

**Southern Connecticut State University
Research Protection Program
Institutional Review Board**

Application Packet for Human Research Review

(The first five items listed below may be found in this section of the application packet. Please print this section and use it as a reference for completing the IRB forms. Please follow closely the “Directions for Application Submission” and if needed, the “Constructing the Informed Consent Document” sections when completing the IRB application forms. Once you have completed your review of the instructions, return to the [“IRB Information Selection”](#) page and select “Application Forms.”)

ITEMS INCLUDED IN THIS PACKET

Item

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With the exception of Form # 12, which may or may not be used, **bolded items are forms which must be included in the application.** The forms are not paginated, rather they are numbered consecutively in the upper right corner as, *IRB Form #___*, and must be submitted serially as numbered. In order to assure all required items have been included and in the proper order, please be sure to complete the submission check-list, IRB Form #11.

INTRODUCTION

Ethical Principles:

The Southern Connecticut State University (SCSU) Research Protection Program (RPP), as part of its responsibility to assure research protections for all aspects of SCSU research, is committed to protecting the rights and welfare of human participants involved in research conducted on the campus or in cooperation with other research agencies, regardless of project funding (external, internal, or no funding support). The SCSU RPP subscribes to the basic ethical principles for the protection of human participants that underlie *The Belmont Report*. Copies of this document may be found in the RPP office (EN A 110 A-B).

The Institutional Review Board:

The SCSU RPP follows regulations published in *The Federal Register*, codified at Title 45 part 46, for establishing and operating an **Institutional Review Board** (IRB). The spirit and substance of these regulations are presented in the *Southern Connecticut State University, IRB Policies and Procedures Manual*, and serve to govern SCSU IRB activities. Copies of this document may be found in the RPP office (EN A 110 A-B).

APPLICATION SUBMISSION

Mandatory Training Program:

Principal and co-investigators, advisors, and research assistants, involved in research submitted for review, must complete the NIH online course *Protecting Human Research Participants* at: <http://phrp.nihtraining.com/users/login.php>. This course must be successfully completed **PRIOR** to developing the IRB application. A copy of a *Completion Certificate* downloaded from the course site as well as the **SCSU Education Certification form**, must be included in the application. Please see IRB Form # 2 in this packet.

Who Must Submit an IRB Research Application:

SCSU faculty, staff, and students, who engage humans as participants in research on the SCSU campus must submit an IRB application for research review. Further, SCSU faculty, staff, and students who, under the auspices of SCSU, conduct research with human participants at institutions external to SCSU must submit an IRB application for research review.

At SCSU, there is an exception to the above. Research activities involving human participants considered to be below the Special Project level, completed in **partial fulfillment of SCSU course requirements**, and the data from which will not be generalized to populations outside of the classroom, may need only instructor approval prior to data collection. In order to approve research in this manner, instructors must complete and have on file with the IRB an approved, up-to-date Certification Form for Course Instructors. An application packet for this certification may be found online at: <http://www.southernct.edu/grad/research/institutionalreviewboard/hrpp/>.

Research conducted by investigators not directly connected to SCSU must follow the IRB External Investigator Responsibilities found online at: <http://www.southernct.edu/grad/externalinvestigatorresponsibilities/>.

When Must the Application be Submitted:

An IRB research application must be submitted, reviewed, and assigned an “Exempt” or “Approved” disposition **prior to any human research participant recruitment.**

Applications may be submitted for initial review **at any time.** Applications will be reviewed in order of receipt. For exempt or expedited research, allow at least two weeks for initial IRB response.

Full Review Submissions:

Academic Year: If initial review determines the need for full board review, during the academic year in any month from September through May, applications received prior to or on **the first Monday of the month** will be full reviewed during that month (usually on the third Friday of the month providing a quorum of board members is available).

Summer: Applications requiring full review received after the first Monday in May will be reviewed according to the academic year schedule provided a quorum of board members can be achieved. Investigators must be aware that board members may not be available during the summer months. Applications unable to receive full review during the summer will be considered for full review on the third Friday in the subsequent September.

What Should be Submitted:

Two hard copies of the entire application should be submitted. **The cover page must be signed by all requested signatories.** Electronic application submission is not permitted.

NOTIFICATION OF IRB DECISIONS:

Exemptions:

Investigators will be informed of exemption status by mail immediately following initial IRB review.

Expedited review approvals:

The IRB will inform principal investigators of approvals by letter immediately following initial IRB review. The approval will outline investigator continuing responsibilities during and at the conclusion of the research. **Initiation of the research will be considered acceptance of these responsibilities.** The letter will be sent using regular mail or campus mail. Included with the approval letter (when applicable) will be a copy of any submitted consent form(s), assent form(s), or parental/guardian permission(s), date stamped by the IRB. Copies of this date stamped form(s) must be presented to potential research participants. The application will not be returned with the approval letter. Further, enclosed with the approval letter and in keeping with investigator continuing responsibilities, will be the following forms: Continuing Review, Request for Revision, Research Completed, and Adverse Event.

Full Board Review:

After initial IRB review, investigators, and sponsors/advisors when applicable, will receive a memo indicating the need for full review and the date of the board meeting at

which the research will be examined. Accompanying this memo may be a request for preliminary application modifications in preparation for full board review. The board at their meeting may approve the application or request further modifications. Once the research is approved by the full board, the investigator will be informed in the same way investigators of expedited research are informed.

Review completion contingent upon modifications:

If after initial or full review, application modifications are required, principal investigators and sponsor/advisors when applicable, will be informed in writing of the required modifications. Regular mail or campus mail will be used for this purpose. Copies of transmissions to and from investigators will be retained as part of the original application. At times, the IRB will have minor questions concerning the application. These questions may be transmitted to investigators by phone or e-mail. Modifications must be completed to the satisfaction of the IRB, prior to completion of the review process.

Disapproval:

The IRB will inform principal investigators, and sponsors/advisors if applicable, of disapprovals in a letter outlining the reasons for disapproval. The letter will be sent using regular mail or campus mail. Disapprovals can only be issued after full IRB review. The decision of the board is final. Resubmission of a disapproved application after modification is permitted.

DIRECTIONS FOR APPLICATION SUBMISSION

1. Entries must be typed into IRB forms on-line, printed, signed in all required locations, and submitted as hard copy to the **SCSU School of Graduate Studies, EN B 110**. Electronic application submission is not permitted. Please note: spell-check is not available on-line when completing forms. If you wish, you may use your local MSWord to construct passages and then paste them into the on-line IRB forms.
2. Please be aware: institution, school, or department-imposed restrictions on research may limit the direction and scope of research.
3. Prior to developing the IRB application, investigators, co-investigators, sponsors/advisors, and research assistants must complete the NIH online course ***Protecting Human Research Participants***. Once successfully completed, an on-line Certificate of Completion, downloaded and printed from the NIH site, and an SCSU Education Certification – IRB Form # 2, which is part of this application, must be submitted along with the application itself, for each member of the research team. SCSU is currently using the following NIH site for computer based training:
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
4. Application Forms:
 - a. Cover Page – IRB Form # 1:
All of the applicable information requested on this form must be provided. This information will assist in making initial review decisions. Be sure all appropriate supplemental information is included and all required signatures are obtained prior to submission.
 - b. Education Certification – IRB Form # 2:
This form must be completed and signed for submission with the IRB

application. Your signature on this form attests to your completion of the required on-line NIH tutorial at:

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

The tutorial must be completed prior to constructing your IRB application. Please be advised: Be sure to submit the actual downloaded and printed NIH Completion Certificate and not a text version of the completion page. Read the instructions and explanation found at the head of IRB Form #2.

Please note: Successful completion of the Collaborative Instructional Training Initiative (CITI) basic course in The Protection of Human Subjects within the past three years may be substituted for the NIH tutorial. Please submit CITI completion documents to validate.

c. Project Information – IRB Form # 3:

The investigator must submit a well thought out and complete summary of the proposed study. Further, project information must include: a brief justification for why the study should be done (e.g. abbreviated results from a literature review); the purpose of the study (research question(s)/hypotheses, expected outcomes).

Please note: If your research is being conducted at an agency/institution external to SCSU and this agency/institution does not have a human research review process, you must submit a signed letter from the administrator of the agency/institution indicating an understanding of the project and agreement for you to conduct your research at the site. The letter must be on site letterhead. Schools, mental health clinics, rehabilitation centers, etc., are some examples of external agencies/institutions.

d. Description and Recruitment of Research Participants – IRB Form # 4:

i. *Participant Description:* The IRB must determine if research participants fall within any of the vulnerable populations described in federal regulations. The principal investigator(s) and the IRB must give special consideration to protecting the welfare of these participants. Please be sure to indicate all participant populations. If, for example, you will be using both children and adults as research participants you must indicate this on the form.

ii. *Research Participant recruitment:* Any advertisements used for research participant recruitment must be attached to the IRB proposal (e.g., *posted notices and newspaper or magazine ads*). It is suggested that advertisements used to recruit research participants be limited to:

1. The name and address of the principal investigator.
2. The purpose of the research, and briefly, the eligibility criteria that will be used to select research participants for this research.
3. A straightforward and truthful description of the incentives to the research participant for participation in the study, if any.
4. The location of the research and the person to contact for further information.

The investigator must indicate how and where research participants will be recruited. The IRB must be able to determine that research participant recruitment was completed without coercion or deception (unless the use of deception is an important component of the study

and has been adequately explained). Further, if payment is offered to research participants to participate in the study, the principal investigator must clearly indicate to the IRB how research participants will be protected from financial coercion. If research participants are to receive any monetary gain by participating in this study including reimbursement for expenses, the arrangements for payment should be described in detail and the name(s) of the person(s) who will be responsible for making the payments should be stated. On the other hand, if, by participating in this study, research participants incur costs, the arrangements for payment of these research participant costs should be described in detail and the name(s) of the person(s) who will be responsible for paying these costs should be stated. The individual who recruits research participants must have appropriate qualifications to carry out the recruitment task and these qualifications must be stated clearly.

e. Undue Influence and Manner of Research Participant Selection – IRB Form # 5:

- i. The IRB must be assured that there is no possibility for undue influence underlying encouragement of participants to take part in the research (e.g. recruiter and/or investigator-to-participant affiliations).
- ii. Principal investigators should be aware that justice must be exercised in the manner of research participant selection and/or exclusion. The IRB must determine that research participant selection and/or exclusion is equitable. The following are points to be considered when selecting/excluding research participants (*from: Protecting Human Research Subjects - Institutional Review Board Guidebook, NIH, 1993*):
 1. Will the burdens of participating in the research fall on those most likely to benefit from the research?
 2. Will the solicitation of research participants avoid placing a disproportionate share of the burdens of research on any single group?
 3. Does the nature of the research require or justify using the proposed research participant population?
 4. Are there any groups of people who might be more susceptible to the risks presented by the study and who, therefore, ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
 5. To the extent that benefits to the research participants are anticipated, are they distributed fairly? Do other groups of potential research participants have a greater need to receive any of the anticipated benefits?
 6. To the extent that participation in the study is burdensome, are these burdens distributed fairly? Is the proposed research participant population already so burdened that it would be unfair to ask them to accept an extra burden?
 7. Will any special physiological, psychological, or social characteristics of the research participant group pose special risks for them?
 8. Would it be possible to conduct the research with other, less vulnerable research participants? What additional expense or inconvenience would that entail? Does the convenience of the researcher or possible improvement in the quality of the

research justify the involvement of research participants who may either be susceptible to pressure or who are already burdened?

9. Has the selection process overprotected potential research participants who are considered vulnerable (e.g. children, cognitively impaired, economically or educationally disadvantaged persons, patients of researchers, seriously ill persons) so that they are denied opportunities to participate in research?
10. If the research participants are susceptible to pressures, are there mechanisms that might be used to reduce pressures or minimize their impact?

f. Interventions - Form # 6:

- i. *Interventions:* The IRB must be able to determine from information in this form, the nature of any interventions which will be used in the study. These interventions should be described in detail. If different interventions are to be used with more than one population in the study, each intervention must be described.
- ii. *Debriefing:* The IRB must know what procedures the principal investigator will have in place to debrief research participants during and following the study. If an intervention, or any other part of the study in which there is human research participant interaction with investigators, develops concern or discomfort in research participants, those research participants must have a specific course of action they may take in order to have their situation attended. A plan must be in place which will permit dealing with research participants concerns.

If deception is to be used as part of the research, a plan for complete debriefing of the participants during (if appropriate) and/or at the termination of the research must be presented.

- iii. *Investigator/Advisor Experience:* The IRB must be able to determine if the individual(s) who will be administering and/or monitoring the intervention is/are qualified to do so. Please include in the IRB application all educational, professional, volunteer or training experiences which qualify the advisor (if applicable), principal investigator, co-investigators, supervisors or assistants to conduct the intervention. Copies of letters, certifications, licenses and other documents which validate qualifications should be attached. **Please do not leave this section incomplete.**

g. Data Gathering and Disposition – IRB Form # 7:

- i. *Data Gathering:* The IRB must be able to determine precisely what will be done to each research participant in the study. A step-by-step chronology can be a useful tool to present this information. Further, to assist in assigning the level of risk to participants, the IRB must see the data gathering instruments to be used in the study. Submitting a copy of all data gathering instruments is therefore required. Presentation of the data gathering procedures should contain enough information so that the reader, following the description, would be able to replicate the procedures.
- ii. *Disposition:* To assist the IRB in assigning the level of research participant risk to the research, a clear discussion of data dissemination plans must also be presented.

- h. Benefits Versus Risk Assessment – IRB Form # 8:
- i. *Benefits:* The investigator must describe in detail the benefits to be gained by the research participant that outweigh any potential risks. This is referred to as the Benefits Versus Risk Assessment and is a federal requirement. The IRB must be satisfied that the potential benefits to be gained from the conduct of this study are sufficient to off-set any known or potential risks imposed on research participants, researchers or institution, by the study. The investigator must also describe the potential benefits to be gained by the researcher's field of study or society in general as a result of conducting this study. This information should support the benefits aspect of the benefits versus risk assessment.
 - ii. *Risk:* If, in the conduct of the study, you will be subjecting research participants to any known or potential risk, you must describe this risk in detail and indicate what measures you will take to minimize the risk. Further, **if the study will place recruiters, researchers, or the institution at known or potential risk you must describe these risks and indicate what measures you will take to minimize these risks.** If you believe that there will be no risks to research participants, researchers or the institution, **you must give reasons for this conclusion.** The IRB requires this information, along with other information in the application, to determine the level of IRB review.
- i. Anonymity, Privacy, and Confidentiality – IRB Form # 9:
- i. *Anonymity:* For purposes of IRB review, anonymity means that information obtained from participants is recorded in such a manner that individual participants cannot be identified directly or indirectly through identifiers linked to the participants. If for example, an anonymous online survey is proposed, the IRB must be assured that in this case, the return of the survey has been electronically stripped of all participant identifiers prior to receipt by the investigator.
 - ii. *Privacy:* For purposes of IRB review, privacy may be defined as a participant's having control over the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with others. Information collected from participants that is not considered necessary to conduct the investigation might be considered an invasion of privacy. Further, methods of collecting data may unnecessarily involve compromising participant privacy. Views on privacy vary greatly across cultures and research populations. Information that is not considered particularly sensitive by one individual may be very sensitive to another individual. The investigator must be aware of the privacy issues of their participants and design data collection and maintenance accordingly.
 - iii. *Confidentiality:* For purposes of IRB review, data confidentiality means treating information that a participant has disclosed to you as part of a relationship of trust you have established with the participant. The participant should be assured that information they disclose will not be divulged to others in ways that are inconsistent with their original consent to participate, unless they give specific permission to do so. The IRB must be assured that the confidentiality of research participant data is not in any way compromised.
 - iv. The principal investigator must have in place procedures for insuring that research participant identity, and the data that is obtained from research participants is protected and that it can in no way be used to

place the research participant in jeopardy.

- v. The principal investigator should consider the below listed items when developing privacy and confidentiality procedures (*from: Protecting Human Research Subjects - Institutional Review Board Guidebook, NIH, 1993*):

1. Does the research involve observation or intrusion in situations where the research participants have a reasonable expectation of privacy? Would reasonable people be offended by such an intrusion? Can the research be redesigned to avoid the intrusion?
2. If privacy is to be invaded, does the importance of the research objective justify the intrusion? What if anything, will the research participant be told later?
3. If investigators want to review existing records to select research participants for further study, whose permission should be sought for access to those records?
4. Will the investigator(s) be collecting sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study? If the information obtained about research participants might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, can a grant of confidentiality be sought from a federal or state agency to protect the research data and the identity of the research participants from subpoena or other legal process?
5. Are the investigator's disclosures to research participants about confidentiality adequate? Should documentation of consent be waived in order to protect confidentiality?

- vi. *Research Records Maintenance*: Investigators must include as part of their privacy and confidentiality procedures, how they will maintain research participant identity and data safe from compromise for three years after the study has been completed and what the disposition of the data will be at the end of the three year period.

- j. Participant Notice of Research Involvement Check List – IRB Form #10:

Please use this page to assure that all appropriate notifications to participants regarding their research involvement will be made. The following should be considered as appropriate notification formats and principles:

- i. *Informed Consent*: Your informed consent document is a critical piece of your IRB proposal. It helps to safeguard your human research participants against: unethical research practices; coercion to participate; undue influence; and undisclosed risks of participation, among others. The consent document insures that prospective human research participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. Informed consent is one of the primary ethical requirements of human participant research, protecting both the research participant whose autonomy is respected, and the investigator, who otherwise may face legal hazards. Please see the section below entitled “**Constructing The Informed Consent Document**” for detailed information

- regarding appropriate contents, order of presentation, language, subtitles, and other critical aspects of informed consent design.
- ii. *Child Assent*: An assent document must be constructed for a child participant to sign when the child: (1) is able to read and understand the document; or, (2) is able to be read to and understand; and, (3) has decision making ability. The assent document must contain elements of a consent document. The assent document must be written at a level the children are able to comprehend. The child must sign the document in the recruiter's presence so parental coercion may be avoided. Children may elect to opt out of participation even if their parents give consent/permission.
 - iii. *Parent/Guardian Consent/Permission*: When children are used as research participants, a parental/guardian consent/permission document must be developed and signed by the parent or legal representative of the child. This document must contain all the elements processes of a consent document as indicated above.
 - iv. *Cover Letter*: The use of an informed consent document in some research may actually jeopardize participants' confidentiality unnecessarily. For example, a researcher employing a signed consent document in an anonymous survey may inadvertently be providing the only link to the participant's identity thus compromising confidentiality and anonymity. Please be advised however, the researcher is not freed of the responsibility of informing participants about the research activity. In such cases, cover letters, which are unsigned documents that contain most if not all of the elements of an informed consent document, can be used. The cover letter must include language that informs potential participants that **the return of the survey indicates their consent to have the data included as part of the research**. Cover letters can not be used to replace consent/assent documents in research involving children.
- k. Submission and Order Check List – IRB Form #11:
Forms must be submitted in serial order. Use this page to check submission of required information and form order. Further, please use this form as a reminder to closely check your submission for syntax and spelling especially in consent/assent documents and cover letters.
 - l. Request for Waiver of Informed Consent – Form # 12:
When a researcher wishes to use a cover letter rather than a consent document, a request to have the consent document waived must be included in the IRB application. A series of six criteria must be met in order for a waiver to be granted. Please see form.

CONSTRUCTING THE INFORMED CONSENT DOCUMENT

Information in the informed consent document must be **written in language that is understandable to the participant and/or participant representative. It has been suggested that writing at the eighth grade level or below, will permit information to be sufficiently clear.** Further, the consent document must be addressed to the participant in the second person (use the pronoun “you” when appropriate). The document must be written in the primary language of the participant or representative (the IRB must review both an English translation and the primary language consent form). If the recipient cannot read, the consent information must be presented orally and a signature obtained indicating that the recipient understands the consent information. The consent process

may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the participant's legal rights, or releases, or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

It must be understood that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Consider, as the research progresses, in some cases subjects may be better protected if incoming data is shared and they are encouraged to reevaluate their participation in light of it.

Investigators are encouraged to carefully proofread their consent documents for spelling, grammar and syntax. Please be reminded, the consent document reflects on you, your discipline, and the institution.

The guidelines below are presented to assist you in the construction of your informed consent document. Please consider the following: (1) revising the guidelines as necessary to encompass the particulars of your research; (2) using the bolded italicized headings when applicable; (3) including all items that apply; (4) using the italicized script as non-italicized regular text in your consent document.

The Consent Document, its subtitles, scripts(italicized), and content:

Introduction:

You must title your study. You must completely identify yourself (name and affiliation), indicate that participation involves research, and the expected duration of participant research activity. Then. . . . *In order to decide whether or not you wish to be a part of this research, you should be aware of all aspects of the study, its purpose, the procedures to be used and any risks or benefits. This consent form provides you with detailed information about the research study. I will discuss any aspects of the study with you that you do not understand. Once you understand the study, you will be asked if you wish to participate, if you do, you will be asked to sign this form.*

Purpose:

A clear statement of the purpose of your study written in simple language is required. Indicators of your study's purpose may be found in your research question(s), your hypotheses, and/or what you hope to discover.

Procedures:

If you decide to volunteer, we will . . . (Describe in simple language what will be done to the participant or what will be required of the participant during the conduct of the study. All procedures that will be followed including their duration, frequency, and recovery time if applicable must be indicated. **The participant, when engaged in the study should not be exposed to anything other than what is presented in this section.**)

Please be advised: If any of the procedures can be considered experimental (a novel or untried activity, device, intervention or treatment) special attention must be given to explaining these aspects to the participant.

Risks and Inconveniences:

Present all risks and protections from risks here. Risks are not limited to the physical.

They may also involve the potential for psychological, social harm, stress, fatigue, embarrassment, feelings of discomfort, inconvenience or other non-physical consequences. For some studies, a statement similar to the following might be useful after risks have been presented (revise for the particulars of your study): *It is possible that some of the items in the (survey, questionnaire, interview, etc.) may make you feel uncomfortable. Although this rarely happens, if you do feel uncomfortable you may: (1) choose not to answer certain items; (2) take a break and continue later; (3) choose to stop the process. If you wish, you can speak to (if applicable, please have appropriate personnel available for research participants) . . . or someone else of your choosing about your feelings.* Some of the issues noted above may not be directly applicable to your study and/or you may have other protections from risk in place. Be sure to describe them here.

Benefits:

Describe all benefits here. Even if your study has no direct benefits to the participant you should describe the general class of benefits which might accrue. For example: *This study was not designed to benefit you directly, however there is the possibility that you may learn about . . . through your participation. In addition, what is learned from this study may help us to better understand . . .*

Costs/Compensations:

Present all costs and compensations. If there are none this should be stated. Participants must know about all costs hidden and/or obvious. For example, the need to purchase items in order to participate must be considered a cost. Compensation does not necessarily have to be monetary. Receiving course credit, a reduction in work load, time-off and similar compensations must be clearly stated.

Voluntary Participation:

The italicized statement below or a similar one must appear in your document. The participant must be fully aware that participation is entirely voluntary, may be terminated by them at any time, and that non-participation or terminating participation holds no punitive consequences.

Your participation in this research is entirely voluntary. You may refuse to participate in this research without any negative consequences for you. If you begin to participate in this research, you may at any time and for any reason, discontinue your participation without any negative consequences. Simply let the researcher know.

Confidentiality:

The participant must have a clear understanding of the plan you have in effect to protect the confidentiality of their data. Further, if the conduct of your research permits anonymity, the participant must be so advised. The italicized statement below or a similar one must appear in your document:

Any and all information obtained from you will be confidential. Your privacy will be protected at all times. You will not be identified individually in any way as a result of your participation in this research. The data collected however, may be used as part of publications and papers related to . . . (Indicate how confidentiality will be protected in this study. Indicate in this section if participation will be anonymous and how anonymity

will be assured.)

Signature Section:

Prior to the concluding signature paragraphs of your consent, please include the italicized statement below or a similar one in your document:

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to decide if you wish to participate. If you have further questions, you may contact (investigator names(s) and phone #(s)). If you have questions regarding your rights as a research participant you may contact the SCSU Institutional Review Board at (203) 392-5243.

The concluding paragraphs of your informed consent must include information consistent with the all of following:

Investigator Signature: *I have explained to _____ (Participant) _____ the purpose of this research, the procedures required, and the possible risks and benefits to the best of my ability. To the best of my knowledge, the information contained in this consent form is true and accurate.*

(Principal Investigator or Assignee Signature)

Date: _____

Participant Signature: *I confirm that _____ (Principal Investigator or Assignee) _____ has explained to me the purpose of this research, the study procedures that I will undergo and the possible risks and discomforts as well as benefits that I may experience. I have read or have had read to me this consent form and I understand it. Therefore, I give my consent (or, for my child, ward etc. if appropriate) to be engaged as a participant in this research project.*

(Participant or Guardian or Legal Representative Signature)

Date: _____

Child Assent Signature: *I have read, or have had read to me, the information contained in this consent form. I understand my part in this research. I give my assent to participate in this research.*

(Signature of Child Participant if Appropriate)

Date: _____

If your form is longer than one page please place a Participant’s Initials indicator in the lower right hand corner of each page as shown (excluding the final signature page):

Participant’s Initials _____

As part of the IRB proposal approval process, your consent/assent form(s) will be date stamped and returned to you. You must use copies of the date stamped document(s) as your consent/assent form(s). The date stamp will be placed in the lower right hand corner of each document. **Please leave room for it.** Further, please submit a document(s) that is ready to be used in your recruitment efforts (blank lines for signatures and dates, no header or footer references to the application).

Presented below is an Experimental Participant's Bill of Rights. Please consider this "Bill of Rights" when constructing your consent/assent document(s).

Experimental Participant's Bill of Rights

1. To be told what the study is trying to find out.
2. To be told what will happen to me, and if the interventions to be used are different from standard practice.
3. To be told about the risks or discomforts I might experience as part of my participation in the research.
4. To be told if I can expect any benefit from participating, and if so, what the benefit might be.
5. To be told of other choices I may have and how they may be better or worse than being in the study.
6. To be allowed to ask questions concerning the study both before agreeing to participate and during the study.
7. To be given a course of action if any complications arise.
8. To refuse to participate or to change my mind about participating without penalty of any kind.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether I wish to participate in the study.