CONSTRUCTING AN INFORMED CONSENT DOCUMENT

UPDATED 5/26/2020

Informed consent embodies the ethical principle of Respect for Persons as described in the *Belmont Report*. All research conducted at SCSU should in some way seek informed consent from the potential participants. Normally, this is done with an **informed consent form** which is signed by both the research and the participant. In research where the use of a signed consent form is not feasible, such as online or remote research, a **consent cover letter** can be used. This method may also be used in situations where a signed consent form presents a burden to the participant, such as an otherwise anonymous survey, or cases where the signed form might incur risk to the participants. A consent cover letter should present the same information as an informed consent form, but not request or refer to a signature. Some or all of the required elements of informed consent may be waived by the IRB. This is done on a case-by-case basis, and requests must be justified by researchers in the protocol.

GENERAL CONSIDERATIONS

1. 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.

2. The consent document must be addressed to the participant in the second person (use the pronoun "you" when appropriate).

3. 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).

4. If the recipient cannot read, the consent information must be presented orally and a signature obtained indicating that the recipient understands the consent information.

5. Researchers and participants are to be reminded that the informed consent form is NOT a contract…the signature serves to document the consent process, not obligate the participant.

6. 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.

7. 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.

8. 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.

SPECIFIC REQUIREMENTS

The information below is presented to assist in the construction of informed consent documents and cover letters. Please consider the following:
(1) Suggested text is presented in *italics*. This text may be revised as necessary to encompass the particulars of the research;
(2) The ***bolded italicized headings*** should be used when applicable;
(3) Any italicized script in this document should be used as non-italicized regular text in the consent document.
(4) DO NOT describe the research as "approved" by the IRB; describing it as "reviewed" is preferred.
(5) Contact information for both the researcher and IRB must be provided. See the *Signature Section* text below for IRB contact information

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.*

Key Elements:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. A short bulleted list of the information in some of the following sections may be effective.

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 workload, 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.

Future Use:

All consent documents need to include a statement about the potential future use of the data that will be collected in additional research. This applies only data that will be de-identified prior to the future use. Therefore, <u>one</u> of the following statements MUST appear on informed consent documents:

1. If the data (in a de-identified form) <u>WILL OR MIGHT BE</u> used in the future: *Identifying information will be removed from the data that will be collected, and the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.*

2. If the data (in a de-identified form) <u>WILL NOT BE</u> used in the future: *The information or biospecimens collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.*

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 or hauseltw1@southernct.edu.

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

Investigator Signature: *I have explained to the 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.*

_____ *Date:*_____

Participant Signature: *I confirm that the researcher 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.*

_____ *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.*

_____ *Date:*_____

As part of the IRB proposal approval process, your consent/assent form(s) may be date stamped to indicate the most recent approved version and returned to you. If so, 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).

Revised 5/28/20