
Yale University Institutional Review Boards

720 GD 2: Depression and Suicidality in Human Research

Overview

Research studies that include measures for depression and suicidality should anticipate that certain participant responses may necessitate some level of intervention. A plan for how these research findings will be handled should they arise is often provided with the IRB protocol. These plans include the time frame for scoring the measure(s) and the participant response thresholds that would prompt further intervention. Details of the planned interventions for differing severities of depression or suicidality findings should be provided including a plan for how imminent risk of harm will be handled for the study's targeted population (Yale students, other Yale affiliates, or non-Yale community participants). When follow-up interactions or interventions are planned for participant responses surpassing certain thresholds, participants should be informed beforehand that there may be a consequence based on their response. Examples of acceptable plans are described below for handling study findings of depression, suicidal ideation and suicidal intent for two measures commonly used to score for depression in research studies, the Beck Depression Inventory (BDI) and the Structured Clinical Interview (SCID). The investigator is encouraged to formulate a plan that fits the specifics of the study, and the IRB will determine the appropriateness of that plan on a case by case basis.

The investigator administering the measure should be a qualified, clinically trained graduate student, faculty member or other clinician, or be closely advised by someone with the proper qualifications and training who is available while participants are being administered the measure. If the investigator administering the measures does not have appropriate clinical training, he or she should immediately contact a designated, qualified clinician to come to the experimental session and administer a thorough risk assessment for any participants endorsing suicidal ideation. The IRB should be notified within 48 hours in cases where imminent risk of harm is determined, or if the rate of depression and/or suicidality is higher than would reasonably be expected in the studied population.

The Beck Depression Inventory (BDI)

The BDI includes 21 items that assess the severity of depression and is oriented toward the symptoms of depression as described in Diagnostic and Statistical Manual for Mental Disorders – Fourth Edition/Text Revision (DSM-IV). The BDI includes a single item that directly assesses suicidal ideation. The scale was developed for use with adults, but has also been used with adolescents. A child-friendly version, known as the Child Depression Inventory (CDI) is used with younger children.

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). Beck Depression Inventory: Second Edition manual. San Antonio: The Psychological Corporation.

Use of the BDI in Research Studies and Scoring for Depression

Investigators should consider providing information regarding appropriate counseling services to all participants in research studies that involve administering the BDI, regardless of their BDI scores. Study specifics including the population being targeted and what identifiers will be linked to responses influence how this may be implemented. For instance, studies involving Yale University students and affiliates should retain a link to identifiers (or justify why this is infeasible) and may refer the students to the Yale Health Plan Mental Health and Counseling. Non-student and community participants can be referred to the Psychology Departmental clinic Yale Anxiety and Mood Services (YAMS) and other local resources. Some studies with community participants can likewise be given contact information for suicide or other appropriate hotlines, with instructions to call these mental health service hotlines if they choose certain answers to specific questions. Providing all participants with contact information for appropriate resources is particularly encouraged in cases where the investigator is unable to correlate a particular score with a given participant. When specific interactions or interventions are planned for individuals with particular threshold responses, participant contact information should be maintained and linked to

responses until the result of the measure is reasonably known and the consent form should inform of the possibility that these follow-up interventions may occur based on their responses.

A participant score above a specific pre-defined threshold on the BDI warrants the investigator (or other qualified, clinically-trained study personnel) sharing these study findings with the participant and providing appropriate referrals and assistance in reaching counseling resources. Each item of the BDI is scored from 0 to 3, and scores across all items are totaled for a possible high score of 63. Authors of the BDI (Beck et al., 1996) have established cut-offs for moderate depression (scores of 20-28) and severe depression (scores of 29-63). A 2009 administration of the BDI to Yale Freshman showed that 14 percent of freshmen score a 20 or higher on the BDI, 8 percent score above a 25 on the BDI, and 5 percent score above a 29 or higher on the BDI, which are higher scores on average than the general population (S. Nolen-Hoeksema). Accordingly, a BDI score of 25 – the mid-range of moderate depression – has been recommended as the scoring threshold for personal follow up with student participants; the cut-off for severe depression (29) could miss participants who might need help; and the cut-off for moderate depression (20) could prompt communicating study results and assisting a very large percentage of participants, many of whom are not in need of help. Other populations may warrant a different scoring threshold for intervention, but the threshold should be defined in the application and the rationale for using a different threshold provided.

Sharing Study Findings with Persons Requiring Follow-Up for Depression

Participants with BDI scores designating them for follow-up should be contacted by a qualified clinician investigator or faculty advisor the same day the BDI is completed whenever possible. Email is an acceptable means of follow-up, and the following has been used previously:

- For students or community participants in survey studies in which there is not direct contact with the experimenter (such as with computer-based BDI administration):

“I am a [investigator / faculty supervisor] of the psychology research study that you recently completed. From your answers to one of the questionnaires, you seemed to be feeling quite down and blue. We provided you with some information about counseling services at the end of the survey, but I wanted to follow-up and offer to provide any other referral information you might want.”

- For students or community participants in face-to-face experiments:

“I am a [investigator / faculty supervisor] of the psychology experiment you did recently. The person who ran your experiment noticed that you seemed to be feeling quite down and blue, according one of the questionnaires you completed. You were given some information about counseling services on the debriefing sheet, but I wanted to follow-up and offer to provide any other referral information you might want.”

Participants who respond to this email should be encouraged to make an appointment with the Yale Health Plan Mental Health and Counseling Services (for students), Yale Anxiety and Mood Services or other counseling resource as appropriate. Assistance in making appointments should be provided if requested. Those requesting referrals outside the University should be given a list of referrals of therapists who specialize in mood disorders.

Sharing Study Findings with Persons Requiring Follow-Up for Suicidality

Further precautions are needed for any student or community participant who indicates possible suicidality or imminent harm. In survey studies in which there is not direct contact with the experimenter, any student or community participant who endorses a response of "I would like to kill myself" or "I would kill myself if I had the chance" to the BDI item 9 is contacted the same day by phone or email, regardless of their total score on the BDI. Further determinations should be made by individuals who are clinically qualified to assess these conditions. Should there be signs of imminent risk in subsequent emails or phone contact, a verbal contract to not hurt oneself would be made and directions to the Yale Mental Health and Counseling (for students) or Yale-New Haven Hospital (for others) must be given. If the individual does not agree to a verbal contract, the police would be informed to provide for more direct

contact with the high-risk individual. The IRB should be informed in cases where imminent risk of harm is discovered.

The Structured Clinical Interview (SCID)

The Structured Clinical Interview (SCID; First, Spitzer, Gibbon & Williams, 1995) is comprised of multiple modules, each assessing for different classes of diagnoses and is generally administered in person. The SCID may be administered to assess for current depression; questions for the depression module of the SCID conform to criteria in the DSM-IV. Depending on the module given, the SCID can also yield results that would have confidentiality issues such as drug abuse.

First, M.B., Spitzer, R.L., Gibbon, M., Williams, J.B. (1995) Structured Clinical Interview for the DSM-IV Axis I Disorders-Patient Edition (SCID-I/P, Version 2.0). New York: Biometrics Research Dept., New York State Psychiatric Institute.

Sharing Study Findings with Persons Requiring Follow-Up for Depression

Referral information for psychological treatment and any additional assistance for participants meeting clinically significant criteria of the SCID for depression should be provided as described above for the BDI.

Sharing Study Findings with Persons Requiring Follow-Up for Suicidality

In research studies in which the SCID is administered for depression, any participant who endorses suicidal ideation during the structured interview would be given a thorough risk assessment by the experimenter (or their qualified clinically-trained advisor) before leaving the experimental session. Specifically, a positive response to either of the questions, "In the past month, were things so bad that you were thinking a lot about death or that you would be better off dead?" and "What about thinking of hurting yourself?" would prompt further clinical examination. If any participant is actively suicidal, students are taken to Yale Mental Health and Counseling or to Yale-New Haven Hospital; non-student and community participants are taken to the YAMS or Yale-New Haven Hospital. Any faculty advisor supervising the study and the IRB monitoring the study must be immediately contacted in such an incident. If the individual does not agree to be taken for additional clinical evaluation, the police would be informed to assist with the high-risk individual. As with the BDI, the IRB should be informed in cases where imminent risk of harm is discovered.