HUMAN SUBJECT RESEARCH

PROGRAM POLICY

Office of Sponsored Programs

University of North Alabama

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Scope.

This policy provides guidance on the use of human subjects in any activity at the University of North Alabama (UNA) deemed to be research, which is defined as a systematic investigation designed to contribute to generalizable knowledge. This policy applies to all entities of UNA (faculty, administration, staff, students, and contracted consultants) engaged in any research activity using human subjects that is directly or indirectly supported by UNA. The Human Subject Committee (HSC) of UNA will administer this policy.

UNA is committed to the responsible and ethical conduct of research and the protection of human subjects used in that research. In all work governed by this policy, the welfare of human subjects is considered preeminent and, along with full compliance with applicable regulations and institutional policy, takes precedence over specific research programs.

Background.

Proper attention to the protection of human research participants is of vital importance to UNA's research activities. Ethical considerations form the foundation for protecting participants, and today regulatory law embodies the ethical review procedures for the vast majority of medical and behavioral research in the United States. This summary is intended to provide investigators with a synoptic overview of the ethical and legal approach to human research participant protections at UNA. Since federal regulation dominates the research landscape in this area, much of the material has general applicability.

A significant advance in the application of ethics to human research was the development of specific codes of ethics for research. The first and most widely known of these codes is the Nuremberg Code, which was published in 1947 following the trial of Nazi physicians for human research-related atrocities. Subsequently, other ethical codes for human research protections were developed such as the Declaration of Helsinki, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects. Links to these important publications on ethics in human research are available from the Office of Sponsored Programs Human Subject Research web page, Ethical Principles tab.

For its human research activities, UNA applies the ethical principles published in the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report provides the ethical basis for the United States' federal regulations pertaining to the protection of human research participants. The Declaration of Helsinki published by the World Health Organization has been adopted by many nations outside of the United States, and investigators doing international research at UNA should inquire about what ethical principles apply in the country where their studies are taking place.

The Belmont Report contains three basic principles:

- Respect for Persons
- Beneficence
- Justice

Respect for persons refers to a competent individual's prerogative to make a knowing and voluntary decision to participate in human research without the threat of undue influence or coercion. Frequently termed the principle of autonomy, this principle demands that participants give informed consent. *Beneficence* refers to the concept of overall benefit to the participant. Whether or not beneficence is attained is determined by weighing both the potential absolute benefits and harms to the participants. Potential harm to research participants should always be minimized and, secondarily, benefits maximized. Generally, individual rights may not be sacrificed to achieve an overall societal good. The third principle, *justice*, refers to fairness. In the context of human research participation, this is frequently determined by whether the benefits to be gained from the research justify the burdens placed on the individuals studied.

Federal agencies have addressed human protections for research under their jurisdiction by promulgating regulations using federal administrative law. A federal regulation has the force and effect of law and when valid may preempt state laws. The major federal regulations pertaining to human research protections are the Federal Policy for the Protection of Human Subjects (The Common Rule, 45 CFR 46 Subpart A) adopted by several federal agencies; the Supplemental Protections for Pregnant Women and Fetuses, Prisoners, and Children promulgated by the Department of Health and Human Services (DHHS); the Food and Drug Administration (FDA) regulations on human subject protections; and the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations administered by the Office for Civil Rights in DHHS. In most instances, more than one set of these regulations apply to a research protocol; when this is the case, each set of regulations must be satisfied independently of each other. Links to these regulations are available from the Office of Sponsored Programs Human Subject Research web page, Regulations tab.

Under the regulations, all institutions receiving funds from any of the departments/agencies under the Common Rule are required to establish institutional review boards (IRB) to review and monitor all funded research involving humans. At UNA the IRB will be known as the Human Subject Committee (HSC). UNA shall review all research proposals involving human subjects, whether funded or not. It is UNA's policy to apply the regulations to all research and research-related activities which involve human subjects.

To receive research funding from the DHHS, each institution must hold an assurance with DHHS to abide by its regulations for human research protections. The same requirement for agency assurance holds for research sponsored by other federal agencies that have adopted the Common Rule. UNA holds a federalwide assurance which is valid for federally funded research sponsored by any of the agencies requiring an assurance. UNA's federalwide assurance is the institution's written, binding commitment filed with the Federal Government that promises to comply with applicable regulations governing human subjects research and states the procedures which must be utilized to achieve compliance. Through its federalwide assurance, UNA applies the DHHS regulations for human research protections (45 CFR 46 Subparts A, B, C, D) to all applicable human research activities regardless of the source of funding for a study. In addition, UNA must satisfy the applicable FDA regulations on human subject protections and HIPAA regulations.

Finally, state law controls the legal age for consent. In Alabama, the age of majority is 18 years; therefore, a 17-year-old does not hold adult status and cannot be legally bound without parental consent. Confusion sometimes arises because in Alabama several exceptions exist that allow individuals under 18 to consent to medical treatment. For instance, Alabama statute §22-8-4

states that any minor who is 14 years of age or older may give effective consent to any legally authorized medical, dental, health, or mental health services for himself or herself, and the consent of no other person shall be necessary. This statute has not been applied to medical research activities per se even though it may apply to standard medical procedures within the context of a research protocol. Because of Alabama's age of majority, UNA review of research protocols including 18-year-olds as eligible enrollees utilize DHHS and FDA rules for additional protections in children.

Public and federal emphasis on human research protections will likely intensify in the future, as evidenced by increased federal oversight and current emphasis on accreditation for human research protection programs. Having a good understanding of the overall framework for human subjects protection will assist stakeholders in the research enterprise to meet their responsibilities in this area. 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, UNA takes the protection of human subjects very seriously for fiscal was well as ethical reasons.

Glossary.

Adverse Event: Any undesirable and unintended event that involves human subjects which could be reasonably related to participation in the study, regardless of whether it was listed on the informed consent document as an expected risk.

Amendment: Change to research protocol or supporting document after approval.

Anonymous Data: The identity of the respondent cannot be determined; no links exist between the data and the individual about whom the data are recorded.

Assent: Agreement to participate in a research study signed by research participants who cannot legally give informed consent (e.g., children) or do not have the capacity to give informed consent.

Assurance: The authority to conduct research involving the use of human subjects.

Certification of Approval: The official notification that a research project involving human subjects has been reviewed and approved by the HSC per UNA's approved assurance and delegated approval authority.

Coded Data: Identifiers have been removed from the dataset under consideration but can readily be replaced through the use of a master list that is accessible to the investigator.

Common Rule: The regulation adopted by multiple federal agencies for the protection of human subjects in research. The overall guiding Department of Health and Human Services regulation is at 45 CFR Part 46.

Confidential Data: Data that contains information that would permit identification of the individual(s) about whom the data were collected but is maintained in a manner that protects the information from release to unauthorized individuals.

Consent: See Informed Consent.

Continuing Review: A periodic administrative reevaluation of ongoing human subject research based on the requirements in 45 CFR 46.109(e), conducted at least annually on ongoing protocols.

De-identified Data: Identifiers have been removed from the dataset under consideration; links between the data and the individual about whom the data are recorded exist but are not readily accessible to the researcher.

Exempt Research: A specific research project that is both minimal risk and meets one of the criteria for exemption listed in the Human Subject Committee Review, Review Categories section below.

Expedited Review: A review of proposed research, modifications to protocols, or continuing reviews by either the Human Subject Committee (HSC) Chair or by one or more designated voting members of the HSC (rather than the full HSC) in order to facilitate approval prior to the next regularly scheduled HSC meeting without sacrificing protection of the subjects.

Federalwide Assurance (FWA): Assurance of an institution's commitment to comply with federal regulations (45 CFR Part 46 and the Terms of Assurance) when engaging in non-exempt human subjects research. Granted by DHHS Office of Human Research Protections (OHRP), FWAs are recognized for research supported by DHHS and other federal departments and agencies that have adopted the Common Rule. UNA's current assurance is available from the Office of Sponsored Programs.

Generalizable knowledge: The knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied to our experiences. Generally, the term is used to refer to the intent to disseminate the research results and conclusions beyond an individual or internal group. Generalizable knowledge is usually created to share with other people, for example through publication of an article in a journal, presentation at a local or national conference, or preparation of a thesis or dissertation.

Greater than Minimal Risk: A probability and magnitude of harm or discomfort to a human subject exceeding that defined as minimal risk (as determined by the element or elements of greatest risk).

Human Subject Committee (HSC): UNA's institutional review board established per 45 CFR Part 46 to review research under the authority of UNA's current Federalwide Assurance to ensure the protection of the rights and welfare of human research subjects.

Human Subject or Participant: A living individual about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Identifiable Data: The identity of the subject can be determined directly (e.g., through a Social Security Number (SSN) recorded on the data collection instrument) or indirectly (e.g., by cross-referencing a unique identifier (such as a student identification number) on a data collection instrument back to the SSN or other identifier of the person with whom it was used).

Informed Consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. Subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents

thereof from liability for negligence. See also the Human Subject Committee Review, Special Consideration for Certain Human Subject Populations section below.

Institutional Review Board (IRB): A committee established per 45 CFR 46 to review research to ensure the protection of the rights and welfare of human research subjects. UNA's IRB is the Human Subject Committee (HSC).

Interaction: Communication (oral or written) or interpersonal contact between researcher and subject.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Investigator's Agreement: A pledge signed by all investigators and associate investigators on a research project in which they acknowledge their responsibilities for the protection of human subjects.

Investigators (or Co-investigators): Individuals who possess the required education, knowledge, skills, experience (credentials) to assist the Principal Investigator in the design and conduct of research.

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-compliance: Deliberate or inadvertent departure from or failure to comply with federal regulations, UNA policies, or HSC requirements for the protection of human subject research; or deliberate or inadvertent deviation from an HSC-approved protocol.

Principal Investigator (PI): An individual who has primary responsibility for the design and conduct of a research project or task. The PI is an individual who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct, and oversee human subject research, and has completed the required training. PIs must be staff or faculty of UNA.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). In order for the collection of such information to constitute human subjects research, the private information must be individually identifiable; i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Publicly Available Dataset: Data that are available to anyone regardless of occupation, purpose, or affiliation, and have legitimately attained such status; i.e., those individuals who are responsible for posting the dataset had legitimate access to the data and have employed the necessary mechanisms to ensure the privacy and confidentiality of the individuals about whom the data were collected. In general, while the use of such data may meet the regulatory definition of research, the definition of human subjects is not met because data about a living person is not obtained through interaction or intervention, and no private, identifiable information about a living individual is obtained.

Research: A systematic investigation to develop or contribute to generalizable knowledge, to include any project, task, test, experiment, evaluation, or similar undertaking. This includes activities undertaken where results are intended for, or contribute to, publication, distribution, or use outside of UNA or for future research activities.

Risk: The possibility of harm, discomfort, or injury (physical, psychological, sociological, or other) as a consequence of any act or omission resulting from participation in a research study. Risk can range from minimal to high.

Training Requirements for Human Subject Research: All investigators and research assistants involved in a human subject research project are required to complete the Protecting Human Research Participants training. A link to the training module is available from the Office of Sponsored Programs Human Subject Research web page Education and Training tab.

Unanticipated Problem: Any incident, experience, or outcome involving risks to subjects or others that is unexpected (in terms of nature, severity, or frequency), not foreseen, or not previously described in the research protocol or informed consent form.

Human Subject Research Determination

When is a human being a subject of research? The borderline between being a human being with whom we work, play, and exchange information and being a human subject of research is not a line at all. It is a misty frontier. Seeing the boundaries and knowing when to treat a human being as a human subject of research requires keen judgment on the part of the PI. In general, UNA prefers to make the judgment on the conservative side, treating most doubtful cases as involving human subjects. By doing this, careful thought is given to ensure protection of the rights of people participating in the research.

All research involving human subjects must be reviewed by the HSC. To help a PI decide if a planned study activity meets the criteria of being human subject research, two concepts must be applied: (1) what constitutes research, and (2) how is participation of human subjects defined.

Definition of Research

According to the regulations, research is any systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion and that is conducted by UNA faculty, administration, staff, students, and contracted consultants or that uses UNA facilities is research for the purposes of this discussion. It does not matter whether the activity takes place within and as a part (however large or small) of some other activity, such as a demonstration or service program, or whether the research is the whole of a project.

Some tests for research: When dealing with data gathering within the context of training, demonstration, or service projects, the PI should examine several questions to determine if any aspect of the work is research as it might be related to human subjects review:

- Will you seek out subjects (or settings that contain subjects) for your training, demonstration, or service project, rather than the subjects seeking the service or training from you in their normal pursuit of professional services?
- Do you anticipate (in advance of conducting the project) that you will analyze, interpret, and disseminate the findings of your investigation?

- Might the knowledge you will gain from your encounter with the subjects be applied beyond the service or training project to similar encounters so as to lead to a new procedure or process?
- Will the project employ invasive procedures? (An invasive procedure is a medical procedure in which part of the body is entered, as by puncture or incision, which might alter the normal physiology of the person)
- Will the project use subjects that are minors (under the age of 18 in Alabama)?

If the answer is "Yes" to any one or more of these questions, then the training, demonstration, or service project has a research component.

Some instances not considered research: There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Here are some examples:

- Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching. In other words, neither the instructor nor the student can foresee or anticipate any dissemination of the data gathered beyond the classroom situation. The assumption here is that the classroom training method does not employ invasive procedures; otherwise, the data gathering will be considered to be research under this policy.
- Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. In other words, no dissemination of the information outside the unit or institution is foreseen or anticipated.
- Evaluation data gathered for a contractor about a project or operation for which the contractor is responsible, if neither the researcher nor the contractor intends or anticipates the dissemination of the data. (Note: In general, evaluation data gathering for federal and state agencies usually results in reports to the agency that is public record, and such reports constitute public dissemination of the information.)

All these categories of data gathering fail to meet the definition of research because there is no foreseeable dissemination of the data. Any record of the data (or interpretations and analyses of the data) remains private, used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work.

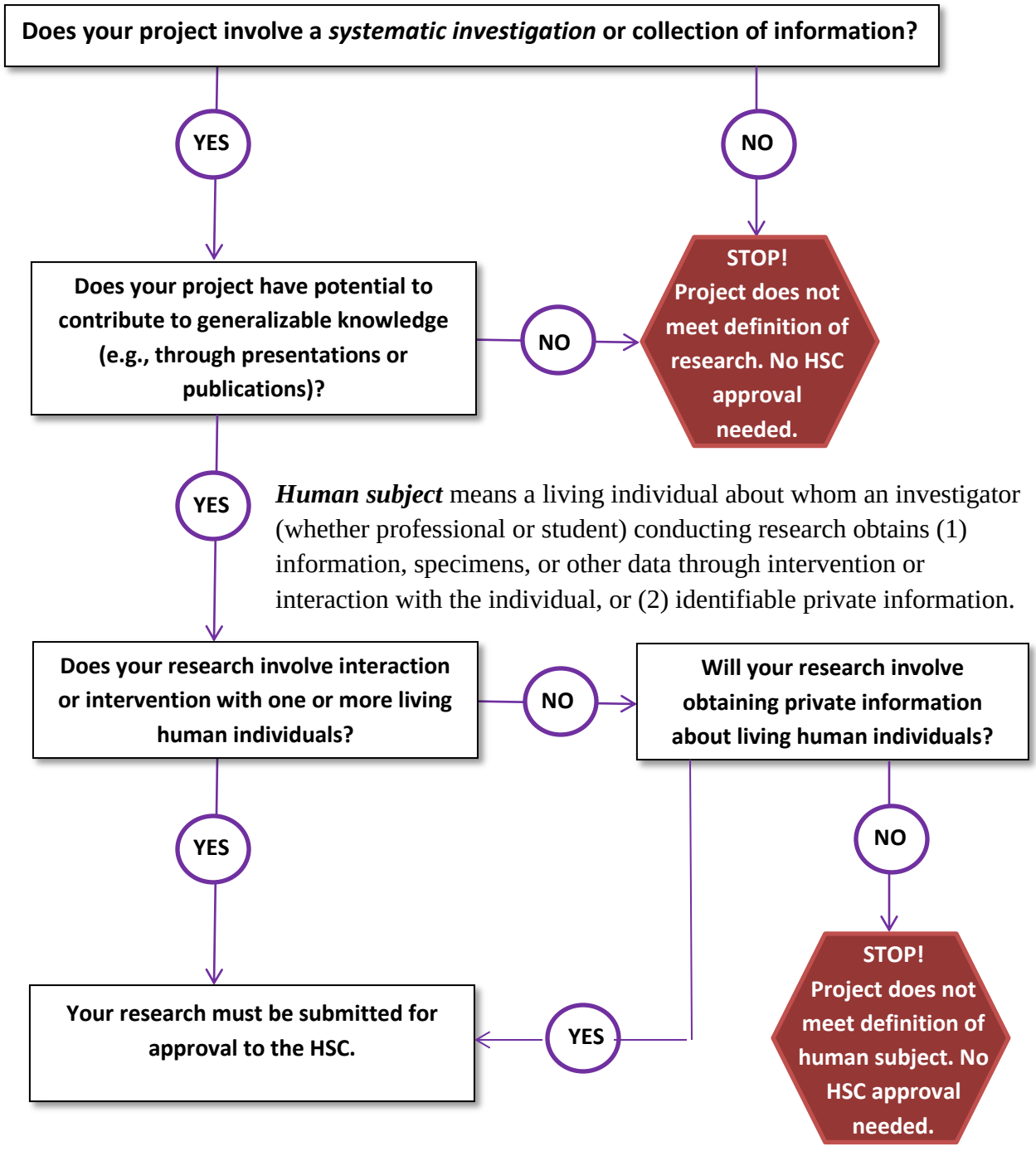
Definition of Human Subject Research

Regulations define a human subject as a living individual about whom an investigator obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention generally includes both physical procedures by which we gather data (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Much more common are interactions which include communication or interpersonal contact between the investigator and the subject. Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place. Thus, the individual will have provided the information for specific purposes and can reasonably expect that the information as associated with his or her identity will not be made public.

Figure 1 provides a quick-reference decision tree for determining if a project is human subject research and must be submitted to the HSC for review.

Figure 1. Does My Project Require HSC Review?

Research is a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.



Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information, specimens, or other data through intervention or interaction with the individual, or (2) identifiable private information.

Some forms of interaction in research: The idea of interacting with a human being is perhaps the key idea in determining whether or not he or she is a subject with respect to the regulations. All forms of interaction are included by the regulatory definitions. Among the most common are these types of research interactions:

a. Mail or electronic questionnaires or surveys;
b. Personal interviews, structured or unstructured, with or without recognized instruments;
c. Personal (i.e., face-to-face) surveys;
d. Telephone interviews or surveys;
e. Classroom instruments, evaluations, or exercises;
f. Examination of private records (e.g., medical, psychological, or school records); and
g. Observations of public behavior by identifiable individuals (e.g., in a classroom).

Remember that there may be non-research occasions for all these forms of interaction. However, if the context of the interaction is research, as discussed above, then the project that includes any of these modes of interaction calls for submission of an HSC review form.

Common forms of research requiring submission: Many of the types of interactions on the list of common forms of research present little, if any, risk to human beings but nevertheless require either review or certification of exemption, simply because they are research and have human subjects. Some of the more common types of these are:

a. Oral history;
b. Case studies of events or individuals, if interviews are involved;
c. Workplace and school observations, whether activities are controlled or uncontrolled; and
d. Surveys for information, attitudes, opinions, and similar matters for publication or for reporting to a federal, state, or local government agency.

Included on the list are surveys seeking information. Many types of information are sought from one or more people via surveys, some of which does not seem to fit the part of the definition of a human subject that specifies a subject as an individual about whom the investigator obtains information or data. Rather, in many cases, individuals surveyed are colleagues from whom—not about whom—information is obtained. One of the questions HSC will often face concerns where, if anywhere, to draw a line between the two types of surveys. The idea of a survey used here is to include any form of systematic data gathering.

HSC recognizes the difficulty of drawing a hard and fast line in this matter. However, it equally recognizes that survey instruments, even those ostensibly designed to obtain "simple facts," lend themselves to interpretation by the individuals who complete them. Often, surveys inadvertently implant viewpoints within questions. Some survey instruments ask for data that are not clearly or wholly public. The end result is that the completed survey instrument contains either explicit or implicit information about the individual who completes it or about his or her business or professional activities or situation. Consequently, virtually all survey research should be submitted for review or for certification of exemption from review. Only where a survey instrument (formal or informal) obtains data that exist in the public record and constitutes merely an easier way to obtain the data can the instrument be considered, in strictest terms, one that obtains information from individuals with no inherent potential for obtaining information about them. Such instruments use the individuals to whom they are sent essentially as librarians.

Submitting all survey research for certification of exemption from review is far simpler than any other method of verifying the non-private, non-personal, nature of a survey, such as submitting survey instruments to experts in instrument design who are qualified to ascertain that no explicit or implicit information about the subject will be obtained through the use of the instrument. Even if one were to opt for such an alternative procedure, UNA would need to know, for the record, that such an inspection of instrument design had occurred. Submission of an HSC review form eliminates the need for such steps and assures UNA that inquiries from outside about human subjects' interactions will not come as a surprise.

Federalwide Assurance (FWA) Number

The Federalwide Assurance of Compliance (FWA) is the contract which the University of North Alabama has signed with the federal government allowing research involving human subjects to take place. The terms of the FWA can be found at http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html. The Office of Sponsored Programs is responsible for renewing the FWA. A copy of the FWA is available from the Office of Sponsored Programs.

Human Subject Research Review Guidelines

Once the PI has determined that a protocol is research involving human subjects, the protocol must be submitted to the HSC for review among these three categories using criteria as indicated.

Review Categories (Exempt, Expedited, Full)

Category 1—Exempt Research. HSC determines protocol is exempt based on circumstances such as the following:

- Project involves collection of data through the use of opinion surveys, questionnaires or interviews (e.g., surveys of faculty instruction, marketing surveys, exit interviews) for which response is voluntary and completely anonymous. When data gathered concern issues of personal sensitivity (e.g., drug use, criminal behavior, sexual behavior), investigators should include in their project proposal how anonymity will be guaranteed.
- Project is limited to activities involving normal education practices in commonly accepted educational settings (e.g., in-class demonstration studies, laboratory exercises, studies of curriculum or teaching strategies). Usually, any study which requires that subjects be removed from their normal classroom situation for testing is not exempt.
- Project is limited to the observation of public behavior for which anonymity of subjects is maintained.
- Project is limited to the examination and analysis of existing data or specimens so long as these are publicly available and individual subjects will not be identified in any report of the research.

Category II—Eligible for Expedited Review.

The project does not meet the criteria for Category I and involves no more than minimal risk to the subject. *Minimal risk* is defined as risk of harm anticipated in the proposed research that is

not greater, considering probability and magnitude, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Projects that may qualify for expedited review include the following:

- Most laboratory investigations of cognition, perception, social behavior and personality.
- Any long-term investigation of the same individuals where identifying information (including coding schemes) must be maintained with the subject's data (i.e., longitudinal studies).
- Studies that require the examination of existing data or specimens that are not publicly available.
- Studies involving the collection of voice or video recordings.
- Studies of healthy individuals involved in moderate exercise.

Category III—Research Activities Subject to Full HSC Review.

- Projects that do not meet the criteria for Category I or Category II because subjects will be exposed to *greater than minimal risk* (e.g., use of invasive techniques or unusual therapeutic techniques such as hypnosis).
- Projects requiring the use of deception.
- Projects requiring the use of subjects from populations in need of special protection (e.g., prisoners, mentally disabled individuals, pregnant women, and in some cases children). General information concerning research with populations requiring special consideration is included below. Assent and parental consent forms for children are included in this policy, but PIs doing research with other special populations must obtain additional guidance as to their consent to participation from the agency sponsoring the research.

Special Consideration for Certain Human Subject Populations

Children

Federal regulations require special protections for "children" in research. The protections are in 45 CFR Part 46 Subpart D and, as applicable, 21 CFR Part 50 Subpart D, and 34 CFR Part 97 Subpart D. However, the criteria that define "children" come from local laws and institutional policy. When research procedures are to be performed in another state, investigators should contact the Office of Sponsored Programs for assistance in obtaining guidance on meeting local requirements.

For research involving children, the HSC may require the investigator to obtain both assent from the child (agreement to participate in the research) and consent from one or both parents or guardians (agreement to allow the child to be a subject of research) depending upon level of risk inherent in the research. In general, assent from a person under the age of 18 (the age of majority in Alabama) is required for participation in research except under the following conditions. Mere failure to object should not, in the absence of affirmative agreement, be constructed as assent.

- Children under 6 years of age are assumed to be incapable of giving assent.
- Assent from children over the age of 6 may be waived by the HSC if the capability of the child to give assent is judged limited by age, maturity, or psychological state (e.g., mental retardation or psychosis).

- Assent from children who are over 14 years of age, or who have graduated from high school, or are married, or having been married are divorced or are pregnant may be waived by the HSC under certain circumstances where medical treatment is involved in the research.

Consent of one or both parents to allow a child to be a subject of research is required as follows. Guardian consent should be substituted for parental consent under appropriate legal constraints. Parental/guardian consent for children who are over 14 years of age, or who have graduated from high school, or are married, or having been married are divorced or are pregnant may be waived under certain circumstances where medical treatment is involved in the research.

- If the proposed research involves no more than minimal risk, or is of possible direct benefit to the child, then the consent of one parent is required.
- If the research involves greater than minimal risk without direct individual benefit, permission must be obtained from both parents unless there is only one reasonably available parent.
- The investigator may request a waiver of parental or guardian consent if the research design does not require such consent to protect the subjects (for example, neglected or abused children), provided an appropriate protection mechanism is substituted (to be assessed by the HSC).
- Special provisions must be made for children who are wards of the state or any other agency, institution, or entity to be included in research involving greater than minimal risk without direct individual benefit.

Investigators who propose research involving persons younger than 18 years of age must provide protocol-specific information about their involvement. The HSC must be able to determine that the proposed research meets the requirements of all applicable federal regulations. Links to assent and parental consent forms are included under the Research Proposal Submission Forms and Guidelines heading below.

Cognitively Impaired

Cognitively impaired persons are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals who may be considered decisionally impaired are individuals under the influence of or dependent on drugs or alcohol, terminally ill patients, and persons with severely disabling physical handicaps. Capacity should be evaluated on an individual basis to avoid incorrect assumptions as to an individual's ability to make decisions. In cases where research involving cognitively impaired individuals is reviewed, the HSC shall consider additional safeguards (e.g., involvement of subject advocates, independent monitoring, formal capacity assessment, waiting periods between consent and participation) as part of the research plan to protect participants. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

Military

It is recognized that military populations in general, and recruits in particular, may have reduced autonomy. Appropriate safeguards shall be employed to ensure that consent to participate in research is informed and voluntary. These safeguards will include not allowing the presence of Officers or senior Non-commissioned Officers at recruitment sessions of Enlisted personnel for

greater than minimal risk research and other research as appropriate; ensuring that consent documents are written to be comprehendible to all potential participants; repeating in consent documents that the activity constitutes voluntary research, and providing ample opportunity to participants to have their questions and concerns addressed by investigators before signing the consent documents. In some instances, an independent ombudsman may be required to oversee the consent process. Before recruiting directly from a military unit, investigators must provide the HSC with written authorization to recruit subjects obtained from the senior level of that organization. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

Pregnant Women, Neonates, Fetuses

If the targeted research population is pregnant women, then the review of the research project would come under category III above. In this case, if any pregnant woman qualifies as a potential subject of research, either the activity must meet the health needs of the mother (while placing the fetus at risk only to the degree necessary to meet these needs) or the activity must present the fetus with minimal risk. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

If the research project does not specifically target pregnant women and the research activity presents only minimal risk (Category I above) to the research participant, then special precaution concerning the health of the mother and fetus are not needed.

Prisoners

In the instance of research using prisoners as subjects, the HSC will comply with all aspects of 45 CFR 46, Subpart C and shall ensure that a prisoner or prisoner representative is seated on the HSC, per requirements of 45 CFR 46.304. DHHS OHRP will be promptly notified when the HSC membership list is modified to meet this requirement. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance. Research on prisoners of war is disallowed by Department of Defense directive.

Students

Student research and the use of students as research subjects are special considerations under this policy. Since this policy applies to all activities deemed to be research at UNA, it applies equally to students.

Class assignments primarily intended for educational purposes (e.g., to demonstrate how research is conducted) are not subject to HSC review so long as such assignments do not involve placing human subjects at more than minimal risk. However, any student research projects involving populations of special concern (such as pregnant women, fetuses, neonates, prisoners, persons with mental disabilities, children, or economically disadvantaged persons) will require HSC approval. If it is anticipated that the study will be publicly presented, and/or published, HSC approval must be obtained. Instructors are responsible for making the initial determination as to whether HSC review is required.

Research with Secondary Data Sources

Research with secondary data sources may call for data from confidential or privileged files. Among such files are school records, medical files, psychological files, attorney files, arrest records, and records held by social service agencies, such as DHHS. By virtue of law or established legal precedent, the data in these files are not open for public inspection without express permission of the file owner. In some instances (e.g., most medical and psychological records), the subject owns the record. In other instances, including school and many social service records, law or regulation forbids an agency or service-provider from disclosing the contents of the files without written permission from the subject of the file or from the subject's parent or guardian. If the proposed research will involve these data sources and the anonymity of the subject is compromised, then a full review of the project is necessary.

Some research with secondary data sources falls into Category I and only needs to be certified by the HSC as exempt. Among the categories of exempt research is the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are either publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The provision appears to give the researcher the right to copy data from private files so long as he/she does not identify, either directly or indirectly, individual subjects. Even though these activities are exempt under the regulations, the researcher must still gain permission for initial access to the subjects' files.

Research Proposal Submission Forms and Guidelines

Application and Protocol Forms, Training Certificates and Investigator's Agreement

In order for the HSC to have adequate information on which to base their review of a proposed project, the investigator or instructor submitting a proposal must attach an application form providing descriptive information, written description of the project protocol, proof of completion of training requirements (automatically generated upon successful completion of the training session), and signed Investigator's Agreements.

The protocol description must at a minimum specify the following:

1. The purpose and significance of the project including a statement of hypotheses to be tested and an indication of the theoretical, biomedical, and/or social significance of potential findings.
2. A description of the population of human subjects that will be used and a description of the procedures that will be used for recruiting subjects, for obtaining informed assent/consent (a copy of the proposed informed assent/consent form(s) must be attached), for assuring the confidentiality of their data and for debriefing the subjects, and safeguarding their well-being.
3. A description of the materials to which subjects will be exposed during the course of the study, procedures for conducting the study, and a description of the independent and dependent variables under study.

Application Form

Research Protocol Form

Investigator's Agreement

All PIs, co-investigators, and research assistants working directly with human subjects, data, or specimens that can be linked back to individual human subjects (including exempt research) must complete the Protecting Human Research Participants training. A link to the module is available from the Office of Sponsored Programs Human Subject Research web page, Education and Training tab. Completed training certificates for all individuals must be submitted along with Human Subject Research Review Form and research protocol. PI training certificates are valid for the duration of the approved protocol, but not to exceed three years from the certificate date. PIs who submit certificates with their Protocol Submission Form due to expire during the approved protocol research period, must retake the training and submit an updated training certificate. Investigator's Agreement forms signed by all investigators and research assistants must also be included with the application package.

Informed Assent and Consent Forms and Guidance

For most research involving human subjects at UNA, an informed consent form must provide the following information.

1. A fair explanation of the procedures to be followed, their purposes, and their duration.
2. A description of any discomforts, risks or benefits (if any) to be expected by the subject to himself/herself or others as a result of participating in the research.
3. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
4. A statement that participation is voluntary, refusal to participate will involve no penalty and that the subject may discontinue participation at any time without penalty.
5. An indication of whom to contact for answers to pertinent questions about the research.

For research involving children an assent form may also be required as described above. For projects involving experimental therapeutic procedures or more than minimal risk to subjects the above information may not be sufficient. Investigators should consult the Office of Sponsored Programs for additional information. For consent requirements for other special populations as described above, consult the Office of Sponsored Programs and/or the agency sponsoring the research.

Guidance for Obtaining and Documenting Assent from Children

Child Oral Assent Script

Child Written Assent Form

Parent Consent Form

Adult Informed Consent Form

Data Security Plan Supporting Document

Include a description in your protocol of the type of data to be collected. Attach as a supporting document the plan for storing, cataloging, and safeguarding that data per guidelines provided.

Data Security Policy Involving Research Data in Human Subject Research

Investigators are responsible for protecting, securing, and destroying data. UNA strongly recommends that data be stored on a UNA network storage share, biometric secured external hard drive, or encrypted laptop/desktop. You should contact Information Technology Services for assistance with any of these services. Data storage on external commercial websites is not recommended. Storage of data in paper format is not recommended. In cases where data is collected in paper format, investigators should convert hardcopies to electronic format or secure paper copies in a secured safe/vault.

Classified and Proprietary Data: Investigators must contact the Office of Sponsored Programs for any data (human subject or otherwise) if research data is designated as classified, secret, top secret, or proprietary by the sponsoring agency.

Medical or Safety Monitoring Plan Supporting Document

Medical or safety monitors are required for all studies classified as "greater than minimal risk" and other studies as stipulated by the HSC. Include with the protocol submission package a supporting document describing the training and relevant experience and the specific duties and responsibilities of the medical or safety personnel who will serve as monitor for the project. If the medical or safety monitor is not a UNA staff member, submit a curriculum vita that includes medical license number or other relevant credentials. Provide qualifications for other medical or safety support personnel. All support personnel dealing directly with subjects in studies of greater than minimal risk should have current certification in basic life support (BLS) and should be referenced in this plan. Append copies of BLS and/or Advanced Cardiac Life Support certifications to the protocol.

Biohazardous Material Handling and Storage Plan Supporting Document

All biospecimens collected by investigators should be handled and stored following the best practices available. To ensure proper stewardship of human biospecimens within UNA the Office of Sponsored Programs has developed guidelines for biospecimen storage and tracking. Attach a supporting document with the protocol describing the nature of any biospecimens to be collected, how those specimens will be collected, catalogued, stored, and disposed per the guidance.

Biohazardous Material Handling Plan Guidance – **Under Construction**

Human Subject Committee

HSC Membership

The HSC is composed of at least twelve members appointed by the Vice President for Academic Affairs or the President. Per the regulations, this committee shall consist of:

- Individuals (total of ten) with expertise in those fields which generate the most research proposals involving human subjects. A minimum of one person should come from each of the following fields:
    - Two (2) from Education and Human Sciences (early childhood, elementary, secondary, special, human environmental science);
    - Two (2) from Nursing and Allied Health (nursing education, nursing interventions, human biology);

  - Two (2) from Chemistry, Biology, or Physics;
  - One (1) from Business (management, marketing, accounting, computer information systems, economics, finance);
  - One (1) from Behavioral Sciences (psychology, child development);
  - One (1) from Social Sciences (social work, sociology, criminology, political science, communications, geography); and
  - One (1) from Health, Physical Education, and Recreation.
- Male and female representation.
- An individual not affiliated with UNA and not part of the immediate family of a person who is affiliated with UNA.
- An individual with primary concerns in non-scientific areas (e.g. English, History, Foreign Languages, Art, Music, Theater, Journalism).
- The University's administrator in charge of academic research or his/her designee is a non-voting member.
- The Vice-Chair has the authority to act in the role of co-chair when required by federal grant regulations.

The members shall be appointed for a two-year term, may be reappointed, and shall be removed during their term only for stated cause. The Dean of Research shall annually appoint a chairperson of the HSC. The chairperson shall be a voting member of the committee.

The HSC will meet at least once a month during the regular academic semester to review proposals that require full committee review, should there be any proposals of that type pending. A schedule of the meetings will be announced at the beginning of the semester.

The HSC will be empowered to draft by-laws to ensure the orderly conduct of business. Once the HSC has been constituted, the by-laws that are developed will become an addendum to this policy.

HSC Review Procedures

To initiate a review, PIs must submit to the HSC Chair the Human Subject Research Review Application Form, protocol description, training certificate, investigator's agreements, and appropriate supporting documents (consent/assent forms, data security plan, medical monitoring plan, hazardous material handling plan) described previously under this heading. Links to the forms are also provided above. The submission deadline is at least ten working days before the scheduled meeting of the Committee.

Upon receiving the application for HSC review, the HSC Chair will determine under which review category the research is classifiable. If the research is deemed to be exempt under the regulations, it will be certified by the Chair by memorandum to the investigator. Upon receiving the memorandum from the HSC Chair the investigator may proceed with the research.

If the research project is determined by the HSC Chair to present minimal risk to subjects, it is eligible for expedited review. The chair of the HSC, or some other member of the Committee designated by the chair, shall be empowered to perform expedited review, approving proposals, which appear to contain no more than minimal risk. However, in evaluating the project, the reviewer may find that it requires review by the full Committee.

All research which is not certified exempt or certified under an expedited review must be reviewed by the full HSC. In order for the Committee to approve a protocol, it must be determined that the proposed research using human subjects satisfies criteria applied to the following elements of the research: risks, risks vs. benefits, subject selection, informed consent, safety and privacy, and other legal and ethical considerations. A consideration of these review criteria is embodied in the guidelines for preparation of protocols and informed consent.

The results of the review will be forwarded to the applicant within five working days of the meeting of the full committee. The committee may take one of the following actions:

1) approve,
2) request minor modifications,
3) request outside consultant review, or
4) disapprove.

The investigator shall NOT commence data collection until approval of the protocol is received in writing from the committee.

HSC Training and Education Requirements

All members of the HSC must complete Human Subject Assurance Training Modules 1-3. Upon completion of the training, HSC members are required to submit the module-generated training completion certificate to the Office of Sponsored Programs. Human Subjects Assurance Training certificates must be renewed every two years. A link to this training is included on the Office of Sponsored Programs Human Subject Research web page, Education and Training tab.

Rights of Appeal

If a research proposal is disapproved, the investigator may resubmit the proposal to the HSC or appeal the decision. The appeal procedure will be established by the HSC and the hearing of the appeal will be independent of the HSC.

Protocol Modifications

Any changes to an approved research protocol, including but not limited to changes to research design, changes to research staff, changes to the assent/consent document(s), or changes to data collection instruments or methodologies must be submitted to the HSC for approval.

Modification of Approved Protocol Form

Any written instruments used in interactions with subjects (consent document, survey, recruitment script, etc.) that are changed must be submitted for review and date-stamping before being used.

The only exception to the requirement for obtaining HSC approval before implementing a change is where a change needs to be implemented to eliminate an apparent, immediate hazard to a subject in the course of the research. The investigator shall immediately notify the HSC Chair of this protocol deviation.

Other Policies of the HSC

- All communications with the HSC should be submitted to the Chair of the Human Subject Committee, Office of Academic Affairs, Bibb Graves Room 214.
- All protocols are approved for no longer than 365 days. If a project continues past 365 days, it is subject to a continuing review. See Continuing Review heading below.
- Problems arising at any point during the project involving the use of human subjects must be reported to the HSC. See Unanticipated Problems/Non-compliance Reviews heading below.
- At the conclusion of a project a memorandum must be filed with the HSC indicating its completion/termination and specifying any unexpected difficulties that occurred with the use of human subjects. See Completions/Terminations heading below.
- Informed consent forms must be retained by the investigator/instructor for a period of not less than three years following the completion or termination of the project.
- PIs are responsible for ensuring that all human subjects' data is protected and stored in a secure location, until otherwise destroyed or properly disposed. Electronic storage of human subject's data must be protected or encrypted. If the PI believes that the security of human subject's data has been compromised, the PI must immediately notify the Chair of the HSC. See the Data Security Plan section above for further guidance.

Continuing Reviews

All protocols that have not been completed must be reviewed by the HSC within a period of not more than 365 days from the previous review. The HSC may set a period of less than one year for the next review as circumstances of the research warrant.

Continuing review must be substantive and meaningful and include all the elements of the initial review plus additional items, such as number of subjects enrolled, a summary of unanticipated problems/adverse events, a summary of recent literature in the research area and any pertinent research findings, any proposed modifications to the research, and new copies of the informed consent document and any recruitment materials for date-stamping.

If a continuing review does not take place during the preceding approval period, the HSC Chair shall inform the PI in writing that the approval period has expired and that all research must halt until re-approved for continuation.

Continuing Review Form

If the PI is proposing modifications to the research protocol (e.g., design, staff, assent/consent documents, scripts, sample size or population, or data collection methodologies) at the time of continuing review, the PI should also submit a protocol modification form.

Modification of Approved Protocol Form

Unanticipated Problems and Adverse Events

An unanticipated problem includes any untoward sign, result, event, misadventure, injury, dysfunction, adverse drug reaction, or any other undesirable happening or unanticipated problem that involves risks to subjects or others not previously reported, and that could reasonably be

related to the activities of the study. Unanticipated problems of even questionable relationship to the research study should be reported to the HSC as relationships between incidents and research procedures may only become evident over time.

The PI must notify the medical monitor (if required in the study), Director of Sponsored Programs and HSC Chair of an unanticipated problem as soon as practicable (but no greater than five days) and in a manner appropriate to the gravity of the event. Unanticipated problems should be reported in writing to the HSC Chair and will be documented in all subsequent continuing review reports and in the completion/termination report.

All unanticipated problems and serious adverse events shall be reported in writing using the unanticipated problem report form. As soon as practicable the HSC will meet to consider the report and recommend whether the study should be continued (with or without revision), suspended, or terminated.

Guidance for Reporting Unanticipated Problems and Adverse Events

Unanticipated Problems and (Reportable) Adverse Event Report Form

Non-compliance

All instances serious or continuing non-compliance with HSC requirements or instances of failure to adhere to the parameters of an approved protocol (whether deliberate or inadvertent) shall be reported in writing to the HSC Chair within five days for determination of appropriate actions.

Guidance for Reporting Non-compliance/Protocol Deviation

Non-compliance/Protocol Deviation Report Form

Completions/Terminations

A Completion or Termination Report to a protocol is prepared by the PI when data collection and all analyses of data have been completed. Typically this coincides with the end of a grant period of performance. A Termination Report will be required if the HSC disapproves continuation of a protocol approval.

Completion/Termination Report Form