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STANDARD OPERATING PROCEDURES

Reporting of Participant Suicide Ideation to the IRB

Many studies include questionnaires or interview questions that ask about participant's mood, feelings and quality of life, after an injury or illness.

These inquiries may ask participants to describe negative emotions, including sadness, depressed mood, thoughts of death, and suicide ideation.

If a participant endorses these questions indicating a risk for self-harm, it is a cause concern for the study team because of the ethical responsibilities to protect research participants from harm while they are involved in our studies. This SOP includes a plan and recommendations about how to handle these situations to minimize the risk for self-harm in our research participants who endorse suicidal ideation.

Steps taken to address participant responses to these questionnaires will differ based on the seriousness of the threat and vulnerability of the participant. If a risk of imminent danger to self is established, a more detailed intervention will be necessary.

The "IRB Report of Participant Suicide Ideation in a Study Protocol" form should be used to document the trigger, follow-up, and outcomes of these situations across departments. The form is set up to guide the process.

STEP #1: A participant endorses a trigger item (see page 1 for examples).

STEP #2: Complete the "IRB Report of Participant Suicide Ideation in a Study Protocol" form to take you through the following:

> SCREEN to determine immediate danger to the participant.
>
> IF POSITIVE SCREEN, then contact PI and/or licensed professional on team to review response and initiate department's response to suicidal ideation. Each department should have a procedure in place that involves a formal suicide assessment by a qualified professional.
>
> IF NEGATIVE SCREEN, then document outcome using the "IRB Report of Participant Suicide Ideation in a Study Protocol" form and provide suicide hotline and resources to the participant.

Page 1 and 2 of the "IRB Report of Participant Suicide Ideation in a Study Protocol" should be kept in the participants' study folder.

Page 3 is provided for the research team to describe additional details, such as highlights of the interviewers' discussion with the participant and study team outcomes to the IRB (add to participants' folder as needed).

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IRB Report of Participant Suicide Ideation in a Study Protocol

Date: __ __/__ __/__ __ __ __ **IRB Protocol #:** _____ **SIMS #**: ____

Study title: _____

Interviewer Script: From your answer(s) to a question(s) on the study questionnaire or in an interview with study staff, it seems that you may be having thoughts of harming yourself. I am going to ask you some follow-up questions to clarify your response.

Identify what triggered the use of the IRB Report of Participant Suicide Ideation in a Study Protocol:

☐ Patient Reported Outcome Measure (e.g., PHQ-9 item 9 "Thoughts that you would be better off dead or of hurting yourself in some way"; BDI item 9 "I would like to kill myself" "I would kill myself if I had the chance") _____

☐ Interview _____

☐ Participant spontaneously volunteered information about having suicidal ideation _____

_____

☐ Other _____

Suicide Ideation follow-up questions for participant:

1. I understand that you may be having thoughts of harming yourself.

Are you feeling this way right now?

YES ☐ → If **YES**, complete #2.

NO ☐ → If **NO**, STOP SCREENER. Place this page in subject's folder. Provide a suicide hotline card and resources to participant. No further action is required

Interviewer's notes: _____

_____

2. Suicidal Ideation: Do you plan to act on these thoughts of harming yourself?

YES ☐ → If **YES**, COMPLETE #3

Interviewer's notes: _____

_____

NO ☐ → If "**NO**", place this page in subject's folder. Provide a suicide hotline card and resources to participant. No further action is required.

Interviewer's notes: _____

_____

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IRB Report of Participant Suicide Ideation in a Study Protocol

3. If participants' response to Question 1 and 2 is "YES", then complete the following:

☐ a. initiate departmental suicide ideation protocol.
☐ b. provide a suicide hotline card and resources to participant.
☐ c. Complete page 2 and submit this report to IRB. Place copy of this form in participant's folder.

[redacted]

4. IRB REPORTING REQUIREMENTS FOR SUICIDE IDEATION

IF SECTION 3 is completed - suicide ideation should be reported to the IRB within 48 hours.

NOTE: PI should determine whether this represents an Adverse Event in the context of their protocol.

Name of Interviewer: _____

Did the study team implemented the departmental response for Suicide Ideation?
YES ☐ NO ☐

_____
Principal Investigator (printed name)

_____ _____
Principal Investigator (signature) **Date**

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IRB Report of Participant Suicide Ideation in a Study Protocol

Describe Study Team Response and Outcome: