



Policy and Procedures

On Use of Human Subjects in Research

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INTRODUCTION

All research projects with human subjects conducted by faculty, staff and students associated with SOWELA Technical Community College must receive approval from the Institutional Review Board (IRB). The information in this document is designed to assist you with this process. For more information about basic ethical questions in the conduct of research, you are encouraged to read the Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> .

A brief review of some historical material is provided here to help investigators better understand the reason for ethical review of research involving human subjects, the primary ethical principles that govern such research, and the statutory basis for enactment of these principles. This material contains information that should assist SOWELA Technical Community College researchers in the preparation of an acceptable application for review of a project that involves human subjects.

1.1 Codes of Research Ethics

Codes of research ethics have been developed to address the disregard for human safety and dignity reflected first and foremost in the scientific experiments by Nazi doctors during WWII, but also with regard to other unethical projects such as the Tuskegee experiment in Alabama between 1932 and 1972 in which treatment for syphilis was withheld from poor black males in order to study the effects of the disease. The Nuremberg Code of 1947 was the first international code of research ethics. The first principle established that “The voluntary consent of the human subject is absolutely essential.” The code clarified that the potential subject should “...have the legal capacity to give consent” and “...should have sufficient knowledge and comprehension ... to make an understanding and enlightened decision.” This basic concept continues to serve as the basic foundation for ethical research involving human participants [\[http://www.hhs.gov/ohrp/archive/nurcode.html\]](http://www.hhs.gov/ohrp/archive/nurcode.html) .

Other codes followed. In 1964, the World Medical Association adopted the Declaration of Helsinki. This code established the concept of ethical review by an independent board. It also recognized a distinction between therapeutic and non-therapeutic research. [\[http://www.wma.net/en/30publications/10policies/b3/index.html\]](http://www.wma.net/en/30publications/10policies/b3/index.html) The American Psychological Association established the first ethical code addressing social and behavioral research in the U.S. in 1972. Based on examples of unethical or questionable behavior, the APA developed ten basic principles for human subjects research. These principles were the first to recognize the principle of confidentiality. Today, most professional organizations have ethical codes that provide guidance on human subjects research. Also, many journals now require that authors state adherence to appropriate ethical principles and guidelines in their research.

The U.S. Department of Health, Education and Welfare (DHEW) issued ethical guidelines in 1971 through the National Institutes of Health. In 1973, an ad hoc advisory panel issued the final report of the Tuskegee Syphilis study. This report concluded that, “Society can no longer afford to leave the balancing of individual rights against scientific progress to the scientific community.” The following year, Congress passed the National Research Act and codified the DHEW guidelines into federal regulations at 45 Code of Federal Regulations (CFR) 46 (also known as the Common Rule) [\[http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm\]](http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm) . The Act also established the National Commission for the Protection of Human Subjects to identify the basic ethical principles that now underlie the conduct of biomedical and behavioral research involving human subjects. Known as the Belmont Report, the report was published in 1979 and identified three basic ethical principles:

Respect for Persons (autonomy) – This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from all potential research subjects (or their legally authorized representatives).

Beneficence – This principle requires the investigator to maximize the benefits and minimize the harms or risks associated with the research. Research-related risks must be reasonable in light of expected benefits.

Justice – This principle requires equitable selection, recruitment and fair treatment of human research subjects.

The three principles were the underpinnings of the Common Federal Policy for the Protection of Human Subjects.

Sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, The Department of Education, and the Department of Energy, have adopted the current version. The current version was published in 1991 and guides the decisions of IRBs. The regulations further require that every institution at which federally funded research is conducted adhere to the principles of the Belmont Report and set forth in writing its ethical principles, policies, and procedures. SOWELA Technical Community College's agreement to abide by the Belmont Report and by 45 CFR 46 (called a Federalwide Assurance) is approved by the federal agency that oversees ethical issues in human research.

1.2 Administration of Research Ethics – Federal

The Office for Human Research Protection (OHRP) is the federal office responsible for the oversight of research involving human participants and is part of the Department of Health and Human Services. Audits conducted by OHRP at several institutions have resulted in the temporary suspension of all research activities involving human subjects. Additional information about this agency is available at [<http://www.hhs.gov/ohrp/>]. Some researchers may also want to consult the National Science Foundation's (NSF) guidelines on protection of human subjects at <http://www.nsf.gov/bfa/dias/policy/human.jsp>.

1.3 Administration of Research Ethics – SOWELA Technical Community College

The **Office of Planning & Analysis** is responsible for the administration of research ethics at SOWELA Technical Community College. The office oversees policies and compliance, which includes the Institutional Review Board (IRB).

1.4 IRB Authority

The IRB has the authority to:

- approve, require modifications in, or disapprove all research activities involving human subjects at SOWELA Technical Community College;
- Observe or monitor ongoing research as is necessary to protect human subjects; and to
- Suspend or terminate approval of previously approved research.

Although the Vice Chancellor's, deans, department chairs and other college officials may have the authority to disapprove research activities approved by the IRB or to set more stringent requirements on research protocols, research disapproved by the IRB cannot be conducted.

THE IRB AT SOWELA TECHNICAL COMMUNITY COLLEGE

2.1 The Institutional Review Board's Charge

The scope of the IRB's charge is broad. Generally, any college research that involves humans, human tissue, surveys of human subjects, or human subjects' records requires IRB review and approval, regardless of funding source. This purview extends to all student research projects. The specific charge to the IRB is to give consideration to the:

- potential risks to the subjects;
- anticipated benefits to the subjects and others;
- importance of the knowledge that may reasonably be expected to result; and
- informed consent process to be employed.

The basis for the board's charge is found in the Code of Federal Regulations (CFR). Although protection of human subjects is a concern of all agencies that sponsor research, regulatory leadership is vested in the federal Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA). The OHRP has general responsibility for the protections of humans as subjects in research, and the FDA regulates the use of drugs and medical devices in experiments.

OHRP regulates compliance of institutions primarily through "assurances." A Federal wide Assurance is a legally binding agreement between the institution and the OHRP. The college's assurance outlines our responsibilities and explains the steps the college will take to meet the federal regulations for research on human subjects.

2.2 Membership and Structure of the IRB

SOWELA Technical Community College's IRB is comprised of eight members. There are two representatives from

faculty and two representatives from staff. The two co-chairs of the IRB are drawn from the Institutional Effectiveness Committee (one faculty one staff) and there are two members from the community (non-scientist) who also serve. Additional members may be appointed to serve in a temporary capacity if the required expertise is not available on the IRB.

The Board strives for a balance of men and women and representation from diverse ethnic groups. Appointment is based on the expertise required, familiarity with applicable laws, regulations, and relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations. Diversity in experience and expertise enables the IRB to evaluate a wide range of research.

2.3 The Office of Planning & Analysis (OPA)

The Office of Planning & Analysis provides administrative support to the IRB.

2.4 IRB Meetings

Convened meetings are scheduled once a semester, fall & spring with the co-chairs alternating Chair position, or one serving if the other is not present. The schedule is set in the summer for the following academic year and published on the OPA website. The deadline for submission of materials for full IRB review is three weeks prior to the scheduled meeting. Members are sent applications and other materials for review approximately one week prior to the scheduled meeting. Members are expected to review all materials prior to the meeting.

The IRB meets in executive session. The Chair may permit persons not affiliated with the IRB to attend meetings, upon request. Investigators or their collaborators are not permitted to be present at IRB meetings during deliberations on their research. However, the IRB may decide to invite investigators to the meetings to answer questions about their research.

2.5 IRB Policies

The IRB's policies are drafted by the IRB members, or designees, and approved by a majority of members present at a convened IRB meeting at which a quorum is present. The policies may be changed or revised as warranted by the majority of the IRB at a convened meeting.

When warranted and appropriate in specific situations, the IRB may waive any of its policies and procedures if: (1) the waiver is not inconsistent with federal regulations and (2) the waiver does not increase the risks to participants in research

2.6 Conflict of Interest

No IRB member may participate in the review of or vote on any initial or continuing application, revision, or other matter involving research in which he or she has a conflict of interest. A conflict of interest is assumed to be present when the member is the Principal Investigator, faculty sponsor, or member of a funded project on any research being reviewed by the IRB or when the member has a financial interest in the sponsor of research under consideration.

Members shall recuse themselves from discussions at IRB meetings of an application or other matter in which they have a conflict of interest. This is recorded in the minutes. Members may provide information requested by the IRB prior to or after formal deliberations.

The Chair recuses him- or herself from reviewing applications for expedited review and revisions or continuations when a conflict of interest is present. The Chair may appoint co-chair or another IRB member to act as chair during the review of such applications or research activities. This is noted in forms indicating the IRB's actions.

All IRB members are encouraged to avoid the appearance of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any IRB matter and to excuse themselves from decision-making in such instances.

WHAT IS SUBJECT TO REVIEW?

3.1 Definition of Research

Research is defined by the federal regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)] This definition may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis of specimens, demographic and epidemiological research, program evaluations, oral histories, secondary analyses of documents and records, and other methods associated with biomedical, behavioral and social sciences. Research is characterized by the intent to share knowledge with others in professional, scholarly, or scientific publications and/or forums.

3.2 Definition of a Human Subject

A human subject is defined in the federal regulations as 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.” Intervention includes both physical procedures by which data are gathered 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. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)]

a. Third Parties – In the course of their research, investigators sometimes collect information about persons other than the participant who has provided informed consent to be part of a study. For example, medical histories often collect information about conditions and diseases among a person's relatives or sociological, anthropological, or psychological research may obtain information about people's experiences and perspectives on others in their lives. Persons who are not primary subjects of research, but about whom information is collected are sometimes referred to as “third parties” or “secondary subjects.” Many IRBs and the OHRP have examined the issue of: when do third parties become “human subjects” from whom informed consent must be obtained?

Investigators have an ethical responsibility to avoid exposing any persons to unnecessary risks or undue harms, whether or not they are research subjects. Information collected about third parties generally should be recorded in a manner that protects their identities, and special steps must be taken to safeguard confidentiality in the case of sensitive information that could cause harm to persons unless this jeopardizes the rights and welfare of the research participants.

The IRBs will consider on a case-by-case basis the circumstances under which third parties should be considered research subjects. In reaching this determination, the IRB will consider the following factors: (1) the amount of private information collected about third parties; (2) the sensitivity of that information; (3) the ability of investigators to maintain the confidentiality of third parties; (4) the welfare of the originally designated research subjects; and (5) the right of the originally designated research subjects to provide information on their personal life experiences. Third parties normally are not considered research subjects from whom consent must be obtained unless information obtained about them pertains to their personal behavior unrelated to the interests and experiences of the originally designated research subjects.

b. Expert Opinion – Faculty, staff and students sometimes solicit the opinions of experts through phone or face-to-face interviews, surveys, and panel discussions. Experts are persons who, by virtue of their training or expertise, have information and knowledge in a substantive area beyond that of the average person and who regularly share this information and knowledge through consultation, teaching or public speaking, or publications and written reports. For IRB purposes, experts are not human subjects when asked to provide information and opinions within their areas of expertise. Communications with experts on non-private information do not require IRB approval.

c. Autobiography or “Auto-ethnography” – In sociology, anthropology and related disciplines, postmodern ethnography, autobiography, or auto-ethnography is a narrative method in which the investigator and “subject” are one and the same. That is, the investigator reports on his or her own experiences and perspectives. In this form of narrative reporting, the investigator is not considered a research subject, and IRB approval is not required.

3.3 Scope of Review

IRB review and approval is required for any research involving human subjects that:

- is conducted by college faculty, staff, or students;
- is performed on the premises of the college;
- involves college students, faculty, or staff;
- satisfies a requirement imposed by the college for a degree program;
- is performed with, or involves the use of, facilities or equipment belonging to the college.

3.4 Research Conducted by “Affiliated Faculty”

Research conducted by “affiliated faculty” – faculty members who hold clinical appointments – is subject to the college's guidelines for research on human subjects and must be submitted for IRB review. Any research project that is conducted by or under the direction of any employee or agent of this institution, in connection with his or her institutional responsibilities, requires IRB approval.

3.5 Research Projects in which the Researcher is a Consultant

College IRB review is required as stated above unless the researcher has a strict consulting relationship in which:

- the researcher is hired on his or her own time; OR
- the researcher holds no rights in the work; and AND
- neither the researcher nor the college retains any data; and AND
- the researcher does not utilize college space, materials and supplies, and secretarial and staff support.

3.6 Research Conducted by Students – The Faculty Sponsor's Responsibility

Theses/dissertation projects, senior honor theses, independent study research projects, and other similar projects must be submitted independently to the IRB by the student-researcher. Faculty sponsors must instruct students on the ethical conduct of research and help them prepare the application for IRB approval. Students should:

- understand the elements of informed consent;
- develop a readable consent form (samples are available from our office);
- plan appropriate recruitment strategies for identifying potential subjects;
- establish and maintain strict guidelines for protecting anonymity or confidentiality; and
- allow sufficient time for IRB review and completion of the project.

To ensure that the college's guidelines will be followed, the faculty sponsor is required to sign the student's application for IRB approval. After IRB approval, faculty sponsors must take an active role in ensuring that projects are conducted in accordance with the IRB's requirements.

3.7 Research Conducted in College Courses

Many research methods courses at SOWELA require students to complete projects as a way of teaching research methods and skills. Institutional review boards at institutions of higher education vary according to whether they require student projects to be reviewed and approved. The IRB does not require student projects conducted in research methods courses to be reviewed if the purpose of these projects is educational in nature and will not be published or used in future research. Activities not intended to provide generalizable knowledge are not subject to IRB review. However, *the instructor of the course is ultimately responsible for the protection of human subjects.*

Students are not permitted to continue projects conducted for a research methods course after the semester has ended without IRB approval.

Students in graduate methods courses, in particular, sometimes use projects to refine their research interests and provide a foundation for a thesis or dissertation. A project initially conducted to learn research methods may yield data that the student subsequently wishes to use to contribute to knowledge. In order to use these data for theses, dissertations, or other research purposes, students must either: (1) demonstrate that individuals provided informed consent for the project at the time, through procedures approved by the instructor; or (2) obtain consent from the individuals to use previously collected information according to procedures approved by the IRB (i.e., an application for exemption, expedited review, or full IRB review). Instructors of methods courses requiring student projects are

encouraged to send a memo to the IRB administrator listing the students and their research projects and indicating that the projects were conducted under the instructor's supervision and in accord with procedures approved by the instructor. The administrator will provide a memo verifying that the student projects did not require IRB approval.

Student projects in courses are subject to IRB review if they are designed at least partially to provide data for research and publication purposes. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate in research that will be submitted for publication. These projects constitute research and must be submitted to the IRB for approval beforehand before the project can begin.

3.8 Research Conducted at Another Institution

Prior to participation in a research project at another institution, the college researcher must obtain approval of the project by the IRB at SOWELA and all relevant institutions. For example, a college researcher engaged in research with College of Houston must secure approval from the IRBs at both institutions.

Changes in protocol or consent forms required by the IRB at the other institution must be brought to the attention of the IRB at SOWELA.

3.9 Research Conducted at SOWELA by Investigators from Other Institutions

SOWELA officials and faculty are sometimes approached by investigators at other institutions for cooperation in their research. For example, department chairs or deans might be asked to assist in the distribution of surveys to faculty or students. This research does not fall under the purview of the IRB unless: (1) college facilities and resources will be used; (2) college officials are actively engaged in or actively cooperate with or encourage participation in the research; or (3) college officials, faculty, staff, or students intend to use the findings or results of these studies for their own purposes. Investigators from other institutions are advised to contact **the Research Office** for additional information on the required procedures.

3.10 Research in Foreign Countries

Research conducted by college investigators in foreign countries remains under the purview and guidelines of the college IRB. While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct or consent process.

While human subjects in foreign countries merit the same level of protection as subjects in the United States, acceptable practices vary from place to place. Different traditions, mores and institutions may require different research protocols, particularly regarding informed consent, recruitment practices, and documentation. Special attention must be given to local customs, culture, and religious norms in drafting written consent documents.

Documentation of "local approval" is a prerequisite to IRB approval at the college. This approval should be from the local equivalent of the college IRB, local experts or community leaders. Researchers should provide sufficient information regarding the language and culture of the country in question. Researchers proposing international research should allow additional time for this review process.

3.11 Research at a Pilot or Feasibility Stage

Investigators sometimes conduct pilot studies designed to develop or refine research procedures and instruments. Although data collected through pilot or feasibility studies (including those involving only one human subject) may not be used in research reports and publications, pilot studies represent part of the research process that leads to the development of or contribution to generalizable knowledge. Therefore, these studies require the same scrutiny as full-scale research projects. Pilot studies should be identified as such in the "Application to Conduct Research using Human Subjects." Ordinarily the data collected from subjects as part of a pilot/feasibility study are not used for study findings. The consent document should clearly identify the project as a pilot study.

Experts reviewing draft research procedures or instruments are not considered human subjects, and IRB approval is not required for this.

3.12 Research Involving Secondary Use of or Archival Data

Federal regulations extend to the use of existing or "archival" data if it was originally obtained from persons who

would meet the definition of a human subject. Exempt category 4 states, "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."

This might include (but is not limited to) student test scores, academic achievement scores, attendance and/or discipline records, data previously collected in a research project, census records, etc. The application must indicate that the data is publicly available (with a description of how it is obtained) or provide a letter from the person s who is the owner or the keeper of the data indicating that permission has been granted for the use of the data in a research activity. Also, the data must be in existence at the time the application is submitted to the IRB.

3.13 Research Involving Tissue/Blood Samples

Research that is conducted on "waste" or "extra" human tissue or fluids must be submitted for review.

"Waste material" is material that is collected originally for clinical or diagnostic purposes only but is no longer needed. "Extra material" is material that is collected above and beyond what is needed for a clinical or diagnostic procedure. It is collected during the same procedure, but solely for investigational purposes.

The IRB may determine that research on waste material qualifies as exempt from full review. If the subject's consent to the clinical procedure outlines research use of the material as well, a separate consent form may not be required. Collecting and using "extra material" requires subjects' written consent and full IRB review.

3.14 Research Involving Deception

The IRB discourages deception in any form of experimental procedure. If an investigator believes that deception is necessary to conduct the research and is the only way to answer the research question(s), he or she must provide a detailed rationale to the IRB and ensure that psychological, social, and other risks will be minimized. Before approving deception in research, the IRB will require a procedure to be put into place that provides for a debriefing process, with the participant being given a statement to sign indicating that debriefing has occurred and that he or she understands that deception occurred and how.

3.15 Research Involving the Internet

For Internet research, investigators must protect the privacy and confidentiality of participants and obtain their informed consent. Investigators may not be required to obtain consent of persons to record information or communications in public Internet forums in which people do not have a reasonable expectation of privacy. For example, an investigator would need to obtain consent of people to record communications in a private listserv, but would not be required to do so in a public chat room with unrestricted access. In communications with persons in public or private Internet forums, investigators must not conceal their identities as investigators or mislead people about their purposes. Investigators must not communicate directly on the Internet with persons whom they believe are minors without their parents' permission.

In electronic surveys or interviews, investigators must take reasonable steps to protect people's privacy and confidentiality, taking into account the sensitivity of questions asked of them. For interviews or surveys on non-sensitive topics, e-mail is generally acceptable. Interviews or surveys on sensitive topics should be conducted on a secure Web site.

3.16 HIPAA and Research

The Health Insurance Portability and Accountability Act of 1996 was adopted with the goal of improving the efficiency and effectiveness of the healthcare system. It also carries with it an associated Privacy Rule that can significantly affect the way researchers obtain, use and disclose protected health information (PHI) in research involving human subjects. The minimum standard necessary requires that only the minimum amount of information needed for any specific purpose be used or disclosed. NOTE: HIPAA IS IN ADDITION TO, NOT INSTEAD OF, COLLEGE IRB POLICIES. WHEN HIPAA AND HUMAN SUBJECT PROTECTION REGULATIONS APPLY, BOTH SETS OF REQUIREMENTS MUST BE FOLLOWED.

Under certain circumstances, the Privacy Rule allows a covered entity to use or disclose PHI for research without an individual's authorization. Therefore, the IRB's role, under HIPAA, is to act on requests for a waiver or an alteration of

the Privacy Rule's Authorization requirement. The IRB may grant a Waiver of Authorization for studies meeting ALL of the following criteria:

- The use or disclosure involves no more than minimal risk to a subject's privacy, based on at least the following principles:
 - A plan to protect identifiers
 - A plan to destroy identifiers at the earliest opportunity that is consistent with the goals of the study, unless there is a health justification for retaining identifiers or retention is otherwise required by law
 - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by the study or law enforcement agencies.
- The research could not be practicably conducted without the waiver.
- The research could not be practicably conducted without access to and use of PHI.

If a waiver is obtained, please note that the following procedures must also be in place:

- The investigator must identify and justify what identifiable information is needed.
- Disclosures of PHI outside SOWELA must be tracked. The purpose of this tracking requirement is to provide patients, upon their request, with a list of where information about them was released for research and certain other non-treatment purposes without their knowledge. The following information must be tracked for each disclosure:
 - Name of individual
 - Date of disclosure
 - Name of person/entity that received the information
 - Brief description of PHI disclosed
 - Brief statement about the purpose of the disclosure
 - Disclosures must be made available to the individual upon request for 6 years following the disclosure
- Any changes to a waiver (for example, the addition of new sources of PHI) must be approved by the IRB.

HOW TO APPLY FOR REVIEW

4.1 The IRB Process

The IRB reviews a proposal first by assessing the risks and benefits of research participation. After determining that the research benefit outweighs the risks involved, the IRB turns to the consent process to ensure that potential subjects are fully aware of the risks and benefits and that they participate in the project voluntarily. The consent is a key element in the review. The IRB will also determine whether or not the scientific questions addressed in the protocol have adequate merit to justify the involvement of human subjects.

After reviewing all materials, the IRB may opt to approve, table, or reject the application. The IRB may require revisions in the protocol. After the investigator revises a project, the IRB reviews the project again to see whether its concerns have been adequately addressed.

To fully protect subjects, the IRB must approve a project before investigators start to work on it – even before they begin to recruit subjects, since recruitment strategies are part of the review. Although there are different types of review, many projects require “full” committee review. The initial full review will occur according the published submission deadlines. All IRB actions are communicated in writing to the investigator by the IRB staff. If the investigator is a student, the letter is addressed to the investigator in the care of the faculty sponsor.

4.2 Recommended Training: The CITI Course in the Protection of Human Research Subjects

Public access is no longer available but you can sign up as an independent learner.

The CITI training is recommended of faculty/staff submitting an application to the IRB, or who are supervising students submitting an IRB application, and by all students submitting an IRB application. The CITI course is hosted on secure servers at the College of Miami (www.citiprogram.org). The CITI training is completely web-based and self-paced. It consists of a number of course modules followed by short multiple choice quizzes. Modules do not have to

be completed at one sitting. Applicants register themselves, can access their records at any time, request new passwords, and print out their completion report. Course curriculum varies between learner groups. Students are in a different learner group than faculty, and biomedical /science applicants are in a different learners group than those in the social and behavioral sciences. The “Basic CITI Course for Faculty and Staff” should take approximately three to four hours to complete. There are two levels of student courses. The “Basic Course for Students” is intended for student researchers or subjects involved in studies that qualify as greater than “minimal risk” or for students requiring a more in-depth education in the protection of human subjects. This course should take approximately an hour to ninety minutes to complete. The other student course, “Students in Research,” is designed for students who may be involved in a human subjects research study as an investigator and/or subject. It is intended for academic projects and/or research studies that qualify as no greater than “minimal risk.” The “Students in Research” course requires approximately 20-25 minutes.

Applicants submitting as *exemption* request do not have to take the CITI training prior to submission.

4.3 Primary Types of Review

The IRB reviews research projects according to the risk to subject and at one of three levels defined in federal regulations:

- 1) full IRB review,
- 2) expedited, IRB review, and
- 3) administrative review for exemption from full IRB review.

The IRB will determine the level of review.

4.4 Full Review

A project that involves greater than minimal risk or does not qualify for exempt/expedited review requires approval from the IRB composed of members qualified to review research in that field. Research that requires full committee review includes:

- research that involves greater than minimal risk;
- non-exempt research that involves children or other vulnerable populations;
- research that involves experimental drugs or devices;
- research that involves invasive procedures; and
- research that involves deception.

Survey research that involves sensitive questions or information about sexual practices or illegal behavior is subject to full review, in keeping with federal guidelines. Additionally, any survey or interview that is likely to be stressful for the subject requires full committee review. The IRB administrator will make this determination.

The administrative staff screens all applications before they are assigned to the IRB. *If incomplete, the application is returned to the investigator.* The IRB reviews only complete applications (see 4.1). After review, the IRB will act on the application. Possible committee decisions include:

- approved as submitted;
- approved with minor requests for minor changes;
- approved with contingencies (conditions that must be met before final approval is granted) – most common decision;
- deferred pending receipt of additional information or major revisions; or
- disapproved.

All non-exempt research is subject to continuing review at least bi-annually.

4.5 Expedited Review

To qualify for expedited review, a research project must be limited to the activities that are federally approved for expedited review and incur no more than minimal risk for participants, or be a minor change in previously approved research that involves no additional risk to the research subject.

The activities approved in the federal regulations for expedited review are:

- Clinical studies of drugs and medical devices, only when condition (a) or (b) is met. (a) research on drugs for which

an investigational new drug application (21 CFR Part 312) is required. (*Note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); or (b) research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with cleared/approved labeling.

- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children (as defined by the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in this research, under the applicable law of the jurisdiction in which the research will be conducted), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

- Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at a delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

- Collection of data from voice, video, digital, or image recordings made for research purposes.

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and additional risks have been identified.

The researcher must demonstrate in the application how the proposed project activities fall into one or more of these categories. To apply for expedited review, investigators complete the Human Subjects Application form and indicate that they are requesting an expedited review in the appropriate section.

The IRB administrator will ensure that all of the elements essential for review, including consent forms and supporting documentation, have been submitted. The administrator will then forward the application for review and approval by either the IRB subcommittee or the full Board, depending on the submission deadlines. Following review, the subcommittee will approve the application (perhaps with contingencies) or forward it to the full Board for review. In accordance with 45 CFR 46.110(c), the applications approved under the expedited procedures by the subcommittee

are reported to all members of the full Board. The full IRB shall receive a copy of the minutes from the subcommittee meeting listing the protocols that were reviewed and the decision.

4.6 Administrative Review for Exempt Status

While research that involves only minimal risk to human subjects is sometimes exempt from full IRB review, it is still subject to review. Investigators do not have the authority to determine whether research involving human subjects is exempt from full review [45 CFR 46.101(b) and (c)]. Researchers must file an application requesting that the IRB determine exempt status for a project. Exemptions are approved for a specific research project conducted by specific investigators. Departments cannot receive blanket exemptions for unspecified research (e.g., surveys, public observations) to be conducted in the future.

Projects that involve contact with subjects may still qualify as exempt. In general, the federal guidelines for research on human subjects allow a project to be exempt from full review only if the research involves no foreseeable risk to the subject and the procedures are limited to the following criteria:

- 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 (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 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 paragraph (2) of this section, if: (i) the human subjects are elected or appointed officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and 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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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 Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The application form is available from the Research office or its web site. Copies of the written consent form should be filed with the application or justification for a waiver of written documentation should be provided. See 45 CFR 46.117.

The IRB administrator will decide whether the project qualifies as exempt, and confirms the decision in writing. If the project does not qualify as exempt, it will be submitted to the appropriate committee based on the posted deadlines. Again, the investigator will be notified in writing.

Exemptions are approved for a maximum of five years after approval. To continue research after that time period, investigators must apply for another exemption.

4.7 Appeal of IRB Determination

Investigators who have been required to make revisions in their applications or whose applications have been disapproved may request further information regarding its reasons from the IRB or may ask the IRB to reconsider its decision. Such requests must be made in writing and will be considered by the IRB at the next convened meeting, if submitted according to the published deadline for submission of materials to the IRB. At its discretion, the IRB may invite investigators to meet with the IRB or a subcommittee of the IRB to collect additional information or to explain the reasons for its decision. The IRB will provide investigators with a written explanation of its reasons or its decision upon reconsideration. The IRB's decision will be final, and no further appeal can be made.

4.8 Application Forms and Original Signatures

All forms that an investigator must file with the IRB to apply for review are available with specific instructions on the IRB website www.sowela.edu or from **the Office of Research**. The IRB members can help researchers determine which application is appropriate for a project. The forms available are:

Application to Conduct Research using Human Subjects
Application for Revision to a Currently Approved Protocol
Application for Renewal

A signature page provides space for the signature of the principal investigator and co-investigators. An original signature certifies that the investigator will be actively involved in the research project and has made a commitment to protect the research subjects according to the federal regulations and institutional policies. Faculty sponsors must sign all student research proposals. Department heads (or college deans) must sign all faculty, staff and student proposals. [Note: Signature from the department head (or college dean) is not required for applications requesting exempt approval.] Signatures must be original.

All other documents submitted to the IRB (such as interim reports, requests for revisions, adverse events reports, renewal applications) also require original signatures. Staff signatures will not be accepted. The principal investigator remains ultimately responsible for the protection of subjects.

Finally, before submitting the application with original signatures, investigators must:

- retain a copy of all submitted materials for their own records; and
- attach the appropriate number of copies required:
 - for full IRB review – original plus 7 copies of the application, appropriate consent documents, interview questions and/or questionnaires, and any additional information.
 - for expedited review – original plus 2 copies of the application, appropriate consent documents, interview questions and/or questionnaires, and any additional information.

4.9 Preparing the Application

To submit a project to the IRB for review, an investigator must complete the application form according to detailed instructions and enclose supporting material as required.

A fully complete application form will include:

- an up-to-date version of the appropriate application form (available online at ORSPA website);
- answers to *every* question on the form;
- appropriate attachments to the application;
- a lay abstract describing the purpose of the study;
- a description of the study population, criteria for inclusion/exclusion, the number of subjects, and the process of identifying potential subjects, and any other plans related to the section selection of subjects;
- a description of the tasks that subjects will be asked to perform;
- a full description of the anticipated risks and benefits of participating in the student study;
- an explanation of how risks will be minimized;

- documentation of provisions to care for subjects in case of accident or injury (if applicable);
- a description of procedures for maintaining confidentiality;
- a description of the process by which informed consent will be obtained from the appropriate individuals;
- documentation of any required approvals or applications for approval from other committees and/or from cooperating agencies;
- all supporting materials and documents, including protocol, interview schedules, solicitation letters, advertisements, and any survey instruments; and
- appropriate original signatures, including the faculty sponsor's signature for student research, and the department head/college dean (when applicable).

The application form will serve as background information for all future reviews of the study. For this reason, “see protocol” or “see attached” are not adequate responses to any application question. The application is designed to provide the IRB with sufficient information about the proposed research activity to make the following determinations prior to approval:

- Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose them to risks.
- Risks are reasonable in relation to anticipated benefits, if any, to participants and the importance of knowledge that may reasonably be expected to result.
- Selection of subjects is equitable. In making this determination, the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, including children, prisoners, pregnant women, persons with impaired decision-making capabilities, and economically or educationally disadvantaged persons.
- Informed consent is sought from each prospective participant or the participant's legally authorized representative and is appropriately documented.
- When appropriate, the research plans make adequate provisions for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and confidentiality of the data.
- For participants who are likely to be vulnerable to coercion or undue influence, additional safeguards are included to protect their rights and welfare.

No form can address adequately the wide diversity of research at SOWELA. Principal investigators should use the form to convey the nature and specifics of the project proposed and attach appendices as necessary.

4.10 Designating the Principal Investigator

The IRB recognizes only one Principal Investigator (PI) for each project. The PI must be a faculty member, student or staff member at SOWELA. On research conducted by students, a faculty member must serve as the sponsor and assume responsibility for exercising appropriate oversight of the student's research.

The PI, including the faculty sponsor in the case of students, must personally review and sign all applications, revisions, renewals, and other documentation submitted to the IRB. The PI is responsible for identifying key personnel involved in the conduct of research, monitoring their activities, informing the IRB of proposed changes, adverse events, and responding in a timely fashion to inquiries or requests from the IRB.

All official correspondence is addressed to the PI. In the case of student researchers, correspondence is addressed to the student, care of the faculty sponsor. All correspondence is sent via campus mail.

Any change in the PI or in the PI's status that affects the project must be communicated to the IRB. [See section 6.2 Making Changes to Research Protocols.]

4.11 Summary of Proposal: Rationale and Methods

Investigators must provide a summary of their proposed research in non-technical terms. For any risks associated with human research to be warranted, and hence, for research to be ethical, studies must have scholarly or scientific merit. Any study that does not have the potential to contribute to knowledge or that is fundamentally flawed in its methods cannot be approved by the IRB. When research is not flawed, but could be strengthened in the opinion of IRB

members, the IRB may provide recommendations to investigators that they may follow at their discretion.

Investigators should summarize the rationale for the research, including the research questions the study is intended to answer or the knowledge to be contributed by the study in the lay summary. This section should not be used to describe the methods in the proposed research.

Investigators must describe the nature of the intervention or interaction with potential participants or the nature of private information to be collected and analyzed. Both the general methodological tradition (e.g., qualitative versus quantitative) and specific methods (e.g., participant observation, interviews, surveys) should be described. The IRB examines applications to ensure that the research methods are appropriate given the research rationale and questions.

The investigator must provide information on specific procedures, the nature and number of interventions or interactions with participants, and the analytical procedures. Researchers using participant observation or anthropological field work methods should be specific regarding where and among whom observations will be recorded and how they will identify themselves. The IRB discourages covert participant observation in which the investigator conceals his or her identity as a researcher and will require a clear justification for this approach. The investigator must demonstrate that the research could not be conducted overtly and that participants will not be harmed or exposed to undue risk.

4.12 Specifying the Number of Research Subjects

The application must specify the number of study subjects to be recruited and tested the number to participate, grouped by age, gender, and population diversity. Exceeding the recruitment limits approved by the IRB is a violation of the protocol. The IRB must give prior written approval for any increase in subjects.

The IRB is charged with the protection of human subjects from the earliest contact for possible recruitment. All subjects who go through the recruitment process screening must be accounted for, even if they fail or decline participation. When calculating the number of subjects in research design, please include a number large enough to account for this group.

If it is difficult to predict how many subjects will be eligible or be attracted to a study, the optimum number should be specified. Responses such as “don't know” or “as many as we can recruit” to questions about the number of subjects are not acceptable.

Multicenter studies, in which data will be pooled and recruitment may vary, present a special problem for investigators. The application should provide information about the total picture, including both the number of subjects to be studied at the college or by college researchers and information on overall recruitment goals.

4.13 Women and Minorities in Study Populations

Research benefits and burdens should be distributed fairly. If an individual or group is denied access to a clinical trial that might be beneficial, or if some people are singled out to bear the burden of risks associated with a study, the requirement for fairness is not met.

In accordance with the policies of the National Institutes of Health, the IRB requires applicants for federal funds to provide data regarding the subject populations by gender and minority group. Studies with the potential to address issues relevant to both genders must recruit both genders, and include minority groups in a study population wherever feasible. Researchers must justify the exclusion of any group of individuals. The IRB makes exceptions if there is adequate scientific justification for exclusion, such as when a disease predominates in one gender or the focus of the research question is on a specific group.

4.14 Students or Employees as Research Subjects

Though the researcher must be careful to avoid potentially coercive behavior, the very nature of the relationship with the subject can create the appearance of coercion. For this reason, researchers should be aware of the potential for coercion that exists when a research subject is also a student, employee, colleague, or subordinate of the researcher. Therefore, researchers should avoid using their own students or employees as research subjects.

If there is sound scientific reason to include their own students, researchers should:

- ensure that students clearly understand that participation will not influence class standing, grades or other

benefits under the control of the researcher.

- limit the use of extra credit points as a reward for participating: points should be used only when the research is closely tied to the course subject matter and should not raise a student's grade by a whole step (for example, from a B to an A). Students should be offered an alternative assignment of a non-research nature that entails the comparable level of time as the research activity. Students who participate in part, but not all of the research should be offered partial credit for participation according to the amount of time spent (an alternative assignment comparable in time must be offered to enable students to receive full credit).
- avoid using class time to recruit subjects or complete study instruments.

Researchers who select colleagues or subordinates as research subjects must be able to provide a rationale other than convenience for recruitment and must show that the recruitment method does not imply penalty or compromise by refusing to participate. Recruitment through bulletin board advertisements or by a third party is preferable.

A detailed description of **how** students and colleagues will be recruited and how coercion will be avoided must be included in the information submitted to the IRB.

4.15 Children as Subjects

All research that involves minor subjects is subject to the application of 45 CFR 46 Subpart D. In all cases, inclusion or exclusion of children is reviewed for appropriateness as defined in the regulation.

In general, if research involves greater than minimal risk, children can be included in the study population only if there is direct personal benefit to the child. This restriction applies to research in both the health sciences and the social sciences. A research protocol that involves anything more than minimal risk and that offers no potential benefit to the subject cannot include children unless all conditions of 45 CFR 46.406 are met. Investigators claiming this provision in 45 CFR 46.406 should be prepared to provide justification.

4.16 Prisoners and Institutionalized Persons

All research that involves prisoners is subject to the application of 45 CFR 46 Subpart C. Prisoners and other institutionalized persons should neither bear an unfair share of the burden of participating in research nor should they be excluded from its benefits to the extent that voluntary participation is possible. Persons confined to institutions must not be selected as research subjects simply because they represent a convenient population to study.

The IRB recognizes the special vulnerability of prisoners and other institutionalized persons who live under the supervision and formal authority of others. Prisons include jails, detention centers, and state and federal prisons. Institutions include psychiatric centers or mental hospitals, development centers for people with developmental disabilities, nursing homes, and similar facilities. The IRB requires that research involving prisoners and institutionalized persons have risks commensurate with risks that would be accepted by non-institutionalized persons and that any possible advantages accruing to individuals are not of such magnitude that their ability to weigh the risks and benefits of the research, given an environment of limited choice, is impaired.

Procedures for selection of research participants in prisons should be fair and immune from the influence of prison authorities or prisoners. Investigators must ensure that participation of prisoners will not have bearing on decisions regarding parole and prisoners will be informed of this. In view of violations of privacy that may occur in prisons, investigators must also take appropriate steps to maintain confidentiality in such settings.

To carry out its responsibilities under Subpart C, the IRB must appoint an additional committee member who serves as a prisoner representative.

4.17 Persons who are Impaired in their Decision-Making

The ethical principle of respect for persons requires respect for the autonomy of individuals and special protections for those with diminished autonomy. Some persons may be limited in their competence to make informed decisions about their lives by virtue of mental, intellectual, or cognitive disabilities. Although investigators should be sensitive to the possibility that persons with disabilities may have limited capacity to consent to participating in research, they must not presume incompetence simply because a person has a disability diagnosis or label. Investigators must respect the autonomy of all persons unless there is clear evidence that they are incapable of decision-making.

For persons who have been formally adjudged incompetent and appointed a legal guardian, their guardians must

provide consent for them to participate in research, with appropriate provisions for assent by the individual. Some adults who are incompetent to make major life decisions by virtue of a disability have not undergone a formal legal proceeding. In these instances, the IRB may require that informed consent be provided by a parent, spouse, or other “next of kin” or by the assignment of an advocate or witness to oversee the consent process.

Persons with mental, intellectual, or cognitive disabilities must not be unilaterally excluded from participation in general research without justification.

4.18 Incentives for Participation

The IRB reviews and approves incentives offered to subjects to participate in research. Subjects cannot receive payment to assume risk, but can receive compensation for the time and inconvenience involved in participation. Incentives may include monetary payment, course credit, gift certificates, toys or educational materials for children, and other items or services. Incentives must not be of such an amount as to result in undue influence on an individual's decision to participate, especially in the case of persons who are poor. In addition, incentives must not be provided on a schedule that results in coercion or undue influence on an individual's decision to continue participation. That is, incentives must not be withheld as a condition of an individual completing the research. If an individual withdraws early, payments or incentives must be prorated to reflect the time and inconvenience of the individual's participation up until that point.

Payment to research participants must be arranged in a way that minimizes potential violations of privacy. For example, investigators should try to avoid linking subjects to participation in sponsored research involving sensitive topics (e.g., HIV and AIDS, drug use).

The IRB discourages lotteries for the payment of research participants, since these may create unrealistic expectations. Incentives for participation in research are not considered as benefits of the research and should not be reported as such on the IRB application.

4.19 Advertising and Recruitment

Advertisements are part of the informed consent process and subject selection process. Samples Copies of all advertisements, such as flyers, newspaper ads, radio and television announcements, URLs, bulletin board tear-offs, and posters, along with an explanation of other methods of recruiting subjects, must be submitted to the IRB.

Advertisements should be submitted with the application or as soon as the principal investigator decides to use them. The content of advertisements should be limited to:

- names of the investigators and the college identified by name along with contact information,
- purpose of the research,
- general eligibility criteria, and
- straightforward and truthful descriptions of potential benefits and risks and payment (if applicable).

Advertisements should include the word “research” and should not claim, explicitly or implicitly, that the research is treatment or is superior to any current practice. Extravagant attention-getting devices such as extremely large, bold typefaces and dollar signs are prohibited. Statements of payment should not be in larger type than the rest of the ad. Advertisements should not pressure readers into participating. All recruitment materials should include the statement, “This project has been reviewed by the SOWELA Technical Community College’s Institutional Review Board (337) 421-6565.”

THE PROCESS OF CONSENT

5.1 A Process – Not a Form

Since subjects retain the right to withdraw from a study, consent is an ongoing process. It starts well before any forms are signed and continues until participation is complete.

The informed consent process is different from the consent form. The process involves meeting with a potential subject, determining whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation with that subject. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed.

If consent is to be informed, the subjects must genuinely understand the study. Hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to demonstrate their understanding of the procedures, risks, and benefits of the study in which they are agreeing to participate.

5.2 When to Discuss Participation

To achieve understanding, potential subjects should not be presented information all at once or only at the last minute. People need time to think about whether or not they want to participate. They may wish to discuss the decision with family, close friends, or religious advisors. They should not feel rushed or coerced. They need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it.

Information must be comprehensible. Even highly educated people must have technical information presented in simple terms. The best method of expression will vary with the proposed population. Researchers may explain a project involving optometry using discipline-specific technology when approaching students of optometry for example. Laypersons, however, should receive as simple and straightforward a presentation as possible. Some of the suggestions offered here for writing comprehensible consent forms are also useful for presenting information in discussions.

5.3 General Requirements of a Consent Form

Federal regulations for human research identify some information as “essential” to understanding any research project [45 CFR 46.116(a)&(b)]. At a minimum, investigators should:

- explain the purposes of the research;
- report the expected duration of the subject's participation;
- describe the procedures to be followed;
- identify any procedures or products that are experimental;
- explain why the subject is eligible to participate;
- describe any foreseeable risks or discomforts that the subject might experience;
- describe any benefits to the subjects or to others that can reasonably be expected;
- disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- explain the confidentiality of any records that identify the subject;
- for research that involves physical contact or physical activity, explain whether compensation or medical treatment will be available if the subject is injured and provide referrals for further information;
- identify people who can answer questions about the research, including the principal investigator (and the faculty sponsor if the investigator is a student) and the institutional IRB; and
- explain that participation is voluntary, that refusal to participate will involve no penalty or decrease in benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at anytime without penalty or loss of benefits. (Note: If the potential subjects are students, it should be clearly explained that their class standing will not be affected by their decision as to whether or not to participate in the study.)

In addition to this essential information, circumstances may require that researchers:

- explain conditions under which the investigator can remove people from the study without their concurrence regardless of their consent .
- explain any additional costs of participation in the study.
- discuss the consequences of, and the procedures for, withdrawing from the study.
- declare that research findings that could affect participants' willingness to remain in the study will be disclosed to them.
- state the approximate number of people involved in the study.
- identify pilot or feasibility studies. Some subjects are willing to participate in a study that has a track record but are not willing to participate in a pilot phase of a study. Participants must be told if they are among the first people to receive the intervention or treatment.
- inform women of child-bearing age whenever a pregnancy test is part of the research protocol. They must also be told whether such tests will be repeated during the course of a research project and whether use of contraceptives is a requisite to participation. Men, too, must be told if contraception is recommended for them.
- explain that a treatment or procedure might involve currently unforeseeable risks (including risks to

- an embryo or fetus, if a participant is or become pregnant).
- make clear whether the procedures or drugs used in a study are standard, standard but used in a non-standard manner, or experimental.
- if the study involves experimental drugs or devices, inform the subject that the research and the medical records may be reviewed by the Food and Drug Administration (FDA) and by the company sponsoring the research.
- avoid stating that drugs or devices have been approved for human use by the FDA if any part of the study is outside the licensed and approved indications of those items. Patients interpret such a claim to mean that the FDA has licensed and approved this use of the item, not that the FDA has merely granted permission to investigate the use of the item.
- distinguish between consent to a study and consent to a treatment. In “treatment studies” (in which a patient who is undergoing a treatment is given a choice between undergoing that treatment as part of a study or undergoing it in a standard health care context), the study and the treatment involve different benefits, risks, and alternatives.

5.4 What Must Be Said About the Conduct of the Research

Confidentiality/Anonymity

The researcher should must describe the level of confidentiality or anonymity of the research data and the measures that will be taken to ensure that protection is maintained. It is important to understand that confidentiality and anonymity are different forms of protection of research data. Confidentiality means that a link exists between the subject's name and the subject's individual participation in the study. Adequate explanation should be provided to the subject regarding the protection of this link, access to the information, and any limits to the protection. Anonymity allows a subject to participate without recording any identifiable information. No one, including the investigator, will have the means to match an individual's responses with their identity.

The phrase “only aggregate data will be presented” is appropriate only when it is true. This phrase implies that the researcher will not describe individual subjects or the subject as an individual, even if the subject has a unique event. What is more common, however, and what the subject should be told, is that the subject's identity will not be disclosed.

Conflict of Interest

The college IRB requires that researchers inform their subjects of any conflicts of interest in the research. For example, researchers should disclose any personal stake in companies that might be affected by the research might affect.

Finder's Fees

Companies sometimes offer researchers incentives for recruiting subjects or conducting research on an investigational drug or device manufactured by the company. The incentive may be either a monetary fee or a donation of equipment or materials. Researchers must report these incentives to the IRB, which may require that this information be disclosed to prospective subjects.

Payments to Research Subjects

If researchers plan to compensate subjects for participating in a study, the consent form must describe the terms of payment and the conditions under which subjects would receive partial compensation or no compensation (for example, if they withdraw from the study before their participation is completed). See section 3.14 Payment to Subjects

5.5 Assessing the Subject's Understanding

The responsibility of ensuring that potential participant genuinely understands the research, including the risks and benefits involved, falls upon the researcher, not upon the prospective subject. Hence it is critical to the consent process that the researcher not only field questions, but also asks questions. Asking questions can further the discussion, elicit questions from the prospective subject, prompt the prospective subject to think more carefully about the project, and help the researcher decide whether the person has adequately understood the project. These questions must be prepared in advance.

Useful questions are open-ended and non-directive. Such questions do not imply a correct answer and invite greater discussion than a simple “yes” or “no.” Open-ended questions often begin with “what,” “where,” “how often,” “when,” and “please describe.” Examples of open-ended questions are:

“So that I can be sure you understand what is expected of you here, would you please explain to me what you think we're going to ask you to do?”

“Describe the purpose of the study in your own words.”

“What more would you like to know?”

In contrast, examples of closed-ended and far less useful questions are:

“Do you understand?”

“Do you have any questions?”

Closed-ended questions tend to stop discussion and therefore should be avoided.

5.6 Documenting the Subject's Consent with a Consent Form

Once a subject understands a study and expresses a willingness to participate, researchers must document the subject's consent with a consent form. A signature certifies the subject's willingness to participate, though a signed form is not equivalent to assuring that the subject has understood the research. Including a date with the signature avoids confusion about whether the subject began to participate before giving consent.

A researcher may need to prepare several consent forms, depending on who the subjects are likely to be. For example, a single project may require a consent form for the guardian or parent of a child, a consent form for a competent adult subject, and a simplified assent form for the 8- to 17- year-old or for the adult who is not competent to give consent alone, and a script for obtaining assent from children younger than 8. [See following sections for discussion of assent forms.] Foreign-language versions of the consent forms are necessary for enrollment of people who do not speak and/or comprehend English. [See section 4.11 for discussion of translated consent forms. This section also discusses unexpected enrollment of non-English speaking subjects.]

The person who prepares the documents should:

- Print all documents in font no smaller than 12 points to make sure they are readable. If the subjects will have difficulty with 12-point font, a larger font is necessary.
- Place the title of the study on the first page, exactly as it appears in the IRB files absent a compelling reason to shorten or change the title. “Informed Consent” is not an acceptable title because it obscures the fact that informed consent is a process, not the document itself, and implies a completeness that the form may not have.
- Number each page after the title page so that pages appear in a logical order and missing pages are readily noted (example: “page 2 of 4”).
- Include a consent form version date. This date should be updated each time a new version of the consent form is approved by the IRB.

Format and Specific Requirements

The consent form should must :

Identify the researcher(s) by name along with their college and departmental affiliation on the first page of the consent form.

If the project is conducted by faculty or staff, the first page of the consent form should be printed on departmental letterhead. For student projects, the words “SOWELA Technical Community College” should appear in the header on the first page, and the faculty sponsor's name and phone number should be given with the student's name and contact information.

Invite participation.

Consent forms should “invite” participation. They should not say that a friend or a school's principal recommends participation, nor should they “offer the opportunity” to participate.

Summarize cautiously.

Information described earlier in the consent form should be summarized only in order to clarify. Summaries that suggest a warning or limitation of liability or opportunity for redress are not acceptable. Examples that are unacceptable are:

“You understand that ...”

“The possible risks associated with this study have been presented.”

“The method and purpose of administration of this study have been explained to you.”

“You have been made aware of certain risks and consequences.”

Readability and Technical Language

In writing consent forms, researchers should must:

- Use the recommended format (see Sample Consent Forms)
- Use declarative sentences suited for an eighth-grade reading level.
- Write in the second person (“you”) rather than the first person (“I”), and avoid shifting from one to the other.
- Avoid strike-out formats (such as “You/Your spouse/Your child”), since they depersonalize the form and often make it difficult to read.
- Keep the description of the study as brief as possible, even if the study is complex. The details can be placed in an appendix.
- Use paragraph headings and illustrations. Use flow charts or calendar-like tables to explain studies that involve multiple visits, that ask subjects to go from one place to another, or that involve different protocols depending on research benchmarks.
- Describe quantities in lay terms (teaspoons, for example). Communicate size with an illustration or a reference common household object of the same size.
- Ask someone who is unfamiliar with the field to read the final draft of a consent form. Software packages that evaluate a text’s “readability” may be helpful.
- Replace technical language with lay terms.

5.7 When to Submit the Form to the IRB

Researchers must submit consent forms when they first apply for IRB review and approval, and when they apply for continuing review. Since the standards for consent forms change over time, in part due to changes in regulatory mandates and community styles and expectations, the IRB reviews the form at renewal to ensure that it is up to date.

In addition, the IRB may ask researchers to modify consent forms at other times, when circumstances warrant. Any revisions made to a previously approved consent form must be submitted to the IRB for approval *before* use.

5.8 When the Consent Requirement can be Waived

On rare occasions, the federal regulations for human subjects research allow a waiver of the requirement for informed consent. For example, a waiver is possible if a study investigates certain aspects of public benefit or service programs (see 45 CFR 46.116[c]). Also, either a waiver or a consent process that omits or modifies the essential elements of informed consent is possible if the IRB finds that:

- the research involves no greater than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research would be impracticable without the waiver or alteration; AND
- the subjects will be informed of the study when it is over (if at all possible).

Only the IRB can waive or modify the consent process. Researchers are not authorized to make this decision.

5.9 Confidentiality

The use of confidential information is an essential element in many research studies, especially in the social and behavioral sciences. The IRB reviews research applications with regard to the necessity of obtaining private and confidential information and the safeguards used to protect breaches of confidentiality that could lead to a loss of privacy that could lead to a loss of privacy and potential harm to participants. Potential harms include the risks of criminal or civil liability or damage to financial standing, employability, insurability, or reputation, stigmatization, and damage to social or family relationships.

The more sensitive the data collected about participants, the greater the protections of confidentiality the IRB will require. Protections and safeguards may include the use of identifying numbers for participants, the storage of data in a secure location (e.g., locked office or file cabinet, with limited access), and computerized security systems (e.g., password protected or encrypted). Investigators should be aware and take appropriate precautions against unauthorized access to computerized data. Violations of confidentiality can occur even when college researchers only have access to participant identification numbers and not their names. For example, if investigators receive data containing identification numbers from another source, which can link the numbers with names, a breach of security at that source can compromise the confidentiality of participants.

Whenever possible, surveys and questionnaires should be anonymous, with no information about participants' names and identifying information recorded.

Although the IRB generally requires investigators to protect the confidentiality of participants, it may waive this requirement when participants explicitly and with knowledge of possible consequences agree to have their names, pictures or other identifying information disclosed in publications or presentations or serve as co-authors of reports or published materials.

5.10 Certificates of Confidentiality

The Public Health Service Act provides protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research. Protection is given in the form of a certificate of confidentiality issued upon application for a particular project (note: federal funding is not a prerequisite).

A “Certificate of Confidentiality” protects subjects' anonymity by protecting research records from compelled disclosure. Protection is available only to “research” (defined as a systematic investigation designed to develop or contribute to generalizable knowledge) under two conditions: (1) the research is on sensitive topics and (2) the additional protection is necessary to achieve the research objectives. Research would be considered sensitive if it involves the collection of:

- information about sexual attitudes, preferences, or practices;
- information about the use of alcohol, drugs or other addictive products;
- information about illegal conduct;
- information that, if released could be damaging to an individual's financial standing, employability, or reputation within the community;
- information in a person's medical record that could lead to social stigmatization or discrimination;
- information about an individual's psychological well-being or mental health; or
- genetic information.

A Certificate of Confidentiality does not prohibit voluntary disclosure of identifying information about research subjects. Researchers, therefore, may voluntarily disclose matters such as child abuse or a subject's threatened harm to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate the circumstances of disclosure.

In some instances, the IRB may require an investigator to obtain a Certificate of Confidentiality. Additional information is available through the NIH (<http://grants1.nih.gov/grants/policy/coc/index.htm>) web site.

5.11 Children and Adolescents

Written parent al (or legal guardian) permission is required for studies involving children under the age of 18. If the research involves greater than minimal risk, signatures from both parents are required unless the second signature is not reasonably available. A single signature is sufficient if only one parent has legal responsibility for the care and custody of the child or if one parent is deceased, unknown, or incompetent. Parental permission is documented in a form similar to a consent form for an adult subject, but tailored to invite “your child” to participate rather than “you.”

The IRB can grant a “waiver of parental consent,” but does so only on rare occasions and only if (1) the research will yield great benefit to the population being studied and (2) the procurement of parental consent would pose a considerable risk to potential subjects.

Once parental permission has been obtained, the agreement of the child is required. Parental permission may overrule a child's decision not to participate in therapeutic settings.

The child's agreement is documented with an “assent form,” a child-friendly document that outlines the essential information about the research. All children between 8 and 17 years old should receive an opportunity to assent; most children 8 years old or older have the cognitive and emotional maturity to understand a research project and to decide whether they want to participate in it.

Some children under the age of 8 may also be capable of granting and withholding assent, and the IRBs ask researchers to be sensitive to the needs of these children on an individual basis. Researchers should draft a form (or a verbal script) that is age-appropriate and study-specific, considers the typical child's experience and level of understanding, and treats the child respectfully while conveying the essential information about the study. The form (or script) should:

- state why the study is being conducted;
- describe what will happen and for how long or how often;
- state that the decision to participate belongs to the child, and that refusal or withdrawal is “okay;”
- explain if participation will hurt and, if so, for how long and how often;
- describe the child's other choices, if any;
- describe any good things that might happen;
- mention any compensation for participating; and
- ask for questions.

The document should be no longer than one page if possible. Illustrations can be helpful, and larger type is easier for young children to read. Studies involving children who are unable to read should provide appropriate procedures for a verbal assent process. Studies involving older children or adolescents should include more information and may use more complex language.

Subpart D of 45 CFR 46.401-409, “Additional Protections for Children Involved as Subjects in Research,” outlines the conditions of participation for minor subjects [<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>].

5.12 Consent and Language Barriers

When planning research that will include non-English speaking subjects, researchers should prepare consent forms in English and in the other relevant language(s). The IRB may consult with language experts or require a “back-translation” into English.

As an alternative to translated consent forms, the IRB may approve a process consisting of an oral presentation of informed consent information in conjunction with a short form document stating that the elements of consent have been presented orally and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must receive copies of the short form document and the summary.

If a subject understands English but does not read or write English, an impartial witness should document that the subject understands the study and the consent process and consents to participate.

5.13 Cross-Cultural Consent Issues

The requirements for documenting informed consent vary among cultures. The IRB does not exempt from the consent requirement projects conducted in foreign countries or with other cultural groups here, but can waive the requirement for written documentation of consent. In some settings, the process of signing the form is very intimidating and is thought to be riskier than the research itself.

Researchers planning to conduct cross-cultural research must justify the proposed method of documenting consent. The justification must include a description of any customs that constrain the typical informed consent process.

Subjects in foreign sites should receive referrals to local contacts for answers to any questions they may have about the research or about their rights.

REPORTING UNANTICIPATED PROBLEMS TO THE IRB

Federal regulations [45 CFR 46.103(b)(5) and 21 CFR 56.108(b)(1)] require the IRB to ensure that investigators promptly report “any unanticipated problems involving risk to subjects or others.” The IRB defines unanticipated problems involving risk to subjects as any problem or event which in the opinion of the investigator was unanticipated, serious AND at least possibly related to the research procedures.

These should be reported to the IRB within 10 working days using the required reporting form.

6.1 What to Report

The following events meet the IRB's definition of unanticipated problems involving risk to subjects or others and should be reported within the 10 day time frame:

- a) Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths or other problems) which in the opinion of the investigator was unanticipated, involving risk to subjects or others, and was possibly related to the research procedures.
- b) Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur.
- c) Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject.
- d) Any publication in the literature, safety monitoring report (including Data and Safety Monitoring Reports), interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
- e) Any breach in confidentiality that may involve risk to the subject or others.
- f) Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff.
- g) Any other serious and possibly related event which in the opinion of the investigator constitutes an unanticipated risk.
- h) Any event that requires prompt reporting according to the protocol or the sponsor.
- i) Incarceration of a participant.

Note that issues such as whether the event was on-site or off-site or whether the event involved a death are no longer of primary relevance in determining what should be reported. If the event meets all 3 criteria of the IRB's definition of an unanticipated event, it should be reported using the reporting form within the 10 day time frame.

6.2 Definitions

Unanticipated (unexpected) problems/events are those that are *not* already described as potential risks in the consent form, *not* listed in the CPHS application or *not* part of an underlying disease. **Anticipated** (expected) problems/events do NOT meet the IRB's definition of an unanticipated problem involving risk to subjects or others.

Serious problems/events are those which in the opinion of the investigator involve risk to subjects or others. Examples may include death, hospitalization, disability as well as breach of confidentiality. **Non-serious** problems/events do NOT meet the IRB's definition of an unanticipated problem involving risk to subjects or others.

Problems/events that are unanticipated or unexpected and serious should be reported to the IRB within 10 working days *only* if in the opinion of the investigator they are possibly, probably or definitely **related** to the research procedures. Those serious, unanticipated problems/events that the investigator deems unlikely or **not related** do NOT meet the IRB's definition of an unanticipated problem involving risk to subjects or others.

Follow-up reports on previous events should be reported as an unanticipated problem involving risk to subjects or others if the initial event itself met the IRB's definition of an unanticipated problem AND in the investigator's judgment, this follow-up report adds value to the initial report.

Reports of off-site events on studies that are closed at this site should be reported as unanticipated problems if the event meets the IRB's definition of an unanticipated problem/event AND in the investigator's opinion, this event may affect the risk to subjects who have completed the study.

6.3 IRB Review of Unanticipated Problems

The IRB staff will forward the report to a designated committee member who shall evaluate the report and determine one of the following outcomes:

- a) no further action is required,
- b) the PI is to submit further information (to be specified by the reviewer),
- c) revisions to the informed consent are necessary – requested revision will be specified and may involve re-consenting of participants already enrolled,
- d) revisions to the protocol are necessary – requested revision will be specified,
- e) suspension of the protocol upon notification to and agreement of the chairperson, or
- f) termination of the protocol by the IRB.

Depending on the severity of the event, the reviewer may ask that the report be presented at the next full committee meeting for discussion and further decision. If referred, the IRB may require the PI to notify subjects of unanticipated problems. This may be required to be in the form of a letter sent to all subjects and/or as part of a revised consent form to be signed by returning participants. The IRB may require more active monitoring of a research study, depending on the perceived risk to the research.

All correspondence and decisions will be communicated/documentated via campus inter-office mail and may in addition be transmitted verbally.

NON-COMPLIANCE

Non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal regulations governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects, inadequate or non-existent procedures for informed consent, inadequate supervision in research involving experimental drugs, devices or procedures, failure to follow recommendations made by the IRB to insure the safety of subjects, failure to report unanticipated problems or proposed protocol changes to the IRB, and failure to provide ongoing progress reports.

7.1 Investigation of Allegations of Non-compliance

45 CFR 46.113 states, “*An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s actions and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.*”

To exercise this statutory authority, the IRB shall review all allegations of non-compliance with human subjects regulations and review any study that has been associated with unexpected serious harm to research subjects. The IRB will follow these policies and procedures for conducting an inquiry and investigation into allegations of non-compliance and in reviewing incidents of unexpected serious harm to subjects.

The IRB will take appropriate action to insure the safety and welfare of human research subjects. These actions may range from corrective or educational measures for the researcher to terminating IRB approval for all active studies of a research. Further, the IRB may suspend approval of research projects at any time during an inquiry or investigation to assure the protection of human subjects.

This policy includes written procedures for reporting actions to appropriate college and federal government officials as required by federal regulations.

Application

These policies and procedures apply to all research activities of faculty, staff, students and others who are involved in research that falls under the jurisdiction of the IRB.

7.2 Reporting Allegations of Non-compliance

The Research Compliance Specialist has primary responsibility for receiving allegations (anonymous or otherwise) or evidence of non-compliance involving human research participants, particularly possible serious or continuing non-compliance

Allegations may also be reported to:

- the principal investigator;
- the Vice Provost for Research;
- the Executive Director of Research & Sponsored Programs; or
- any IRB staff member.

The IRB itself may initiate a complaint based on information available to the IRB (e.g., deficiencies noted in IRB files, media or scholarly reports of research activity subject to IRB jurisdiction).

7.3 Review of Allegations of Non-compliance

Purpose

In the inquiry stage, factual information is gathered and expeditiously reviewed to determine if an investigation of the complaint is warranted. An inquiry is not a formal hearing or an in-depth analysis of the allegations; it is designed to separate allegations deserving further investigation from those that are frivolous, unjustified or related to minor infractions.

Process

Whenever an allegation or complaint of non-compliance is made, the Research Compliance Specialist will forward the allegation to the Vice President for Research who will appoint an inquiry panel. Written notice of the allegations will also be sent to the researcher and a response will be requested within 10 working days. If the complaint raises issues of safety and welfare for research subjects that are apparent upon initial review, the researcher will also be given notice of an opportunity to address in his/her response the possible summary suspension of the researcher's project(s).

The inquiry panel will review the allegation of non-compliance, the response from the principal investigator and any other information necessary to determine whether an investigation is warranted. The inquiry panel may interview the researcher and others, but is not obligated to do so. It may be necessary to secure critical data or materials at the outset of an inquiry to protect the integrity of those data or materials or records. The IRB maintains the authority to secure such materials at any time during an inquiry or investigation.

Recommendations and Outcomes

At the conclusion of the inquiry phase, the inquiry panel will make a recommendation to the Vice President for Research. Possible recommendations include: 1) dismissal of the allegation or complaint as unjustified; 2) referral of the matter to another more appropriate system within the college for resolution (e.g., Grievance, Academic Misconduct; Student Conduct Code); 3) resolution through corrective or educational measures where the violation of human subjects regulations is minor or inadvertent; and 4) a formal IRB investigation where the allegation or complaint appears founded and is of a serious nature.

The Vice Provost for Research will promptly act upon the recommendation of the inquiry panel and notify the researcher in writing of the outcome of the inquiry phase. This notice will include a statement of the reasons for the decision. Depending on the nature of the allegations and the extent of the review required, the inquiry phase is expected to be completed within thirty working days. The Vice President for Research may grant an extension of this time frame if warranted.

7.4 Suspension and Reporting

At any time during the inquiry or investigation process, the IRB may determine that it is necessary to suspend the accrual of research subjects or suspend approval of research project(s) to assure the protection of human subjects. The authority to suspend research rests with the IRB; both the inquiry and investigation panels may recommend suspension to the IRB. If suspension is warranted, it normally will occur at the end of the inquiry phase. Except in cases of imminent harm to research subjects, the IRB will not suspend approval of research studies until the researcher has had an opportunity to respond to the initial allegation of non-compliance.

When the IRB makes a decision to suspend approval of research, it will notify the Vice Provost for Research and other appropriate college officials. These may include the researcher's department head, dean of the college, and senior administrative officers. The Vice Provost for Research, who serves as the authorized institutional official, will send written notice on behalf of the IRB to the following entities, as required under federal regulations:

- the Federal Office for Human Research Protections (OHRP);
- the Federal Food and Drug Administration (FDA) if the suspension of research approval involves an investigation drug or device;
- the OHRP and FDA as applicable, if the matter involves the non-submission of a project which should have been reviewed by the IRB, and the researcher's failure to do so has resulted in unanticipated risks to human subjects or serious or continuing non-compliance with IRB requirements; and
- external and internal sponsors funding a study under suspension. Reports will be filed within five working days of suspension.

In some cases reporting to professional licensing boards or state agencies may also be required. These reports will be

made by the Vice President for Research or other appropriate College officials.

7.5 Investigation Purpose and Process of Non-compliance

Purpose

The purpose of the investigation is to explore the allegations by assembling and examining relevant information. The investigation panel's charge is to generate a report that summarizes the information it considered, its conclusions as to whether there was non-compliance with human subjects regulations and recommendations for action. During an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The researcher shall be informed if new and different allegations are discovered during the course of the investigation.

Process

The investigation will be conducted by an ad hoc panel of at least three IRB members established by the Vice President for Research. One of the panelists shall be a member of the inquiry panel. All other members will be IRB members whose areas of expertise are suited to reviewing the complaint and area of study. Depending on the nature and scope of the complaint, IRB members may be relieved of their regular IRB duties during the investigation so as not to be overburdened.

The investigation panel may use any and all materials and reports gathered during the inquiry phase, but is not limited by actions or conclusions of the inquiry panel. The investigation panel may obtain documents and other records relevant to the investigation, such as researcher records, medical charts, grant applications and other scientific or scholarly data. The investigation panel may interview any persons who may have information relevant to the complaint. All interviews will be tape recorded. The panel may draw on the resources of the institution or external consultant to assist in the review of issues which require expertise beyond or in addition to that available on the investigation panel.

The researcher under investigation will be given an opportunity to submit written comments and appear before the panel on at least one occasion prior to the panel issuing its report. The researcher may offer relevant information to the panel and suggest other individuals to be interviewed. The researcher also may be accompanied by an advisor, including an attorney, at any time the researcher appears before the panel. The researcher shall give the panel notice of the advisor's participation at least 48 hours prior to any interview.

At the conclusion of its investigation, the investigation panel will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The investigation panel will forward a copy of this preliminary report to the researcher and give the researcher ten working days in which to submit comments to the report. The investigation panel will review any comments received from the researcher and decide, based on these comments, whether to modify its preliminary report. When finalized, the investigation panel will send the Vice President for Research its report with any comments received from the researcher. Depending on the case, the investigation phase is expected to be completed within 60 working days. The Vice President for Research may grant extensions if warranted and may request interim reports.

Outcome

The Vice Provost for Research will base his decision on the report of the investigation panel and any comments submitted by the researchers. Actions the Vice Provost may take with respect to the investigation include, but are not limited to: 1) dismissal of the complaint as unjustified; 2) remediation or educational measures; 3) increased reporting by the researcher of his/her human subjects research activities; 4) restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; 5) suspension of approval for one or more the researcher's studies; 6) termination of approval for one or more of the researcher's studies; 7) withdrawal or retraction of publications/presentations; and 8) referral to other college officials or committees for possible further review and action by those bodies.

7.6 Appeals/Reconsideration

Purpose

The purpose of an appeal is to give the researcher an opportunity to request reconsideration of the Vice President's decisions under certain limited circumstances. Grounds for appeal are limited to: 1) new information not reasonably available during the investigation; 2) material failure to follow these policies and procedures; and 3) sanction exceeds the severity of the violation. No other grounds will be considered.

Process

The appeals panel will be comprised of three IRB members who have not served on any other panel involved in the process (i.e., inquiry or investigation panels). The appeals panel will review the written statement of appeal by the researcher and make a recommendation as to whether the Vice President for Research should reconsider any aspect of his decision based on the ground outlined above. In reaching this recommendation, the appeals panel may seek a response from the investigation panel. The decision whether to forward a request for reconsideration should be made within 10 working days.

If the appeals panel denies the appeal, the Vice President's prior decision becomes final. If the appeals panel recommends reconsideration, the Vice President re-opens the case. When the Vice President re-opens the case, he may choose to reconvene the investigation panel or reconsider the matter on his own. The Vice President (or the investigation panel, if reconvened) will offer the researcher the opportunity to appear personally to present the appeal.

Upon reconsideration, the Vice President determines whether to modify or uphold his original decision. This action is final. The reconsideration phase is expected to be completed within 30 working days.

7.7 Dissemination of Findings

At the stage when the Vice President's decision becomes final (i.e., 5 working days after his original decision if there is not appeal; upon a decision by the appeals panel to deny the appeal; or upon the Vice President's final determination if the case is forwarded for reconsideration), the findings will be released to the researcher and to appropriate College and governmental officials as required under federal regulations. The same guidelines as set forth above for reporting suspensions will apply. Further, it may be necessary to inform these same officials of the status of the proceedings while they are pending.

Coordination with other Investigative Processes

Some complicated cases require review by other institutional or external entities. The IRB will cooperate in the review of allegations of academic misconduct, financial mismanagement, FDA inspections, etc. In cases that appear to involve academic misconduct, the investigation panel may report allegations of such misconduct to appropriate institutional officials. Where academic misconduct and IRB investigations are pending against the same researcher, the IRB will participate in a close coordination of processes to avoid duplication of effort and minimize competing use of resources.

Conflict of Interest/Commitment

As with all IRB processes, any IRB committee member who has a conflict of interest or commitment relating to the matter under review will excuse himself/herself from the proceedings and an alternate will be designated by the senior chair. It is permissible to allow substitution of non-IRB members for conflict of interest/commitment concerns at any stage in the establishment of an inquiry or investigative review panels.

Confidentiality for Complainants and Witnesses

Generally, the researcher under review should have access to the identity of complainant(s) and others who provide information. However, if such individuals are in a status subordinate to the researcher and wish to maintain their anonymity, the IRB will make every effort to protect their identities while at the same time affording the researcher access to the substance of the allegations and information presented against him/her. The IRB cannot guarantee absolute anonymity.

Retaliation

Reviewing complaints and allegations of non-compliance is critical to the IRB's ability to protect human subjects. A climate free of sanction is required to foster appropriate reports and ensure a fair review of allegations. Retaliation against good faith "whistle blowers" is illegal and will not be tolerated at this institution. Whistle blowers who report IRB related concerns may utilize other mechanisms at the College for protection from retaliation.

CONTINUING REVIEW

Institutional Review Board review is an ongoing process – not a one-time step. Regular reevaluation ensures that research is conducted responsibly. Even in responsibly conducted studies, a one-time review is inadequate, since risks can really be understood only after research has begun, and since the regulations for human subjects research are constantly being refined as the risks and benefits are better understood. Unexpected developments in a project can raise questions about the conduct of the research, and new findings can raise questions about the project.

8.1 Continuing Review

“Continuing review” refers to regularly scheduled complete reappraisals of a project. The goals of continuing review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard subjects are adequate, that the approved protocol is followed, and that the project reflects any changes that have been made in the regulations for human subjects research since the last approval.

The IRB may require changes in protocol or revisions in the consent form if the study's risks were originally underestimated, but the converse can also occur: the investigators and the IRB may have underestimated the benefit to research subjects.

When Continuing Review is Required

The Department of Health and Human Services (DHHS) regulations 45 CFR 46, require that “an IRB shall conduct continuing review covered by this policy at intervals appropriate to the degree of risk, but not less than once per year...” This continuing review must be substantive and meaningful. Research may be renewed up to three times for a total of four years for each project (initial approval plus three renewals. After four years, investigators must submit a new IRB application to continue their research. The IRB may grant a one-time extension, no longer than three months, of this four-year limitation when circumstances warrant (e.g., an investigator is in the final stages of completing the project). An extension will not be granted to avoid a lapse in approval during the life cycle of the project or to prepare a new application if all renewals have been used.

A notice for renewal and a “continuing review form” are sent to the principal investigator approximately 60 days before the review date. The form should be completed and returned to the ORSPA office by the indicated deadline. The notice for student projects are sent to the faculty sponsor and this person is responsible for notifying the student and ensuring timely submission of the renewal form. The study expiration date is crucial for the continuation of the study. If the study is allowed to expire, all data collection must cease and no funds may be spent (if funded). Any lapses in approval for the use of human subjects must be defended to the IRB and to regulatory or funding agencies. A new application and review will be required to reinstate the study if it expires.

If the investigator does not respond, the IRB will classify the study as “inactive.”

The IRB is required to report all federally funded studies inactivated due to lack of response to requests for continuing review to the Office for Human Research Protections (OHRP).

If the study is complete, the investigator is asked to complete several portions of the continuing review form as a “final report” on the project.

What to Report

Continuing review requires that you complete the Continuing Review Form and attach a current consent form if subjects are currently being recruited. The form requires the following information:

- the number of subjects enrolled since the last review and the total number of subjects enrolled to date;
- breakdowns of the subject population by gender and other demographics;
- a summary of the results of the research to date, including
- any unanticipated risks or adverse outcomes, and
- any early indication that one of the treatments under study is significantly better or worse than others;
- any difficulties recruiting or retaining subjects, an explanation of the difficulties, and the number of subjects who withdrew from the study;
- changes in the last year that were approved and the dates they were approved;
- if currently recruiting subjects, a copy of the consent form currently in use (as most recently

approved by the IRB).

Incomplete forms will be returned, which may cause a delay in getting the study on the appropriate committee agenda.

8.2 Making Changes in Research Protocols

A project approved by the IRB must be executed according to the approved protocol. Any changes in subject population, recruitment plans, research procedures, study instruments, study sites, or major research personnel require prospective approval by the IRB. Changes enacted without prior approval constitute protocol violations.

Researchers who plan a change must complete the Request for Revision form. The title should be that of the approved study and a description of the proposed changes should in lay language. Explain why the change is needed, describe any implications for subjects, and provide the appropriate revised consent documents. All requested changes should be highlighted in the submitted materials.

Absent and Exiting Principal Investigators

If a principal investigator on an approved project goes on sabbatical leave from the college, an interim PI must be appointed. The IRB should be informed of this person's qualifications and the new PI should write to the IRB accepting the responsibility for the treatment of subjects. If a researcher leaves the college permanently, the IRB should be notified both of any interim investigators and of the final replacement. Otherwise, the study will be filed as "inactive."

How Changes are Reviewed

All requests for revisions are reviewed by the Chair or his or her designee. The Chair, or designee will provide approval, if the changes are minor and do not alter the risks and benefits to the subjects, affect the equitable enrollment of subjects, or modify informed consent protections. Examples of minor changes include the substitution of one research instrument for a comparable one or the replacement of a co-investigator with an investigator with equivalent qualifications. If the requested modifications in research are not minor and represent a significant revision in the approved research or increase the risks to subjects, the Chair or designee will refer the request for revisions to the full IRB for consideration at a convened meeting unless the amended research would qualify for expedited review.

Investigators are notified in writing of IRB decisions on revisions. If a request for revision is not approved, the IRB will provide the reasons for its decisions.

8.3 New Findings

Adverse Events

Adverse events are unexpected problems of a nature, severity, and frequency not described in the information provided to the IRB or to participants. Examples include unexpected complications in a subject, missteps in the consent documentation, or breaches of confidentiality. Adverse events should be reported to the IRB within 10 working days.

The report of the event should discuss:

- the facts of the case, including the date and a description of the subject;
- whether the event is related to the study's procedures or drugs or to the subject's underlying disease or condition;
- the steps that have been taken to address the problem;
- whether the event is likely to recur; and
- whether the event provides new information about the study's risks that should be conveyed to participants, in a revised consent form.

A study may be suspended to ensure subjects' safety. Reports of events occurring at other sites receive expedited review, but in some cases the full IRB is involved. All events that occur at SOWELA Technical Community College are reviewed at a full IRB committee meeting.

Events at Other Institutions in a Multicenter Trial

If the project is a multicenter trial and the event occurred at another institution, the researcher must write to the IRB, describing the nature of the event, its severity, the likelihood that it will occur at the college, and the implications for future subjects.

Death of a Research Subject

Researchers should alert the IRB immediately to the death of any study subject, whether the death is believed to be related to the study or not.

New Risk/Benefit Findings

As a study progresses and the risks and benefits of participating in the study are better understood, researchers may find that the study must be stopped. For example, in some placebo-controlled trials, preliminary findings may give compelling evidence that a new treatment is efficacious. It then becomes unethical to continue giving placebos. (This occurs most frequently in multicenter trials in which a central statistical center receives and processes large volumes of data from several sites.)

In such cases, the investigator should write to the IRB, describe the findings and the need to suspend the placebo portion of the study. If the IRB agrees, the researcher should identify all subjects who received a placebo and invite those subjects to continue in an “open label” study in which all subjects receive the study medication.

8.4 Keeping Records

Researchers should maintain a file of all documents concerning the use of human subjects in research for not less than five years after conclusion of the study. The file should include copies of all documents and include original paperwork whenever possible. The principal investigator's records should mirror the IRB's records: where the IRB holds an original, the principal investigator should hold a copy, and vice versa.

Researchers should have the following documents on file:

- a copy of the original application submitted to the IRB, including the consent form and the research protocol;
- the original of the IRB's response;
- a copy of responses to IRB contingencies or requests for additional information;
- the original notice of final approval;
- a copy of the “Certification of Approval” sent by the IRB to any funding agencies;
- copies or originals of all other correspondence with the IRB;
- copies of completed “Continuing Review” forms and attachments;
- the original notice of renewal of approval and certification, where applicable; and
- copies of any inspection or audit reports.

Original signed consent forms should be kept in a secure location separate from correspondence with the IRB but readily available to inspectors. IRB records are subject to inspection by federal authorities. Sanctions for incomplete or nonexistent records include suspension of funding, fines, exclusion from future funding, and suspension of laboratory access.

SPONSORED PROJECTS: ADDITIONAL REQUIREMENTS

Most federal and private funding agencies will not award a grant for a research project involving human subjects until the Institutional Review Board has certified its approval. However, the college's system allows for concurrent processing of the human subjects review and the management review of a proposal.

9.1 The RSPA Transmittal Form

The Proposal Transmittal Form is the form used by the Office of Research to obtain and document required management approvals when seeking external funding. This form contains a number of assurances, one of which pertains to involving human subjects. The proposal should be submitted to the IRB in time for a decision before the proposal due date or at the time of award consideration.

Ideally, all research proposals would be reviewed and approved by the IRB before the proposal is submitted for

external funding. Investigators should affirm the approval on the Transmittal Form by specifying the date that the IRB approval was given. (This is the date of the IRB meeting – not the date of the letter.) Concurrent processing is more common however. The Transmittal Form, indicating that IRB approval is pending and providing the date the project was submitted for review, may be processed.

9.2 Special Situations

Submission to the funding sponsor prior to IRB approval:

Occasionally, IRB approval may still be pending when ORSPA receives the proposal for submission. If the funding sponsor's policy allows submission before IRB approval, then ORSPA will submit the proposal. The investigator is then responsible for notifying the sponsor when IRB approval is received.

Funding awarded prior to IRB approval:

Though unusual, a funding sponsor occasionally will make a conditional award before IRB has approved the research project. When this occurs, the funding sponsor will specify a time limit (usually sixty days or less) for IRB approval. Again, the investigator is responsible for notifying the sponsor of IRB approval.

Developmental proposals:

Proposals in the development or concept stage pose a dilemma for investigators, funding sponsors, and the IRB. Funding agencies may be unwilling to consider a proposal without IRB approval, yet given the early stage of the project, the investigator may not be able to provide a complete protocol or consent document. In these situations, the IRB may grant a “conditional approval” that will satisfy the sponsor, yet allow for additional review to protect the subjects. The investigator should include an explanation for the deficiencies in the application as well as a statement that research will not begin until the complete project has IRB approval.

Program project grants and training grants:

Program projects are large, multiproject studies designed to produce a coherent body of research from many subprojects. Training grants also may include a variety of subprojects. The initial application to the IRB should include the title of the overall program project, the principal investigator's name and contact information, and a list of the subprojects with the investigators' names and contact information for each. All subprojects in the program grant must be submitted to the IRB separately. It is the responsibility of the principal investigator for the overall project to ensure that the subproject investigators submit their applications in time to allow for review and approval. The IRB will certify its approval of the overall project only after it approves all subprojects.

Additional endorsements:

Funding sponsors occasionally require additional documents of special assurances. If this situation arises, the investigator may contact the IRB Coordinator for additional signatures or forms.

9.3 Changing the Title of a Research Project

Occasionally an investigator wants to change only the title of a research project to make it more competitive for a particular funding sponsor. Any change in the protocol of a research project must be approved by the IRB.

Changes in the title can be handled in two ways:

- If the original title will no longer be used, the principal investigator should explain the change in a letter to the IRB that includes the original title and the latest IRB approval date. A revised consent form must be enclosed (since the consent form gives the project's title). If the change is approved, the most recent approval date for the original study will apply to the new title.
- If the original title is to remain active but funding is sought from another agency for a different title, the investigator should write to the IRB office and request approval of an additional title. This request should certify that the study with the new title is identical to the student study under the original title. The request should include a revised consent form as well as a copy of the grant application associated with the new title. This procedure may be used only when the

research procedures are genuinely identical to those approved previously.

Several cautions apply to the second procedure:

- If the project does not receive funding and the investigator does not intend to use the title for another submission, the investigator should notify the IRB that the title will be “retired.”
- The IRB does not want research titles to proliferate. Investigators who overuse the procedures may be prevented from employing them in the future.

Researchers must file for these changes **at least 30 days** before the grant submission date. In all cases investigators **must provide a copy of the grant proposal**.

9.4 Unfunded Proposals

If a proposal is not funded, the investigator should inform the IRB whether or not the work will be conducted in the absence of external funding.

GLOSSARY TERMS

Assent – a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Children – persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. The legal age of consent in the State of Texas is 18.

DHHS - the Department of Health and Human Services

FDA – the Food and Drug Administration

Federalwide Assurance (FWA) – a document that fulfills the requirements of 45 CFR 46 and is approved by the Secretary of Health and Human Services. SOWELA Technical Community College an approved FWA on file with DHHS. The FWA number is 00002936.

HIPPA - the Health Insurance and Portability and Accountability Act of 1996. This act protects the privacy of a research participant's health information.

Human Subject – a living individual about whom the investigator conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

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 reasonable 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 reasonable 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 associated with the information), in order for obtaining the information to constitute research involving human subjects.

Informed Consent/Authorization – the knowing agreement/authorization of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Information conveyed in this the consent document must include all essential elements listed in Section 5 of this manual.

IRB – Institutional Review Board established in accord with and for the purposes expressed in 45 CFR 46.

Legally Authorized Representative – an individual or judicial or other body authorized under applicable law to consent/authorize on behalf of a prospective subject to that subject's participation in the particular activity or procedure.

Minimal Risk – the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
[NOTE: The definition for minimal risk for incarcerated persons is different. It is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.]

OHRP – the Office for Human Research Protections. This is an office in the Office of the Secretary of Health and Human Services responsible for regulatory oversight of human subjects research

Research – a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research is defined as both the Common Rule (45 CFR 46) of the Federal regulations and by the Privacy rule of HIPPA