DATA MANAGEMENT AND SHARING PLAN

Note on Tribal Sovereignty and NIH Policy: NIH's Data Management and Sharing (DMS) Policy recognizes Tribal sovereignty and the importance of Tribal data governance. In research involving Tribal communities, standard DMS elements may not apply and should be adapted in consultation with Tribal partners.

See NIH Notice NOT-OD-22-064 for guidance:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-064.html

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

Aim 1 and 2 involve qualitative data collection among stakeholders knowledgeable about the communities and patient populations and potential patients who would benefit from the interventions being piloted. Aim 3 involves quantitative and qualitative data collection among patients ages 18+ who screen positive on a brief suicide risk screening tool and healthcare providers and administrators.

B. Scientific data that will be preserved and shared, and the rationale for doing so:

De-identified individual and aggregate quantitative data will be preserved and shared. The de-identification process will remove direct and indirect identifiers. Given the heightened risks posed by sharing qualitative data (described below), transcripts from in-depth interviews and focus groups will not be shared. Audio recordings from qualitative data collection will be destroyed after transcription is completed and resulting data are processed/de-identified.

C. Metadata, other relevant data, and associated documentation:

All data collection instruments (e.g., quantitative surveys, interview guides) and data dictionaries will be freely available to outside investigators. We will also make the contents of the adapted screening tool, safety planning intervention protocol, and caring contacts messages available to outside investigators. Copies of consent forms will also be freely available.

Element 2: Related Tools, Software and/or Code:

Quantitative data be analyzed using custom STATA or R code. Data will be made available in csv format, and data collection instruments and data dictionaries will be made available in pdf format. Neither will require the use of specialized tools to be access or manipulated.

Element 3: Standards:

Data dictionaries that describe the structure, content, and meaning of variables will be made freely available. The dictionaries will include information about the response options (e.g., free text, numerical, categorical, or group data), the full wording of questions, what values are allowable (e.g., numeric ranges, multiple choice codes), and what those values mean. The data dictionaries will be available in commonly used formats, such as CSV files and/or PDFs. These data will also include information about relevant skip patterns.

We will collect all standard data elements that are required including Age and Sex. Since we are not examining diagnostic groups or RDoc relevant groups, we will not collect the other additional common data elements.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:

All data will be deposited to the NIMH Data Archive starting 12 months after the award begins and will be deposited every six months thereafter following the usual NDA data submission dates.

B. How scientific data will be findable and identifiable:

Data will be findable for the research community through the NDA Collection that will be established when this application is funded. For all publications, an NDA study will be created. Each of those studies is assigned a digital object identifier (DOI). This data DOI will be referenced in the publication to allow the research community easy access to the exact data used in the publication.

C. When and how long the scientific data will be made available:
The research community will have access to data when the award ends. As required by NDA, studies will also be created that contain the data used for every publication. Those studies will be shared when the pre-print is available. NDA studies have digital object identifiers (DOI) to aid in findability. We will include that DOI in relevant publications. NDA will make decisions about how long to preserve the data, but that data archive has not deleted any deposited data up to now.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:
All participants will receive information about how the data from the study will be shared during study enrollment procedures and in informed consent documents. To ensure the privacy and safety of research participants, we will de-identify the quantitative data made publicly available. For example, we will remove date of birth, after calculating age, and other variables that may place the participant at greater risk of re-identification. All aims involve qualitative data collection. The resulting transcripts from the interviews and focus groups can potentially reveal sensitive information and identify individual participants. The higher level of redaction needed to remove potentially identifying and sensitive information would substantially reduce the utility of transcripts in future analyses. Moreover, our prior experiences working on suicide prevention indicate that ensuring confidentiality is necessary to discuss the sensitive topic. To ensure participants' complete engagement in the study and honest responses, we will not share transcripts or coding summaries from the qualitative data.

B. Whether access to scientific data will be controlled:
To request access of the data, researchers will use the standard processes at NDA, and the NDA Data Access Committee will decide which requests to grant. The standard NDA data access process allows access for one year and is renewable.

C. Protections for privacy, rights, and confidentiality of human research participants:
If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Once data collection for this study has concluded, all direct participant identifiers (e.g., names and addresses) will be destroyed. During data collection, participant's identifying information will only be accessible by approved staff as part of study project duties within a secure computing environment. Deidentification processes of all data will be completed prior to depositing data in the Johns Hopkins Research Data Repository. Study participants will receive detailed information about the use of their data, including how it may be accessed by the broader research community. The privacy, rights, and confidentiality of human subject participants in this study will be protected through the suppression of all direct identifiers and a Certificate of Confidentiality. Further, qualitative transcripts will not be made available as it carries a greater risk to the identification of participants.

Element 6: Oversight of Data Management and Sharing:
Monitoring of and compliance with this Data Management and Sharing Plan will be the responsibility of the project's Principal Investigators ([List of PIs]). The plan will be implemented and managed by study staff working under the direction of the MPIs.