Alert Protocol for NCGENES 2 distressed adult participants

The purpose of this alert protocol is to ensure that participants reporting clinically elevated anxiety and depression symptoms have resources to cope. It is not designed to identify and intervene for imminent suicide risk. Even though the NCGENES 2 alert protocol is not designed to assess *imminent* risk, it is reasonable for the study clinical psychologist to screen study participants with elevated anxiety and/or depression symptom scores who are called and reached by study psychologist for suicidal ideation and behavior. If they happened to be at *imminent* risk on the call, then the study psychologist implements the suicide screening script referenced in this alert protocol.

The system will score the GAD7 (anxiety measure) and the PHQ8 (depression measure) as electronic data is collected and entered in the patient tracking system (the usual route of survey administration). The measures appear on the questionnaires listed below that are a part of both the Pre-Visit Parent Survey, 2-week Post-Return of Results (RoR) and the 6-month Post-RoR Parent Surveys:

* Pre-clinic visit 1 parent survey: **Question 6, A-G** (GAD7, anxiety, 7 items)
* Pre-clinic visit 1 parent survey: **Question 6, H-O** (PHQ8, depression, 8 items)
* Post-Return of results (2 weeks after RoR) parent survey: **Question 21**\*, **A-G** (GAD7, anxiety, 7 items)
* Post-Return of results (2 weeks after RoR) parent survey: **Question 21**\*, **H-O** (PHQ8, depression, 8 items)
* Final Follow up (6 months after RoR) parent survey: **Question 14**\*, **A-G** (GAD7, anxiety, 7 items)
* Final Follow up (6 months after RoR) parent survey: **Question 14**\*, **H-O** (PHQ8, depression, 8 items)

\*Questions numbers subject to change

Both the GAD7 and the PHQ8 should be scored (separately) as follows:

* Not at all=0, Several days=1, More than half the days=2, Nearly every day=3
* Sum the items to create measure score
* If a participant scores 15 to 21 on the GAD7 (indicating severe/clinically elevated symptoms) AND/OR scores 20 to 24 on the PHQ8 (indicating severe/clinically elevated symptoms), the system will create an alert.

**IMPORTANT NOTE:** For any surveys administered by paper or over the phone, the data will be entered directly into the electronic data collection system within 24 hours of collection or first thing Monday morning if the data is collected late on Friday afternoon. Expedient data entry will allow for rapid distress score calculation, alert reporting, and appropriate follow-up action according to the protocol described above. (NOTE: The NCGENES 2 staff has also been trained regarding how to calculate manual scores in the rare case that the tracking system is not functioning). If this manual score calculation is required, the questionnaire responses and calculated scores, are verified by a member of the Measures and Outcome (M&O) team. When meeting alert protocol requirements, the score(s) is reported to the Study Coordinator immediately who contacts both the Clinical Director and Study Clinical Psychologist within 24 hours of verification by the M&O team.

Immediately upon data entry, the system will score the measures (or scores will be manually calculated) and, when score(s) meet the specified cutoffs described above, automatically an email alert will be sent to the Clinical Director, notifying them of the participant’s alert status and distress score(s). The Clinical Director will inform the study coordinator that an alert has been triggered and provide the score result (s). The study coordinator will complete the first section of the Distress Call Form (attached) and email it to the study clinical psychologist within 24 hours of receiving the alert message. NOTE: 1) this email will include a receipt confirmation. 2) The study coordinator will indicate whether this alert score was generated from the Pre-Visit Parent Survey or the 2-week or 6-month Post-RoR Parent Survey, or if this is a repeat alert for this patient – having had an alert of some type at multiple time points (this will be indicated on the Participant Distress Call Form). The study coordinator will also call the study psychologist to confirm that they have received the emailed form if receipt confirmation is not obtained. The purpose of this call will be to inform them of the participant who reported high distress and to provide the measure(s) (GAD7 and/or PHQ8) that triggered the alert for that participant. If the alert is received on a Friday afternoon, the study coordinator will contact the study psychologist by end of day on the following Monday.

The study psychologist will then follow up with the participant (e.g., by phone, or in-person) within two weeks, making a minimum of three call attempts, to assess the report of distress and provide any relevant support/resources. The study psychologist will complete the bottom section of the Distress Call Form (regardless of whether they were able to reach the participants of not) and return it to the study coordinator.

The study psychologist will follow the NCGENES Distress Screening Script developed for this study to evaluate the participant. **NOTE:** It is critical to note that this distress call reporting protocol is not meant to identify *imminent* risk for suicide. The NCGENES study does not include items about suicidality, and thus individuals flagged for high distress may or may not be experiencing suicidal ideation. The purpose of this alert protocol is to ensure that participants reporting clinically elevated anxiety and depression symptoms have resources to cope. It is not designed to identify and intervene for *imminent* suicide risk.  A suicide screening instrument based off the Columbia Suicide Severity Screen is provided for use in case a participant signals possible suicidal ideation during the clinical psychologist’s screening call.

After the study psychologist evaluates the participant, they will complete the NCGENES Participant Distress Call Form and return it via email to Jeanette Bensen (jeannette\_bensen@med.unc.edu) and the study coordinator (Tracey Grant, traceyg@unc.edu). The study coordinator will email the study PIs to inform them that the psychologist has been notified about a participant with an elevated anxiety and/or depression score (clinically elevated symptoms). The study coordinator will be responsible for recording all alert protocol actions taken in the patient tracking system. When relevant the study coordinator will also report on the status of action taken for severely distressed NCGENES 2 caregivers/adult participants at Steering Committee meetings.