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Respect for persons
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 agencie 746.52 Tm[(8)TBT1 0 0 1 72.024 39.0

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

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 subjec
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?

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 constitute40.3 6ect is

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.

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 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 o the Ofp:7(a)4von of extion of insatrve sr(i)6CID 11e4 lET88 BDC BT5uusur sr(w1

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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

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., 1s TJETBT49BT1

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

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.
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
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