Suicidal Assessments for Research Subjects or Subject Screening

Modified: November 2018

Background:

Investigators often include some depression and/or suicide assessment questionnaire as part of a screening tool or as part of a research protocol. Typically the Beck’s Depression Inventory (BDI) is used. Investigators using these tools range from those who are trained to address the results of such tools, to those that are not.

1. Q: What concern does the IRB have with an investigator using a tool that assesses someone’s suicidality or depression?

The IRB goal is to protect human subjects. If as part of your research, you learn that a subject or a potential subject is suicidal, the Board has to be confident that the research team has a plan to address this circumstance.

2. Q: Is the IRB concerned about both suicidality and depression?

Yes; however, since the immediate concern regarding suicidality is more acute, the IRB will want a plan to address that circumstance.

3. Q: What elements of an emergency plan is the IRB looking for?

The IRB is looking for the following:

a. A clear reason why the submitted research requires the need to screen or identify for suicidality.

b. A justification for using the tool you have chosen to identify suicidality.

c. That the answer to any question regarding suicidality is reviewed by study staff prior to the subject leaving the sight of the study staff.

d. Should the subject or potential study subject indicate anything other than they are not suicidal, the following are suggestions for actions that could be included in your plan (you could include all or some, or something different you feel appropriate):

- If the study staff reviewing the answer is not a qualified physician or mental health professional, then immediately contact such a person on your study team or a specified consultant.
- Refer the individual to the Crisis Hot Line
- If not used, have the subject or the potential study subject take the “Columbia-Suicide Severity Rating Scale (for Primary Care – available on the IRB website) – the results of this 6-question survey will guide further action
4. **Q: What elements of an emergency plan is the IRB looking for if the interactions with (potential) subjects are entirely online?**

The IRB is looking for the following:

   a. The consent script must include a statement about counseling resources that are available if the subject has any concerns that are raised by the questionnaire.

   b. For anonymous surveys there really is nothing more than can be done. However, branching logic on questions about suicidality (or severe depression) could be used to trigger immediate feedback of concern, encouragement to seek counseling, links to the hotlines mentioned in the consent, or other appropriate responses that would maintain anonymity.

   c. For surveys that are not anonymous, the investigator must review answers daily and describe additional plans for intervention or further assessment when responses either to specific questions or in free-text responses indicates suicidality (or severe depression), and describe your plan for intervention, as with 3(d) above. (Even in the cases where online respondents are identifiable to the researcher, you should consider using some version of the “branching logic” described in 4b, to provide immediate feedback to the respondent, and to inform them of any additional actions that you may be taking to intercede).

5. **Q: Where should this plan be located in the submission?**

   The submitted protocol must have the suicidality plan as part of study procedures.

6. **Q: Should there be mention of this suicidality plan in the informed consent?**

   No, there is no need to include your plan in the consent form.