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# Depression, Non-Suicidal Self-Injury (NSSI), and Suicidality Guidance Office of Research Compliance University of Maine

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## ****Overview****

University of Maine (UMaine) researchers frequently include measures and questions about depression, non-suicidal self-injury (NSSI), and suicidality in their research studies. The Institutional Review Board for the Protection of Human Subjects (IRB) at UMaine has developed this guidance to assist researchers as they write IRB applications that include depression, NSSI, and/or suicidality measures (e.g., Beck Depression Inventory [BDI], Children’s Depression Inventory [CDI], Center for Epidemiologic Studies Depression Scale [CES-D], Revised Child Anxiety and Depression Scale [RCADS], Self-Injurious Thoughts and Behaviors [SITBI], Structured Clinical Interview).

The IRB’s goal is to ensure that applications for studies assessing depression, non-suicidal self-injury (NSSI), and/or suicidality have appropriate justifications, descriptions, and safeguards in place when participants’ responses raise concerns regarding their level of depressive symptoms, NSSI behavior, or suicide risk. This guidance was written for research conducted in non-clinical settings where assessment and intervention resources may be limited. The IRB has included suggestions and examples for researchers to consider when developing their protocols, but it is ultimately the researchers’ responsibility to tailor the protocols to their study and population. The IRB will evaluate the suitability of the safeguards proposed within the application on a protocol-by-protocol basis.

### You should follow this guidance and include a safety protocol as an appendix if either of the following apply to your research:

1. The research study includes measures or questions about depression, NSSI, and/or suicidality; or
2. The research study will recruit populations diagnosed with depression, NSSI, or a history of/current suicidality even if the study itself may not ask about these topics.

## Guidelines for the Narrative of the IRB Application

In the narrative of the IRB application, researchers should include the following information. Some information may not apply to certain study designs and researchers should adapt as necessary. For example, in an anonymous survey, it is not possible to explain the conditions under which confidentiality would be broken because the participants’ identities are not known. For studies conducted with people currently undergoing treatment (whether inpatient or outpatient), although researchers should address study design and the qualifications of research personnel, they may not need to develop a full safety protocol and instead might state that participants are already under treatment.

### Summary:

* Include (1) a scientific rationale for why the inclusion of depression, NSSI, and/or suicidality measurements is necessary for the research, and
* (2) a description of the tools, measurements, or questions that will be used to identify or screen for depression, NSSI, and/or suicidality.
  + *Please note:* if a measure will be used that includes a suicide item and the researchers do not wish to include the suicide item, they should explain why based on their research goals (e.g., the research goal is to assess only depressive symptoms and not specifically suicide risks).

### Personnel:

* Explain (1) the affiliations and qualifications of personnel relevant to assessing depression or NSSI severity and suicidality risk, and (2) who is responsible for fulfilling different aspects of the proposed safety protocol.
* For studies in which non-clinical research personnel are involved in data collection or monitoring, qualified research personnel (e.g., faculty sponsor who is a health care provider) should be readily available to assess imminent risk and intervene as needed (by email, phone, videoconferencing platform, or in-person depending on the research design).
* All personnel who interact with participants should be trained in the study’s safety protocol.

### Participant recruitment:

* If applicable, include if your population may have a higher likelihood of experiencing suicidality (i.e., recruiting individuals with diagnosed depression or a history of NSSI behavior or suicidality). In these populations, researchers should consider if a safety protocol is necessary even if self-harm or suicide is not explicitly asked about (e.g., asking questions about mood, stress, or history).

### Confidentiality:

* Indicate if the study is anonymous or confidential.
* For confidential research, researchers should indicate:
  + (1) the conditions under which confidentiality would be broken, and
  + (2) to whom the researchers would report the concern and what information would be shared, and
  + (3) if contact information (or a key) is stored to facilitate follow-up with participants with concerning results, where the contact information (or key) will be stored and for how long.

### Risks to participants:

* Describe (1) the risks that may arise from measuring participants’ depressive symptoms, NSSI behavior, and/or suicidality (loss of confidentiality is often a risk in these studies) and the steps taken in the research concerning participant safety and balancing risks and benefits. Please consider your study setting and population in this discussion; and
* (2) describe the safety protocol, if applicable, and how this addresses the identified risks.

## Guidelines for the Informed Consent

For research that measures depression, NSSI, and/or suicidality or includes high-risk populations, additional information beyond that listed in the “Informed Consent Checklist” on the IRB website should be included in the informed consent. These additions are designed to ensure participants are aware that the research will include questions about depression, NSSI, and/or suicidality, the potential risks, and any instances in which confidentiality may be broken.

The consent should include the following information in the sections listed:

### What Will You Be Asked to Do?

* You must tell participants that questions about depression, NSSI, and/or suicidality will be asked about in the study.

### Risks:

* Address risks listed in the narrative relative to negative emotional or psychological responses involving depression, NSSI, and/or suicidality. For example, you could say “You may feel discomfort/upset when answering questions.”
* Provide the participants with a list of resources appropriate for the sample. See [“Counseling Services Referral Handout Template” (Word)](https://umaine.edu/research-compliance/resource/counseling-services-referral-handout-template/) on the Office of Research Compliance (ORC) website.
* For confidential studies that include a follow-up in the safety protocol, describe the planned follow-up procedure from the safety protocol.

### Confidentiality:

* For confidential studies, researchers must tell participants the conditions under which confidentiality may be broken, to whom confidentiality would be broken, and the information that would be shared.
* The IRB has suggested the following language for researchers to adapt to their research protocols:

“Your name and contact information will be collected in this confidential survey in case we need to follow up with you. This identifiable information will be destroyed by [month] [year]. Your confidential survey responses will be stored on a password-protected computer and will only be accessible to research personnel, except if you express or endorse thoughts of hurting yourself. If you indicate severe depressive symptoms, current NSSI behavior, or that you have thoughts about killing yourself or plan to do so, our research personnel may give you referrals for treatment or work with you on a plan to keep you safe. After your name and contact information are deleted by [month] [year], your de-identified survey responses will be stored on a researcher’s password-protected computer indefinitely.”

## Guidelines for the Safety Protocol

A safety protocol should be included as an appendix in the IRB application for studies that measure depression, NSSI, and/or suicidality. Follow the guidance below based on the proposed study design in the IRB application.

### *Risk Assessment*

Safety protocols should include an explanation of how risk will be assessed within the study, when and how investigators will review participants’ responses to the relevant questionnaires and assessments, and who will perform this assessment. The IRB will evaluate the assessment plan and if the project personnel have the appropriate training in the assessment and implementation of the safety protocol on a protocol-by-protocol basis. It may be helpful to include a decision tree (see end of this guidance for example) to guide the IRB through your risk assessment and follow-up plan.

### *Follow-Up*

How and when researchers intervene will depend on the study population, types of assessments, and research design. Researchers should thoroughly describe when and how they would follow up with participants as appropriate for their study and who will do so. The IRB has provided guidance for follow-up with participants based on study design and the age of participants. It is up to the researcher to determine if the guidance below is suitable for their research and whether alternate follow-up procedures may also be appropriate.

### For an anonymous survey:

If the study is anonymous, then participants’ responses to depression, NSSI, and/or suicidality measures cannot be connected to the participant. Thus, monitoring participants’ responses and following up individually is not possible. Thus, researchers should provide referrals (template available on the ORC website) for mental health services in the consent form (parental/guardian consent form and assent form for studies with children and other vulnerable populations) and repeat the referrals at the end of the survey.

* Referrals should be appropriate for the study’s population. For example, UMaine resources should be provided if the sample is UMaine students, but not if the sample is national. Researchers can also add additional resources specific to their study population. For instance, research with LGBTQIA+ youth could also include the chat, phone, and text line resources available from the Trevor Project (see template on the ORC website for a comprehensive list of available resources).

In addition to the referrals, the IRB encourages researchers to consider using branching logic within an online survey to provide immediate feedback to participants at imminent risk of suicide. For example, if a research study includes the suicidality item from the Beck Depression Inventory, the researcher could branch to various tailored messages at the end of the survey if the participant answers that they have suicidal ideation or are at imminent risk of suicide. The IRB has suggested the following language:

#### Example for adults:

“From your answers in this survey, our research team is concerned about your safety. You are not alone and help is available. We want to encourage you to use one of the resources below to seek support and counseling.[Include referral resources]”

#### Example for children and other vulnerable populations:

“From your answers in this survey, our research team is concerned about your safety. You are not alone and help is available. We want to encourage you to use one of the resources below for support and to speak with an adult/person you can trust to talk about how you feel. [Include referral resources]”

### For a confidential survey:

If the study is confidential, then participants’ responses to these measures can be connected to the participant. Thus, researchers are required to monitor participants’ responses and assess the level of depressive symptoms, NSSI behavior, and/or risk of suicide.

#### Contact Information:

Researchers will need to obtain contact information from participants (and from adults responsible for the participants for studies with children and other vulnerable populations) at the start of the study. This is especially critical for community participants. This could be done via a sentence at the end of the consent form asking for a participant’s (and adult’s responsible for the participants, if applicable) preferred contact method. In studies where identifying imminent suicide risk is likely, researchers should consider if gathering a physical address for participants is necessary to adequately perform the safety protocol.

#### Referrals:

Researchers should provide referrals (see template on the ORC website) for mental health services in the consent form (parent/guardian and assent form for studies with children and other vulnerable populations) and repeat the referrals at the end of the survey.

* Referrals should be appropriate for the study’s population. For example, UMaine resources should be provided if the sample is UMaine students, but not if the sample is national. Researchers can also add additional resources specific to their study population. For instance, research with LGBTQIA+ youth could also include the chat, phone, and text line resources available from the Trevor Project (see template on the ORC website for a comprehensive list of available resources).

#### **Follow-up if measuring suicidality:**

Researchers should plan to monitor participants’ responses within 24 hours of submission if the survey is not set up to automatically prompt review when a certain threshold is met. If a participant requires follow-up according to the study’s assessment plan, then the research personnel responsible for follow-up with these participants (typically a research personnel who is also a health care provider) should do so according to the identified level of risk. For research with children and other vulnerable populations, an adult responsible for the participant (e.g., parent/guardian) may be contacted with concerns. If research with children is conducted in schools, it may be the case that the guidance or school counselor is the first point of contact, and researchers should check with schools to design the follow-up procedures.

* *If assessed as imminent risk (e.g., active suicidal ideation with a plan and intent):* Immediately follow up with the participant (and adult responsible for the participant for studies with children and other vulnerable populations) via phone or email to provide referral resources and assess if immediate intervention is required. If immediate intervention is necessary, researchers should coordinate emergency care with the participant (and adult responsible for the participant for studies with children and other vulnerable populations).
  + For UMaine students, you can contact the UMaine Police Department or 911.
  + For community participants, contact Community Health & Counseling Services (CHCS) (if based in Penobscot or Piscataquis counties; [CHCS Mental Health](https://www.chcs-me.org/mental-health/),1-888-568-1112), which has a mobile crisis team that will respond on-site. Other Maine regions have mobile crisis response teams (more information can be found at [The Opportunity Alliance: Crisis](https://www.opportunityalliance.org/crisis)).
* *If assessed as non-imminent risk (e.g., suicidal ideation without plan or intent or passive suicidal ideation):* Follow up with the participant via phone or email within 1 week of finishing the study to provide referral resources. The research personnel conducting the follow-up should also assess if immediate intervention is required. If necessary, the researcher should follow procedures in the *imminent risk* section above. If the participant is a University of Maine student, the researcher could extend an offer to connect the participant with the Counseling Center.
  + The IRB recognizes that the timeframes for follow-up about *non-imminent risk* may need to be adjusted depending on the research protocol (e.g., in the case of longitudinal studies, researchers may adjust the follow-up to avoid confounds in their data). If a researcher adjusts these timeframes, then they should justify doing so within the Risks section of the Narrative of the IRB application.

The IRB has suggested the following language for follow-up communication (via email/phone). You should adapt the language as appropriate for your study.

##### Example for adults:

I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, I am concerned about your safety. In the survey, we provided some information about counseling services, but I wanted to follow up and encourage you to contact those services or your primary care provider. [Include the Counseling Center information for UMaine students or the community resources originally listed for community participants].”

##### Example for children and other vulnerable populations:

“I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, I am concerned about your safety. In the survey, we provided some information about counseling services, but I wanted to follow up and encourage you to contact those services and to speak with an adult/person you can trust to talk about how you feel.”

##### Example for adults responsible for the participant:

“I am [investigator/faculty supervisor] of the research study that your child/the person you represent recently participated in. From their answers to items about suicide on the survey, I am concerned about their safety. We provided some information about counseling services in the consent form, but I wanted to follow up and encourage you to contact those services or the primary care provider of your child/the person you represent. [Include the community resources originally given to the adult responsible for the participant].”

#### **Follow-up if measuring depression or current NSSI behavior:**

Researchers should plan to monitor participants’ survey responses if the survey is not set up to automatically prompt review when a certain threshold is met. If a participant requires follow-up according to the study’s assessment plan, then the research personnel responsible for the follow-up with these participants (typically a researcher who is also a health care provider) should do so within 1 week of the participants’ submission. The IRB recognizes that the timeframes for follow-up about elevated depressive or current NSSI behavior may need to be adjusted depending on the research protocol (e.g., in the case of longitudinal studies, researchers may adjust the follow-up to avoid confounds in their data). If a researcher adjusts these timeframes, they should justify doing so within the Risks section of the Narrative of the IRB application.

The IRB has suggested the following language for follow-up communication (via email/phone). You should adapt the language as appropriate for your study.

##### Example for adults:

“I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, you seemed to be feeling quite down/it sounds like you need some support. We provided some information about counseling services in the consent form, but I wanted to follow up and encourage you to contact those services or your primary care provider. [Include the Counseling Center information for UMaine students or the community resources originally listed for community participants].”

##### Example for children and other vulnerable populations:

“I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, you seemed to be feeling quite down/it sounds like you need some support. We provided some information about counseling services, but I wanted to follow up and encourage you to contact those services and to speak with an adult/person you can trust to talk about how you feel.”

##### Example for adults responsible for the participant

“I am [investigator/faculty supervisor] of the research study your child/the person you represent recently participated in. From their answers to items on the survey, they seemed to be feeling quite down/it sounds like they need some support. We provided some information about counseling services in the consent form, but I wanted to follow up and encourage you to contact those services or the primary care provider of your child/the person you represent. [Include the community resources that were originally given to the adult responsible for the participant].”

### For an in-person or remote interview, experiment, etc.

#### **Follow-up if measuring suicidality:**

Researchers should assess participants’ responses to questions or instruments as soon as possible. If the questions can be reviewed and/or instruments can be scored very quickly, then the follow-up with the participant (or adult responsible for the participant for studies with children and other vulnerable populations) could take place in the lab or on the audio/video conferencing platform. This is highly preferred for assessing imminent risk. If this is not possible, the researcher should explain why in the application, and then assessment and follow-up communication within 24 hours via email or phone may also be acceptable.

If a participant requires follow-up according to the study’s assessment plan, the research personnel responsible for follow-up with these participants (typically a researcher who is also a health care provider) should do so according to the identified level of risk. For research with children and other vulnerable populations, an adult responsible for the participant (e.g., parent/guardian) may be contacted with concerns. If research with children is conducted in schools, it may be the case that the guidance or school counselor is the first point of contact and researchers should check with schools to design the follow-up procedures.

##### If assessed as imminent risk (e.g., active suicidal ideation with a plan and intent):

* The research staff must remain with the participant in-person or on the audio/video call and connect them with a health care provider. This could be a research personnel named on the application. If there are no health care providers on the research protocol, researchers can use University (for UMaine students only) and/or community resources. The health care provider should assess if immediate intervention is required. If immediate intervention is necessary, researchers should coordinate emergency care with the participant (or the adult responsible for the participant for studies with children and other vulnerable populations).
  + For UMaine students, the researcher could plan to call 911, contact the Community Health & Counseling Service’s Crisis Response Line ([CHCS Mental Health](https://www.chcs-me.org/mental-health/),1-888-568-1112), or call the University of Maine Police Department (UMPD) (207-581-4040) who will direct you to the available resources (e.g., local hospital, crisis phone line, etc.).
  + For community participants, researchers can contact Community Health & Counseling Services (CHCS) (if based in Penobscot or Piscataquis counties; [CHCS Mental Health](https://www.chcs-me.org/mental-health/),1-888-568-1112), which has a mobile crisis team that will respond on-site. Other Maine regions have mobile crisis response teams (more information can be found at [The Opportunity Alliance: Crisis](https://www.opportunityalliance.org/crisis)).
  + For children, the procedures researchers should follow may differ depending on if the research is conducted within or outside of a school. As stated previously, if the study is conducted at a school, researchers should check with the school when designing follow-up procedures. The Community Health & Counseling Services mobile crisis team Services (if based in Penobscot or Piscataquis counties; [CHCS Mental Health](https://www.chcs-me.org/mental-health/),1-888-568-1112) is also a resource for research with children in and out of school settings. Other Maine regions have mobile crisis response teams (more information can be found at [The Opportunity Alliance: Crisis](https://www.opportunityalliance.org/crisis)).

The IRB has suggested the following language for follow-up communication **when a participant is assessed at imminent risk** (in person). You should adapt the language as appropriate for your study.

###### Example for adults:

“From your answers in our study, I am concerned about your safety. I am going to connect you with [name of service] to provide support and counseling.”

###### Example for children and other vulnerable populations:

“From your answers in our study, I am concerned about your safety. I am going to connect you with [name of service] to provide support and counseling.”

###### Example for adult responsible for the participant

“From your child’s/the person you represent’s answers to items about suicide in our study, I am concerned about their safety. I am going to connect your child/the person you represent with [name of service] to provide support and counseling.”

##### If assessed as non-imminent risk:

* Follow up with the participant (and the adult responsible for the participant in the case of research with children and other vulnerable populations) in person, or via phone or email within 1 week to provide referral resources. The research personnel conducting the follow-up should also assess if immediate intervention is required. If necessary, the researcher should follow procedures in the *imminent risk* section above. If the participant is a University of Maine student, the researcher could extend an offer to connect the participant with the Counseling Center.
  + The IRB recognizes that these timeframes may need to be adjusted depending on the research protocol (e.g., in the case of longitudinal studies, researchers may adjust the follow-up to avoid confounds in their data). If a researcher adjusts these timeframes, they must justify doing so within the application.

The IRB has suggested the following language for follow-up communication **when a participant is assessed at non-imminent risk** (in-person, via phone, or email). You should adapt the language as appropriate for your study.

###### Example for adults:

“I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, I was concerned about your safety. In the survey, we provided some information about counseling services, but I wanted to follow up and encourage you to contact those services or your primary care provider. [Include the Counseling Center information for UMaine students or the community resources that were originally listed for community participants].”

###### Example for children and other vulnerable populations:

“I am [investigator/faculty supervisor] of the research study you recently participated in. From your answers to the survey, I am concerned about your safety. In the survey, we provided some information about counseling services, but I wanted to follow up and encourage you to contact those services and speak with an adult/person you can trust to talk about how you feel.”

###### Example for adults responsible for the participant:

“I am [investigator/faculty supervisor] of the research study that your child/the person you represent recently participated in. From their answers to items about suicide on the survey, I was concerned that they may have thoughts about harming themselves. We provided some information about counseling services in the consent form, but I wanted to follow up and encourage you to contact those services or the primary care provider of your child/the person you represent. [Include the community resources originally given to the adult responsible for the participant].”

#### **Follow-up if measuring depression or current NSSI behavior:**

Researchers should plan to monitor participants’ responses during the interview, experiment, etc. If a participant requires follow-up according to the study’s safety plan, we recommend adapting the procedures for in-person/remote research above and the scripts under the confidential survey section of this guidance as is appropriate for your study.

### Example Decision Tree

#### Flowchart/Diagram Example

#### Plain Text Example

##### **Does the participant have ≥20 on BDI-II or endorses "2" and/or 3" on suicidality item on BDI-II?**

###### If No:

* Participant is provided list of local counseling services (see Appendix C) via email.

###### If Yes (Principal Investigator [PI] notified automatically via email)

* PI sends participant personalized email with resources and PI calls participant within 24 hours to conduct risk assessment:

If participant discloses **suicidal intent** to PI:

* Faculty sponsor (or other faculty if unavailable) is informed, will call participant, assess further, and provide coping resources if necessary, *and*
* Participant is encouraged to contact 911/emergency department.

If participant discloses **no** suicidal intent to PI:

* Participant is encouraged to reference/contact resources provided via earlier email and phone. No further action taken.