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 ttsuF()-12ko(ts)-5--2(f)3H

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 procedu-10(e)4

consent to medical treatment. For instance, Alabama statute 8-22 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 sub

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thereof from liability for negligence.ee 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 we

- 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 19 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.

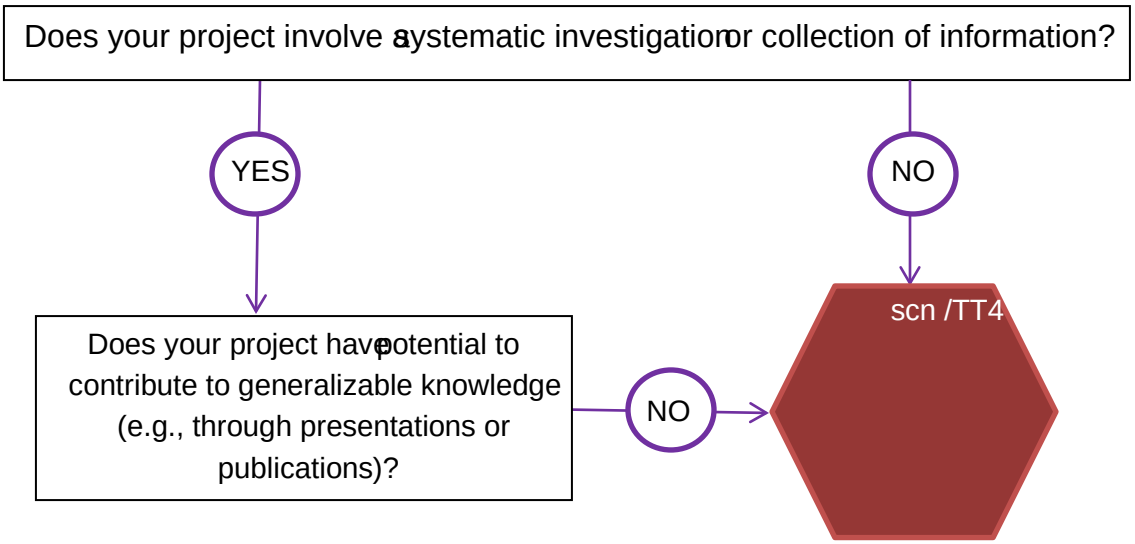
Some instances not considered research: There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Here are some examples:

- 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 dissemin(a)4(nri)-5(n)-13(n(a)4(1.(he)4(pe)-6d)-2(a)4( )-10(g)10(a)4(t)-2(he)-6(r)3(

Figure 1provides 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?

Researchis 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.



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 more 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: 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 nonprivate, nonpersonal, 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-

- 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 c

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, Of>n(or

- 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.

x Male and female representation.
x An individual not affiliated with UNA and not part of the immediate family of a person who is affiliated with UNA.
x An individual with primary concerns in non-scientific areas (e.g. English, History, Foreign Languages, Art, Music, Theater, Journalism).
x The University's administrator in charge of academic research or his/her designee is a non voting member.
x The Vice-Chair has the authority to act in the role of 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

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 Module 1. Upon completion of the training, HSC members are required to submit the 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 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 obtaining approval 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.

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