SOUTHEASTERN COMMUNITY COLLEGE

INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

Standard Operating Procedures

Adopted June 2007
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Introduction

Southeastern Community College encourages and supports the scholarly endeavors of students, faculty, and staff of the College. Pursuit of scholarly work and research will often involve the use of human participants for data collection and analysis. Southeastern Community College's Institutional Review Board (IRB) reviews human participant research proposals to ensure that the rights and welfare of human participants used in research studies by College personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human participants only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit participant participation or begin data collection until they have obtained clearance by the Southeastern Community College Institutional Review Board.

Some research projects involving human participants are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the participants are not identified; and surveys or interviews in which the participants volunteer and are not personally identified.

The Institutional Review Board (IRB) for Human Subjects Research at Southeastern Community College has responsibility to oversee procedures for carrying out the College's commitment to protect human participants in research. The role of the IRB is to review proposed research projects that involve the use of human participants; ensure that the individuals involved in the project are treated ethically; ensure that all participants are provided with substantial information about the study and consent to be a participant in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human participants.

Institutional Authority and Purpose

I. Institutional Authority

This Charter and Standard Operating Procedures establishes and empowers the Southeastern Community College (SCC) Human Subjects protection committee. Currently Southeastern Community College has one committee, registered with the federal Office for Human Research Protections (OHRP) as IRB00007885 Southeastern Community College IRB #1. This committee is hereinafter referred to as "the IRB." The IRB registration must be renewed at least every three years.

II. Purpose

The primary purpose of the IRB is to protect the welfare of human participants in research.

III. Basic Principles

A. The basic principles that govern the IRB in assuring that the rights and welfare of participants are protected are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979; see http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#

B. Therefore, the following principles apply to all research involving human participants at Southeastern Community College to ensure that adequate safeguards are provided:

1. Participants' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
2. Risks to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to results.
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research participant.
4. Adequate provisions should be made for recruiting a participant population base in terms of gender and minority representation unless scientifically justified.
5. Research involving human participants must be supervised by qualified persons.
6. Participation of a human participant in research must be voluntary, and the right to withdraw at any time must be provided. Information to gain participant consent must be adequate, appropriate, and presented in lay language appropriate to the participant population.
7. All research protocols that involve human participants must be reviewed by and must receive approval of a formally constituted review *prior* to their initiation or *prior* to initiating any changes to the protocol. Continuing research programs are participant to periodic review, to be carried out no less than once a year.

IV. Applicability of the IRB

A. Southeastern Community College holds a Federalwide Assurance (FWA00016644) through its IRB registration with the ORHP (http://ohrp.cit.nih.gov/search/IOrgDtl.aspx). As part of this Assurance, SCC agrees to consider *all* research involving the use of humans as research participants as being participant to federal regulations, regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution, unless it is conducted at another institution with which SCC has an *IRB Authorization Agreement*; or
2. The research is conducted by or under the direction of any employee or agent of this institution, unless the research is conducted at another institution with which SCC has an *IRB Authorization Agreement*; or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution; or
4. The research involves the use of this institution's non-public information to identify or contact human research participants or prospective participants.

B. Student Research

In some instances, faculty develop course-related activities that are designed to provide opportunities for students to practice research methods, i.e., research design, interviews, surveys, observation, data analysis, etc. Such activities that are limited to class members, present no more than minimal risk to participants, and do not lead to generalizable results do not require IRB review. Such activities that include gathering original data from people outside of class do require IRB approval, thus completion of SCC's *Application for IRB Review*, before data collection from human participants can begin. Class projects that rely on collecting information from people outside of class to provide material for class discussions, reflection, demonstrations, etc., are not research and do not require IRB approval.

C. Cooperative activities relating to human participants are those which involve Southeastern Community College and another institution. The IRB of one institution may rely on the IRB of the other instruction if

1. Both institutions have Federalwide Assurances (FWAs) approved by OHRP;
2. Both institutions have entered in an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and
3. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

Absent these conditions, the investigator must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approval to the other IRBs. The IRB chair will verify (via the OHRP website) that the other institution(s) has/have approved FWAs.

D. The IRB reviews all projects and programs involving human participants in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

E. The IRB provides continuing advice and counsel to personnel engaged in activities involving human participants.

F. The IRB has approval authority of human participant protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human participant protection. Research that has been approved by the IRB may be participant to further appropriate review and approval or disapproval by the Southeastern Community College president. However, the SCC president may not approve the non-exempt research if it has not been approved by the IRB.

G. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

H. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the participants in that study.

I. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

J. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an *IRB Authorization Agreement*), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

V. The IRB's Functional Relationships

A. The institutional officer overseeing IRB activities is the executive director of institutional advancement. The title for this position is IRB Administrator.

B. The IRB functions administratively through the Office of Institutional Research. This structure provides for administrative coordination for the IRB with the various academic and administrative units at Southeastern Community College.

C. The IRB advises and makes recommendations to the college president, to policy and administrative bodies, and to any member of the Southeastern Community College community on all matters related to the use of human participants in research.

D. Policies and procedures developed for human participant research are approved by the current IRB members.

Membership of the IRB

I. Membership Criteria

A. The IRB is composed of at least six voting members. Membership occurs when qualified persons are nominated by current IRB members, consensus is reached, and written invitations to serve are extended by the IRB chair. Once accepted, individuals are appointed by Executive Memorandum and reported to OHRP.

B. The institutional research secretary serves as the secretary to the IRB and is not a voting member. The IRB secretary is charged with notifying members of meetings, recording complete minutes of all meetings, and maintaining membership documentation.

C. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of Southeastern Community College regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

D. The IRB must include both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated with the Southeastern Community College. An individual is considered to be 'affiliated' if he or she is a current or former employee or family member of any current or former employee, retiree, trainee, consultant, or board member of Southeastern Community College, or any institution for which Southeastern Community College has served as the IRB of record; or if that person's relationship with the institution is anything other than that of an IRB member.

E. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

II. Alternate Members

Alternate and non-voting members may be appointed and need to represent the functional areas from which they were appointed. An alternate member must possess qualifications that are comparable to those of the IRB member(s) for whom the alternate will serve. Alternates are listed on the membership roster of the IRB along with the name(s) or class(es) of IRB members for whom the alternate may serve.

Alternates are authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. When the alternate member substitutes for the regular member at a convened meeting, the alternate is counted in the quorum and has voting privileges.

III. Membership Documentation

A current roster of all IRB members is kept in the IRB folder on the SCC network, to which all members have access, and contains the following information:

A. Name

B. Degrees earned (if any)

C. Gender

D. Representational capacity (scientist, non-scientist)

E. Relationship to the institution (affiliated, non-affiliated)

F. Identification of specific role, if any, e.g., chair, specified alternate

G. Representative of specific entity, e.g., psychology, student services

H. Training in human subjects research

I. Conflict-of-interest disclosures.

Changes in membership are reported online to the OHRP as they occur by the IRB chair.

IV. Tenure

Members and alternates of the IRB shall serve for a tenure of three (3) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will solicit nominations from current IRB members, extend invitations, and once accepted, appointments are made by Executive Memorandum and reported to OHRP.

The IRB chair will be appointed by current IRB members and shall have served as an IRB member prior to the appointment as Chair and thus demonstrate knowledge of human participants' protections. The IRB chair is a voting member of the IRB, presides over all convened IRB meetings, and has the authority to sign all IRB action items. The IRB chair shall serve initially for three years and may serve multiple terms.

V. Training

All IRB members and all alternates must demonstrate knowledge of human research protection by providing documentation of having completed such formal training as that provided online by HRSA at http://www.hrsa.gov/publichealth/clinical/humansubjects/. The IRB secretary will maintain a log of training completion dates. Retraining should be done every three years. A newly appointed member or alternate must complete the training before casting a vote at a convened IRB meeting.

VI. Conflict of Interest Guidelines

An investigator can be a member of the IRB; however, the investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest.

IRB members will, at the beginning of their service on the IRB, and annually thereafter, report their potential conflicts of interest by filling out the *Research Investigator Financial & Other Personal Interests Disclosure For*m.

IRB members do not receive compensation for their service.

Liability coverage for IRB members is provided through Southeastern Community College's liability insurance coverage, whether or not the IRB member is an employee of Southeastern Community College.

Operations of the IRB

I. Meetings

A. There is at least one IRB meeting scheduled every quarter, in March, June, September, and December. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven days prior to the meeting. Members may attend the meeting from a distant location via telephone or Internet connections.

B. Convened meetings are open to the public, but materials submitted for review, discussions of protocols, and individual votes are confidential and should not be discussed outside of the meeting context. The Chair can move the meeting to Executive Session, during which time visitors will need to leave.

II. Review Assignment

A. The IRB chair assigns one primary reviewer and may assign at least one secondary reviewer for each new protocol, who receive the complete study documentation for review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that protocol.

B. All IRB members have access to complete study documentation, which will be posted on the SCC Network drive in a folder to which only the IRB has access. If external reviewers are also assigned, they must be participant to the same conflict of interest policies as IRB members.

C. All actions of the IRB will be electronically communicated to the Principal Investigator via email. This communication will include the IRB decision (Approved, Approved with restrictions, or Disapproved), a listing of any restrictions, and a summary of the reasons for any decisions other than Approved. Information on how the PI can appeal the decision will be included.

III. Voting Requirements

A. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

B. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines. It will also be acceptable for voting to occur via email.

C. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

D. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

IV. Minutes

A. Complete minutes of all convened IRB meetings are taken by the IRB secretary.

B. Minutes are provided to all committee members prior to the subsequent meeting for their review prior to the meeting.

C. Minutes are approved by the committee at the subsequent meeting. Once approved, they may not be altered by anyone, including any higher institutional authorities.

D. The IRB secretary will provide a copy of the minutes via email to all IRB members within 3 weeks of the meeting date, and a copy will be posted in the IRB folder of the college network drive.

E. Minutes include the following elements:

1. Member attendance at the meeting, including when an alternate member has replaced a primary member, and (if both are present) which is being counted for purposes of establishing a quorum. The minutes will document the members who attend via teleconference.

2. Visitor attendance at the meeting.

3. Roles (e.g. community representative, representative of vulnerable populations, VA representative) of each person present at meeting, including any alternate members who are replacing primary members at the meeting.

4. Any changes in attendance for each action taken by the committee (e.g. changes due to members who have left or joined during the meeting). Names of members will be recorded as changes in attendance occur. If members have absented or recused themselves due to a conflict of interest, the member name and this reason are recorded in the minutes.

5. A summary of any controversial issues and their resolution.

6. For any protocol requiring revision prior to approval, a complete summary and justification of all items requiring modification in sufficient depth to allow the researcher to address the areas of concern to the committee.

7. For any protocol that is disapproved, the basis for disapproving research will be clearly recorded.

8. A decision on the protocol (approval, approval with restrictions, disapproval, table pending clarification from the principal investigator) and the length of the approval period. This will include the specific number of votes for each protocol as numbers for, against, abstaining, and recusal (and reason for recusal).

9. A decision on the body responsible for reviewing the principal investigator's response to a protocol which has been approved with restrictions by the IRB.
10. A record of approval of all actions taken by the IRB chair or designee on exempt or expedited research. This will also include the specific category used to determine exemption for protocols categorized as exempt.
11. A record of all protocols that were contingently-approved at a prior meeting and that have since fulfilled the requirements for approval as specified by the IRB.
12. Reports of significant adverse events or unanticipated problems and a determination if these are serious, unanticipated and research-related (for adverse events) or (for unanticipated problems) if these involve noncompliance, and/or are serious and continuing in nature.

V. Record Requirements

The IRB prepares and maintains in the IRB folder of the college network drive adequate documentation of IRB activities, including the following:

A. Detailed minutes of IRB meetings

B. A log of all IRB research applications, including:

1) Name of the PI

2) Title of the research

3) Date of initial application

4) Date of each disposition

5) if approved, date of approval and date of approval expiration

6) Appeals or continuations, with all documentation

B. Electronic copies of all complete research proposals reviewed, approved consent documents, and continuing reports submitted by investigators

C. Copies of all correspondence between the IRB and PIs

D. Any statements of significant new findings (i.e., unanticipated risks) provided to participants

E. Adverse reactions reports and documentation that the IRB reviews such reports

F. General project information provided to participants (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be available for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave Southeastern Community College, signed consent forms are to be transferred to the IRB chair.

The IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments.

Categories of Review for Human Subjects Research

All research protocols involving human participants, all modifications to approved research, and all continuing reviews must be submitted to the IRB for review. The IRB chair or designee will determine whether the research qualifies for exempt status, expedited review, or whether the research will be reviewed by the IRB at a convened meeting.

I. Criteria for IRB approval of research

In order to approve research, the IRB must determine that all of the following requirements are satisfied:

A. Risks to participants are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the review should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The review should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

C. Selection of participants is equitable. In making this assessment the review should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by §46.116.

E. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

F. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

G. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

H. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

II. Categories

A. Exempt

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise [see §46.101 http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(c)]. Only the IRB chair or designee may make the determination that the research is exempt from continuing review.

Exempt types of research include:

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

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (1) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or

approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

B. Research that is Expedited

Under federal regulations certain types of research qualify for an 'expedited' review [see §46.110 http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(c)]. Research qualifying for expedited review are those that

1. present no more than minimal risk to human participants, and/or
2. for which there are minor changes in previously approved research during the period (of one year or less) for which approval is authorized. Under an expedited review, the IRB chair or his/her member-designee, rather than the full IRB, reviews the research protocol and may approve but not disapprove the research. Disapproval requires review by all IRB members.

A summary of expedited research projects approved by the IRB chair will be presented at quarterly meetings of the full IRB.

IRB Review of Human Subjects Research

All research at the college involving human subjects shall be submitted to the IRB for review and must be reviewed at a convened meeting of the SCC IRB unless the IRB chair determines the research qualifies for expedited review or exempt status.

I. Research defined

A. Human participants research includes all activities that meet the Department of Health and Human Services' definition of "research" as any 'systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge' and which involve person(s) who qualify as 'human participants' within the meaning of relevant regulations (45 CFR 46.102.d) as any 'living individual about whom an investigator conducting research obtains

   I. data through intervention or interaction with an individual, or

   II. identifiable private information, or data from which the identify of the participant is or may be readily ascertained by the investigator (§46.102(f)).

B. To meet the definition of research with human participants, the investigator has designed a study to collect information in a systematic say with the intention of making statements about the human population from which the information is collected, thereby contributing to a field of knowledge. This means that the investigator will be

   1. interacting with living human beings in order to gather data about them, using methods such as interviews, focus groups, questionnaires, and observation, or

   2. conducting interventions with living human beings such as experiments and manipulations of participants or participants' environments, or

   3. observing and/or recording behavior that individuals have a reasonable expectation will not be observed and/or recorded, or

   4. obtaining private identifiable information that has been collected about or provided by individuals, such as a school record or identifiable information collected by another researcher or organization.

C. Examples of studies that may not meet the HHS definition of "research:"

   1. analysis of de-identified data

   2. program evaluations and quality improvement studies, if the data are collected to improve a program within an institution and will be used only for that purpose

   3. classroom research that is purely pedagogical and not designed to contribute to a body of knowledge

D. Protocols submitted to the IRB will be reviewed and the determination made if the proposed activity constitutes research involving human participants. The protocol will be reviewed and the

results conveyed to the investigator by letter. Additionally, the results will appear in the minutes of IRB meetings.

E. If the IRB receives a protocol for review after a human subjects research study has been completed, without prior IRB approval, the protocol will not be reviewed. The investigator will be notified of the regulatory requirements for prospective IRB approval of human subjects research and will be informed that the data may not be used for publications, presentations, theses, or dissertation requirements. The same is true when the IRB becomes aware of human subjects research for which no protocol was submitted for review.

II. IRB Initial Review of New Protocols

Requirements for submission of new protocols for review by the SCC IRB are posted on the SCC IRB website at http://www.scciowa.edu/aboutscc/inst_effectiveness/instres/revboard.aspx. Necessary forms are downloadable.

Requirements for submission include the following, all of which will be made available to all reviewers:

A. Completed *SCC Application for IRB Approval*, which requires a description of the complete research protocol and all supporting documents

1. PI contact information and title of the study
2. Purpose of the study, including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits
3. Sponsor of the study
4. Participant inclusion/exclusion criteria (including scientific and ethical reasons for excluding participants who might otherwise benefit from the research)
5. Justification for use of any special/vulnerable participant populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons)
6. Study design (including, as needed, a discussion of the appropriateness of research methods)
7. Description of procedures to be performed
8. Provisions for managing adverse reactions
9. Risk assessment and safety monitoring provisions
10. Circumstances surrounding consent procedure, including setting, participant autonomy concerns, language difficulties, and vulnerable populations
11. Procedures for documenting informed consent, including any procedures for obtaining assent from minors, using legally authorized representatives, witnesses, translators and document storage
12. Remuneration to participants for their participation

13. Any compensation for injured research participants
14. Provisions for protection of participant's privacy
15. Inclusion/exclusion of women, minorities, and/or children
16. Investigator's brochure (when one exists)

B. Copies of the proposed informed consent document, including translated consent documents, as necessary, considering likely participant population(s); or request for waiver of the requirement to obtain informed consent

C. Copies of any general communication with research participants, including introductory letters and/or scripts, emails, advertisements and surveys, questionnaires, or other materials provided to participants

D. Copies of all data collection instruments, including surveys, interview scripts, observational schedules, online surveys, etc.

E. Copies of relevant grant applications (if any)

F. Completed *Research Investigator Financial & Other Personal Interests Disclosure* form

G. All documents are submitted electronically to the IRB through the IRB secretary

III. Cooperative Activities

Cooperative activities relating to human subjects are those which involve Southeastern Community College and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

A. Both institutions have Federalwide Assurances (FWAs) approved by OHRP;

B. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

C. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB chair will verify (via the OHRP website) that the other institutions have approved FWAs.

IV. Criteria for Approval by the IRB

The IRB has the final authority to determine if the requirements for human subjects research will be met in the proposed study. Those requirements include

A. Risks to participants are minimized.

If risks are likely to be greater than minimal, the investigator must describe

1. how risks will be minimized and why they are reasonable in relation to anticipated benefits to participants;
2. what data will be reported and monitored;
3. how the data will be reported, including a plan to assure reporting of adverse events and unanticipated problems involving risk to participants or others;
4. procedures for analyzing and interpreting the data;
5. the frequency of monitoring the data. The IRB will evaluate the frequency of data review, whether after a specific length of time or after a specific number of participants are enrolled, based on the likelihood or magnitude of risk to participants;
6. how and by whom the data will be reviewed. The IRB will evaluate whether the method is appropriate, based on the size and complexity of the research and magnitude of risk to participants;
7. proposed actions to be taken for specific events that may be anticipated;
8. what data and safety information will be provided to the IRB and the frequency with which it will be reported.

B. The research uses procedures that are consistent with sound research design. The protocol must be designed so that 1) the knowledge sought will be obtained, 2) the methods will yield the knowledge that is sought, and 3) the knowledge itself must have an importance for understanding human behavior.

C. The research design is likely to answer the proposed scientific question.

D. The importance of the knowledge expected to result justifies approval of the research.

E. The investigator has sufficient time to conduct and complete the research.

F. The investigator has adequate resources to conduct the research.

G. Risks to participants are reasonable in relation to anticipated benefits, if any to participants, and the importance of the knowledge that may reasonably be expected to results.

H. Selection of participants 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, and the IRB should be particularly aware of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, and others, as designated by the IRB.

I. The investigator (or spouse or dependent children) or other person(s) responsible for the research have no financial interests which may be a perceived or real conflict of interest.

J. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by §46.116 and the law of the state where the research is conducted, and as required by college policy.

K. When investigators need to obtain consent from the legally authorized representative of an adult participant (i.e., to conduct essential research on problems that are unique to persons who are incompetent or who have an impaired decision-making capacity), such consent will be obtained from

   1. a health care agent appointed by the person in a Durable Power of Attorney for Health Care or similar document, or

   2. a count-appointed guardian of the person.

L. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 and the law of the state where the research is conducted, and as required by college policy.

M. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. This includes assuring that only private information essential to the research is collected; that the circumstances in which private information is collected are conducive to privacy; and that this information is maintained in a secure environment.

N. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

O. Incentives to participate, if they are used, are fully described.

V. Actions of the IRB

A. New Protocols

The IRB may take one of the following four actions in regard to proposed new protocols: *Approved, Approved Participant to Restrictions, Tabled,* or *Disapproved.*

1. Approved

   Approval for new research will be granted for a period of up to one year from the date on which the protocol was initially approved. A shorter time may be specified based on the recommendation of the IRB. Reasons for a shorter period for review may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to participants, projects involved vulnerable populations, and projects conducted by a PI who has previously failed to comply with IRB requirements.

   When a protocol has been approved, the IRB chair indicates on the *Notification of IRB Action* form that the study is "Approved," signs and dates it, and distributes one copy of the form to the principal investigator, one copy for the IRB files, and, if appropriate, one for the performance site.

   The *Notification of IRB Action* form for approved research will state the beginning and ending dates during which IRB approval is valid. The *Notification* form cautions PIs to submit any

revised protocols *prior to* their implementation, except when it is necessary to eliminate apparent immediate hazards to participants.

2. Approved Participant to Restrictions or Conditions

   The IRB may approve the research protocol and at the same time impose additional conditions on the research if, in the judgment of its reviewers, such conditions are necessary for the protection of human participants. In these cases, the IRB chair completes the *Notification of IRB Action* form indicating the study is "Approved Participant to Restrictions or Conditions" and outlines the modifications required to secure IRB approval. The Chair signs and dates the form and distributes one copy to the principal investigator and one copy for the IRB files. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above. The date of approval remains that of the meeting at which the protocol was approved (with restrictions) and not the date that the restrictions were met.

3. Tabled

   Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the IRB chair completes the *Notification of IRB Action* form and indicates that the study is "Tabled" because the proposal provides insufficient information. An explanation of the additional information necessary for completion of the IRB review is provided. The Chair signs and dates the form and distributes one copy to the principal investigator and one copy for the IRB files. In the case of a tabled protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

4. Disapproved

   If the protocol is disapproved, the IRB chair completes the *Notification of IRB Action* form and indicates that the study is "Disapproved" and provides a detailed explanation of the reasons. The Chair signs and dates the form and distributes one copy to the principal investigator and one copy for the IRB files. The PI may revise and resubmit his/her protocol for another review.

VI. IRB Review of Existing Protocols

A. Continuing Review

The IRB may conduct continuing reviews of research at intervals appropriate to the degree of risk, but not less than once per year. “Not less than once per year” means that the research must be reviewed before the one-year anniversary of the previous IRB review date, even though the research activity may not have begun until some time after the IRB gave its approval. Continuing review of protocols originally approved by the full board will continue to be performed by the full board. Continuing review of protocols originally approved by expedited review will continue to be reviewed by expedited review. These may be referred to the full committee if it is found that the research activities no longer meet the expedited criteria for review and approval (e.g., are now at more than minimal risk).

1. Notification

   Principal Investigators will be informed of the annual review by receipt of a *Continuing Review Questionnaire* sent by the IRB chair or his/her designee. The *Continuing Review Questionnaire* is to be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken (e.g., Approved, Approved Participant to Restrictions or Conditions etc.) via the Notification of IRB Action form.

2. Criteria for Continuation/Renewal

   Continuing review must be substantive and meaningful. When considering whether or not to renew a study, the IRB revisits the same criteria used to grant initial approval. These include (but are not limited to):

   i. The risks to participants continue to be minimized and reasonable in relation to the anticipated benefits;

   ii. The selection of participants continues to be reasonable in relation to anticipated benefits;

   iii. Informed consent continues to be appropriately obtained and documented;

   iv. Significant new findings that have arisen during the study and which might relate to participants' willingness to continue participation have been provided to participants

   v. There are appropriate

      - Provisions for monitoring of the data to assure patient safety,
      - Protections to ensure the privacy of participants and confidentiality of data,
      - Safeguards for vulnerable populations.

   When a Continuing Review request is submitted, the IRB shall consider changes to the research protocol since the last scheduled review; adverse event reports; and reports of unanticipated problems involving risks to participants.

   If the protocol and/or other documents used in the project have been amended within the past five years, the PI will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

   Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB chair find that it is in the best interests of individual participants to continue participating in the research interventions or

interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new participants cannot occur nor can any data collected be used for research purposes.

B. Amended Protocols

1) Minor modifications/changes

i. Changes in research-related activities that do not significantly affect an assessment of the risks and benefits of the study and do not substantially change the specific aims or design of the study

ii. Examples of minor changes

- Addition or deletion of study members
- Addition of procedures that do not significantly increase risk to participants, considering the original purpose and study design of the approved study
- Removal of research procedures that would thereby reduce the risk to participants;
- Addition of non-sensitive questions to invalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

iii. Notification

The *Notification of IRB Action* form cautions investigators that the IRB must review and approve all revised protocols prior to their implementation, except when necessary to eliminate apparent immediate hazards to participants.

iv. IRB approval

Minor modifications/changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB chair. Such approvals are then put on the agenda of the next IRB meeting for concurrence.

2) Significant modifications/changes

i. Changes in research-related activities that significantly affect an assessment of the risks and benefits of the study or substantially change the specific aims or design of the study

ii. Examples of significant changes

- Addition of a new and/or separate participation population, i.e., control group, additional cohort, vulnerable population, etc.
- Addition of research procedures that involve greater than minimal risk to participants;

- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for participants or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring participant safety and welfare.

iii. Notification

The *Notification of IRB Action* form cautions investigators that the IRB must review and approve all revised protocols prior to their implementation, except when necessary to eliminate apparent immediate hazards to participants.

iv. IRB approval

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed, either by the initial reviewer or by the full IRB. However, if an amendment is determined by the initial reviewer to increase the level of risk beyond minimal risk, that reviewer will refer the amendment to the full IRB.

C. Sponsor agency modifications

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol. The investigator should then provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

D. Verification that No Material Changes have Occurred

1. Applicability

The IRB shall have authority to determine which studies, on a case-by-case basis, need verification from sources other than the investigators that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to participants; (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

PIs shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to participants;

PIs shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.

The IRB shall be informed of all grievances (e.g., of a research participant against a PI) and, if requested, the board will act in an advisory capacity.

2. Process

The IRB chair or designee or a full convened board may request independent verification of ongoing research activities. Independent verification may be requested by anyone knowledgeable about the research in question. This request must include the specific reason for the request.

The review will focus on assessing relevant research documents or observing the contact of the research and/or consent process to verify the accuracy of the information presented to the IRB.

3. Reporting Results of Verification

Findings from independent verification will be reported to the IRB according to the risks to participants. Those that present increased harm to participants or others and those requiring immediate action will be presented to the IRB by the IRB chair, who will report them to the executive director of institutional advancement. Other findings will be reported to the IRB at its quarterly meetings.

Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the executive director of institutional advancement so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

In all cases, the IRB decision is communicated to investigators through the *Notification of IRB Action* and indicating that the project is Approved, Approved Participant to Restrictions or Conditions, Tabled, Disapproved, or Administratively Terminated. A "hard copy" of the *Notification* and an electronic copy will be sent.

E. Administrative Termination

A study may be suspended or terminated if the research is not being conducted in accordance with Federal regulatory requirements, IRB requirements, or if the study has been associated with unanticipated problems or serious harm to participants (§46.113). The steps for addressing noncompliance are described in the Noncompliance section of this document. The IRB chair completes the *Notification of IRB Action* form and indicates that the study is "Administratively Terminated" and provides a detailed explanation of the reasons. The Chair signs and dates the form and distributes one copy to the principal investigator and one copy for the IRB files.

Noncompliance

Noncompliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, the policies or procedures of the SCC IRB, or institutional policies governing human research. Noncompliance with respect to human research participant protection violates SCC's Federalwide Assurance Registration (FWA) http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc). Even in the absence of intent, and unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.

I. Examples of Noncompliance

Conducting human participant research without IRB approval, i.e., before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during the suspension of IRB approval; after termination of IRB approval; Disregarding or otherwise violating IRB-approved informed consent procedures, i.e., failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process; Deviating from the protocol approved by the IRB; Modifying an approved protocol without IRB consent; Failing to report or tardily reporting unanticipated problems; Failing to main adequate records; Failing to train research team members in the proper procedures; Failing to follow recommendations by the IRB to ensure the safety of research participants

II. Examples of Serious Noncompliance

Bringing harm to research participants; Exposing research participants to a significant risk of substantive harm; Compromising the privacy and confidentiality of research participants; Causing damage to scientific integrity of the research data that have been collected; Engaging in willful or knowing noncompliance; Affecting ethical principles adversely

III. Investigating Allegations of Noncompliance

A. The IRB may become aware of an allegation of noncompliance or of circumstances indicating noncompliance upon the receipt of a complaint from a participant, researcher, SCC employee, or member of the public, or by interpreting information gained during Continuation, Amendment, Unanticipated Problems reviews.

B. Within three weeks of becoming aware of an allegation on noncompliance, the IRB chair and a designee will investigate the allegation(s), possibly including meeting with the PI, to determine 1) if noncompliance has occurred, and 2) if it indicates the need for immediate action. The full IRB will be informed electronically of the results of the investigation and asked to develop a recommendation for corrective action.

C. The IRB will make a recommendation for corrective action to the executive director of institutional advancement, who will direct the IRB chair to notify the PI.

IV. Corrective Actions in Response to Noncompliance by Severity

A. Take no action

B. Request a protocol and/or consent form modification

C. Require that all participants be re-consented

D. Require previous participants to be informed of changes to the protocol and/or consent procedures

E. Require observation of consent procedures

F. Require more frequent review of the conduct of the research

G. Require additional training for the PI, and if existent, the research team

H. Suspend the research

I. Terminate the research

All decisions will be communicated by the IRB chair to the PI via the *Notification of IRB Action* form.

Unanticipated Problems and Adverse Effects

An unanticipated problem that is related to the research and involves risk to human participants or others is one that was unforeseen at the time of its occurrence and indicates that participants or others are at an increased risk of harm. Principle investigators are notified on the *Notification of IRB Action* that they are to immediately report to the IRB any unanticipated research-related problems involving serious or non-serious harm, i.e., adverse event, or increased risks to the participants or others.

I. Non-serious Unanticipated Problems, including Non-Serious Adverse Events

A. Non-serious problems and adverse events need to be reported via the *Unexpected Event Report* form to the IRB secretary within two weeks of first awareness of their occurrence

B. Examples: Display of unanticipated emotional upset or degree of emotional upset by a research participant; Accidental or unintentional change to the IRB-approved protocol that harmed research participants or others or that indicates that such persons may be at an increased risk of harm; Release, including inadvertent release, of personal information of a research participant, or some other breach of confidentiality; Complaint of a participant which indicates unanticipated risks or which cannot be resolved by the researcher.

II. Serious Adverse Events

A. Serious adverse events require immediate reporting to the IRB via the *Unexpected Event Report* form to the IRB secretary within 24 hours of the first awareness of their occurrence.

B. Examples: Death or serious injury to a research participant

III. Actions in Response Unanticipated Problems and Adverse Effects

A. All members of the IRB will have access to the *Unexpected Event Report* to review and develop a recommendation to be presented to the executive director of institutional advancement, who will direct the IRB chair to notify the PI. Possible actions include:

1. Modification of the protocol
2. Modification of the information disclosed during the consent process
3. Providing additional information to past participants
4. Notification to current participants when such information might relate to participants' willingness to continue to take part in the research
5. Requirement that the current participants re-consent to participation
6. Modification of the continuing review schedule
7. Monitoring of any modified informed consent process
8. Suspension or termination of the research

All decisions will be communicated via email from the IRB chair to the PI via the *Notification of IRB Action* form.

Principles of Informed Consent

No investigator may involve a human being as a participant in research unless the investigator has first secured the participant's informed consent or the IRB has waived the requirement that informed consent be obtained.

"Informed consent" means insuring that potential participants and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101(c).

If the participant is not competent to give informed consent, the investigator may get informed consent from a legally authorized representative. The "legally authorized representative" is determined by the law of the state where the research is being conducted.

I. The Informed Consent Process

A. The Informed Consent Process will be described in the protocol or petition and reviewed by the IRB.

B. The investigator or other study personnel who conduct the consent process must present information objectively so as to minimize the possibility of coercing the individual to participate or using undue influence.

C. Prospective participants must be given sufficient time to consider whether to participate in the study and must have the opportunity to have all their questions answered.

D. The researcher must provide information in language that is understandable to the participant.

E. When the IRB believes appropriate, the investigator may be required to use tools or techniques that assess and confirm a participant's understanding of the consent. Such techniques may include using a written comprehension tool, requiring a friend or family member to be present, requiring a waiting period or prior approval of the research by a community review board.

F. The informed consent process will not contain any language through which the participant waives or appears to waive any legal rights or releases the investigator, the institution, the sponsor or its agents from liability for negligence.

G. The IRB, the Institutional Official, or the designee of any of these has authority to observe the consent process for any approved study. This may be done as one means to protect participants, particularly if there is cause for concern (for example, if there have been complaints registered by participants). The IRB coordinator will make arrangement with the researcher should this be desired.

II. Documentation of Informed Consent

Unless the IRB has waived the requirement for written informed consent, the investigator must get documentation of informed consent by use of a written consent form, approved by the IRB that is signed

and dated by the participant or the participant's legally authorized representative. This consent must embody the basic and appropriate elements of disclosure (see following section). All informed consent forms should be written at a level appropriate for the potential population. General formatting, readability and clarity must be acceptable to the IRB, and medical terminology must be defined in lay terms, ideally at a 7th grade (or lower) reading level. The participant (or the participant's legally-authorized representative) must be given adequate opportunity to read the consent document before it is signed.

In addition to the signature of the participant providing consent, the person obtaining consent of the participant must also execute the consent form. These individuals must: 1) complete required human subjects protection training; 2) complete a *Research Investigator Financial & Other Personal Interests Disclosure Form*; 3) be listed on the IRB petition and approved by the IRB as "investigator" or "key personnel"; 4) be trained on the protocol as documented in writing; and 5) delegated by the principal investigator to obtain informed consent.

The researcher will give a copy of the signed informed consent to the participant, and the original will be placed in the research record maintained by the investigator. The IRB, the sponsor of the research, regulatory and accrediting agencies, and the designees of any of them are authorized to randomly review protocols for compliance with informed consent requirements.

III. Required Elements of Informed Consent Forms

In accordance with 21 CFR 50.25, and 45 CFR 46.116, the following information will be provided to each participant:

A. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

B. A description of any reasonably foreseeable risks or discomforts to the participant.

C. A description of any benefits to the participant or to others that may reasonably be expected from the research.

D. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant.

E. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. The consent form will include all individuals and organization that have access to a participant's record, including the sponsor, funding entities, agents of Southeastern Community College, and any other federal agencies.

F. For research involving more than minimal risk to participants if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

G. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

H. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.

IV. Waiver of Some or All Elements of Informed Consent

A. Conditions whereby the IRB may choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

B. Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

C. When deemed appropriate, the IRB may require the investigator to prepare a written description of the research to be given to the participants (either before or after participation as appropriate to the study). The IRB will review this description as part of the approval process.

D. Some research may not impose on the rights and welfare of human participants so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all participants in some cases when it finds:

1. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.
3. Consent to participate in survey research is implied when survey materials clearly state that by responding to the questions and returning the completed survey, respondents have

agreed to participate in the research. This is a permissible informed consent process if the IRB has approved the informed consent alteration and waived the requirement for documentation of informed consent (http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/).

E. Non-English Speaking Participants

Individuals unable to speak English may not be excluded from participating in a study, unless the approved research protocol requires that participants speak English. Investigators must provide an ethical and scientific justification for excluding non-English speaking participants from research. Inconvenience or expense for the investigators is not an acceptable justification for excluding non-English speaking participants. Participants who are not English - speaking should be provided with a translation of the consent document in a language understandable to them.