Research Involving Human Subjects and the Institutional Review Board (IRB)

What is human subjects research?

All research which involves any form of participation of human subjects qualifies as human subjects research, and, as such, must be reviewed and approved by the Institutional Review Board (IRB). This includes survey research, research by students as well as by faculty and staff, and both internally and externally funded research. The university's policy is mandated by federal regulations and is meant to safeguard the welfare of human subjects in research.

Functions of the IRB.

Review by the IRB is meant to assure that (1) risks are minimized and are reasonable in relation to anticipated benefits, if any, to the subjects, (2) there is informed consent by the subjects, and (3) rights and welfare of subjects are maintained in all respects.

Filing for review.

A researcher who plans any project which involves human subjects research should fill out the "IRB Application Form," which can be found on the university's website and from the chair of the IRB. Once it is completed it is returned to the IRB chair.

The review process.

As previously stated, all proposed human subjects research, including proposed thesis research, is subject to review and cannot take place without institutional approval. The review process begins with a determination by the committee chair as to whether the proposed research qualifies as being exempt from further review. The criteria for exemption are listed. If the proposed research does not qualify as exempt, it will then be subjected to further review. The research may qualify for expedited review if certain criteria are met. This determination is made by the chairperson or an appointed subcommittee of the IRB. If the proposed research is not exempt and does not qualify for expedited review, it is then sent to full review by the IRB. If a research project (that was already approved) extends longer than one year, the principal investigator is required to submit the proposal annually to the IRB to ensure compliance with the guidelines.

Criteria for approval.

In general, a human subjects research protocol should provide that (1) risks are minimized through procedures consistent with sound research design, using, whenever available, procedures already being performed on the subjects for diagnostic or treatment purposes, (2) any risks beyond those incurred in daily life are outweighed by benefits to the subjects, (3) selection of subjects is equitable and the setting appropriate, (4) informed consent is

adequate, (5) consent is documented, (6) continued monitoring takes place to insure the safety of the subjects, and (7) privacy and confidentiality are maintained.

Time required and notification.

Submitted proposals are initially reviewed by the chair to determine if they can be treated as exempt or expedited. If the proposal is classified as either exempt or expedited, notification is given to the investigator with the decision subject to confirmation by the full IRB at its next meeting. Proposals that are subject to full IRB review are discussed and decisions made at the next meeting of the IRB. The researcher is notified in writing of the review's outcome by the committee chairperson.

Cooperative research.

In many cases, human subjects research will involve cooperation among two or more institutions. In such cases, the institutions may use joint review, reliance on the review of another qualified Institutional Review Board or similar arrangements aimed at avoidance of duplication of effort. However, the researcher at SOSU is still obligated to file an "IRB Application Form" with the SOSU IRB.

DEFINITIONS OF TERMS USED IN HUMAN SUBJECTS RESEARCH

Research means 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 purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Identifiable private information is data in which the identity of the subject is associated with the information or may be readily found out by the researcher.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes 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 (for example a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or an associate with the information) in order for obtaining the information to constitute research involving human subjects.

Informed consent means that the subject, or a legally authorized representative, has received an explanation of the research involved and its potential risks, and has agreed to participate. Informed consent has eight essential points, which are listed on a separate page.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. The use of a legally authorized representative to gain approval of human subjects research is by analogy with clinical treatment where consent must be obtained, for example from parents or guardians in the case of minor children.

Minimal risk means that 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.

An assurance is a document sent with a research proposal to a federal, state, or private agency to affirm that the institution will observe all mandated and ethical considerations in the research project. The university has a "general assurance" which it has filed with the federal government, but the existence of the general assurance does not eliminate the requirement for filing an assurance form with a specific proposal when the granting agency requires it.

QUALIFICATION FOR EXEMPTION

The chair of the IRB or his/her designate may determine that the proposed research is exempt from further review if the research in which human subjects are involved falls into one or more of the following categories:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    - Any disclosure of the human subjects' responses outside the research could responsibly place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving

observations of public behavior when the investigator(s) do not participate in the activities being observed.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, that is not exempt under (2) above, if:
  - the human subjects are elected or appointed public officials or candidate for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are 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.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - public benefit or service programs;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in or alternatives to those programs or procedures; or
  - possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the EPA or the Food Safety and Inspection service of the U.S. Department of Agriculture.

QUALIFICATION AND EXPEDITED REVIEW

Research may qualify for expedited review by the chair of the IRB or an appointed subcommittee if the research involves no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories:

- Collection of : hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth extracted through normal dental therapeutic practice.
- Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
- Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally

occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible spectrum (e.g., x-rays, microwaves).

- Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- Voice recordings made for research purposes such as investigations of speech defects.
- Moderate exercise by healthy volunteers, consistent with the guidelines published by the American College of Sports Medicine.
- The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

QUALIFICATION FOR FULL REVIEW

All proposed research which does not qualify for either exemption or expedited review must go to the full IRB for review. Typically, the project description is sent by mail to the IRB members who then discuss the proposal at the next monthly meeting of the IRB with a recommendation to approve, deny, or approve the project with specific modifications. NOTE: Survey and interview research involving children is NOT exempt, but rather requires full IRB.

ESSENTIAL COMPONENTS OF INFORMED CONSENT

No investigator may involve a human being as a subject of research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

Conditions of consent

An investigator shall seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Language

Information given to the subject or his/her representative shall be in language understandable to the subject or representative. This will usually be language understandable to a layperson.

No exculpatory language

Informed consent, whether oral or written, may not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability or negligence.

The basic elements of informed consent include:

- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation is to be given and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and subject's rights, and whom to contact in the event of a research-related injury. The name of whom to contact should be accompanied by an office location and a telephone number;
- A statement that participation is voluntary, refusal to participate will involve no penalty to which the subject is otherwise entitled, and the subject may discontinue participation at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

Altered or waived consent

In some cases, IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent. This is usually the case where the informed consent would seriously compromise the research. In most such cases the IRB would insist on (1) minimal risk, (2) no adverse effects on rights and welfare, and (3) the research could not practicably be carried out without the waiver or alteration, and (4) providing additional information to the subject at a later time. Rarely does the IRB agree to waive informed

consent, but some familiar kinds of research that might justify alteration or waiver include (1) necessary deception in behavioral or social science, (2) examination of existing data, documents, records, or specimens, (3) research on medical emergencies, and (4) subjects whose comprehension varies over time.

Documentation of informed consent shall include a signed form, with a copy provided to the subject or his representative. In certain cases, the signed form may be waived, for example if the consent document is the only link between the subject and the research and the main risk to the subject is a breach of confidentiality. For example, if the only record linking the subject to the research or data is the written, signed informed consent, its use may be waived by the IRB. However, a statement describing the procedures and objectives of the research shall still be supplied to the subjects in a written format. An example of such a project would be the analysis of a questionnaire which is distributed and returned anonymously through the mail. A cover letter should include all the elements of informed consent. If informed consent is to be obtained orally (i.e., prior to a telephone interview) a written summary of what the subject will be told must be provided to the IRB for review and approval. In such cases, the subject decides whether or not to use a signed form. The signed document may also be omitted if the risk is minimal and written consent is not normally required outside the context of the research.

Examples of various types of informed consent forms are available from the committee. These are only to be used as examples or guides for the formulation of individual informed consent forms and not as standard forms.