**UNIVERSITY OF NORTH ALABAMA**

**POLICY ON THE USE OF HUMAN SUBJECT IN RESEARCH**

The policy on the use of human subjects in research applies to any activity deemed to be research at the University. The applicability of this policy is to all entities of the University: faculty, administration, staff, students, and contracted consultants. This policy applies to any research activity using human subjects that is directly or indirectly supported by the University. The Human Subject Committee (HSC) of the University of North Alabama will administer this policy.

**BACKGROUND**

The National Research Act of 1974, recognizing the need for safeguard regulations concerning the use of human subjects in social and behavioral science research, requires institutional review, letters of assurance, and documentation thereof for such research. The Federal Policy for the Protection of Human Subjects, known as the Common Rule and published in the Federal Register, Vol. 56, No. 117, June 18, 1992, beginning at 28001, represents the latest Federal regulations for protection of human subjects. This Policy went into effect August 19,1991. The 16 Federal departments and agencies that have adopted these regulations are: Office of Science and Technology Policy, Dept. of Agriculture, Dept. of Energy, NASA, Dept. of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency (AID), Dept. of Housing and Urban Development, Dept. of Justice, Dept. of Defense, Dept. of Education, Dept. of Veterans Affairs, EPA, Dept. of HHS (Office of Secretary & FDA), NSF, and Dept. of Transportation. The Office of Protection from Research Risks within the Department of Health and Human Services (HHS) retains general jurisdiction over these matters.

 Under the regulations, all institutions receiving funds from any of these departments/agencies are required to establish institutional review boards (IRB) to review and monitor all funded research involving humans. At the University of North Alabama the IRB will be known as the Human Subjects Committee. Institutions are further required to submit periodic letters of assurance to the Federal government that they are complying with the regulations. The University of North Alabama, like most institutions, shall review all research proposals involving human subjects, whether funded or not. It is the policy of this University to apply the regulations to all research and research-related activities which involve human subjects.

 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, the University takes the protection of human subjects very seriously for fiscal was well as ethical reasons.

 A copy of the HHS regulations (45 CFR 46 Protection of Human Subjects) pertaining to the use of human subjects in research is available from the Office of Academic Services, Bibb-Graves Room 214.

**DEFINITION OF TERMS**

 A researcher meeting review system for the first time might find the regulations and procedures complicated. The following information is to provide and introduction to the realm of human subjects research.

WHEN IS 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 f the researcher. The notes that follow are designed to assist you making that judgment.

 In general, at UNA, we prefer to make the judgment on the conservative side, treating most doubtful cases as involving human subjects. By doing this, we ensure that we have given careful thought to how we can protect the rights of the people with whom we deal in our research.

 All research involving human subjects must be reviewed by the Human Subjects Committee (HSC) or be certified as exempt from HSC review by the Chair of the Human Subjects Committee. However, our task is not to decide whether the proposed research is exempt or not. Rather, the first task is to decide whether we must submit any form at all, and that decision requires us to determine whether we are conducting research that involves human subjects. Two important concepts will help us reach an answer. The first is the idea of research and the second is the idea of human being a human subject.

**RESEARCH**

 According to the regulations, research is any systematic investigation designed to develop or contribute to generalize knowledge. Any activity that meets this broad criterion and that is conducted by UNA faculty, administration, staff, or students or that uses UNA facilities is research for the purposes of our 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, you may want to ask yourself several questions to determine if any aspect of your work is research as it might be related to human subjects review:

1. 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?
2. Do you anticipate (in advance of conducting the project) that you will analyze, interpret, and disseminate the findings of your investigation?
3. 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?
4. 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)
5. Will the project use subjects that are minors (under the age of 18)?

If you can answer “Yes” to any one or more of these questions, then your 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:

1. **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. 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.**
2. 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.
3. Evaluation data gathered for a contractor about a project or operation for which he 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 be 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.

**THE HUMAN SUBJECT**

 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.

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:

1. Mail questionnaires or surveys;
2. Personal interviews, structured or unstructured, with or without recognized instruments;
3. Personal (i.e., face-to-face) surveys;
4. Telephone interviews or surveys;
5. Classroom instruments, evaluations, or exercises;
6. Examination of private records (e.g., medical, psychological, or school records); and
7. 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 a HSC review form.

Common Forms of Research Requiring Submission: From the list of types of interactions, we can see that many common forms of research that present little, if any, risk to human beings nevertheless require either review or certification of exemption, simply because they are research and have human subjects. Some of the more common types are these:

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

In the list that we have just examined, we included surveys seeking information. There are many sorts of information we can seek from one or more people, 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, we think of individuals, even in a survey, as colleagues from whom—not about whom—we obtain information. One of the questions HSC will often face concerns where, if anywhere, to draw a line between the two types of surveys. We shall use the idea of a survey here 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 individuals 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, to obtain information from individuals, with no inherent potential for obtaining information about them. Such instruments use the individuals to whom they are sent as, essentially, 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, the University would need to know, for the record, that such an inspection of instrument design had occurred. Submission of a HSC review form eliminates the need for such steps and assures the University that inquiries from outside about human subjects’ interactions will not come as a surprise.

**KINDS OF HUMAN SUBJECT RESEARCH**

The determination of the need for HSC review of a research project is the responsibility of the investigator. Investigators should use the following three categories of research activities to determine whether or not they should submit a protocol for HSC review. Questions concerning the classification of a particular study into one of these three categories should be directed to the chair of the HSC.

**CATEGORY I—Exempt Research (No HSC review but HSC form filed)**

1. Projects involving 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 in 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.
2. Projects 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.
3. Projects limited to the observation of public behavior for which anonymity of subjects is maintained.
4. Projects 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—Research Activities Subject to 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 “the risks of harm, anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (HHS regulations).” Projects that may qualify for expedited review include the following:

1. Most laboratory investigations of cognition, perception, social behavior and personality.
2. 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).
3. Studies that require the examination of existing data or specimens that are not publicly available.
4. Studies involving the collection of voice or video recordings.
5. Studies of healthy individuals involved in moderate exercise.

**CATEGORY III—Research Activities Subject to Full HSC Review**

1. Projects that do not meet the criteria for Category I or Category II because subjects will be exposed to more than minimal risk (e.g., use of invasive techniques or unusual therapeutic techniques such as hypnosis).
2. Projects requiring the use of deception.
3. 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). Information concerning research with children and pregnant women are covered below. Guidelines for other special populations may be obtained from the Office of Sponsored Programs, in Bibb Graves Hall Room 208.

**RESEARCH INVOLVING CHILDREN AS SUBJECTS**

 For research involving children, the following conditions must be met:

1. **Assent of Child:** Assent means the potential subjects’ affirmative agreement to participate in the research. Mere failure to object should not, in the absence of affirmative agreement, be constructed as assent. The following list indicates how assent of children should be handled for children of different ages.
2. For children under 7 years of age, the child is assumed to be incapable of giving assent (see “Parental Consent” below).
3. For children 7-13 years of age, the assent of the child or documentation of the reason for waiver of the assent is required. Assent of the child may be waived if the capability of the child to give assent is judged limited by age, maturity, or psychological state (mental retardation or psychosis). Consent for Research with Children can be found at http://www.una.edu/sponsored-programs/.
4. Adolescents 14 years of age and over are considered able to sign a consent form as an adult.
5. **Parental Consent**
6. 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.
7. 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. Guardian consent should be substituted for parental consent under appropriate legal constraints.
8. 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).
9. 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.

**RESEARCH WITH PREGNANT WOMEN**

 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 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.

**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 HHS. 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, the subject owns the record, for example, most medical and psychological records. 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 of **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 highlighted 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.

**STUDENT RESEARCH**

 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, abort uses, prisoners, persons with mental disabilities, children, or economically disadvantaged persons) will require HSC approval. If it is anticipated that the study will be funded 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.

**HUMAN SUBJECTS COMMITTEE REVIEW PROCESS**

Human Subjects Committee (HSC)

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

1. Individuals (total of 5) 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:

EDUCATION (early childhood, elementary, secondary, special, health/physical)

NURSING (nursing education, nursing interventions, human biology);

BUSINESS (management, marketing, accounting, computer information systems, economics, finance);

BEHAVIORAL SCIENCES (psychology, child development); and

SOCIAL SCIENCES (social work, sociology, criminology, political science, communications, geography).

1. Male and female representation
2. An individual not affiliated with the University and not part of the immediate family of a person who is affiliated with the University.
3. An individual with primary concerns in non-scientific areas (e.g. English, History, Foreign Languages, Art, Music, Theater, Journalism).
4. An individual with primary concerns in scientific areas that traditionally do not use human subjects (biology, chemistry, physics, geology).

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 be available. 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 part of this policy.

**HUMAN SUBJECT ASSURANCE TRAINING**

All members of the HSC must complete ‘Human Subject Assurance Training’ Modules 1-3. The training modules can be found at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/default.asp>. 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.

All PI’s initiating a human subjects review request must complete ‘Protecting Human Research Participants’ training module; <http://phrp.nihtraining.com/users/login.php>. Completed training certificates must be submitted along with ‘Human Subjects Review Form’ and ‘Protocol Submission Form to the chair of the HSC. PI training certificates are valid for the duration of the approved protocol, but not to exceed three years from the certificate date. PI’s 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.

**THE REVIEW PROCESS**

 To initiate a review, PI’s must submit ‘Human Subjects Review Form’, and ‘Protocol Submission Form’ to the chair of the HSC. These forms can be found at[**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/) **.** The forms shall be submitted with appropriate support documentation (project proposal, consent forms, human subjects training certificate). The investigator should indicate on the forms the category (exempt research, expedited review, or full review) she or he believes the research project falls into. Refer to the categories of research mentioned in the Kinds of Human Subject Research section.

Exempt Research

 Upon receiving the application for HSC review, the chair of the HSC 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 of the HSC by memorandum to the investigator. Upon receiving the memorandum from the chair the investigator may proceed with the research.

Expedited Review

 If the research project is determined by the chair of the HSC 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.

Full Committee Review

 All research which is not certified exempt or certified under an expedited review must be reviewed by the full Human Subjects Committee. The submission deadline is at least ten working days before the scheduled meeting of the Committee.

 In order for the Committee to approve a proposal, it must be determined that the proposed research using human subjects satisfies the following criteria: 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 preparations of protocols, proposals, 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. approval,
2. request for minor modifications,
3. request outside consultant review,
4. disapprove.

**Only when the project has received approval of the committee shall the investigator commence with data collection.**

**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.

**HOW TO PREPARE A PROJECT PROPOSAL/PROTOCOL**

 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 a written description of the project. This 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 consent (a copy of the proposed informed consent form must be attached), for assuring the confidentiality of their data and for debriefing them, 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.

**PREPARATION OF INFORMED CONSENT FORM**

 For most research involving human subjects at UNA, an informed consent form must provide the following information: Informed Consent Forms are located at http://www.una.edu/sponsored-programs/.

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 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.

**ADDITIONAL POLICIES OF THE HUMAN SUBJECTS COMMITTEE**

1. All communications with the HSC should be submitted to the Chair of the Human Subjects Committee, Office of Academic Affairs, Bibb Graves Room 214.
2. Approved research proposals are valid for a period of one year. If a project continues beyond one year and the investigator/instructor has not made any significant changes in the procedures outlined in the original proposal, a memorandum requesting reapproval is all that must be submitted **for each** **year of continuation**. Any significant change requires a new review by the HSC.
3. Informed consent forms must be retained by the investigator/instructor for a period of not less than three years following the termination of the project.
4. Problems arising at any point during the project involving the use of human subjects must be reported to the HSC.
5. At the conclusion of a project a memorandum must be filed with the HSC indicating its termination and specifying any unexpected difficulties that occurred with the use of human subjects.
6. PI’s 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 in a UNA password protected or encrypted file server is highly recommended. 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.