

# Institutional Review Board

## Guidance for Researchers

### Depression and Suicidality in Human Research

#### **Overview**

University of Maine research studies often include measures that screen for depression (e.g., Beck Depression Inventory (BDI), Children's Depression Inventory (CDI), Structured Clinical Interview). The Institutional Review Board for the Protection of Human Subjects (IRB) has developed this guidance to assist researchers as they develop and write their human subjects application proposing to use such measures. The IRB's goal is to be sure that applications for studies assessing depression and/or suicidality consistently contain information on the use of such measures, as well as plans for follow-up with participants whose responses raise concerns regarding level of depressive symptoms and/or intent to harm him/herself.

#### **Adult Participants:**

1. **Information to be included in an IRB application where adult participants are anonymous:**

If research is proposed where data collection will be anonymous (e.g., on-line surveys, paper/pencil surveys):

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks).
- The consent form must include referrals for mental health services (following the referral template found on the IRB website). In addition to the consent form, referrals should be repeated at the end of the survey.

2. **Information to be included in an IRB application where adult participants' identities are known:**

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks).

- The risk section must, in addition to stating that referrals for mental health services will be provided, describe the researcher's plan for follow-up in situations where a participant's responses/score indicate a high level of depressive symptoms and/or intent to harm him/herself.
- The consent form (risk section) must, in addition to listing referrals in case they become upset (following the referral template found on the IRB website), inform the potential participant that the researcher will follow-up with them if their responses to the questionnaires cause the researcher to be concerned for their well-being.

### **Instructions for follow-up:**

- **In the case of follow-up for depressive symptoms**, the researcher should follow-up as soon as possible after the measures are completed. For studies done in the lab, if the instruments could be scored quickly, a discussion could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):
  - "I am [investigator/faculty supervisor] of the research study that you recently completed. From your answers to the questionnaires, you seemed to be feeling quite down. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the Counseling Center information for UMaine students and the community resources that were originally given community participants.
  - Researchers will need to be sure contact information is obtained at the start of the study (especially critical for community participants). This could be a sentence at the end of the consent form asking for preferred method of contact.
- **In the case of follow-up for responses indicating suicidality or imminent harm:** (regardless of the participant's total score), the researcher must follow-up the same day the measure is taken. For studies done in the lab, if the instruments could be scored quickly, a discussion could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):
  - "I am [investigator/faculty supervisor] of the research study that you recently completed. From your answers to the questionnaires, I am concerned that you may harm yourself. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider." Repeat the Counseling Center information for UMaine students and the community resources that were originally given community participants. If the researcher feels immediate intervention is required, contact the Counseling Center (UMaine Students only) or Community Health & Counseling Services has a mobile crisis team that will respond on-site.

- Researchers will need to be sure contact information is obtained at the start of the study (especially critical for community participants). This could be a sentence at the end of the consent form asking for preferred method of contact.

## **Minor Participants:**

### **1. Information to be included in an IRB application where minor participants are anonymous:**

If research is proposed where data collection will be anonymous (e.g., on-line surveys, paper/pencil surveys):

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide item, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks, school district will not allow question to be used, etc.).
- Referrals for mental health services must be provided in the consent form to parent/guardian (following the referral template found on the IRB website).

### **2. Information to be included in an IRB application where minor participants' identities are known:**

- The summary section should name the instrument(s) to be used and why (this is not a new requirement). If a depression measure will be used that includes a suicide item and the researcher does not wish to include the suicide question, he/she must explain why. The reason must be based on research goals (e.g., research goal is to assess only depressive symptoms and not specifically suicide risks, school district will not allow question to be used, etc.).
- The risk section must, in addition to stating referrals for mental health services will be provided, describe the researcher's plan for follow-up in situations where a minor's responses/score indicate a high level of depressive symptoms or intent to harm him/herself. (If the study is conducted at a school, it may be the case that parents/guardians are informed that the guidance counselor will be informed and he/she will follow up with them.)
- The parental consent form (risk section) must, in addition to listing referrals in case their son/daughter become upset (following the referral template found on the IRB website), inform the parent/guardian that the researcher will follow-up with them if their child's responses to the questionnaires cause the researcher to be concerned for his/her well-being. (If study is conducted at a school, it may be the case that

parents/guardians are informed that the guidance counselor will be informed and he/she will follow up with them.) The assent script should tell children that if the researcher is concerned about how they are feeling, they will talk with their parent (or guidance counselor).

### **Instructions for Follow-up:**

- **In the case of follow-up for depressive symptoms.** The parent/guardian is most often the one who will be contacted with concerns. When research is conducted in schools, it is often the case that the guidance counselor is the first point of contact. Researchers need to check with schools to design follow-up procedures. For studies done in the lab, if the instruments could be scored quickly, a discussion with the parent/guardian could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):
  - “I am [investigator/faculty supervisor] of the research study that your son/daughter recently completed. From his/her answers to the questionnaires, he/she seemed to be feeling quite down. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider.” Repeat the community resources that were originally given community participants.
  - Researchers will need to be sure contact information is obtained at the start of the study. This could be a sentence at the end of the consent form asking for preferred method of contact.
- **In the case of follow-up for responses indicating suicidality or imminent harm.** The parent/guardian is most often the one who will be contacted with concerns. When research is conducted in schools, it is often the case that the guidance counselor is the first point of contact. Researchers need to check with schools to design follow-up procedures. For studies done in the lab, if the instruments could be scored quickly, a discussion with the parent/guardian could take place in the lab. Follow-up communication via email or phone is also acceptable. The following text may be used for the follow-up communication (in person or via email/phone):
  - “I am [investigator/faculty supervisor] of the research study that your son/daughter recently completed. From his/her answers to the questionnaires, I am concerned that he/she may have thoughts about harming him/herself. You were provided with some information about counseling services, but I wanted to follow-up and encourage you to contact those services or your primary care provider.” Repeat the community resources that were originally given community participants.

- Researchers will need to be sure contact information is obtained at the start of the study. This could be a sentence at the end of the consent form asking for preferred method of contact.