Southern Connecticut State University
Institutional Review Board

Guidance on Protocol Submission

INTRODUCTION

This document is intended to provide information about the protocol submission process and the information that must be included. Questions about the technical aspects of the Kuali software are not addressed here, and should be addressed to the SCSU Sponsored Programs and Research Office.

Ethical Principles:

Southern Connecticut State University 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 Institutional Review Board (IRB) subscribes to the basic ethical principles for the protection of human participants that underlie *The Belmont Report.* Copies of this document may be found online.

The Institutional Review Board:

SCSU IRB follows regulations published in *The Federal Register,* codified at Title 45 Part 46, which sets forth rules for establishing and operating an Institutional Review Board. The spirit and substance of these regulations are presented in the *Southern Connecticut State University Human Research Protection Program, IRB Policies and Procedures Manual,* and serve to govern SCSU IRB activities.

PROTOCOL SUBMISSION

Mandatory Training Program:

Principal and co-investigators, advisors, and research assistants, involved in research submitted for review, must complete the CITI online course titled *Social & Behavioral Research - Basic*. The CITI course is accessed through the Sponsored Programs and Research website. This course must be successfully completed **PRIOR** to developing the IRB application, and within three years of the submission. Completion of the NIH ethics course can be substituted for the CITI course. A copy of the course completion record must be included in the application. The IRB may require that additional training courses be completed.

Who Must Submit an IRB Research Protocol:

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 and completed in partial fulfillment of SCSU course requirements may need only instructor approval prior to data collection. Instructors must complete a form to notify the IRB of these activities. A form by which the IRB is notified of these activities can be obtained on the SCSU IRB website.

Research conducted by investigators not directly connected to SCSU must contact the IRB office for application instructions.

When Must the Application be Submitted:

An IRB research application must be submitted, reviewed and assigned a disposition **prior to any human research participant recruitment.**

All protocols undergo an initial review in order of receipt. Applications may be submitted for initial review at any time. Allow at least two weeks from submission for an initial IRB response. This initial review determines if the project is under the purview of the IRB, and if it is, the level of review that is required.

Minimal Risk (Exempt and Expedited Review): Protocols that present no more than minimal risk qualify for exempt or expedited review, and can be processed by one or more designated reviewers in two weeks from submission. It is the IRB reviewer, not the researcher, who makes this determination.

Greater than Minimal Risk (Full Board Review): If initial review determines that the risk presented to participants is greater than that normally experienced in participants' daily lives, the protocol must be reviewed at a convened meeting of the IRB. These meetings are held during the academic year in any month from September through May. A schedule of the meetings and respective submission deadlines is posted on the IRB website. Protocols received prior to or on posted submission deadline will be reviewed during that month (usually on the third Friday of the month). Protocols requiring full review received after the submission deadline will be reviewed in the following month. If full review is required during the summer months, the application must be submitted on or before July 15th. Applications received after July 15th will be considered for full review in the subsequent September.

What Should be Submitted:

In addition to addressing every question on the protocol applications, investigator must submit all supporting materials. This includes copies of training certifications, recruitment flyers or emails, consent forms or consent cover letters, surveys, interview questions, and anything else relevant to the study.

NOTIFICATION OF IRB DECISIONS:

Exemptions:

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

Expedited review approvals:

The IRB will inform principal investigators of approvals by email 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.**

Full Board Review:

After initial IRB review, investigators, and sponsors/advisors when applicable, will receive notice of the need for full review and the date of the board meeting at which the research will be examined. Accompanying this notice may be a request for preliminary application modifications in preparation for full board review. The board may approve 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 the initial or full review finds that any modifications or clarifications are required, principal investigators (and sponsor/advisors when applicable) will be informed. These questions may be transmitted to investigators through Kuali. 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 as well as Kuali. Disapprovals can only be issued after full IRB review at a convened meeting. The decision of the board is final. Resubmission of a disapproved application after modification is permitted.

DIRECTIONS FOR COMPLETING THE PROTOCOL APPLICATION

Please be aware: institution, school, or department-imposed restrictions on research may limit the direction and scope of research.

1. Protocols are submitted through the Kuali Protocols system. Students MUST list the faculty advisor/sponsor as the Principal Investigator/faculty Advisor.

2. Prior to developing the IRB application, investigators, co-investigators, sponsors/ advisors, and research assistants must complete the CITI *Social & Behavioral Research - Basic* online course. Training (either CITI or NIH) must have been completed within three years of application submission. Once successfully completed, documentation of the course completion (printed or downloaded from the site) for each member of the research team must be uploaded in the application.

3. Protocol Description:

   The investigator must submit a well thought out and complete summary of the proposed study. Further, project information must include: a 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).

4. <u>Participants</u>
   a. *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.

b. *Research Participant Recruitment*: The plan for recruiting participants must be presented. 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 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.

c. <u>Participant Selection</u>
    i. The possibility of investigator influence over potential participants must be addressed. The IRB must be assured that there is no possibility for undue influence underlying encouragement of participants to participate in the research as a result of investigator/participant affiliations. The possibility of undue influence exists whenever the researcher is in a position of authority over potential participants. **Best practice is to avoid such situations**.
    ii. The qualities that would lead to participants being excluded from the research, if any, must be fully described along with the mean by which the exclusion criteria will be determined.

d. <u>Interventions</u>
    i. *Interventions*: Interventions are any treatment or independent variable that will be part of the research. 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.

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.

e. Data Gathering

i. *Data Gathering*: The IRB must be able to understand 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. **Presentation of the data gathering procedures should contain enough information so that the reader, following the description, would be able to replicate the procedures.** 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.

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.

f. Benefits Versus Risk

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 regulatory 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 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.

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g. Anonymity, Privacy, and Confidentiality - 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. The protocol must explicitly state that any tracking mechanisms of any online platform will be disabled.

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. *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 at least 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.

h. Participant Notice

Please use this section to assure that all appropriate notifications to participants regarding their research involvement will be made. See the separate guidance entitled "**Constructing The Informed Consent Document"** for detailed information regarding appropriate contents, order of presentation, language, sub- titles, and other critical aspects of consent design. The following should be considered as appropriate notification formats and principles:

i. *Informed Consent*: The informed consent document is a critical piece of any research project with human participants. It documents that researchers have fulfilled their obligation to educate potential subjects about the research. 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.

ii. *Cover Letter*: The use of a signed informed consent document in some research may actually jeopardize participants' confidentiality unnecessarily. For example, a researcher employing a signed consent document in an otherwise 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**.

iii. *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 or guardians give consent.

iv. *Parent/Guardian Consent*: When children are used as research participants, a parental/guardian consent 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.

i. <u>Request for Waiver of Informed Consent</u>

i. 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.

ii. 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.

j. <u>Attachments</u>

i. In general, anything that is seen by participants must be uploaded as an attachment for IRB review.

ii. Certificates for the CITI Social & Behavioral Research (Basic or Refresher) must be submitted and must have been completed within three years of submission. Given the nature of the research, the researchers may complete addition training on their own initiative. The IRB may require more training.

k. <u>Submission</u>

The protocol can be submitted when the entire Kuali checklist is populated with green arrows. Faculty advisors must submit the protocols on behalf of the students that they sponsor. This indicates to the IRB that the faculty sponsor approves of and takes responsibility for the research.