SOUTH COLLEGE
POLICIES AND PROCEDURES MANUAL FOR HUMAN SUBJECTS RESEARCH

Revised
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Institutional Review Board (IRB)
South College

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1. INTRODUCTION

South College is committed to the protection of human research subjects. The South College Institutional Review Board (IRB) was established to protect the rights and welfare of human research subjects. This manual is designed to assist South College faculty, staff, and students who plan to perform research involving human subjects. The manual describes South College policies and procedures concerning the involvement of humans in research, and the requirements for submitting research protocols to the IRB for approval.

Prior to the initiation of any research activity involving human subjects, a research application must be submitted to the IRB and receive approval. Research activities include all contact with human subjects, including advertising, recruitment, and/or screening of potential subjects.

The IRB is a committee that determines and certifies that all research involving human subjects conforms to the regulations and policies set forth by the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), Tennessee State regulations, and South College policies regarding the health, welfare, safety, rights, and privileges of human subjects. The IRB also assists investigators in conducting ethical research that complies with these regulations and policies.

The IRB is comprised of faculty representatives from various academic disciplines at South College, including scientists and non-scientists, as well as a community representative who is not affiliated with South College. The IRB operates within federal guidelines with respect to the review and approval of research applications involving human subjects. The welfare and dignity of individuals who participate in research is a central concern of everyone involved with the protection of human research participants. South College's primary goal is to have a fair and transparent process in which participants voluntarily decide to take part in a study based on intelligent and knowledgeable assessment of the risks and benefits of the research.

South College administrators, research investigators, and the IRB share the collective responsibility for the ethical conduct of research. This collaboration must exist in a culture of trust, complete openness, and honesty by upholding the highest standards; we build public support for the pursuit of greater knowledge in a safe research environment.

The South College IRB is here to help you with your human subjects research! If you have any questions or concerns, please do not hesitate to contact us.

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2. ACTIVITIES OF THE SOUTH COLLEGE IRB AND FEDERAL REGULATIONS

The IRB is responsible for reviewing and overseeing human subjects research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality.

Two agencies within the U.S. Department of Health and Human Services (DHHS) share responsibility for IRB oversight: the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Federal regulations for the protection of human research subjects are set forth in *45 Code of Federal Regulations (CFR) 46*. Part A of *45 CFR 46* covers basic policies and is referred to as "the Common Rule." Parts B, C, and D of *45 CFR 46* address additional protections for pregnant women, fetuses, and neonates; prisoners; and children; involved as subjects in research, respectively. Many federal agencies and other funding sources have adopted “the Common Rule.”

The OHRP's main tool for oversight is the process of registration and the assurance document. Any institution that intends to conduct DHHS-funded research must have a registered IRB of its own or an association with a registered IRB. The Federal-Wide Assurance (FWA) is a commitment by the institution that it will comply with federal regulations. South College has an FWA and the South College IRB operates under this FWA. The OHRP also conducts a small number of site visits.

Additional regulations for research involving drugs and devices regulated by the FDA are set forth in *21 CFR 50*, *56, 312, and 812*. The FDA's main mechanism for IRB oversight is the inspection process. The FDA also inspects research sponsors and research investigators.

Other federal agencies that adopt the Common Rule may add special requirements to these basic regulations. If you are proposing to apply for funding to those agencies, you should check with them and with the IRB Administration to get information about any such requirements.

3. ETHICAL PRINCIPLES

The federal regulations that protect human research subjects are grounded in fundamental ethical principles, as set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The *Belmont Report* encompasses three key ethical principles: **respect for persons (autonomy), beneficence, and justice.** The South College IRB adheres to these ethical principles.

4. AUTHORITY OF THE IRB

The South College IRB has the authority to approve, disapprove, or require modifications in research activities that fall within its jurisdiction, as specified by federal regulations, state regulations and South College policies.

The South College IRB has the authority to:

- **Approve, disapprove, or modify studies based upon consideration of the protection of human research subjects.** Research that has been reviewed and approved by the South College IRB may be subject to further review and disapproval by officials of the Institution. However, those officials may not approve research if it has been disapproved by the IRB.

  The IRB also functions independently of other committees and makes independent determinations to approve or disapprove the application based upon whether or not human subjects are adequately protected. The South College IRB has jurisdiction over all human subjects research.
- **Require progress reports from investigators and oversee the conduct of the study.** Any approved Full Review research is subject to continuing South College IRB review and must be reevaluated at least annually. The intent is not to interfere with ongoing research but to ensure that human participants are protected.
- **Suspend or terminate approval of a study.** South College has the authority to suspend or terminate approval of research 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 action and shall be reported promptly to the Principal Investigator (PI). The suspension or termination of an application will also be reported to the Institutional Official (IO) and any federal funding agency as required by regulations.
- **Conduct post-approval reviews.** The South College IRB has the authority to conduct post approval reviews on any applications for any reason. Review may consist of a review of documents and/or review of the activities to determine if the research is being conducted in accordance with the IRB's requirements (the approved application).

5. WHAT IS HUMAN SUBJECTS RESEARCH?

Federal, state, and South College regulations require the IRB to review and monitor ***human subjects research***. Several terms are defined below to help investigators determine if IRB review of a project is required. In support of South College's mission to protect human research subjects, and the regulatory consequences of not obtaining IRB review and approval, investigators should consult with the IRB office if they have any doubt about whether or not a study involves human subjects research.

Research: Federal regulations define research as: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to

generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(l)]

For purposes of this part, the following activities are deemed not to be research:
(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. [45 CFR 46.102(l)]

Human subjects: The DHHS regulations define a human subject as "a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." [45 CFR 46.102(e)]

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
Interaction includes communication or interpersonal contact between investigator and subject.
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. [45 CFR 46.102(e)]

Coded private information or biological specimens: DHHS Office of Human Research Protection (OHRP) policy considers private information or biospecimens to be individually identifiable when they can be linked to specific individuals either directly or indirectly through coding systems. The IRB must determine if coded private information or biospecimens constitute research. Investigators do not have the authority to make an independent determination that research involving coded private information or biospecimens does not involve human subjects.

Clinical investigation: The Food and Drug Administration (FDA) defines clinical investigation as "any experiment that involves a test article and one or more human subjects and that either must meet the requirements for prior submission to the Food and Drug Administration... or need not meet the requirements for prior submission to the Food and Drug Administration... but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit." [21 CFR 56.102(c)]

6. POLICIES ON CLASSROOM PROJECTS AND CLASSROOM RESEARCH INVOLVING HUMAN SUBJECTS

The purpose of this section is to assist faculty and students in determining the difference between a Classroom Project and Classroom Research, and the IRB requirements for each type of activity. All South College instructors who supervise students in a Classroom Project or Classroom Research that involves human subjects are required to complete a web-based training program in the protection of human research subjects (see Section 8, Required Training for Human Subjects Research).

An important aspect of a college education is for students to engage in classroom activities designed to help them develop the knowledge and skills necessary to conduct research, which may involve human subjects. For the purposes of the South College IRB, these activities fall into two different categories with the following requirements:

Classroom Project

a. Instructor **must** complete Human Subjects Research Training.
b. Instructor **does not** need to submit a Human Subjects Research Protocol to the IRB if specific conditions are met (see below).
c. Instructor **must** submit a Request for Classroom Project Waiver of IRB Protocol.

Classroom Research

a. Instructor and student researchers **must** complete Human Subjects Research Training.

b. Instructor and student **must** submit a Human Subjects Research Protocol to the IRB.

Classroom Projects: Definition. South College recognizes that some student classroom projects conducted to fulfill course requirements involve activities that might be viewed as research in another context. As a general rule, when classroom projects are conducted *solely* to fulfill a course requirement, an element of the definition of research is lacking, which is the intent to develop or contribute to generalizable knowledge. Classroom projects with human subjects for which the sole purpose is a student learning experience in the methods and procedures of research do not require the submission of a Human Subjects Research Protocol to the IRB if **ALL** of the following conditions are satisfied:

a. The activity is a requirement for a South College undergraduate or graduate course.
b. The sole purpose of the activity is to give students a learning experience in the methods and procedures of research.
c. The instructor is aware of all aspects of the project and takes responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of all project activities.
d. There is no intent on the part of the instructor or student to produce generalizable knowledge and findings from the study will **NEVER** be disseminated beyond presentation to instructors or peers in a South College classroom setting. If the possibility exists that the instructor or student would consider disseminating the data as generalizable knowledge (such as presenting the results in a Master's thesis or Doctoral dissertation, poster or talk at an academic conference, publication, etc.), then the activity is a research project and a Human Subjects Research Protocol must be submitted to the IRB **before** any research activities are performed.
e. The project involves minimal risk to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
f. The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed. Examples include, but are not limited to:
    - Information relating to an individual's psychological well being or mental health.
    - Information relating to sexual attitudes, preferences, or practices.
    - Information relating to the use of alcohol or drugs.
    - Information relating to illegal behavior.
    - Information that if released could reasonably place the individual at risk of criminal or civil liability or be damaging to the individual's financial standing, employability, or reputation.
    - Information that would normally be recorded in a patient's medical record and the disclosure could reasonably lead to social discrimination or stigmatization.
    - Genetic information.
g. The project does not involve persons from vulnerable populations as participants. Examples include, but are not limited to:

- Individuals under the age of 18 (Exception – Projects conducted in established or commonly accepted educational settings involving normal educational practices, such as: investigation of regular and special education instructional strategies, or investigation of the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods).
- Prisoners
- Individuals with impaired decision-making ability

h. The project involves the voluntary participation of subjects without any coercion or deception.

i. No audio/video/photo recording of subjects, except under the following circumstances:
   - Instructors are required to oversee the process and ensure permission is granted by the subjects before audio/video/photo recording is performed; and
   - Instructors must submit to the IRB a course syllabus with the Request for Classroom Project Waiver of IRB Protocol. The syllabus must state that all audio/video/photo recording gathered as part of the classroom project remains the property of South College and will be forfeited to the course instructor at the end of the project; and
   - The audio/video/photo recordings, and any other data produced in the project, are to be exhibited only in the classroom, in departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations, or in the company/agency/organization from which the data were gathered.

Classroom Projects: Instructors are Required to Complete Human Subjects Research Training. All South College instructors who supervise students in a Classroom Project or Classroom Research that involves human subjects are required to complete a web-based training program in the protection of human research subjects. See Section 8, Required Training for Human Subjects Research, for instructions on completing the training. The training is good for a period of three years. A refresher course must be completed every three years.

Classroom Projects: Instructors are Required to Obtain a Waiver from the IRB. Instructors who supervise student Classroom Projects that involve human subjects are required to submit to the IRB a **Request for Classroom Project Waiver of IRB Protocol**. The form is available on the South College IRB website. The waiver is good for a period of three years as long as the same project is performed in the same course. If any aspect of the project is changed, if the instructor is changed, or if the project is conducted in a different course, a new waiver request must be submitted. A copy of the instructor's CITI training completion report must accompany the waiver request.

Classroom Projects: Disclosure to Human Subjects. All activities conducted under the Classroom Project policy ***must*** be preceded by a disclosure of the following information to the human subjects. If an Informed Consent Document is used, these points must be included in that document:

a. The student identifies her/himself as a South College student who is performing the activity to fulfill a course requirement, and the course is specifically identified.

b. The name and contact information for the supervising faculty member to contact for questions is provided.
c. The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/agency/organization).
d. Subjects are informed that their participation is voluntary, that they can skip any questions they do not wish to answer (e.g., for surveys, interviews, focus groups, etc.), and that they can stop participating at any time.
e. The disclosure should ***not*** state that the project has been approved by the South College IRB.

Classroom Projects: Important Considerations for Instructors. Classroom project data may never be shared outside of the classroom setting, such as in a thesis or dissertation, poster or talk at an academic conference, publication, etc. **The IRB cannot grant retroactive approval for a research project.** Therefore, it is very important that you give careful consideration to whether or not you may want to first submit a Human Subjects Research Protocol to the IRB before your students begin your project. For example, if a classroom project results in important findings and you or your students want to present the data at an academic conference, this will not be possible because the project did not receive review and approval from the IRB before the study was conducted. However, if you first submit a Human Subjects Research Protocol to the IRB for your project and it is approved before your students begin the research, then you and your students have the option of presenting or publishing the results.

Classroom Research: Definition. Classroom activities designed to teach students the knowledge and skills necessary to conduct research with human subjects, and that also contribute to generalizable knowledge, fit the definition of human subjects research. In general, contributing to generalizable knowledge refers to the dissemination of study findings outside of the classroom setting.

Master's theses, Doctoral dissertations, other forms of publication, talks and posters at academic conferences, etc., usually contribute to generalizable knowledge and fit the definition of research.

All students and faculty performing classroom research involving human subjects must first complete human subjects research training. See Section 8, Required Training for Human Subjects Research, for instructions on completing the training. The principal investigator (PI) of a classroom research project must submit a Human Subjects Research Protocol to the IRB for review and approval before the research begins. See Section 11, Types of IRB Review, and Section 13, Steps in the IRB Application and Review Process for instructions on submitting a protocol to the IRB.

Student Research Projects

South College students may serve as the principal investigator (PI) on an IRB application for student-initiated research involving human subjects. However, student-initiated research involving human subjects, whether thesis, dissertation, or other research, must include a South

College faculty member as the Co-PI. The South College faculty member will share full responsibility with the student for all aspects of the protocol and research. The only time that a South College IRB protocol will have a Co-PI is if the PI is a student.

The IRB must review and grant final approval to projects before any research activity or study procedures can take place. There is no retroactive approval for data previously collected for the current study. **Failure to seek approval for student research may invalidate the study and/or result in a delayed graduation.** If it comes to the attention of the IRB that IRB approval has not been obtained for student research prior to initiation of research involving human subjects, the IRB will refer the faculty member(s) and student researcher(s) to the appropriate Dean and/or Department Chair, and to the Institutional Official.

7. RESPONSIBILITIES OF ALL INDIVIDUALS CONDUCTING HUMAN SUBJECTS RESEARCH

All faculty, staff, and students associated with South College who perform research involving human subjects are required to:

- Ensure that all research activities have **IRB approval** and other approvals required by the institution **before human subjects are involved**.
- Complete a web-based training program in human research subjects protections.
- Design and implement research in a manner that excludes or minimizes risks to human participants.
- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Personally conduct or supervise the research.
- Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are informed about the study, the regulations governing research, and the institutional policies.
- Implement the research activity as it was approved by the IRB.
- Obtain the informed consent of subjects before the subject is involved in the research and document consent as approved by the IRB.
- Maintain written records of IRB reviews and decisions and obtain and keep documented evidence of informed consent of the subjects or their legally authorized representatives.
- Obtain IRB approval for any proposed change to the research protocol prior to its implementation.
- Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.

- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions.
- Notify the IRB regarding the emergency use of an investigational drug or device within 3 working days of the administration of the test article.

If any South College faculty, staff, or students perform human subjects research without an approved IRB protocol, or perform research activities that are not in compliance with an approved IRB protocol, the individual(s) will be reported to their Dean and/or Department Chair for disciplinary action.

Failure to follow IRB regulations may result in:

- Suspension of a research project.
- Suspension of all of a principal investigator's research projects.
- Inability to use data or publish results.
- Notification of sponsors, regulatory agencies, and funding agencies of noncompliance.
- Debarment by FDA from using investigational products.
- Inability to receive funding from federal agencies.
- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities.
- Termination of employment.
- Loss of licenses.
- Immediate shut-down of all research at South College.

Some or all of these consequences have occurred at institutions where human subjects research was conducted improperly or without IRB approval.

8. REQUIRED TRAINING FOR HUMAN SUBJECTS RESEARCH

South College policy requires all faculty, staff, and students who wish to perform human subjects research to complete a web-based training program in the protection of human research subjects. Additionally, South College faculty who supervise student classroom projects that involve human subjects are required to complete a web-based training program in the protection of human research subjects. The training is administered through the Collaborative Institutional Training Initiative (CITI). The CITI program is widely accepted as an industry standard among university and college IRBs, and by the federal government and other funding agencies. The IRB members are also required to complete CITI training. This policy assures that all individuals performing or reviewing human subjects research receive the training necessary for South College's compliance with federal regulations. The web-based training program allows individuals to complete the training at their convenience. Initial CITI training is valid for a period of three years. After the initial training period, a refresher course must be complete every three years. The document titled **Human Subjects Research Training Instructions**, located on the South College IRB website, provides instructions on how to complete the required training.

The IRB will not grant approval of human subjects research applications until all investigators associated with the project have completed Human Subjects Research Training and provided the IRB with a certificate of completion.

9. INFORMED CONSENT (ADULTS) AND ASSENT (CHILDREN)

Informed consent (of participants 18 years of age and older) is one of the primary requirements of research involving human subjects. Informed consent is a demonstration of how investigators and those involved in human subjects research show respect to research subjects, and it is mandated by the DHHS and FDA. It is important to remember that informed consent is an ongoing process, not a single event. Informed consent regulations were developed to:

- protect human subjects;
- ensure that potential study subjects clearly understand the benefits and risks associated with their participation in a study; and
- provide the potential study subjects with all information needed to reach a decision on whether or not to participate in a research study.

General Requirements for Informed Consent

General requirements for informed consent, whether written or oral, are as follows:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the

subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject or the legally authorized representative:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
    - The South College injury compensation clause must be included: "South College has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge."
    - In studies that involve greater than minimal risk and are sponsored, include a statement regarding the sponsor's injury compensation policy. The sponsor's injury compensation clause must be included if the sponsor will pay for compensation to injured research participants, or pay for treatment of research-related injuries (Note: Investigator must provide verification of sponsor's injury compensation clause when sponsor will pay.)
    - If the sponsor will not provide any compensation for injuries related to the research, then include in the South College injury compensation clause, "South College and [name of sponsor] have not provided for any payment….";
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

One or more of the following elements of information, when appropriate to the research being proposed, shall also be provided to each subject or the legally authorized representative:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable. Examples of when the IRB requires this element are:
    - Phase 1, 2, 3, and 4 Drug Trials;
    - Experimental procedures or treatments with limited available data on risks;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent. Examples of when the IRB requires this element are:
    - If the sponsor may stop the study;
    - If the investigator reserves discretion to remove the participant from the study;
    - If the investigator may remove the participant from the study should the investigator determine it is in the best interest of the participant;
    - If the participant does not follow study instructions;
3. Any additional costs to the subject that may result from participation in the research. Examples of when the IRB requires this element are:
    - If study procedures result in potential billing to the participant or third party payers;
    - If participants may have out-of-pocket costs from participation in the research (e.g., parking, meals, transportation);
    - If a possibility exists that a study drug becomes commercially available and no longer provided at no cost to the participant;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. Examples of when the IRB requires this element are:
    - If drug dose tapering is required and has risks to participants;
    - When a follow-up visit or testing is required for safety reasons;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study;

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

South College Informed Consent Form

An informed consent template, which includes the Basic Elements of Informed Consent and Additional Elements of Informed Consent is available on the South College IRB website. The document is titled, "**Informed Consent Template**." Researchers must complete this template and submit it with the research protocol.

Requirement to Obtain Signatures

In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative. This consent form must contain the required elements of informed consent in language understandable to the subject. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed.

Unless the IRB waives the requirement to document informed consent, an investigator must obtain the **written** legally effective informed consent of an individual (or, in certain circumstances, the individual's legally authorized representative) **before** the individual can participate or be involved in **any research activities** involving human subjects.

Because the signed document is a written record of the consent discussion,

- the investigator must retain the **original, signed** document, and
- each participant must be given a **copy of the signed** document.

Waiver of Documentation of Consent

In some situations (e.g., telephone survey or mailed survey, internet research, certain international research), the IRB may waive the requirement for obtaining a signed informed consent form. Investigators can request a waiver by submitting a **Waiver of Consent Documentation** form. Investigators must justify the reason for requesting a waiver of the requirement to obtain a signed consent form for some or all of the subjects.

As per 45 CFR 46.117(c), the IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. **NOTE:** Documentation of consent cannot be waived for FDA-regulated research that meets these conditions.
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documentation that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Waiver or Alteration of Informed Consent
Some research studies (e.g., medical record review, deception research, collection of biological specimens) would not be possible if some/all elements of informed consent were required from participants. The IRB may consider waiving the requirements for some/all elements of informed consent when the research meets **all of the following conditions** (the researcher needs to explain for each condition how it applies to the research):

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

NOTE: The investigator must describe the element(s) of consent for which a waiver or alteration will be requested and justify the waiver or alteration. The IRB does not approve waiver of informed consent for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.

Posting of clinical trial consent form.
For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the

Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

Requirement to Use Understandable Language

The informed consent document must be in a language understandable to the participant. When the prospective participant is fluent in English, and the informed consent discussion is conducted in English, then the consent document should be in English. However, when and if the study population is to include non-English-speaking participants, so that the principal investigator or the IRB anticipates that the consent discussion is likely to be conducted in a language other than English, the investigator should address the following criteria in the description of the informed consent process:

1. Describe research and other personnel (e.g., PI, staff, translator) who will conduct the consent procedures/discussion, communicate other information, and be available to answer questions in a language understandable to the participant.
2. Submit translations and back translations of the informed consent documents for targeted populations for review and approval. The IRB strongly encourages the use of a full translation of the entire informed consent document.
    - For international research with local IRB review this requirement applies to locally approved documents.
    - For the South College IRB to grant approval, informed consent documents must include, at a minimum, the required elements of informed consent and the signatures of the participant, or legally authorized representative if applicable, and the person obtaining consent.
4. Provide certification that verifies that the informed consent document has been properly translated into the non-English language.
5. Provide the qualifications of the individual or the service that was used to translate the informed consent documents (e.g., credentials, certifications, education, or native language fluency).
6. Provide participants with the IRB-approved non-English-language informed consent document as part of the informed consent discussion and give them an opportunity to read and discuss the document with a fluent translator present.

Child Assent

Parental consent is a prerequisite to the recruitment of children (under the age of 18 in TN) as human research subjects. In addition to parental consent, assent from the child is also required. Assent is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research."

Assent is generally required if:

1. subjects are minors between the ages of 7 and 17 (children below the age of 7 are generally not asked to provide assent, only the parental consent form is required); or
2. subjects are 18 or older and are intellectually or emotionally impaired and not legally competent to give their informed consent.

The child assent form should be brief and study specific, with language that is appropriate to the age ranges and levels of mental development found within the proposed participant population. The assent form should have a simple format that is easy to read.

The assent form does not replace a thoughtful discussion with the child regarding participation in the research. The assent process should illustrate respect for the child and convey the essential information the child requires in order to make a decision about participating in the research.

South College Child Assent Form

The assent form must include:

1. Study title
2. Study purpose (provide a brief explanation of the purpose of the study)
3. Procedures (describe what the subject is being asked to do)
4. Withdrawal privilege (describe how a subject can stop participation later even if he/she agrees to start)
5. Voluntary participation (include a statement that the subject does not have to participate)
6. Confidentiality statement (indicate that the experimenter will not tell anyone – e.g., parents, teachers – what the subject says or does in the study)
7. Signature lines (include a signature line for the subject and for the investigator)
8. Date line

10. PRIVACY AND CONFIDENTIALITY

The protection of privacy and confidentiality are important issues in the protection of human research subjects. Protection of human research subjects' privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

The investigator must describe plans to protect the subject's identity as well as the confidentiality of the research records. Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects, for example, the use of numbering or code or safely locked files in private offices. Furthermore, the investigator should describe who has access to the data and under what circumstances a code may be broken. Without appropriate safeguards, problems may arise with long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal civil prosecution of the participating human subject, the IRB may require the destruction of all data that can identify the subjects. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose, what period of time, or whether and when data will be de-identified or destroyed.

A special situation arises for video or taped data and photographs since these media provide additional potential means for subject identification. Investigators must secure subject consent explicitly mentioning these practices. They should also explain plans for final disposition or destruction of such records.

Health Insurance Portability and Accountability Act (HIPAA)
The Health Insurance Portability and Accountability Act "Privacy Rule" (HIPAA) is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing "protected health information" without written authorization from the patient.

If an investigator intends to use or release to others (e.g., sponsors, other investigators, collaborators) any identifiable health information in connection with their research, he/she must indicate that in the IRB application. Protected health information is health information transmitted or maintained in any form or medium that includes ALL of the three following characteristics:

- identifies or could be used to identify an individual; **and**
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; **and**
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

11. TYPES OF IRB REVIEW

There are four categories of **human subjects research** reviewed by the South College IRB:

Exempt Status Review
Limited Review
Expedited Review
Full Committee Review

Projects that receive IRB approval following a Full Committee Review must also apply for a **Continuing Review** at least annually from the date of initial approval. **After a project is approved, an investigator is not permitted to make any revisions or amendments to an approved project without prior review and approval by the IRB.**

Exempt Status Review
Although this category is called "Exempt," this type of research requires IRB review and approval. Only the IRB can assign Exempt status to a project. The **determination of Exempt status by the IRB must be made prior to initiation of the research**; it cannot be made retroactively. After initial approval, an exempt research project does not require continuing review by the IRB, unless it is amended in such a way that it no longer meets exemption status. Although a project may be granted Exempt status, no interaction with human participants is exempt from the ethical principles described in the *Belmont Report*. The principal investigator is responsible for ensuring that informed consent is obtained from human subjects participating in research determined to be exempt.

Exempt research is research with human subjects that falls under one or more of the following six exempt categories listed in the federal regulations (45 CFR 46.104d):

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

3. Research involving benign behavioral interventions (only for behavioral research, not biomedical research) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

    Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
    If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

    a. The identifiable private information or identifiable biospecimens are publicly available;

    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

    c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or

    d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information

that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

   Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
   a. If wholesome foods without additives are consumed, or
   b. 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.

Federal regulations specify that the following research activities **CANNOT be Exempt**:

1. Research that includes educational tests, survey procedures, interview procedures, observation of public behavior, or benign behavioral interventions if the information is recorded in such a way that it can be linked back to the subject either directly or indirectly through the use of a code and any disclosure of the human subjects' responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

2. Research involving prisoners.
3. Surveys, interviews, or benign behavioral interventions given to children (individuals younger than 18 in TN).
4. Observations of public behavior when the investigator participates in the activities being observed.

Limited Review

Limited Review research is research with human subjects that falls under one or both of the following two limited review categories listed in the federal regulations (45 CFR 46.104d):

1. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
   Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
   If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Expedited Review

If the research presents no more than minimal risk to human participants and it falls under one of nine expedited categories listed in the federal regulations, the IRB may determine that it qualifies for an expedited review.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. ([45 CFR 46.102(j)] and [21 CFR 56.102(i)])

Expedited research is research with human subjects that falls under one or more of the following nine expedited categories in the federal regulations [45 CFR 46.110]:

1. 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 312) is not required.
    b. Research on medical devices for which:
        i. An investigational device exemption application (21 CFR 812) is not required.
        ii. Or, the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, nonpregnant 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.
    b. Or from other adults and children, 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.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples in this category include:
    a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
    b. Weighing or testing sensory acuity.

c. Magnetic resonance imaging.
d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
8. 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.
    b. Or where no subjects have been enrolled and no additional risks have been identified.
    c. Or where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
    a. Categories two (2) through eight (8) do not apply, and
    b. The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Committee Review

Research projects that involve more than minimal risk require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present. Categories of research that require a Full Committee review include:

1. Studies with procedures that present more than minimal risk to human subjects.

2. Studies involving subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
3. Studies taking place internationally (particularly those with little or no provisions for protection of human subjects).
4. Studies where information may be disclosed that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.), or damage the participant's social standing, financial standing, or employability.
5. Studies involving deception, which raises the risk level of the subjects.
6. Studies that fall under the jurisdiction of the Food and Drug Administration.

Continuing Review

Continuing Review of all projects initially approved by Full Committee Review is required at least annually. The IRB may require more frequent review of a project depending on the risks to human subjects.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research that received Exempt status from the IRB,
- Research approved by the IRB in accordance with Limited Review,
- Research approved by the IRB in accordance with Expedited Review,
- Research approved by the IRB in accordance with Full Review if the approved research has progressed to the point that it involves only one or both of the following:
    - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

As a courtesy, the IRB will send Continuing Review reminders to investigators approximately 90, 60, and 30 days before a project expires. However, it is ultimately the investigator's responsibility to initiate a Continuing Review application and to allow sufficient time for the review and re-approval process to be completed before the current approval expires.

If an IRB approved project expires, all research activities involving human subjects must stop. These activities involve subject contact, data collection, and data analysis.

Revisions and Amendments

All revisions and amendments to a project need IRB approval before they are implemented. If the investigator wants to **change anything** in the research that would impact the subjects, such as recruitment procedures, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document/process, or data elements collected, the investigator must obtain IRB review and approval prior to implementation of the changes. The only exceptions are changes necessary to immediately protect the safety of subjects. To request revisions or changes to an approved protocol, submit the **Human Subjects Research Protocol: Project**

Revisions or Amendments form, which is available on the South College IRB website.

12. SPECIAL APPROVALS

Human subjects research that involves certain materials and procedures requires **prior approval** from other South College committees before the application will be reviewed by the IRB. These special approvals include research that involves: the introduction of radioactive materials or radioactive devices into humans; the use of recombinant DNA; gene therapy projects; and vaccine trials. Contact the IRB for guidance on the procedures for obtaining these special approvals.

13. STEPS IN THE IRB APPLICATION AND REVIEW PROCESS

To obtain IRB approval for a human subjects research project, researchers should take the following steps:

1. **Select the type of IRB review that is required for the project.** Refer to Section 11 (Types of IRB Review) and determine if the project fits the definition of Exempt Status Review, Limited Review, Expedited Review, or Full Committee Review. If the investigator has any doubt about the appropriate level of review for a project (Exempt, Limited, Expedited, or Full Committee Review), the IRB staff is available to aid applicants in making this determination. The final determination of whether the proposed research meets federal criteria for the requested review category will be made by the IRB.

2. **Complete Human Subjects Research Training.** Human Subjects Research Training must be completed by all investigators associated with the project before IRB approval of an application will be granted. All investigators should submit a certificate of completion of Human Subjects Research Training with the IRB application form. Directions for completing the training and obtaining a certificate are provided on the South College IRB website in the document entitled, **Human Subjects Research Training Instructions**.

3. **Complete the appropriate IRB application form.** The **Human Subjects Research Protocol: Exempt or Limited Review** form will be used for projects requesting Exempt Status Review or Limited Review. The **Human Subjects Research Protocol: Expedited or Full Review** form will be used for projects requesting Expedited Review or requiring Full Committee Review. The forms may be downloaded from the South College IRB website. A student performing research must complete the IRB application under the guidance of his/her faculty advisor. The faculty advisor must serve as the Co-PI on the IRB application form. The student's advisor is responsible for guiding the student investigator in the development of the research plan as well as the conduct of the research project.

4. **Obtain Departmental approval of the completed IRB form.** The Department Chair (or his/her designee) must review and sign off on the IRB application before it is submitted

to the IRB for review. This signoff may address issues of scientific merit, availability of resources, institutional policies, or other issues at the department level.

5. **Submit the application to the IRB for review.** Upon receipt of the application, the IRB Coordinator will pre-review the application for completion before it is submitted to the IRB Chair for review. An IRB application may be submitted to the IRB office at any time. The IRB will attempt to complete Exempt, Limited, and Expedited Reviews within 10 business days of the receipt of the completed application. Full Committee Reviews occur once each month. The meeting dates are posted on the South College IRB website. To receive review of a project requiring Full Committee Review, the application must be complete and received by the IRB office a minimum of two weeks before the scheduled meeting.

6. **The IRB will notify the researcher with the outcome of the review.** The IRB will attempt to notify the researcher of the outcome within 5 business days of completion of the review. The IRB will notify the researcher in writing with one of the following outcomes after the application has been reviewed:
    - **Approved**. The application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted. Although a project has been approved by the IRB, institutional administrative officials may disapprove a project for considerations outside the scope of the IRB.
    - **Approved Pending Modifications**. The application is complete but there are minor issues/changes that must be addressed before the project can begin. Once a satisfactory response to these contingencies is received and approved by the IRB, the review is complete.
    - **Deferred for Re-review**. Applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher's response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.
    - **Disapproved**. Criteria for IRB approval are not met. Only the Full Committee may disapprove a study. Institutional administrative officials may not override this decision.
    - **Not Human Subjects Research**. Projects that do not meet the definition of *research* and/or do not involve *human subjects*.

7. **Conduct the research and report to the IRB as necessary.** Once the application is approved, the researcher may begin recruiting subjects and conducting study procedures. The researcher must verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions. During the course of the study, the researcher must submit reports to the IRB if any of the following occurs:

- **Revisions and amendments to the approved protocol.** Changes to the original submitted study must be reviewed and approved by the IRB before they are implemented. To request revisions or changes to an approved protocol, submit the **Human Subjects Research Protocol: Project Revisions or Amendments** form, which is available on the South College IRB website.
- **Adverse events/effects and unanticipated problems involving risks to subjects or others.** The IRB must be notified immediately if any undue harms result from the study. To report problems to the IRB, submit the **Human Subjects Research Protocol: Problem Report** form, which is available on the South College IRB website.
- **Complaints regarding human subjects research.** The IRB must be notified immediately if any complaints, either from the subjects or the study staff, are made regarding the research study. To report complaints to the IRB, submit the **Human Subjects Research Protocol: Problem Report** form, which is available on the South College IRB website.
- **Breach of confidentiality.** If any personal/confidential data have been inappropriately disclosed by any member of the study staff, the IRB must be notified immediately. To report breach of confidentiality to the IRB, submit the **Human Subjects Research Protocol: Problem Report** form, which is available on the South College IRB website.
- Refer to Section 15 (Reporting Project Revisions and Amendments) and Section 16 (Reporting Research-Related Problems) for additional reporting requirements.

8. **Submit an application for Continuing Review to the IRB.** Projects that received approval following a Full Committee Review must apply for Continuing Review at least once every 365 days from the date of initial approval. The IRB may require the Continuing Review to occur more frequently depending on the risk to participants compared to the potential benefits. The **Human Subjects Research Protocol: Continuing Review** form will be used and may be downloaded from the South College IRB website.

   If an IRB approved project expires, all research activities involving human subjects must stop. These activities involve subject contact, data collection, and data analysis. As a courtesy, the IRB will send continuing review reminders to investigators approximately 90, 60, and 30 days before a project expires. However, it is ultimately the investigator's responsibility to initiate a continuing review application and to allow sufficient time for the review and re-approval process to be completed before the current approval expires.

9. **Submit a final report to the IRB.** The investigator must submit a final report to the IRB **within 30 days** of completion or termination of all research activity. The **Human Subjects Research Protocol: Final Study Report** form will be used and may be downloaded from the South College IRB website.

10. **Maintain secure records of the study.** The investigator will ensure the confidentiality and security of all information obtained from and about human subjects, both during the study and after the study. The investigator will make provisions for the secured retention of complete research records and all research materials for at least three years after the completion of the study.

14. CRITERIA FOR IRB APPROVAL

Federal policy lists criteria [45 CFR 46.111 and 21 CFR 56.111] that the IRB must apply when reviewing research involving human subjects. To approve a research project, the IRB must determine that the following conditions exist at the time of initial review and at each subsequent review conducted by the IRB:

1. Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented or appropriately waived.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

15. REPORTING PROJECT REVISIONS AND AMENDMENTS

No protocol, informed consent process, or informed consent document may be modified without prior approval from the IRB unless it is necessary to eliminate an apparent and immediate hazard to one or more of the participants.

Modification means any change. It encompasses two commonly used terms: A *revision* is a change in something that exists, such as increasing the number of participants. An *amendment* adds something new, such as a person who will obtain informed consent.

Commonly Reviewed Modifications
The list below includes some common modifications that the South College IRB reviews:

1. A change in the procedures of the protocol, such as:
    - when the inclusion/exclusion criteria change,
    - when a genetic or sample-storage component is added or changed,
    - when the protocol is no longer open for enrollment of new participants,
    - when a sponsor temporarily suspends enrollment,
    - when the protocol ends.
2. A change in the procedures used to recruit or enroll participants, such as:
    - new or newly revised advertisements,
    - new or newly revised script or questionnaire for screening
    - a change in the circumstances under which informed consent is discussed or obtained,
    - a change in the wording or format of the informed consent document.
3. Changes in study personnel, such as:
    - adding or removing an investigator,
    - adding or removing key personnel,
    - adding or removing persons who are involved in the informed consent process,
    - changing the Principal Investigator.

Applying for Modifications
Any planned modification must be submitted to the IRB for review and approval before being implemented or used with participants. Investigators submit the **Human Subjects Research Protocol: Project Revision or Amendment** form for review of any change in the protocol, including changes undertaken as necessary to eliminate a hazard. Some modifications require that the investigator include materials in addition to the Project Revision or Amendment form. For example, sponsors often initiate modifications in procedures or documents used with participants. In these cases, the investigator also provides the IRB with a copy of all investigator-sponsor correspondence and other documents related to the change.

Change in principal investigator. The outgoing investigator submits the Project Revision or Amendment Form. In addition, the following written and signed notifications must be submitted:

1. The current Principal Investigator notifies the IRB that he or she has relinquished the responsibilities of Principal Investigator to the person named, or will do so on a specified date.

2. The newly named Principal Investigator notifies the IRB that he or she has read the protocol and agrees to accept the responsibilities of Principal Investigator.

Changes in the informed consent document. When a modification makes it necessary to change the informed consent document, regardless of whether any participants are enrolled, include two copies of the revised consent form:

1. One "mark-up" copy showing all changes from the previous version (e.g., highlighting all additions and striking-through all the deletions). You may use the "track changes" function available in most word processing software.
2. One "clean" copy for the IRB-approval stamp, without highlighting or outdated text.

Addendum informed consent documents. If participants have already signed a consent document and it becomes necessary to inform them of modifications or new information, an addendum informed consent document may be necessary when:

1. The protocol is open for recruitment and enrollment,
2. some participants are already enrolled, **and**
3. the change might be related to the participants' willingness to continue their participation in the study.

OR

1. The protocol is closed to enrollment, **and**
2. the change might be related to the participants' willingness to allow the continued use of data from their participation.

The FDA does not require re-consenting of participants who have completed their active participation in the study, or who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled participants.

Modifications to eliminate apparent immediate hazards to human subjects. There are situations where a serious unanticipated event or adverse event requires an immediate change to an application in order to relieve an apparent immediate hazard to research subjects. In these situations, the principal investigator may implement a change necessary to protect the welfare of the research subjects. Investigators are encouraged to contact the IRB if this type of situation arises prior to implementation of the application change, if the time taken for notification does not place the subject in danger.

Investigators are required to notify the IRB in writing of the change within 5 working days and include a written description of the change and the events that necessitated immediate implementation of a modification to the approved protocol. Notify the IRB of unanticipated or adverse events using the **Human Subjects Research Protocol: Problem Report** form, which is available on the South College website. Notify the IRB of modifications to the protocol that were necessary to eliminate apparent immediate hazards to human subjects using the **Human**

Subjects Research Protocol: Project Revision or Amendment form, which is available on the South College website.

16. REPORTING RESEARCH-RELATED PROBLEMS

Reportable Problems

South College policy requires that "unanticipated problems involving risks to research subjects or others" be promptly reported to the IRB, the Institutional Official, the sponsor, and appropriate federal agencies. *Others*, in "research subjects or others," includes investigators, research staff, or other individuals affected by the research project.

In accord with this policy, the IRB has published a list of problems (below) that investigators must report to the IRB. The Principal Investigator must report the problems listed to the IRB within the timeframes indicated. The IRB may request further information as necessary and will determine whether any research project that has been associated with unexpected serious harm to the participants must be terminated.

Investigators are responsible for meeting all reporting requirements that apply to their projects. For example, investigators have reporting responsibilities to sponsors of FDA-regulated research. Investigators serving as sponsors of FDA-regulated research have additional reporting responsibilities (see FDA-Regulated Research).

Investigator Reports to the IRB

Adverse events and safety reports that require prompt reporting should be submitted to the IRB using the **Human Subjects Research Protocol: Problem Report** form. If the event being reported leads to a change in the informed consent document, see "Changes in the Informed Consent Document" in Section 15 (Reporting Project Revisions and Amendments).

Within 5 working days. As soon as possible but in all cases within 5 working days, the investigator must report to the IRB:

- Any changes to the protocol that were taken to eliminate an apparent hazard to a participant in an emergency.
- Any deviations from the investigational plan for an investigational device taken to protect the life or physical well-being of a participant in an emergency.
- Any emergency use of an FDA-regulated test article or Humanitarian Use Device prior to IRB approval.
- Any serious adverse event that is related or possibly related to the research, regardless of whether the event occurred at a South College site or non-South College performance site**.**

Within 10 working days. As soon as possible but in all cases within 10 working days, the investigator must report to the IRB:

- Any adverse event occurring at a performance site under South College IRB oversight that, in the opinion of the principal investigator, is both unexpected and related or possibly related to the research.
- Information that indicates a change to the risks or potential benefits of the research. For example:
    - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different from those initially presented to the IRB.
    - A paper is published from another study that shows the risks or potential benefits of the research might be different from those initially presented to the IRB.
- A breach of confidentiality.
- Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject.
- Incarceration of a subject enrolled in a protocol not approved to enroll prisoners.
- Event that requires prompt reporting to the sponsor.
- Sponsor-imposed suspension for risk.
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (i.e., an accidental or unintentional change to the IRB-approved protocol) that harmed subjects or others or that indicates subjects or others may be at increased risk of harm.
- Safety monitoring reports and Data and Safety Monitoring Board (DSMB) reports from the sponsor.

At the time of Continuing Review and in the Final Study Report. Along with the **Human Subjects Protocol: Continuing Review** form and the **Human Subjects Protocol: Final Study Report**, the investigator must report to the IRB:

- Summary on the **Problem Summary Sheet** of all adverse events at performance sites under South College IRB oversight.
- Summary on the **Problem Summary Sheet** of all problems reported to the South College IRB, including serious adverse events.
- Safety monitoring or DSMB reports received from sponsor and not previously forwarded to the IRB, if any. The investigator will be notified in writing if the IRB requires that all such reports be submitted for continuing review.

IRB and Institutional Reporting

If the IRB determines that a reported event constitutes an unanticipated problem that alters the risk of the research, it promptly reports its determination and actions to the investigator and the Institutional Official. The Institutional Official, in turn, is responsible for promptly reporting the IRB findings to the sponsor and applicable federal agencies.

Definitions Related to Research-Related Problems

The "correct" terminology for an event can vary because different agencies use different terms. For example, a "serious adverse drug experience" under FDA regulations may or may not be an "unanticipated problem involving risks to subjects or others" under DHHS regulations. To help investigators plan their strategies for reporting, this section defines these terms in relation to South College requirements.

Unanticipated problems involving risks to research subjects or others includes any incident, experience, or outcome that meets **all** of the criteria below:

1. Is unexpected in terms of nature, severity, or frequency given
    a. the research procedures that are described in the protocol-related documents, such as the IRB-approved Human Subjects Research Protocol and informed consent documents; **and**
    b. the characteristics of the subject population being studied; **and**
2. Is related or possibly related to participation in the research (*possibly related* means there is some likelihood in the judgment of a reasonable investigator that the incident, experience, or outcome may have been caused by the procedures involved in the research); **and**
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory findings), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subjects' participation in research. Adverse events encompass both physical and psychological harms.

Serious adverse event (includes *serious adverse drug or biological experience* and *unanticipated adverse device experiences* under FDA regulations) is any adverse event temporally associated with the subject's participation in research that meets **any** of the following criteria:

- Results in death.
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability/incapacity.
- Results in a congenital anomaly/birth defect.
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition. Examples include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood

dyscrasias or convulsions that do not result in inpatient hospitalization, and the development of drug dependency or drug abuse.

IND Safety Reports

The phrase "IND safety reports" originates in FDA regulations 21 CFR 312 Investigational New Drug Application. The regulations require a **sponsor**, not a study investigator, to submit IND safety reports to the FDA and to participating investigators.

IRBs are required by FDA and DHHS human subjects protection regulations to review "unanticipated problems involving risks to participants or others." IND safety does not necessarily meet the definition of an unanticipated problem. Often, however, sponsors send IND safety reports to investigators and instruct the investigators to submit them to the IRB. The IND safety reports concern a product under study and such reports may not necessarily apply to events that occurred in the protocol conducted at South College.

The South College principal investigator must submit IND safety reports to the South College IRB only in the following cases:

1. When the report meets the definition of an unanticipated problem, OR
2. When an IND safety report triggers a sponsor-required change in the research protocol or consent form, OR
3. When the sponsor indicates the safety information must be reviewed by the IRB to determine that either a change in research is required or currently enrolled subjects should be informed of the new information.

17. IRB MEMBERSHIP AND MANAGEMENT

Numbers and qualifications of IRB members. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect

for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Every effort will be made to ensure that at least two of the following disciplines/fields of expertise will be represented on the IRB: Business, Education, Legal Studies, Nursing, Pharmacy, Physician Assistant Studies, and Science.

The IRB Coordinator will serve on the IRB as an ex-officio member with voting privileges.

IRB membership roster. The IRB Coordinator will submit a copy of the IRB membership roster to the U.S. Department of Health and Human Services' Office for Human Research Protections along with registration renewals or updates as necessary. The membership of the IRB is also maintained by the South College Institutional Official.

The IRB Chair

Selection and Appointment. The IRB Chair is appointed by the Institutional Official and serves as Chair for one year. The Chair may be reappointed for additional one year terms.

Duties. The Chair directs the IRB meetings in accordance with institutional, state, and federal requirements. The Chair works closely with the IRB members, the IRB Coordinator, institutional officials, and investigators to ensure the rights and welfare of research participants are protected. The Chair designates the reviewers for exempt, limited, expedited and full-board applications and may delegate in writing the ability to assign reviewers to the IRB Coordinator. Such requests should be in writing, signed by the Chair, and for a period not to exceed one year. The Chair also designates the IRB Coordinator to send official letters and some IRB related correspondence on behalf of the Chair.

The Chair carries broad responsibilities and an obligation to:

1. Determine the type of IRB review appropriate for initial review of projects, continuing review of projects, and review of project modifications based on regulatory criteria.
2. Complete the IRB member training through the Collaborative Institutional Training Initiative (CITI).
3. Participate in pre-IRB planning meetings with the IRB Coordinator to ensure optimal review procedures, assignment of duties, and preparation of convened meeting agendas.
4. Conduct limited and expedited reviews and approvals.
5. Assign primary reviewers for full committee reviews and run the convened meetings.

6. Review revisions to protocols and other documents that are required as conditions of project approvals.
7. Sign the application form certifying project approval.
8. Suspension of research procedures.
9. Referral to the full IRB for consideration of termination of research projects.
10. Reviewing and signing reports of unanticipated problems involving risks to research subjects or others, adverse events, complaints, or suspension or termination of a research project.
11. Assist in communications with federal agencies.
12. Assist in communicating with faculty and institutional administration regarding IRB resources and functionality.
13. Assist in orientating new members to the board.
14. Delegate responsibilities to IRB committee members as needed.

Removal. The Chair may be removed or replaced by the Institutional Official.

IRB members

Selection and Appointment. South College faculty members are appointed by the Institutional Official and serve on the board for a three-year term. Faculty appointments to the committee begin August 1st of the year appointed and end July 30th of the final year of the appointment.

Community and/or non-affiliated IRB members will be appointed to the board for a three-year term and appointments have the same schedule as the South College faculty IRB members.

At the conclusion of a term, a committee member may (or may not) be appointed to an additional term and/or year of service on the IRB.

Duties. IRB members are responsible for protecting the rights and welfare of human research subjects by reviewing, approving, and monitoring human subject research in a manner consistent with federal regulations, state and local laws, and institutional guidelines and policies. Members must complete the IRB member training through CITI.

Removal. IRB members may be removed or replaced by the Institutional Official. Additionally, IRB members may be recused from participation in matters being decided by the IRB for reasons of conflict of interest or other reasons.

Use of Consultants by the IRB

The IRB is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be South College faculty or staff, affiliates, or experts not affiliated with South College. The consultants may present their assessments in writing, by telephone, or in person.

The IRB Coordinator

Selection and Appointment. The IRB Coordinator is appointed by the Institutional Official and serves on the board for a three-year term. Appointment to the committee begins on August 1st of the year appointed and ends July 30th of the final year of the appointment.

At the conclusion of a term, the IRB Coordinator may (or may not) be appointed to an additional term and/or year of service on the IRB.

Duties. The IRB Coordinator is a member of the administrative support staff with the responsibility to coordinate the privileged and confidential institutional review and approval process of proposed research activities involving human subjects.

The IRB Coordinator:

1. Serves as ex-officio member, with vote, on the IRB, to present evaluations, recommendations, historical information and precedents regarding compliance with laws, regulations, and ethical and safety standards.
2. Completes the CITI training and attends regional and/or national IRB conferences when possible for continuing education.
3. Assists the IRB in complying with federal and state laws, regulations, and Institutional policies and guidelines relevant to the use of human subjects in research.
4. Communicates committee requests to investigators for additional information and revisions and review responses.
5. Prepares correspondence, reports, agendas, and certifications of review for funding agencies related to review and approval process.
6. Independently reviews and approves administrative and procedural modifications; facilitates approval for emergency or unique opportunity situations.
7. Advises faculty, staff, and students in preparation of applications for research involving human subjects and consent documents.
8. Provides education to the South College community about the human subject protection process.
9. Completes the pre-review of applications.
10. Takes minutes at convened IRB meetings.

Removal. The IRB Coordinator may be removed or replaced by the Institutional Official.

18. CONFLICT OF INTEREST POLICY

When an investigator involved in research enrolling human subjects has disclosed a potential financial conflict of interest the Chair of the IRB may refer the case to the South College Conflict of Interest Committee as appropriate. The Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest. The IRB will collect the information necessary to fully inform the rest of the IRB as recommended in Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection (DHHS, May 5, 2004).

The IRB will carefully consider specific mechanisms to minimize the potential adverse consequences of the conflict in an effort to optimally protect the interests of the research subjects. In general, if there are any conflict of interest issues on the part of the researcher, he/she should not be directly engaged in aspects of the trial that could be influenced inappropriately by that conflict. These could include: the design of the trial, monitoring the trial, obtaining the informed consent, adverse event reporting, or analyzing the data. The IRB will also consider if the source of funding and funding arrangements should be included in the consent form.

In all cases good judgment, openness of process and reliance upon objective, third party oversight can effectively minimize the potential for harm to subjects and safeguard the integrity of the research.

No selection of IRB members by investigators. Investigators are not allowed to select which IRB member will review their application.

Prohibition of participation in IRB deliberations and voting by investigators. Review of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IRB on actions concerning research in which they have an active role or conflict of interest related to any person or entity connected with the application. Failure to abide by these provisions may be cause for removal of a member from the IRB.

IRB members must not vote on an application if they are investigators on the application or have any other conflict of interest with any person or entity connected to an application. The IRB member must make any conflict of interest known to the Chair and IRB Coordinator. The member may provide information to the IRB if requested. The fact that an application is submitted by another investigator from an IRB member's department or area does not, in and of itself, constitute a conflict of interest.

The member is not required to identify the exact nature of the conflict of interest. They may simply inform the Chair and IRB Coordinator that one exists. If the member has been assigned to review an application they should inform their unavailability to review the protocol to the IRB Coordinator as soon as possible so that the application can be reassigned to another reviewer. The member with the conflict of interest may participate in the discussion or deliberation to answer questions from the committee regarding the application under review to the same extent as any investigator when attending an IRB meeting. If there are no questions for the conflicted member, or after the conflicted member has answered any questions, he/she will be recused for the committee's deliberation and vote.

19. OPERATIONS OF THE IRB

Scheduling of Meetings

The IRB will meet once each month. The meeting dates are posted on the South College IRB website. The monthly meetings of the IRB may be conducted by email if it is not necessary to hold a convened (in person) meeting. Federal guidelines require IRBs to hold convened meetings of the full board to evaluate Full Review protocols. The IRB will convene once each month, as necessary, to evaluate Full Review protocols. Additional full board meetings or subcommittee meetings may be called by the Chair. The IRB will hold a convened meeting of the full board at least once per calendar year, even if no Full Review protocols are received. A convened meeting of the full board will occur in December if no other convened meetings occur during the calendar year. Monthly meetings will be arranged by the IRB Coordinator. The IRB Coordinator will make meeting sites available at the Parkside or Lonas campuses, as well as via online access, and notify committee members of the meeting details, i.e., location and time.

Receipt of Applications

Investigators may submit applications to the IRB office at any time. The types of IRB review are described in Section 11 (Types of IRB Review) and the review process is described in Section 13 (Steps in the IRB Application and Review Process). The IRB will attempt to review Exempt Status, Limited Review, and Expedited Review protocols within 10 business days of receipt of a complete application. Projects requiring Full Committee review must be submitted at least two weeks prior to the next convened meeting of the Full Committee.

Review of Applications

Pre-review. Upon receipt of all applications, the IRB Coordinator will pre-review the application for completeness before it is submitted to the IRB Chair for review. The IRB Chair will verify that the proposed research meets federal criteria for the requested review category. The IRB Coordinator will contact the investigator(s) in writing (email is acceptable) if any additional materials are required. The application will be assigned a registration number, YY-xxx, where YY indicates the last two digits of the year that the application was submitted, and xxx is the number given to the application in order of receipt.

Exempt Status Review. The IRB Chair, or any IRB member designated by the Chair, is authorized to independently review exempt status applications. If the reviewer needs additional information, he/she will communicate requests for additional information to the IRB Coordinator, who will ask the investigator for the information in writing (email is acceptable). Upon receipt of the additional information, the reviewer determines whether the research activities qualify under one or more of the exemption categories. The reviewer will make a determination within 10 business days of receipt of the application. After review of the application, the reviewer will make one of the following determinations:

- *Certification of Exemption.* The reviewer determines that the protocol qualifies under one or more of the exemption categories; the project is certified exempt from IRB continuing review with no changes required. An exemption notice is issued that

specifies the exemption category(ies). The investigator is sent notification in writing that their project has been certified as exempt and does not require continuing IRB review.

- *Certification of Exemption Pending Modifications.* The reviewer determines that there are minor issues/changes that must be addressed before the project can begin. The IRB Coordinator will notify the investigator of the requested revisions in writing. Upon receipt of the investigator's response, the reviewer determines if the revisions are sufficient. If the reviewer determines the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the reviewer determines whether the research activities qualify under one or more of the exemption categories.
- *Deferred for Re-review.* If the reviewer determines that the project does not qualify for exemption from IRB review, the IRB Coordinator will notify the investigator in writing that the request for exemption status has been denied, and that the investigator must submit an application for either Limited, Expedited, or Full Committee Review.
- *Not Human Subjects Research.* If the reviewer determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Coordinator will provide the investigator with a "Not Human Subjects Research" determination letter.

All members of the IRB committee will be informed of applications receiving exemption through Exempt Status Review in the monthly meeting minutes.

Limited Review. The IRB Chair, or any IRB member designated by the Chair, is authorized to independently review limited review applications. If the reviewer needs additional information, he/she will communicate requests for additional information to the IRB Coordinator, who will ask the investigator for the information in writing (email is acceptable). Upon receipt of the additional information, the reviewer determines whether the research activities qualify under one or both of the limited review categories. The reviewer will make a determination within 10 business days of receipt of the application. After review of the application, the reviewer will make one of the following determinations:

- *Approved.* The reviewer determines that the protocol qualifies under one or more of the limited review categories; no changes are required; all criteria for IRB approval are met.
- *Deferred for Re-review.* If the reviewer determines that the project does not qualify for or require limited review, the IRB Coordinator will notify the investigator in writing that the request for limited review status has been denied, and that the investigator must submit an application for Exempt Status Review, Expedited Review, or Full Committee Review, as appropriate.
- *Not Human Subjects Research.* If the reviewer determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Coordinator will provide the investigator with a "Not Human Subjects Research" determination letter.

All members of the IRB committee will be informed of applications approved through Limited Review in the monthly meeting minutes.

Expedited Review. The IRB Coordinator pre-reviews the application for completeness before it is submitted to the IRB Chair for review. The IRB Chair verifies that the proposed research meets federal criteria for Expedited Review. The Chair (or designee) selects a subcommittee of two members of the IRB to review the application. The IRB Chair may serve as one of the reviewers at his or her discretion. The IRB Chair may independently review the application at his or her discretion. If the reviewers need additional information to make a determination of expedited status, they will communicate requests for additional information to the IRB Coordinator, who will ask the investigator for the information in writing (email is acceptable). Upon receipt of the additional information, the reviewers will determine whether the research activities qualify under one or more of the expedited categories. The reviewers will make a determination within 10 business days of receipt of the application. After review of the application, the reviewers will make one of the following determinations:

- *Approved.* Both reviewers (or the Chair, if a single reviewer) determine that the protocol qualifies under one or more of the expedited categories; no changes are required; all criteria for IRB approval are met. The approval letter will indicate whether or not continuing review of the project is required.
- *Approved Pending Modifications.* One or both reviewers determine that there are minor issues/changes that must be addressed before the project can begin. The IRB Coordinator will notify the investigator of the requested revisions in writing. Upon receipt of the investigator's response, the reviewer(s) determine if the revisions are sufficient. If the reviewer(s) determine the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the reviewer(s) determine whether the research activities qualify under one or more of the expedited categories.
- *Deferred for Re-review.* If one or both reviewers determine that the project does not qualify for or require expedited review, the IRB Coordinator will notify the investigator in writing that the request for expedited review status has been denied, and that the investigator must submit an application for Exempt Status Review, Limited Review, or Full Committee Review, as appropriate.
- *Disapproved.* Only the Full Committee may disapprove a study if the criteria for IRB approval are not met.
- *Not Human Subjects Research.* If the reviewer determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Coordinator will provide the investigator with a "Not Human Subjects Research" determination letter.

All members of the IRB committee will be informed of applications approved through Expedited Review in the monthly meeting minutes.

Full Committee Review. All human subjects research that does not qualify for Exempt, Limited, or Expedited Review must receive Full Committee Review. Also evaluated by a Full Committee

Review are reports of unanticipated problems, and allegations of serious and/or continuing noncompliance.

The IRB Coordinator conducts a pre-review of the application for completeness and forwards it to the IRB Chair, who determines that the project requires Full Committee Review. The Chair (or designee) selects three members of the IRB to serve as primary reviewers based on an appropriate balance of scientific and non-scientific expertise required for each application. If the Chair determines that the appropriate scientific expertise is not available within the IRB, the Chair may invite an internal or external consultant to serve as one of the primary reviewers. If the application involves vulnerable populations, such as children, cognitively impaired, or prisoner populations, the Chair may invite a special subject population representative to serve as one of the primary reviewers.

The IRB Coordinator distributes the application and related study materials to the primary reviewers and all other IRB members at least one week in advance of the scheduled meeting date to allow sufficient review of the materials. If the primary reviewers identify the need for additional information about an application, they will communicate these requests to the IRB Coordinator, who will ask the investigator for the information in writing (email is acceptable).

Any additional information needed for review of an application should be obtained before the full committee is convened at the scheduled meeting. All IRB members are expected to review and be familiar with all protocols prior to the Full Committee Review.

The Full Committee Review must be conducted at a convened meeting at which a quorum consisting of a majority of the members of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. If an IRB Member is unable to attend a convened meeting, he/she is responsible for informing the IRB Coordinator with sufficient lead time so that an IRB Alternate Member may be assigned to review the proposal and attend the convened meeting. Approval of research is by a majority vote of the quorum. An IRB member with a conflicting interest on a project may be present to answer questions about the project, but must recuse himself/herself and may not participate in the subsequent discussion and voting. The IRB Coordinator is responsible for documenting a quorum in the meeting minutes and monitoring the maintenance of a quorum during the meeting. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a non-scientist member), discussion of protocols may continue, but the IRB may not take further actions or votes unless the quorum can be restored. Each IRB member has one vote and no proxy votes are allowed.

At the discretion of the Chair and/or primary reviewers, the investigator may be invited to attend the Full Committee Review meeting (in person or by phone) for the purpose of additional clarification or discussion. The investigator is required to leave the meeting for subsequent discussion and voting. The primary reviewers are each responsible for providing a brief summary of the project to the committee, identifying any concerns, and making a recommendation for the disposition of the application. All other IRB members are expected to have reviewed all materials in sufficient depth to discuss them at the convened meeting. After

discussion of the application is completed, all IRB members will vote on one of the following determinations:

- *Approved.* A majority vote of the quorum determines that all criteria for IRB approval are met and that no changes are required. The approval letter will indicate if review of the project is required more often than annually based upon determination of the committee.
- *Approved Pending Modifications.* A majority vote of the quorum determines that there are minor issues/changes that must be addressed before the project can begin. The IRB Coordinator will notify the investigator of the requested revisions in writing. Upon receipt of the investigator's response, the Chair will determine if the revisions are sufficient. If the Chair determines the revisions are insufficient, the investigator may be asked to make additional modifications. This process will repeat until the Chair determines that that issues/changes raised by the full committee have been adequately addressed.
- *Disapproved.* A majority vote of the quorum determines that criteria for IRB approval have not been met. Only the Full Committee may disapprove a study. Institutional administrative officials may not override this decision.
- *Tabled.* Criteria for a convened Full Committee Review are not met, and/or appropriate expertise is not available at the meeting.
- *Deferred for Re-review.* If a majority vote of the quorum determines that the project does not require Full Committee Review, the IRB Coordinator will notify the investigator in writing that the investigator must submit an application for Exempt Status Review, Limited Review, or Expedited Review, as appropriate.
- *Not Human Subjects Research.* If a majority vote of the quorum determines that the project does not meet the definition of *research* and/or does not involve *human subjects*, the IRB Coordinator will provide the investigator with a "Not Human Subjects Research" determination letter.

Continuing Review. Continuing Review of all projects initially approved by Full Committee Review is required at least annually. The IRB may require more frequent review of a project depending on the nature of the study, the degree of risk involved to human subjects, and the vulnerability of the study population. The initial approval letter sent to investigators will include the date of approval and the date on which the project will expire without receiving approval of a Continuing Review application.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- research reviewed by the IRB in accordance with the limited IRB review;
- research eligible for expedited review; and
- research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

As a courtesy, the IRB will send Continuing Review reminders to investigators approximately 90, 60, and 30 days before a project expires. However, it is ultimately the investigator's responsibility to initiate a Continuing Review application and to allow sufficient time for the review and re-approval process to be completed before the current approval expires. If an IRB approved project expires, all research activities involving human subjects must stop. These activities involve subject contact, data collection, and data analysis.

Communication from the IRB to Investigators
IRB actions are communicated to investigators in writing (email is acceptable) by the IRB Coordinator within 5 business days of the rendered decision.

Stamping the Materials with IRB Approval
After the study materials have been reviewed and approved by the IRB, prior to sending the approval letter on non-exempt applications, the IRB Coordinator stamps the English and non-English signed consent, parent permission and assent forms, and HIPAA authorization forms. The PI needs to submit these forms via e-mail to the IRB Coordinator to facilitate the stamping process. The approval stamp is placed on the Word version of the forms electronically and converted to PDF before sending out to the researchers. The stamp includes the South College IRB number, along with the activity number, the word "Approved," the date of approval (MM/DD/YYYY), and valid until date (MM/DD/YYYY). The IRB approval stamp will appear in the bottom, middle of the written materials. If there is no space in that location for the stamp, then it will appear in the top portion of the document. Copies of the stamped materials will be e-mailed to the researcher along with the approval. The approved materials should be used by the researchers during the consent process. This requirement does not apply when the consent process is via e-mail, verbal, or consent is embedded in a survey or questionnaire on the online system.

During continuing review, the investigator indicates on the continuing review form if there are any changes on the forms, and submits the new forms to the IRB. The IRB will review the changes and re-stamp the materials if necessary. If there are no changes, the IRB will use the previously approved consent forms to re-stamp with a new date of approval.

Appeal of IRB Decisions
If an IRB application receiving Full Committee Review is disapproved, the reasons for disapproval will be conveyed to the investigator in writing. The investigator may request the IRB to reconsider by responding in writing, and may request an opportunity to appear before the IRB. The application may be resubmitted if the reasons for disapproval have been corrected.

Cooperative Agreements and Individual Investigator Agreement
The South College IRB enters into written cooperative agreements or individual investigator agreements with the IRBs of other institutions when such agreements facilitate and streamline the IRB process while ensuring that the rights and welfare of human participants are fully protected. The cooperative agreements allow South College faculty, staff, and students to complete the review forms for the other institution's IRB and submit the form to the South

College IRB. The South College IRB Coordinator documents the application form, completes administrative review, and forwards the material to the other institution's IRB for review. The South College IRB will receive documentation of actions taken on the application and subsequent reviews of the application from the other institution's IRB. This allows South College faculty, staff, and students to complete one IRB application and receive review from only one IRB, thus facilitating the review and approval of certain research covered by the appropriate cooperative agreement while simultaneously ensuring that human participants are fully protected.

Allegations of Non-compliance

The IRB will investigate any allegations of non-compliance as stipulated in the federal regulations. Any allegation will be discussed with the principal investigator of the IRB application in question. Any investigation of alleged non-compliance will require close cooperation and coordination with the principal investigator of the research.

If there appears to be credible evidence of non-compliance, this situation will be presented to the Dean and/or Department Chair and to the Institutional Official. Any non-compliance based upon federal regulations will be reported to federal agencies and funding agencies as required. Based on the nature of any non-compliant activity, the IRB has the authority to suspend or terminate the project.

Complaints

The IRB Coordinator will communicate any research participants' complaints or concerns that may arise to the IRB Chair. In general, the IRB can respond to complaints or concerns regarding the participant's rights as a paid participant or a volunteer participant in the research. The IRB Coordinator will assist the participant to get answers to any other complaints or concerns from the principal investigator.

Post-approval Review and Monitoring

The IRB may initiate reviews of approved IRB applications at any time. Post-approval reviews may be initiated for cause (request of the principal investigator, allegation of non-compliance, questions from research participants, post-approval monitoring, etc.) or for no cause (random sampling of approved applications, etc.). Post-approval review findings that indicate variances from approved applications, adverse events, or unanticipated events will be reported to the Institutional Official and federal agencies as required by the federal regulations. Based on the nature of any non-compliant activity, the IRB has the authority to suspend or terminate the project.

20. IRB RECORD REQUIREMENTS

The IRB will prepare and maintain adequate documentation of IRB activities, including:

1. Copies of all research proposals reviewed, scientific evaluations (if any) that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings that are in sufficient detail to show:
    a. attendance at the meetings,
    b. actions taken by the IRB,
    c. the vote on these actions including the number of members voting for, against, and abstaining,
    d. the basis for requiring changes in or disapproving research; and
    e. a written summary of the discussion of controverted issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.
6. Written procedures that the IRB will follow:
    a. for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
    b. for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and
    c. for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
7. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of:
    a. any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and
    b. any suspension or termination of IRB approval.
8. A statement in the informed consent documents that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

IRB records will be retained for at least 3 years, and records relating to research that is conducted will be retained for at least 3 years after completion of the research. All records will

be accessible for inspection and copying by authorized representatives of the federal department or agency at reasonable times and in a reasonable manner.

The IRB Coordinator will maintain IRB meeting agendas, meeting minutes, and IRB rosters as a permanent record of the committee's activities.

Policy guidance and forms will be disseminated from and stored by the IRB Coordinator until replaced by new and/or revised documents.

21. DISCUSSION OF SPECIAL TOPICS AND ACTIVITIES

Alcohol

Consistent with the National Advisory Council on Alcohol Abuse and Alcoholism, South College recognizes the legitimate and important need for research involving the biological and behavioral effects of the ingestion of ethyl alcohol on human subjects.

It is essential that such research conform to the (ethical) principles that govern all research involving human subjects. These principles are elaborated upon in the latest report prepared for the National Institute on Alcohol Abuse and Alcoholism by the National Advisory Council on Alcohol Abuse and Alcoholism. The NIAAA website (http://www.niaaa.nih.gov/) provides information on research involving the administration of alcohol and also contains the latest NIAAA guidelines (http://www.niaaa.nih.gov/Resources/ResearchResources/job22.htm).

The IRB refers to and is guided by the NIAAA guidelines when reviewing research involving alcohol and researchers are strongly encouraged to review these guidelines prior to submitting applications to the IRB.

Depending on the nature of the research and the perceived risk to the participants the IRB may require frequent blood alcohol level (BAL) measurements, based on time intervals or numbers of participants. The IRB also may approve a limited number of initial human participants and require submission of BAL measurements for review before approving additional participants.

Certificate of Confidentiality

A certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. These certificates are issued by the NIH. Certificates protect against compulsory legal demands, such as court orders, and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information: https://humansubjects.nih.gov/coc/index

Children

South College adheres to Subpart D of the DHHS regulations (Additional Protections for Children Involved as Subjects in Research). Children are persons who have not attained the

legal age of 18 years. The IRB will require that children 7 years old and older provide their assent to participate in research activities. Written assent should be obtained from children 7 through 17 years of age.

The regulations contain specific requirements and documentation for research involving children. Research that does not involve greater that minimal risk can be approved only if the IRB finds that adequate provisions are made for soliciting the assent of children and the permission of the parents. Research involving greater than minimal risk may be approved under three general conditions:

1. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects;
2. Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalized knowledge about the subject's disorder or condition; and
3. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

In general, research involving children will be reviewed at the expedited or full board level. When the research involves observation of public behavior and the investigator does not participate in the activities being observed an exempt review may be utilized. Unless there are compelling reasons not to obtain parental permission and/or child assent the IRB will generally expect that both will be obtained.

Confidentiality Agreements

Depending on the confidentiality of the material being collected, the IRB may request signed confidentiality agreements with certain study personnel (depending on the role in the research). Individuals with limited involvement (e.g., translator, transcriptionist, specific data analyses duties) may be asked to sign confidentiality agreements.

The IRB does not require confidentiality agreements in all situations except when the confidentiality (sensitivity of the material) warrants such consideration.

NOTE: Certificate of confidentiality is different from confidentiality agreement.

Facilities/Locations

Whenever South College faculty, staff, or students, will be conducting human subjects research at other facilities (such as hospitals, clinics, schools, school districts, factories, offices, etc.), the researcher must ensure that the outside entity is aware of the proposed research activity and has no objections (i.e., agrees to participate). If the research will be conducted at any location other than South College, the investigator is responsible for obtaining a letter of support from each site. The letter will be from a person in authority to grant permission to perform research at the site. The letter will be addressed to the investigator and indicate that they are knowledgeable about the nature of the research project that will be performed and that they

approve of this research to be conducted in their business or facility. A copy of the letter should be attached to the submitted research protocol.

Genetic Research

Genetic testing and analysis is increasing and evolving rapidly. The IRB is concerned with protecting human participants, following OHRP/FDA advice and guidelines, and assisting researchers who are conducting genetic research.

In general, genetic research will require detailed and specific disclosure in the informed consent documents. Examples of items the IRB will look for:

1. Will samples be identified, confidential, or anonymous?
2. What tests/analyses will be performed on the material?
3. Will samples be destroyed (if so, when) or will the samples be stored for future analyses?
4. If stored for future analyses, what type of research/analyses will be conducted? Any research study (open for any use), broad class of disease/study (diseases of the eye), or specific disease or genes only?
5. If samples will be stored for future use (data repository), how will the samples or identities remain protected?
6. If serious illnesses/diseases are detected/identified, will the participant be informed or not receive any tests results?
7. If results are given, how will the participant be counseled? More details from OHRP are available at: http://www.hhs.gov/ohrp/policy/gina.html

Internet (or On-line, Computer) Based Research

Use of the internet and other computer based research methods is evolving rapidly and offering many new methods for researchers to contact research participants and collect data for research (including opportunities for large numbers of participants, ease of data collection, possibilities for anonymity, etc.). All of the same IRB considerations and federal regulations apply; however, use of the internet also creates challenges for the IRB.

- Recruitment. There are many methods of recruitment. Indirect recruitment would include using flyers and announcements that direct individuals to websites to participate in the research. Direct recruitment may include sending e-mails or letters directly to individuals whom the researcher would like to recruit. Researchers should ask themselves the following questions: For direct recruitment, would the participants reasonably expect the researcher to contact them regarding the research topic? Authentication can be a major challenge for internet based research. How does the researcher know who the researcher is actually communicating with/recruiting?
- Informed consent. Minimal risk research may qualify for a waiver or alteration of consent, or a waiver of documentation of consent. The IRB would generally require the information normally contained in the consent be provided to participants so participants may make an informed decision as to whether to participate. Greater than minimal risk research may require more traditional methods, such as mailing an informed consent document and receiving the participant's signed copy, although

researchers may present suggestions to the IRB. Again, authentication may be a challenge for internet based consent.

- Anonymity/confidentiality. The internet and computer based research can offer a "false sense" of anonymity/confidentiality. The researcher will be required to explain to the IRB how anonymity/confidentiality will be maintained. This will often rely on server administration/security. The use of encryption should be considered and may be encouraged or required by the IRB. Whenever possible, identifiable data should be de-identified. Any code linking data to identities should not be stored on the same server as the data.
- Data collection. Depending on the type of data being collected, encryption may be suggested or required.
- Data storage/disposal. Whenever possible, personal identifiers should be stored separately from the data and/or the codes linking the data to individuals. Back-up storage is always a consideration with electronic media. The IRB will be as concerned with the security of the back-up material as it is with the original material. Final data destruction of electronic media can be complex. The IRB will want assurance that the data deleted is truly not recoverable.

Prisoners

The federal regulations have specific requirements for research involving prisoners. These requirements are found in Subpart C of the DHHS regulations (45 CFR Part 46). "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statue, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Subpart C contains many specific requirements for research involving prisoners and should be reviewed by the researcher. In order to review research involving prisoners, the IRB is required to have a prisoner representative with appropriate background and expertise to serve in that capacity on the committee. The OHRP has specific guidance for involving prisoners in research.

Recording (Photographs, Audio, Video)

Federal regulations require that whenever voice, video, digital, or image recordings are made, the application must be reviewed by Expedited or Full Committee Review. Expedited Reviews are possible if the research does not involve vulnerable participants and the information collected is not of a sensitive nature (e.g., sexual behavior, illegal activities, etc.).

The type of recording must be disclosed in the informed consent document. The investigator must clearly specify the steps taken to maintain the confidentiality of this identifiable information, both in the IRB application and in the informed consent documents. When the recording is deemed necessary to the research the informed consent must clearly indicate such. When recording is not absolutely necessary to the researcher a separate signature line for the

recording acceptance should be included on the consent form so that the participant could choose to participate in the study but decline the recording of their participation.

The IRB considers recording for purposes of transcription only not to be part of the research that would automatically require Expedited Review.

Suicide/Depression

Research involving depression indices and scales can reveal information or disclosures that carry additional responsibilities for researchers. Studies with suicide or suicidal ideation related questions also require additional safeguards and responsibilities on the part of the researcher. The consent document will also need to contain specific information regarding the risks, resources for counseling, and reporting of certain information. The IRB will consider the following:

1. What is the level of risk? A brief depression index or a detailed questionnaire on suicidal ideations?
2. Is the individual obtaining consent or administering the survey/interview qualified to provide counseling? If not, how will counseling be made available?
3. Does the informed consent provide specific phone numbers or locations where counseling services can be accessed by other participants?
4. If a participant expresses the potential for self-harm or harm to others, how will the situation be handled? Who will be contacted? Such situations may require mandatory reporting to law enforcement (this should be disclosed in the informed consent).

22. DEFINITIONS

Anonymous: Subjects' identities are unknown to the investigator, not requested, and not given. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should use implied consent, to preserve anonymity.

Application: The formal design or plan of a study's activity; specifically, the plan submitted to an IRB for review and to an agency for support. The application includes a description of the design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Assent: Agreement by subjects not competent to give legally valid informed consent (e.g., children or cognitively impaired people) to participate in the study. Assent refers to a child's affirmative agreement to participate in the research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance: A formal written, binding commitment that is submitted to a federal agency, in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979.

Benefit: A valued or desired outcome to the study that will be an advantage to the subjects participating. Compensation is not considered as a benefit.

Biomedical Research: Studies that are designed to evaluate the safety, effectiveness, or usefulness of an intervention including research on therapies (e.g., drugs, diet, exercise, surgical interventions, medical devices), diagnostic procedures (e.g., CAT scans, prenatal diagnosis through amniocentesis, chronic villi testing) and preventive measures (e.g., vaccines, diet, fluoridated toothpaste). It can also include normal human functioning and development, comparing the functioning of a particular physiological system at different stages of development (e.g., infancy, childhood, adolescence, adulthood, old age), or define normal childhood development. It includes research used to develop and refine hypotheses. Research on specific disease (e.g., research on the biochemical changes associated with AIDS or schizophrenia, the neurological changes associated with senile dementia of the Alzheimer type) and the human genome and genetic markers fall under biomedical research.
Biomedical research is focused on:

- Specific diseases and health conditions (mental or physical), including: detection, cause, treatment, prevention, and rehabilitation.
- Evaluation and testing of the safety, effectiveness, or usefulness of an intervention, treatment or therapy.
- Normal and abnormal physiology, human functioning, and development.
- Cognitive, emotional, and behavioral responses to real or potential health problems.
- The human genome and genetic markers.
- The incidence and prevalence of illness and injury among populations and strategies for prevention and health promotion.

Certificate of Confidentiality: A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information: http://grants.nih.gov/grants/policy/coc/

Certification: Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Common Rule: A large majority of Federal Agencies simultaneously published a regulation or "Common Rule" on June 18, 1991 to regulate the conduct or support of human subject research. The rule is set forth in 45 CFR Part 46, Subpart A. Subpart A consists of 45 CFR 46.101 to 46.124. On January 18, 2017, The U.S. Department of Health and Human Services and 15 other federal agencies issued a final rule to update regulations that safeguard individuals who participate in research. Most of the revisions to the Common Rule will go into effect on January 19, 2018.

Confidential: Subjects' names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. This is usually used, for example, when the investigator must match test results with surveys or if there will be a follow-up survey. The investigator must know the subjects' names.

Continuing Review: Continuing Review of all projects initially approved by Full Committee Review is required at least annually. The IRB may require more frequent review of a project depending on the nature of the study, the degree of risk involved to human subjects, and the vulnerability of the study population.

Crime: A crime is a wrongdoing which has been classified by the state or federal legislative body as a felony or misdemeanor.

Data: Refers to information that is collected for analysis or used to reason or make decisions.

Deception: Deception is the intentional misleading of subjects or the withholding of full information about the nature of the experiment. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns because it interferes with the ability of the subject to give informed consent. However, deception is arguably necessary for certain types of behavioral research. Because humans act differently depending on circumstances, full knowledge by the subject might bias the results.

De-identified Data: De-identified data excludes all eighteen HIPAA Identifiers. De-identified data is not "anonymous data" under the Common Rule.

Directly or Indirectly Identifiable: Identities of individual subjects are kept by the investigator. If subjects' identities are inseparable from data, then data is directly identifiable. If subjects' identities are kept separate from data with information connecting them maintained by codes and a master list, then the data is indirectly identifiable. In either case, the investigator must assure that confidentiality will be maintained, and must explain how subjects' identities will be protected.

- **Direct identifiers (HIPAA Identifiers):** Direct identifiers in research data or records include: names; geographic subdivisions smaller than a State; dates (except year) directly related to patient; telephone numbers; fax numbers; e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web URLs; Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other unique identifying number, characteristic, or code, except as permitted under HIPAA to re-identify data.
- **Identifiable data or records:** Contains information that reveals or can likely associate with the identity of the person or persons to whom the data or records pertain. Research data or records with direct identifiers removed, but which retain indirect identifiers, are still considered identifiable.
- **In-direct identifiers:** Indirect identifiers in research data or records include all geographic identifiers smaller than a state, including street address, city, county, precinct, zip code, and their equivalent postal codes, except for the initial three digits of a zip codes; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such age and elements may be aggregated into a single category of age 90 or older.

Educational Setting: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management method.

Exempt: The Common Rule specifies that research activities may be classified as exempt in the policy if human subjects' involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or not personally identifiable. Exempt Status Reviews are evaluated by the IRB and will take approximately 10 working days for certification once they arrive at OSPR.

Generalized Knowledge: Knowledge that could be applied to populations outside of the population served by the covered entity. This definition can vary. Examples of activities that typically are not generalized include:

- Biographies.
- Oral histories that are designed solely to a create record of specific historical events.
- Service or course evaluations, unless they can be generalized to other individuals.
- Services, or concepts where it is not the intention to share the results beyond South College or any agency supporting the research.
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices.

- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the South College community.

HIPAA: Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased.

HIPAA Research Authorization: The Research Authorization required under the HIPAA Privacy Rule is a written patient authorization that must specify:

- Who can use or disclose Protected Health Information (PHI)
- To whom PHI may be disclosed
- What PHI may be used or disclosed
- The purposes of the used or disclosed PHI
- The duration of the authorization (expiration date or event)

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable Private Information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Informed Consent: The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Institutional Review Board (IRB): A committee formed to facilitate the protection of human subjects in research.

Intentionally Identified: Subjects' names are identified in connection with the data when the research results are presented to the public. This procedure is common for journalistic-type interview studies, where subjects are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the subjects for the use of their names in connection with their data.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Interpreter/Translator: An agent of the researcher(s), who assists in the facilitation of communication between the researcher(s) and participants who are not fluent in the language of the researcher(s).

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Neonate: Newborn.

Personally Identifiable Health Information: Health or medical data or information that can be linked manifestly or inferentially to an individual.

Population: A group of people in society meeting certain criteria to be eligible as subjects in a research protocol.

Principal Investigator (PI): The individual with primary responsibility for the design and conduct of a research study. When a South College student serves as the PI, a South College faculty member must serve as the Co-PI and the faculty member shares full responsibility for the design and conduct of the study.

Prisoner: A prisoner is defined by federal regulations as any individual involuntarily confined or detained in a penal institution and/or individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to incarceration.

Privacy: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

Protected Health Information (PHI): Individually identifiable health information recorded in any form or medium that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of heath care to an individual.

Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from a contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Publicly Available Data: Public sources of data, such as census data.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Risk: The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Secondary Research: Re-using identifiable information and identifiable biospecimens that were collected for some other 'primary' or 'initial' activity.

Significant Risk: A study's design that presents a potential for serious risk to the health, safety or welfare of the subjects.

Social and Behavioral Research: Behavioral and social sciences research is a large, multifaceted field, encompassing a wide array of disciplines. The field employs a variety of methodological

approaches including: surveys and questionnaires, interviews, randomized clinical trials, direct observation, physiological manipulations and recording, descriptive methods, laboratory and field experiments, standardized tests, economic analyses, statistical modeling, ethnography, and evaluation. Yet, behavioral and social sciences research is not restricted to a set of disciplines or methodological approaches. Instead, the field is defined by substantive areas of research that transcend disciplinary and methodological boundaries. In addition, several key cross-cutting themes characterize social and behavioral sciences research. These include: an emphasis on theory-driven research; the search for general principles of behavioral and social functioning; the importance ascribed to a developmental, lifespan perspective; an emphasis on individual variation, and variation across sociodemographic categories such as gender, age, and sociocultural status; and a focus on both the social and biological contexts of behavior.

Substance Abuse: Substance abuse refers to the use of substances when said use is causing detriment to the individual's physical health or cause the user legal, social, financial or other problems , up to, and including, endangering their lives or the lives of others. Substance abuse is not specific to illegal substances. Substance abuse also includes the abuse of legal substances that are legitimately purchased or prescribed.

Systematic: Step-by-step, methodical procedure presented or formulated as a coherent body of ideas or principles.

Vulnerability: Vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research.

Voluntary: Free of coercion, duress, or undue inducement.

Written, or In Writing: Writing on a tangible medium (e.g., paper) or in an electronic format.