

# **Supplementary Material**

Article Title: The Challenge of Clinical Research and Suicidality: Participant Feedback on a Safety

Protocol

Authors: Rachel Vanderkruik, PhD, MSc; Marlene P. Freeman, MD; Katherine A. Dunn, BS;

Charlotte A. Clifford, BA; Sona Dimidjian, PhD; and Lee S. Cohen, MD

**DOI Number:** 10.4088/JCP.22m14737

## **List of Supplementary Material for the article**

1. Figure 1 Summary of UPWARD-S Safety Protocol

2. Appendix 1 Suicidality Safety Protocol Feedback Questionnaire

3. Figure 2 Participant Flow Diagram

#### Disclaimer

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

#### Supplementary Figure 1. Summary of UPWARD-S Safety Protocol

#### Endorsement of SI from Interview:

Endorsement of SI from Self-Report Survey:

MADRS question 10 >2, MINI Depression Module endorsement of question A3g as "yes", OR participant verbally expresses suicidality during interview

PHQ-9 question 9 > 0 OR EPDS question 10 > 0





Participant is given Columbia Suicide Severity Rating Scale (C-SSRS)



Participant endorses questions 3, 4, or 5 on C-SSRS



- 1) Study staff remains on the phone with the participant, informing the participant that a study doctor will follow up with them as quickly as possible (at most within 2 hours), and providing them with the National Suicide Hotline, if necessary.
- 2) After hanging up with participant, study staff contacts the designated call chain until a study doctor confirms they will contact the participant.



- 1) Resources including the National Suicide Prevention Lifeline are automatically sent to the participant along with a notification that a study doctor will follow up with the participant as quickly as possible (at most within 2 hours).
- 2) All study staff are notified of the safety protocol trigger through an automatic alert and must confirm receipt of this alert. Study staff determine which study doctor will followup with the participant.





Study doctor connects with participant, assesses the acuity with which the participant exhibits suicidality, and provides safety planning recommendations.



Study doctor completes a note to file documenting their findings from speaking with the participant.



Study staff notify the participant's local provider by forwarding a completed safety follow-up letter via fax.

#### Supplementary Appendix 1. Suicidality Safety Protocol Feedback Questionnaire

- 1. Were you expecting to receive this call from the study psychiatrist? [Yes/No]
- 2. Thinking about how you felt during and after the call, how comfortable were you with this call from the study psychiatrist? [0: Not Comfortable to 5: Very Comfortable]
- Overall, did the phone conversation with the study psychiatrist have a positive impact, negative impact, or essentially no impact on your wellbeing? [Positive Impact/Negative Impact/No Impact]
- 4. After the call with the study psychiatrist, did you make any changes in your care for depression? For example, did you increase the frequency of seeing your caregiver or seek out additional treatment? [Increased Engagement/Decreased Engagement/No Change in Engagement]
- 5. Your safety is of utmost importance to the UPWARD-S team. What recommendations do you have to modify or update the safety protocol, if any? Please also describe any other comments or feedback about your experiences with the UPWARD-S safety protocol. [open text]

### Supplementary Figure 2. Participant Flow Diagram

