest in the research with value that exceeds \$5,000 or 5% ownership of any single entity when aggregated for the IRB member and their immediate family;
- has received or will receive any compensation whose value may be affected by the outcome of the study;
- has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement);
- may be affected by the outcome of the research;
- has received payments from the sponsor that exceed \$10,000 in one year when aggregated for the IRB member and their immediate family;
- is an executive or director of the agency/company sponsoring the research;
- directly supervises or serves on the thesis committee of a student-led project, and/or
- any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

IRB members with a conflicting interest will not be present during board deliberation and voting on protocols in which they have a conflicting interest. The Chair will allow for Board discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum, and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes. If the Conflict of Interest status

of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair.

Possible IRB Actions Taken by Vote Approval. The study is approved as submitted. **Conditional Approval.** The protocol and/or consent form require revisions, as agreed upon during the IRB meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. Only the IRB Chair or a designated subcommittee of the IRB may approve the study upon receipt and approval of the revisions without further action by the IRB. Approval of the protocol application will not be granted until all IRB stipulations are met. **Deferred.** This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided).

Reporting IRB Actions All IRB formal actions are communicated to the Responsible Principal Investigator (RPI) and when appropriate, the Responsible Research Supervisor (RRS), or designated primary contact person for the protocol, in writing signed by the Director, ORSP. Ordinarily, protocols can be processed within ten (10) working days. Requests for additional information from the RPI may be made electronically, via email or phone. For an approval, a copy of the approved consent form (when applicable) containing the approval stamp with the date of expiration will be sent to the investigator, along with written notification of approval. For a conditional approval, a copy of the approved consent form (when applicable) containing the approval stamp with the date of expiration will be sent to the investigator, along with a letter stipulating that the protocol has been approved but that the Responsible Primary Investigator must provide formal documentation of permission to collect data from the institution or agency that will serve as the data collection site. For a deferral, the notification will include the modifications required for approval along with the basis for requiring those modifications. For a disapproval, termination, or suspension, the notification will include the basis for making that decision. All letters to investigators must be filed in the protocol files maintained by the IRB. The IRB reports its findings and actions to the institution in the form of its minutes, which are made available to the Provost.

Basic Elements of Informed Consent Informed consent must be sought from each potential subject or the subjects' legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. The basic elements of informed consent are: 1. a statement that the study involves research; 2. an explanation of the purposes of the research; 3. the expected duration of the subjects' participation; 4. a description of the procedures to be followed, and identification of any procedures which are experimental; 5. a

description of any reasonably foreseeable risks or discomforts to the subject; 6. a description of any benefits to the subject or to others which may reasonably be expected from the research; 7. when a protocol involves medical or other therapeutic treatments, it must include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; 8. a statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained; 9. for research involving more than minimal risk of physical, emotional, or psychological harm, information about the availability of professional services will be provided; 10. contact information for the person who can answer pertinent questions about the research; 11. contact information for the person to notify in the event of a research-related injury to the subject; 12. contact information for the HSRO, so that subjects' can report concerns or complaints about the research or obtain answers to questions about their rights as research participants; and 13. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. 14. a place for participants to initial, when voice, video, digital, or image recording is involved. 15. a statement about the potential for publication or presentation of the study results, including an explanation about how potential identifying information will be managed. The IRB will carefully review the protocol to determine whether there might be situations where participants should be withdrawn from the research, or if it is reasonable to expect that participants may be withdrawn from the research, without their consent.

Assent from Children Because assent means a child's affirmative agreement to participate in research, [45 CFR 46.402(b)], the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The Alcorn IRB has the discretion to determine children's capacity to assent on a subject group basis (i.e., considering all of the children to be involved in a proposed research activity) or on an individual subject basis. Although the IRB may employ a consultant to help make this determination, the ultimate decision regarding ability to assent will be made by the IRB. The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective subjects'. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include

information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity levels limit their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree he or she is capable of, what participation in the research would involve. The IRB presumes that children ages 7 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script should be obtained from children 7 through 11 years of age. Written assent, using a written document for the children to sign, may be sought for older children. At times there may be inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide affirmatively to be in research over the objections of a parent. Obviously, there are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life threatening disease is being considered). The general idea, however, is that children should not be forced to be research subjects, even when their parents consent to it. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even when the IRB determines that the subjects' are capable of assenting, the IRB may still waive the assent requirement.

The Assent Form Researchers should draft a form that is age-appropriate and study-specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

- tell why the research is being conducted;
- describe what will happen and for how long or how often;
- say it's up to the child to participate and that it's okay to say "no";
- explain if it will hurt and if so, for how long and how often;
- say what the child's other choices are;
- describe any good things that might happen;
- say whether there is any compensation for participating; and
- ask for questions.

For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents should include more information and may use more complex language.

Children Who are Wards Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects', but only if it is likely to yield generalizable knowledge about the subject's disorder or condition and is: (a) related to their status as wards; or (b) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects' are not wards. If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Research Involving Pregnant Women, Human Fetuses and Neonates The following applies to all research regardless of funding source. Since, according to the Alcorn FWA, Subpart B of 45 CFR 46 applies only to HHS-funded research, the funding source-specific requirements are noted in the appropriate sections. Definitions Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means. Fetus: the product of conception from implantation until delivery. Neonate: a newborn. Nonviable Neonate: a neonate after delivery that, although living, is not viable. See definition of viable below. Pregnancy: the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. Viable: as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Research Involving Pregnant Women or Fetuses Research Not Funded by HHS For research where the risk to the fetus is no more than minimal and is not funded by HHS, no additional safeguards are required, and there are no restrictions on the involvement of pregnant women. For research involving more than minimal risk to fetuses and that is not funded by HHS, pregnant women or fetuses may be involved if all of the following conditions are met: 1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses; 2. 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; 3. Any risk is the least possible for achieving the objectives of the research; 4. 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, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent; 5. 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 provisions for informed consent, 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. 6. Each individual providing consent under Paragraph 4 or 5 of this Section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; 7. For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent; 8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; 9. 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 10. Individuals engaged in the research will have no part in determining the viability of a neonate.

Research Funded by HHS For HHS-funded research, 45 CFR Subpart B applies to all research involving pregnant women. Under 45 CFR Subpart B, pregnant women or fetuses may be involved in research funded by HHS if all of the following conditions are met: 1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses; 2. 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; 3. Any risk is the least possible for achieving the objectives of the research; 4. 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, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent. 5. 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 provisions for informed consent, 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. Each individual providing consent under Paragraph 4 or 5 of this Section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate; 7. For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent in Parental Permission and Assent; 8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy; 9. 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 10. Individuals engaged in the research will have no part in determining the viability of a neonate.

Research Involving Neonates The following policies and procedures apply to all research involving neonates, regardless of funding source. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met: 1. Scientifically appropriate preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. 2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. 3. Individuals engaged in the research will have no part in determining the viability of a neonate. 4. The requirements of the following policy section, titled Neonates of Uncertain Viability or Nonviable Neonates, have been met as applicable. Neonates of Uncertain Viability. Until it has been ascertained whether a neonate is viable or not, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met: The IRB determines that: 1. the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research; and 2. the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. Nonviable Neonates. After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met: 1. Vital functions of the neonate will not be artificially maintained; 2. The research will not terminate the heartbeat or respiration of the neonate; 3. There will be no added risk to the neonate resulting from the research. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and

assent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph. Viable Neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of the IRB Review Process and Research Involving Children.

Research Involving Prisoners Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules protecting them. In the past, prisoners were viewed as a convenient research population. They are housed in a single location, constitute a large and relatively stable population, and live a routine life. Unfortunately, all the things that make prisoners a convenient research population also make prisoners vulnerable to exploitation. The concern that 45 CFR 46 Subpart C, and this policy based on Subpart C, attempt to address is whether prisoners have any real choice in participation in research, or whether incarceration prohibits free choice. The following applies to all research involving prisoners, regardless of funding source. The requirements in this section are consistent with Subpart C of 45 CFR 46, which applies to HHS-funded research.

Applicability This policy applies to all research conducted under the auspices of Alcorn involving prisoners as subjects'. Even though the ALCORN IRB may approve a research protocol involving prisoners as subjects' according to this policy, investigators are still subject to the Administrative Regulations of the Mississippi Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

Purpose Prisoners may be under constraints because of their incarceration, which can affect their ability to make a truly voluntary decision to participate as subjects' in research; thus, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities. [45 CFR 46.302]

Definitions Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Minimal Risk: the probability and magnitude of physical or psychological harm that is normally encountered in

the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Persons with Mental Disabilities or Persons with Impaired Decision-Making Capacity Research involving subjects' who are mentally ill or subjects' with impaired decision-making capacity warrants special attention. Research involving these populations may present greater than minimal risk; may not offer direct medical benefit to the subject; and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion. The requirements in this section apply to all research involving persons with mental disabilities or persons with impaired decision-making capacity regardless of funding source.

Approval Criteria Research involving persons with impaired decision-making capability may only be approved when the following conditions apply: 1. Only persons with a mental disability and/or impaired decision-making capacity are suitable as research subjects. Mentally competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include mentally incompetent individuals or persons with impaired decision-making capacity as subjects'. Incompetent persons or persons with impaired decisionmaking capacity must not be subjects' in research simply because they are readily available. 2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects' of research that imposes a risk of injury, unless that research is intended to benefit that subject and the potential benefits of participation outweigh any risks. 3. Procedures have been devised to ensure that subjects' representatives are well-informed regarding their roles and obligations to protect incompetent subjects' or persons with impaired decision making capacity. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] or guardians must be given descriptions of the proposed research studies and the obligations of the subjects' representatives. Health care agents or guardians must be told that their obligation is to try to determine what the subject would do if competent, or if the subjects' wishes cannot be determined, what the health care agent or guardian thinks is in the incompetent person's best interest.

Additional Concerns Investigators and IRB members must be aware that some subjects' decision-making capacity may fluctuate. For subjects' with fluctuating decision-making capacity or those with decreasing capacity to give consent, a reconsenting process with surrogate consent may be necessary. It is the responsibility of investigators to monitor the decision-making capacity of subjects'

enrolled in research studies and to determine if surrogate consent must be re-obtained. The IRB will require investigators to conduct a competency assessment whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects'. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

Non-Compliance All members of the campus community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional policies governing the conduct of research involving human subjects. Research being conducted without prior IRB approval is considered serious non-compliance. Continuing Non-Compliance is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or full IRB committee, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance. Allegation of Non-Compliance is defined as an as-yet unproved assertion of non-compliance. Finding of Non-Compliance: is an authoritative determination that non-compliance has occurred. The determination can be supported by a finding of fact or by investigator self-report of noncompliance.

Review of Allegations of Non-Compliance All allegations of non-compliance will be reviewed by the Director, ORSP, who will review: (a) all documents relevant to the allegation; (b) the last approval letter from the IRB; (c) the last approved IRB application and protocol; (d) the last approved consent document; (e) the grant, if applicable; and (f) any other pertinent information (e.g., questionnaires, reports, etc.). The Director will review the allegation and make a determination as to the truthfulness of the allegation. He or she may request additional information or an audit of the research in question. If, in the judgment of the Director, ORSP, the reported allegation of non-compliance is not true, no further action will be taken. If, in the judgment of the Director, ORSP, the reported allegation of non-compliance is true, the non-compliance will be processed. If, in the judgment of the Director, ORSP, any allegation or findings of noncompliance warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the Director, ORSP may suspend or terminate the research.

Suspension or Termination with subsequent review by the IRB. Review of Findings of Non-Compliance If, in the judgment of the Director, the reported non-compliance is not serious, not continuing, and the proposed corrective action

plan seems adequate, no further action is required, and the IRB is informed at the next meeting. Otherwise, the matter will be presented to the IRB at a meeting with a recommendation that a formal inquiry be held. All findings of non-compliance referred to the IRB will be reviewed at a meeting. All IRB members will receive (a) all documents relevant to the allegation; (b) the last approval letter from the IRB; (c) the last approved IRB application; and (d) the last approved consent document. At this stage, the IRB may: • find that there is no non-compliance; • find that there is non-compliance that is neither serious nor continuing, and that an adequate corrective action plan is in place; • find that there may be serious or continuing non-compliance and direct that a formal inquiry (described below) be held; or • request additional information. A determination may be made by the IRB that an inquiry is necessary based on factors that may include but are not limited to: • subjects' complaint(s) that rights were violated; • report(s) that investigator is not following the protocol as approved by the IRB; • unusual and/or unexplained adverse events in a study; and/or • repeated failure of investigator to report required information to the IRB.

Research may only be terminated by the full IRB committee. Terminations of protocols approved under expedited review must be made by the full IRB committee. The IRB can suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been shown to have caused unexpected harm to participants. When study approval is suspended or terminated by the full IRB committee or an authorized individual, in addition to stopping all research activities, the full IRB committee or individual ordering the suspension or termination will notify any subjects' currently participating that the study has been suspended or terminated. The full IRB committee or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects' are necessary to protect the rights and welfare of subjects'. Such procedures for withdrawal include: transferring participants to another investigator; making arrangements for care or follow-up outside the research; allowing continuation of some research activities under the supervision of an independent monitor; or requiring or permitting follow-up of participants for safety reasons. If follow-up of subjects' for safety reasons is permitted/required by the full IRB committee or individual ordering the suspension or termination, the full IRB committee or individual ordering the suspension or termination will require that the subjects' be so-informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

Reporting Serious or continuing non-compliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval, will be reported to the appropriate regulatory agencies and institutional officials according to the procedures.

Failure to secure necessary Alcorn IRB approval before commencing human subject research must be reported by the IRB to the appropriate Dean and the Provost for disciplinary action. Investigators should also be aware that, in general, Alcorn indemnifies them from liability for adverse events that may occur in Alcorn studies approved by the Alcorn IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator personally liable in such cases.