An Exposure-Based Implementation Strategy to Decrease Clinician Anxiety Around Suicide Prevention

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City of Philadelphia IRB study protocol document for participants recruited outside of the City of Philadelphia mental health system

Social and Behavioral Sciences Human Research Protocol

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PROTOCOL TITLE: An Exposure-Based Implementation Strategy to Decrease Clinician Anxiety about Delivering Suicide Prevention Evidence-Based Practices

INTRODUCTION AND PURPOSE:
Despite the availability of effective screening and interventions for suicide prevention, the rate of suicide in the US has increased over the past several decades. A potential lever to reduce suicides is to increase the use of evidence-based **s**uicide **s**creening, **a**ssessment, and **i**nterventions (SSAIs) in community settings by targeting known barriers to effective implementation of SSAIs. Suicide is inherently an affectively charged topic and clinicians often experience anxiety and low self-efficacy in detecting and intervening with those at risk. Clinician anxiety and low self-efficacy related to SSAI use are thus candidate targets for implementation strategy design to optimize SSAI uptake in diverse mental health settings. This study aims to design a novel, exposure-based implementation strategy (EBIS) directly targeting clinician anxiety and low self-efficacy for SSAI use with patients at risk for suicide in community settings.

This is one of three exploratory projects through the NIMH-funded P50 Penn Innovation in Suicide Prevention Implementation Research Center (INSPIRE) Center which brings together psychology, implementation science, health economics, machine learning, health information technology, psychiatry, and participatory research experts to apply innovative interdisciplinary research to tackle suicide prevention.

OBJECTIVES:
This exploratory project brings together an interdisciplinary team to leverage decades of research on behavior change from exposure theory to design and pilot-test an EBIS to target clinician-level anxiety about SSAI use to improve SSAI implementation for two gold-standard SSAIs: the Columbia Suicide Severity Rating Scale (CSSRS; Posner et al., 2011) and the Safety Planning Intervention (SPI: Stanley & Brown, 2008).

In partnership with a team of clinicians, setting leaders, implementation scientists, and suicide experts we propose to:

Aim 1: Develop an EBIS to reduce clinician anxiety and bolster self-efficacy to deliver SSAI. The EBIS will leverage exposure-based therapies to manage core clinician fears and anxiety related to suicide in high-risk patient encounters. Using participatory design methods, design and adaptation will be conducted collaboratively with key stakeholders.

Aim 2: Iteratively refine the EBIS in pilot field-testing using rapid cycle prototyping. We will engage 20 clinicians who will receive pilot iterations of EBIS; qualitative feedback will inform further refinement.

Aim 3: Test acceptability, feasibility, and preliminary effectiveness of the EBIS compared to Implementation as Usual (IAU) to target SSAI implementation mechanisms and implementation outcomes in a pilot randomized clinical trial with 40 clinicians. EBIS acceptability and feasibility will be measured via surveys and interviews. Exploratory analyses will examine impact of both conditions on putative implementation mechanisms (clinician anxiety, self-efficacy) and outcomes (SSAI adoption, fidelity). We will triangulate implementation outcomes via surveys, chart-stimulated recall, and standardized role plays coded by objective observers. Qualitative interviews with clinicians will further explore implementation outcomes and identify which changes to the EBIS are needed before confirmatory trials.

Note that our objective in the Aim 3 trial is to test whether the EBIS approach to clinician training results in better clinician self-efficacy and increased use of and fidelity to the gold standard SSAIs of interest in this study (the CSSRS and SPI), which are currently already the recommended practice in many City of Philadelphia agencies. We are *not* testing any patient level

outcomes in this exploratory study nor are we recruiting or interacting with any patients in this study.

BACKGROUND:

Designing and testing scalable implementation strategies to increase use of evidence-based practices (EBPs) for suicide prevention are critical next steps for reducing suicide rates, which have risen since the turn of the century,[18] with particularly notable increases for disadvantaged populations in recent years.[21] Evidence-based suicide screening,[22] assessment, and interventions (SSAIs) for individuals at risk for suicide[24,43,44] can reduce suicidal behavior,[45] yet they are underused in routine practice,[46] particularly in publicly-funded settings that serve disadvantaged populations.[47,48] There is an urgent need for research focused on testing and refining implementation strategies, including optimizing clinician training, to improve quality of care for those at-risk for suicide.[49]

Implementation strategy design should target mutable implementation mechanisms[50] to optimize the likelihood of clinician behavior change. The implementation science literature purports that implementation strategies addressing specific facilitators and barriers to EBP delivery will be more successful than general strategies.[50–52] Tailoring strategies requires targeting the specific mechanisms that affect implementation success. To date, implementation strategies for delivery of suicide prevention EBPs have been largely atheoretical.[53] Thus, an important next step in practice-based suicide research is development of theoretically informed implementation strategies to increase uptake of suicide prevention EBPs.

Clinician anxiety and low self-efficacy related to SSAI use are candidate target barriers to EBP uptake. *Clinician anxiety* about working with patients at-risk for suicide is well-documented.[1,2] In our team's formative qualitative work in this area, while some clinicians perceived themselves to have anxiety that is adaptive and helpful in motivating them to critically assess risk, nearly one-third reported moderate to severe anxiety related to using SSAIs.[10,42] Patient death by suicide is the greatest fear therapists report from a long list of possible adverse outcomes.[54] This anxiety can manifest in several ways. First, clinicians report experiencing *anticipatory anxiety* about screening patients for suicide risk (e.g., fear of patients endorsing suicidal risk and not knowing how to intervene, not having enough time to intervene, or concern that asking about suicide will increase risk).[7,8,55] In such cases, clinicians may avoid asking about suicide altogether or ask in inappropriate ways that limit the likelihood of identifying a patient at risk for suicide (e.g. "you are not having thoughts about suicide, are you?").[8] Second, clinicians may fear misclassifying a patient's risk level (e.g., incorrectly deeming a patient safe to go home), fearing that the patient will attempt suicide or that they will be liable for making the wrong decision. This may lead to over-referring patients to emergency rooms or crisis centers or unnecessary hospitalization,[17] even though there is limited evidence that inpatient hospitalization reduces suicide risk,[17] and concerns about hospitalization's iatrogenic effects.[56]

High anxiety about SSAIs is also caused by *low self-efficacy*, or lack of confidence in one's ability to effectively intervene to mitigate suicide risk.[55,24] Higher self-efficacy to intervene with patients at risk for suicide is an important independent predictor of SSAI use[7] and has emerged in the broader literature as a key driver of EBP implementation and sustainment.[57] Anxiety and self-efficacy are related but distinct constructs.[58,59] Theoretical models of maladaptive anxiety posit that low self-efficacy can increase anticipatory anxiety and, thus, the likelihood of maladaptive avoidance.[60] **Figure 1** illustrates our conceptual model of maladaptive anxiety applied to SSAI use. To our knowledge, no efforts have specifically targeted clinician anxiety about SSAI use other than offering training,[55] which the implementation literature has established is a necessary, *but insufficient*, implementation strategy to change behavior.[61,62]

Exposure therapy for clinicians to reduce maladaptive anxiety and bolster clinician self-efficacy related to SSAI use is a compelling, but untested, approach. *Exposure therapy* is the key mechanism through which effective psychosocial treatment reduces anxiety.[28,34,35] Exposure therapy is grounded in learning theories and cognitive behavioral models. Maladaptive anxiety comprises unhelpful cognitions (e.g., threat overestimation) and avoidance behaviors related to feared stimuli; anxiety is maintained and worsened through continued avoidance of feared stimuli,[30] which also contributes to low self-efficacy to engage with these stimuli[60,63] (see Figure 1). Exposure *breaks the cycle of avoidance* by supporting individuals to gradually confront and increase their tolerance of feared stimuli.[31] Importantly, exposure is well-tolerated, has few side effects,[64] and a robust literature supports the utility of brief, one-session exposure-based treatments to target specific fears[65–67] (in this case, fears about treating suicidal patients). Exposure-based strategies to address clinician anxiety and improve implementation have shown success for increasing uptake of exposure therapy itself – another anxiety-provoking EBP for clinicians[33] – but have not been tested for SSAI.

In sum, clinician anxiety and low self-efficacy are key implementation barriers to SSAI use but have not been implementation strategy targets. We will target these mechanisms by developing and pilot-testing an exposure-based implementation strategy (**EBIS**) for implementing the following evidence-based SSAIs: the Columbia Suicide Severity Rating Scale (CSSRS) screener and assessment tool[22] and the Safety Planning Intervention (SPI).[24] Data will inform an R01 to test EBIS at scale.

CHARACTERISTICS OF THE STUDY POPULATION:

1. Target Population and Accrual:

Aim 1: Aim 1 is a preparatory aim and does not involve human subjects research.

Aim 2: Aim 2 participants will be community clinicians (n = 20) recruited from any local community mental health clinics in the Philadelphia region.

Aim 3: Aim 3 participants are community clinicians (n = 40) recruited from 3-5 community mental health clinics in the City of Philadelphia.

2. Key Inclusion Criteria:

Aim 1: N/A

Aims 2 and 3: Participants must be:

1) Practicing mental health clinicians in the City of Philadelphia who provide direct mental health services to a treatment-seeking population.
   **This may include mental health clinicians who are both licensed or unlicensed (i.e., intern or trainees seeking licensure or practicing under another provider's license). If the participant is a practicing clinician at a clinic from which we recruit, they will be eligible for the study. Potential licensures may include but are not limited to:
   a. Licensed Family and Marriage Therapist (LMFT)
   b. Licensed Clinical Social Worker (LCSW)
   c. Licensed Social Worker (LSW)
   d. Licensed Professional Counselor (LPC)
   e. Licensed Mental Health Counselor (LMHC)
   f. Licensed Clinical Professional Counselor (LCPC)
   g. Licensed Professional Clinical Counselor of Mental Health (LPCC)
   h. Licensed Clinical Mental Health Counselor (LCMHC)
   i. Licensed Mental Health Practitioner (LMHP)
   j. Clinical Psychologist (Licensed PsyD or PhD)
2) Proficient in the English language
3) Have access to a computer with internet connectivity

3. Key Exclusion Criteria:

Aim 1: N/A

Aims 2 and 3: Participants will be excluded if they do not see any mental health patients that are at risk for suicide (e.g., they screen out all high-risk patients for their individual practice). Participants will not be excluded based on sex, demographics, and or past experience.

4. Subject Recruitment and Screening:

Aim 1: N/A

Aim 2: Community clinicians for Aim 2 activities (n = 20) will be recruited from local community mental health clinics across the Philadelphia region. Our close partnership with the City of Philadelphia Department of

Behavioral Health and the guidance of our Advisory Board (formed under Aim 1 activities) will facilitate recruitment. In our experience, local clinicians are eager for training opportunities, and we will further incentivize participation by offering continuing education credits for participating clinicians. To recruit clinicians, the study team will develop email scripts and flyers to disseminate to local agency partners who will in turn share these recruitment materials with their clinicians on staff. Clinics will be eligible if they have clinicians who provide direct mental health services to a mental health treatment-seeking population. We will only connect with clinicians working in these institutions if we receive clinic leadership approval. We will not contact any clinicians if we do not have approval from clinic leadership or the clinician does not express interest in participating. These materials will instruct potential participants to contact the study coordinator to confirm study eligibility, at which point the coordinator will present a study overview and proceed with study consent if the clinician is interested. Additional recruitment methods may include senior investigators on the project (Oquendo, Becker-Haimes, Jager-Hyman) making brief presentations (in person or virtually) at local agency meetings, during which details of the project and requirements of participation will be discussed. At these meetings, clinicians will complete a paper or electronic "consent to contact" via REDCap with their preferred contact information. Study staff will then follow up with interested clinicians with more information and to review all elements of informed consent. This approach ensures that clinicians do not feel pressured to make a decision to participate. *Recruitment materials and scripts specific to the procedures in Aim 2 are included for the IRB's review.*

Aim 3: We will recruit clinicians for the pilot trial (n = 40) from 3-5 of our local partner community agencies with whom we have close relationships. Recruited agencies will be identified in collaboration with our Advisory Board and our partners within the City of Philadelphia Department of Behavioral Health. Clinics will be eligible if they have clinicians who provide direct mental health services to a mental health treatment-seeking population. We will only connect with clinicians working in these institutions if we receive clinic approval. We will not contact any clinicians if we do not have approval from clinic leadership or the clinician does not express interest in participating. To recruit clinicians, the study team will develop email scripts and flyers to disseminate to local agency partners who will in turn share these recruitment materials with their clinicians on staff. If it is preferred by the agency, the study team will collaborate with leadership in these agencies to identify a time for Dr. Becker-Haimes or Dr. Oquendo or another senior member of the study team to attend a clinic team meeting (either virtually or in person) to present an overview of the study to interested clinicians. At this meeting, clinicians will complete a paper or electronic "consent to contact" via REDCap with their preferred contact information. Following the same procedures described in Aim 2 above, study staff will then follow up with interested clinicians to provide more information and to review all elements of informed consent.
Recruitment materials and scripts specific to the procedures in Aim 3 are included for the IRB's review.

5. Early Withdrawal of Subjects:

There is little risk associated with this study, and there is no safety concern associated with participation that would lead to participants being withdrawn from the study by the investigators. Importantly, exposure-based treatments upon which the EBIS implementation activities are based are generally well-tolerated with few, if any, side effects (see ***Risks*** below). As outlined in the informed consent document, there will be no consequences for any providers or other personnel who indicate interest and then do not enroll in the study. All participants will be free to withdraw their participation at any time by contacting study staff to inform them that they no longer wish to participate in the study.

6. Vulnerable Populations:

We will work directly with clinicians. Vulnerable populations will not be recruited.

7. Populations vulnerable to undue influence or coercion:

N/A

STUDY DESIGN:

This study brings together an interdisciplinary team with expertise in suicide prevention, implementation science, and exposure therapy to design a novel, exposure-based implementation strategy (EBIS) directly targeting clinician anxiety and low self-efficacy for SSAI use with patients at risk for suicide.

Study activities will take place over approximately three years. The estimated length of individual clinician participation in Aim 2 is 3-4 weeks. The estimated length of individual clinician participation in Aim 3 is 4-6 months. The proposed start date for all study activities is 8/1/22. See below for proposed timeline:

Study Timeline (By Project Quarter)												
Activity	Project Period Quarter											
	Y1				Y2				Y3			
	1	2	3	4	1	2	3	4	1	2	3	4
Preparation (secure IRB, hire staff, finalize data collection procedures)												
Aim 1												
Initial adaptation and refinement of EBIS w/ Advisory board												
Aim 2												
Iterative refinement via field test through rapid cycle prototyping (n=20 clinicians)												
Cumulative Enrollment Benchmark: 5 clinicians												
Cumulative Enrollment Benchmark: 20 clinicians												
Aim 3												
Pilot randomized trial (n = 40 clinicians)												
Cumulative Enrollment Benchmark: 10 clinicians												
Cumulative Enrollment Benchmark: 20 clinicians												
Cumulative Enrollment Benchmark: 30 clinicians												
Cumulative Enrollment Benchmark: 40 clinicians												
Interview transcription and coding												
Data analysis												
Manuscript preparation, dissemination of findings, R01 submission												

METHODS:

Overview

Aim 1: *Develop an implementation strategy grounded in exposure theory (EBIS) to reduce clinician anxiety and bolster clinician self-efficacy to deliver SSAIs.* We will develop and refine EBIS via presentation and workshopping with a stakeholder Advisory Board over multiple meetings, using a modified process of co-design.[40,75] The outcome of Aim 1 will be a drafted manual to guide EBIS administration that will be further refined in Aim 2.

A conceptual prototype for EBIS has been developed through our preliminary work and is described below. *Final materials will be developed based on Aim 1 output and submitted for IRB approval.*

Description of EBIS prototype. EBIS will be informed by the latest science in exposure theory,[31] borrowing heavily from brief exposure-based treatments that can be delivered in a single session.[66,67,72] We anticipate that EBIS will occur in four phases that map on to standard exposure therapy practice for patients with anxiety disorders: psychoeducation, assessment, practice, and relapse prevention; however, the final version will depend on the outcomes of Aim 1. **Table 1** presents each anticipated component; each is also described below.

Psychoeducation. In exposure therapy, psychoeducation is a critical step toward obtaining buy-in to engage in exposure practice. Typically, psychoeducation includes information about both adaptive and maladaptive anxiety. We will provide brief information about the role of anxiety in SSAI delivery, explain the "cycle of avoidance" that can occur when one experiences anxiety related to patient suicide risk, and present clinical implications (**Figure 1**).

Assessment/Hierarchy-Building. We will use the "post-it method" in a group format for assessment and hierarchy-building. Clinicians will be presented with 8-12 flashcards that delineate various fears about interacting with a suicidal patient (e.g., "patient endorses passive suicidal ideation") and fears related to outcomes of intervention (e.g., "patient completes SPI but attempts suicide after leaving clinic,"). Clinicians then rank-order each fear with respect to how anxiety provoking it is, and for each scenario, rate their anticipated level of anxiety using the Subjective Units of Distress Scale (SUDS) ranging from 0 (no anxiety) to 10 (maximal anxiety). We will select each clinician's three most-feared scenarios for exposure practice.

Guided Practice (In Vivo & Imaginal Exposure[63]). Clinicians will engage in either *in vivo* practice or imaginal exposure with a trained actor (research assistant, RA) based on feared scenarios selected in the step above. Consistent with a standard exposure model,[73] RAs will be trained to guide clinicians to (1) identify core fears and anticipated anxiety via SUDS, (2) engage in targeted practice to violate assumptions of core fears and track SUDS changes, (3) engage in targeted cognitive debriefing to enhance coping self-efficacy. RAs will be guided by an "exposure checklist" that Project Co-PI Dr. Becker-Haimes developed and supervised closely by Dr. Becker-Haimes during administration.[74] A final adapted copy created in Aim 1 activities will be submitted to the IRB for review before use in Aim 2 or Aim 3 activities.

Relapse Prevention/Application to Clinical Practice. Clinicians will be guided to summarize their experience and set intentions for managing anxiety they may experience in practice. Follow-up consultation will also include targeted discussion of clinician anxiety and avoidance to facilitate maintenance of gains.

Table 1. Anticipated EBIS Components and Rationale

EBIS Component	Rationale
1. Psychoeducation	Obtain clinician buy-in, explain how anxiety can interfere with suicide EBP delivery
2. Assessment/ Hierarchy Building	Identify tailored exposure practice targets that best match an individual clinician's fears
3. Exposure Practice	Provide exposure to feared outcomes to foster clinician self-efficacy in managing high-risk patients, facilitate clinician practice managing anxiety in high-risk encounters.
4.Relapse/ Prevention Application to Clinical Practice	Transition "learning" about one's ability to manage high-risk encounters to clinical practice; continue to use an exposure frame to support implementation

Aim 2: *Iteratively refine EBIS in a pilot field test using rapid cycle prototyping***.** The primary goal of Aim 2 is to identify feasibility challenges to inform refinements to EBIS needed prior to formal testing, using rapid cycle prototyping. Secondary goals are to collect qualitative feedback from clinicians on the extent to which EBIS successfully engages target mechanisms of clinician anxiety and self-efficacy. The outcome of Aim 2 will be a refined manual to guide EBIS in the Aim 3 clinical trial.

Aim 3: *Test acceptability, feasibility, and preliminary effectiveness of EBIS to target implementation mechanisms and outcomes relative to implementation as usual (IAU) via a pilot randomized clinical trial with 40 community clinicians.* Our primary Aim 3 dependent variables are EBIS acceptability and feasibility, measured through questionnaires, interviews, and recruitment and retention statistics. Secondary outcomes are preliminary effectiveness of EBIS on implementation outcomes (SSAI adoption and fidelity), and engagement of target implementation mechanisms (clinician anxiety and self-efficacy related to SSAI use), assessed via mixed methods (questionnaires, chart-stimulated recall, observer-coded role plays, and interviews). We also will gather data on other possible implementation mechanisms (e.g., SSAI knowledge, attitudes, intentions, norms, and organizational factors). Qualitative interviews with clinicians will probe for contextual implementation barriers to SSAI use not addressed by EBIS to inform augmentation prior to fully powered evaluation.

1. Study Instruments:

Aim 1: N/A

Aim 2: Data will consist of responses to semi-structured interviews and completion of a brief survey about clinician background and perceptions related to work with patients at risk for suicide. Qualitative data will be integrated to iteratively adapt and refine the EBIS implementation strategy in preparation for the Aim 3 trial. All data will be used exclusively for research purposes.

- The qualitative interview guide and Aim 2 brief survey battery was previously reviewed and approved by the IRB

Aim 3: Clinical trial data will consist of clinician responses to self-report questionnaires, chart-stimulated recall, semi-structured interviews, and fidelity role-plays with research staff. In addition, recruitment and retention

statistics will capture feasibility metrics. *No identifiable data about patient level information will be collected.* All data will be used exclusively for research purposes and will be administered at the following time points: T1 = baseline/pretraining; T2 = post-training; T3 = 2-week follow-up; T4 = 12-week follow-up. Specific measures that will be administered are described below. Table 2 shows the anticipated assessment battery for the Aim 3 clinical trial. All measures will be administered to all clinicians enrolled in the trial, regardless of assigned condition.

Primary Outcomes: Acceptability & Feasibility

- *Acceptability of Intervention Measure:* A 4-item, psychometrically-validated measure that indexes the extent to which stakeholders believe an implementation strategy (in this case, IAU or EBIS) is acceptable. This will be administered at Time 2 and Time 4.
    - This measure was previously reviewed and approved by the IRB.

- *Feasibility of Intervention Measure*. A 4-item, psychometrically-validated measure that indexes the extent to which stakeholders perceive an implementation strategy (in this case, IAU or EBIS) is feasible. This will be administered at Time 2 and Time 4.
    - This measure was previously reviewed and approved by the IRB.

- *Qualitative Interview*. This interview will consist of three sections. Section 1 will query about the acceptability of the implementation condition to which they were assigned (EBIS or IAU) and any barriers that arose in engaging with any component of the study. Section 2 will focus on how the implementation condition engaged target implementation mechanisms. The final section will be guided by the Consolidated Framework for Implementation Research to query about barriers to SSAI use, with the primary goal of identifying contextual determinants of use not adequately addressed by EBIS. This will be administered at Time 4.
    - This measure was previously reviewed and approved by the IRB.

Secondary Outcomes: Target Implementation Mechanisms

- *Subjective Units of Distress Scale (SUDS).* The SUDS is a one-item, 10-point rating scale of perceived distress, commonly used to guide exposure therapy. This will be administered at Time 1- 4.
    - This measure was previously reviewed and approved by the IRB

- *Suicidal Patient Comfort Survey.* A brief, 5-item measure assessing clinician anxiety about interacting with and treating patients with suicidality. This will be administered at Time 1- 4.
    - This measure was previously reviewed and approved by the IRB.

- *Self-Efficacy Questionnaire.* Established question stems from behavioral measuring clinicians' perceptions of themselves as having the skills and abilities to perform a task (in this case, SSAI use) on a 7-point scale. This will be administered at Time 1- 4.
    - This measure was previously reviewed and approved by the IRB.

Secondary Outcomes: Implementation Outcomes

- *Chart Stimulated Recall (CSR).* An established technique for examining clinician decision-making and clinical processes beyond what can be determined from chart review or self-report alone. A trained research team member will review the clinician's caseload with them for the past clinic week and ask them brief questions (no more than 5 minutes) related to the clinician's suicide-related practices (e.g., "Did you conduct a screen for suicide risk? How did you screen for risk? If risk was present, was a full CSSRS/SPI administered?). This will be administered at Time 1 and 3-4. No identifiable patient information is collected during the CSR and the study staff will not ever view the chart directly. Clinicians are instructed to refrain from sharing any identifiable patient details during the CSR administration.
    - This measure was previously reviewed and approved by the IRB.

- *Brief Role Plays.* Participants will receive a vignette and prepare for a 45-60-minute role play, during which they will be asked to complete an SPI with a patient who was determined to be at-risk for suicide following CSSRS administration with a trained actor. Role plays will be audio-recorded and coded for competence with the Safety Planning Intervention Rating Scale (SPIRS). This will be administered at Time 3 and Time 4.

- *An example of the procedures and coding scheme for the role play are included for the IRB's review.*

<u>*Secondary Outcomes: Additional Mechanisms of Interest*</u>

- *Self-Perceived Knowledge & Attitudes About Suicide Scale.* Selected subscales (Knowledge, Attitudes) of the Short Survey on Knowledge, Self-Confidence, and Attitudes Towards Suicidal Behavior will assess a clinician's perceived knowledge about suicide and how to intervene. This will be administered at Time 1- 4.
  - This measure was previously reviewed and approved by the IRB.

- *Clinician Attitudes Toward Safety Planning.* A 12-item questionnaire assessing clinician attitudes and beliefs about the use of safety planning interventions in clinical practice with suicidal patients. This will be administered at Time 1- 4.
  - This measure was previously reviewed and approved by the IRB.

- *SSAI Intentions and Determinants of Intention.* Established question stems from behavioral science using items on a 7-point scale asking how willing and how likely one is to use SSAIs as well as attitudes and perceived norms of SSAI use. This will be administered at Time 1- 4.
  - This measure was previously reviewed and approved by the IRB.

- *Clinician Demographics.* Brief questionnaire about clinician demographic (e.g., age, sex) and professional characteristics (e.g., years of experience, theoretical orientation, caseload descriptions), work setting, and a question about the clinician's person experience with suicide (e.g., "Have you ever had a client die by suicide while under your care?"). This will be administered at Time 1.
  - This measure was previously reviewed and approved by the IRB.

- *Anxiety Sensitivity Index (ASI-3).* Questionnaire about the clinician's physical, cognitive, or social concerns about anxiety. This will be administered at Time 1.
  - This measure was previously reviewed and approved by the IRB.

- *Organizational Innovation Specific Capacity for Suicide Prevention Evidence-based practices (OISCSE).* Questionnaire about the organizational policies, procedures, and practices within the clinician's organization to observe potential factors that could influence use of SSAI's. This measure has 14-items on a Likert scale plus a yes or no question to query any additional factors about the clinician's organization not mentioned in the first 14-items. If the clinician responds positively, they are asked an additional open response question. This measure was adapted from a previously developed measure to assess policies and procedures needed to support exposure therapy delivery, guided by responses to qualitative interviews completed in Aim 2 of this study and items from the Zero Suicide Organizational Self-Study in collaboration with suicide prevention and implementation science experts.
  - *A copy of this measure is included for the IRB's review.*

Table 2. Assessment Schedule for Aim 3

Outcome	**Measure**	T1	T2	T3	T4
Primary Outcomes					
EBIS Acceptability	Acceptability of Intervention Measure; Qualitative Interview (T4 only)		X		X
EBIS Feasibility	Feasibility of Intervention Measure; Recruitment/Retention statistics		X		X
Secondary Outcomes					
Target Implementation Mechanisms					
Clinician Anxiety	Subjective Units of Distress Scale;[71] Suicidal Patient Comfort Survey[55]; Anxiety Sensitivity Index (ASI-3) (Time 1 only)	X	X	X	X
Clinician Self-efficacy	Established question stems[81]	X	X	X	X
Implementation Outcomes					
SSAI use (CSSRS, SPI)	Chart Stimulated Recall[82]	X		X	X
SPI Fidelity	Role Play coded w/ SPIRS			X	X
Additional Implementation Mechanisms of Interest					
SSAI Knowledge	Self-Perceived Knowledge About Suicide Scale[83]	X	X		X
SSAI Attitudes	Attitudes Toward Suicide Prevention;[84] Clinician Attitudes Toward Safety	X	X	X	X

	Planning[85]				
SSAI Intentions	Established question stems [81]	X	X	X	X
SSAI Norms	Established question stems [81]	X	X	X	X
Demographics	Demographics survey	X			
Organizational Factors	Organizational Innovation Specific Capacity for Suicide Prevention Evidence-based practices (OISCSE)		X		
T1=baseline. T2=post-training. T3=2-week. T4=12-week follow-up.					

2. Group Modifications:

Aims 1 and 2: N/A

Aim 3: After consenting to participate, clinicians will be randomly assigned to one of the two implementation conditions; the measurement battery will be identical for clinicians in each condition, with the exception that qualitative interviews for clinicians randomized to the EBIS condition will include several additional questions about their specific experience with EBIS.

3. Method for Assigning Subjects to Groups:

Aim 1: N/A

Aim 2: No participants will be randomized as a part of Aim 2 activities.

Aim 3: Clinician participants will be randomized 1:1 to receive either Implementation as Usual (IAU) or IAU+EBIS. Randomization will take place after the informed consent process and prior to beginning either training condition.

4. Administration of Surveys and/or Process:

Aim 1: N/A

Aim 2: To accomplish Aim 2, we will deliver the draft version of EBIS as outlined in the procedures below. Following receipt of the draft version of EBIS, clinicians will complete brief 45-60 minute qualitative interviews with trained study staff. Qualitative interviews will take place via phone, videoconference, or in person, depending on participant preference.

Aim 3: During the clinical trial, all measures will be administered by trained research staff in accordance with the assessment schedule outlined above. Questionnaires at each time point will be administered either in paper format or electronically using REDCap, depending on participant preference (See *Study Instruments* above). Qualitative interviews will take place via phone, videoconference, or in person, depending on participant preference.

5. Data Management:

Drs. Maria Oquendo (PI) and Becker-Haimes (co-PI) will oversee all data cleaning and management with support from co-Investigator Dr. Jager-Hyman.

All primary data, including audio-recordings, will be stored using Research Electronic Data Capture (REDCap), a HIPAA-compliant web-based survey platform. The REDCap system provides secure, web-based applications that are flexible enough to be used for a variety of types of research, provide an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. These systems offer easy data manipulation with audit trails for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). REDCap servers are housed in a local data center at the CRCU at the Perelman School of Medicine and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines. REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners on six continents and over 26,000 research end-users (www.project-redcap.org). Any physical copies of the surveys, field notes, and interview data collected in Aims 2 and 3 will be kept in a locked filing cabinet with

access by research staff only. All participants will be assigned an ID number. The file linking participants' ID numbers and identifiable information will be stored in a separate REDCap database with access by study staff only. All consent forms with identifiers will be stored in a separate locked filing cabinet or obtained electronically and maintained in a separate REDCap database.

All personnel will complete required training before being granted access to any identifying information. This includes training on confidentiality through the Collaborative IRB Training Initiative (CITI) course. All personnel will also sign confidentiality statements. These confidentiality statements will specify the procedures for reporting unintentional breaches in confidentiality to the PIs. The confidentiality statements also specify that violations of participants' confidentiality, either unintentional or deliberate, may result in termination of hire. The PI will conduct training with all research personnel regarding data, limits of confidentiality, maintaining confidentiality, and proper study procedures. Participants will be notified of the above procedures during informed consent. No identified data will be disclosed to personnel not listed on the study protocol.

7. Subject Follow-up:

The study investigators have a robust record of conducting community-partnered research to enroll clinicians in research trials. We attribute the success of these studies to: 1) taking a true partnered approach to research by including key stakeholders in research design at all stages of the research process, 2) the training of staff to build rapport with participants, and 3) local travel to participants to facilitate their completion and/or use of phone interviews to facilitate the gathering of qualitative data. The senior investigative team (Oquendo, Becker-Haimes, Jager-Hyman) will meet weekly with study staff to monitor project enrollment and retention so that any problems can be identified early and remediated. The project has clear benchmarks for recruitment (see **Study Timeline**), so any deviations from projected benchmarks will be readily apparent. We will track data on clinician enrollment and reasons for non-enrollment and study dropout. These data will help us identify specific barriers to participation that might be addressed through revised recruitment procedures. In addition, the investigative team has a robust record of conducting community partnered research to enroll clinicians in research trials with similar demands of participants. We attribute this success to strong community partnerships, rigorous training of all study staff in building rapport with participants and working closely with participants to facilitate data collection and completion. To facilitate retention of clinicians across the multiple assessment time points in Aim 3, we will additionally employ the following strategies that have been successful in our prior studies: (1) We will spread out clinician payments for research activities so that clinicians are compensated after each assessment to increase motivation to complete each activity, (2) We will collaborate closely with clinician participants to schedule standardized role-plays and interviews at hours most convenient for them, including after business hours and on the weekends, and (3) We will collaborate with our Advisory Board to identify additional strategies for keeping clinician participants engaged and motivated throughout the study period. Furthermore, the City of Philadelphia Department of Behavioral Health has expressed support and enthusiasm for this work (see Letter of Support).

STUDY PROCEDURES:

1. Detailed Description:

Aim 1: *Develop an implementation strategy grounded in exposure theory (EBIS) to reduce clinician anxiety and bolster clinician self-efficacy to deliver SSAIs.*

We will develop and refine EBIS via presentation and workshopping with a stakeholder Advisory Board over multiple meetings, using a modified process of co-design.[40,75] An initial prototype for EBIS has been developed through our preliminary work, as described above. The Advisory Board will be assembled leveraging established community partnerships cultivated by Co-PI Becker-Haimes. Select faculty from the larger P50 Penn INSPIRE Center also will provide content expertise to the Advisory Board. The Board will be kept under 6, an ideal size for generating ideas.[76] If an advisory board member discontinues participation, we will work to identify another board member for feedback on the development process.

Drs. Oquendo and Becker-Haimes will co-facilitate all Advisory Board meetings. In the first meeting, we will present initial prototypes for each EBIS component and engage in group discussion about how best to refine them to maximize acceptability and feasibility while also maximizing ability to target clinician anxiety and self-efficacy about SSAIs. Questions posed to the Board for EBIS components will be general (e.g., "Tell us

your thoughts on the psychoeducation component?" "What exposure tasks do you think will be most important?") and specific (e.g., "How can we make the psychoeducation component more engaging?" "How can we optimize imaginal exposure to a feared outcome of being sued?"). We will query the Board about their perceptions as to how EBIS can be designed to be maximally acceptable and feasible for diverse settings. Drs. Oquendo and Becker-Haimes will integrate all feedback into a revised prototype that will be presented to the Advisory Board in a second meeting. We will repeat this until saturation is reached (anticipated max. 4 meetings) and a final prototyped version of EBIS is identified for field-testing in Aim 2.

As noted previously, all Aim 1 activities are considered preparatory to human subjects research. All members of the Advisory Board are considered consulting members of the research team, not participants.

Aim 2: *Iteratively refine EBIS in a pilot field test using rapid cycle prototyping***.**

We will use rapid cycle prototyping to iteratively refine EBIS based on feedback from up to 20 clinicians to optimize its acceptability and feasibility and identify early implementation challenges. Recruited clinician participants will receive approximately 3-4 hours of training in the CSSRS and SPI and the drafted EBIS prototype (exact sequencing of didactic and EBIS-based activities will be determined in Aim 1) either virtually or at a location on the University of Pennsylvania's campus. We will be in communication with clinic leadership during the study. As part of the communication, we will ask the leadership at each participating clinic if the study activities may be done on work time. Based on this response, we will communicate to all participants at each respective clinic site if the study activities are permitted to take place during work hours. To avoid selecting for a specific type of therapist, we will consider designing trainings to take place in smaller increments of time that are maximally feasible to be completed in the work setting (e.g., over the lunch hour); we will also clarify to leadership that study training activities with accompanying CEUs will satisfy licensure requirements for suicide training. Bachelor level RAs, shown to be effective in administering exposure, will be guided to administer EBIS by Co-PI Dr. Becker-Haimes, an exposure therapy expert. RAs will receive close supervision from Dr. Becker-Haimes.

In this prototyping phase, EBIS will be administered either individually to clinicians or in small groups of 2-4 clinicians. The syllabus that will guide EBIS administration is included for the IRB's review. All trainings and consultation sessions will be video recorded and transcribed using HIPAA compliant software. During administration, study staff will take field notes on implementation challenges. Clinicians will complete a brief demographic questionnaire before and after completing the training. After receiving EBIS, clinicians will complete brief qualitative interviews (45-60 minutes) about their experience with EBIS either virtually or at a private location (e.g., the University of Pennsylvania campus or your office location). Interviews will be audio-recorded and transcribed. The first part of the interview will query clinicians on acceptability and feasibility of EBIS. The second part will comprise semi-structured questions about perceptions of how EBIS influenced anxiety and self-efficacy to deliver the CSSRS and SPI. The last part will solicit suggestions for improvements to optimize EBIS. Clinicians will also receive continuing education credits for training activities. We anticipate it will take clinicians approximately 4-5 hours to complete study procedures (up to 4 hours of training and 1 hour for the interview).

We will make iterative refinements after each EBIS administration in response to observed implementation challenges and clinician feedback until saturation is reached (anticipated maximum: 20 clinicians). When clarity is needed on whether certain adaptations are needed, we will return to our Advisory Board for guidance.

The finalized manual that will guide EBIS administration in Aim 3 was submitted for the IRB's review.

Aim 3: *Test acceptability, feasibility, and preliminary effectiveness of EBIS to target implementation mechanisms and outcomes relative to implementation as usual (IAU) via a pilot randomized trial.*

After consenting, clinicians will be randomized to one of two implementation arms: IAU (n=20), or EBIS (n=20), which comprises all IAU activities plus EBIS as refined in Aim 2. If a clinician drops out of the study prior to attending their initial workshop (which is when official randomization will occur), we will make efforts to replace that individual to obtain a final sample of 40 clinicians randomized.

IAU Condition. Gold-standard IAU for SSAIs typically comprises pre-implementation

preparation, didactic training, knowledge tests, experiential role plays, ongoing expert consultation, and providing certification status to clinicians who attain established benchmarks. Pre-implementation preparation will include provision of materials (e.g., SPI manual,[78] instructions,[79] and forms). Didactic training will occur in two parts: (1) CSSRS screening and assessment, and (2) SPI use. Part one will consist of materials we previously developed based on community clinician feedback. Part two will follow established SPI guidelines, including didactic training about SPI rationale and evidence base and experiential practice. IAU also will include supports for electronic health record integration (e.g., previously developed templates). After training, clinicians will receive six, one-hour sessions of expert consultation over the course of 12 weeks to discuss implementation barriers and receive more role play practice.

EBIS Condition*.* Clinicians randomized to EBIS will receive all IAU elements outlined above plus the exposure-based intervention described above and refined in Aims 1 and 2 (see **Table 1**).

In both arms, clinicians will complete study measures as outlined in **Table 2** above at four time points: baseline/pre-training (T1), post-training (T2), two-week follow-up (T3), and twelve-week follow-up (T4). A 12-week follow-up was selected based on base rates of suicidal ideation in outpatient settings to maximize likelihood that clinicians will encounter at least one patient at risk for suicide during the trial and to align with the traditional length of many evidence-based treatment protocols.[77] Training will either take place virtually or at a location on the University of Pennsylvania's campus. All trainings and consultation will be video recorded using HIPAA compliant software (in both implementation arms). Surveys will be completed online or on paper, depending on participant preference. Interviews will take place either virtually or at a private location that is convenient for the clinician (e.g., the University of Pennsylvania's campus or your office location). All interviews will be audio-recorded and transcribed. We will be in communication with clinic leadership during the study. As part of the communication, we will ask the leadership at each participating clinic if the study activities may be done on work time. Based on this response, we will communicate to all participants at each respective clinic site if the study activities are permitted to take place during work hours. To avoid selecting for a specific type of therapist, we will consider designing trainings to take place in smaller increments of time that are maximally feasible to be completed in the work setting (e.g., over the lunch hour); we will also clarify to leadership that study training activities with accompanying CEUs will satisfy licensure requirements for suicide training.

The time allotted for the training in Aim 3 will be standardized across conditions, but the content of the training will differ. Exact hours and time the training takes to complete may vary slightly depending on the number of clinicians in each training session, but the content of the training and the trainer will be the same for each session. As described throughout the protocol, the control training will we are using gold standard implementation as usual (IAU) training, role plays, and IAU-focused consultations. The intervention or EBIS condition would receive additional EBIS constructs in training (i.e., specific psychoeducation about how clinician anxiety is normal and to be anticipated in suicide prevention work), exposure-focused role plays (vs. traditional role plays in the IAU condition) and consultations (IAU = traditional consultation; EBIS = emotion-focused consultation). The training for both conditions will be led by Dr. Shari Jager-Hyman, an expert in suicide prevention EBP implementation, and Jesslyn Jamison, a post-doctoral candidate, who will be trained and supervised by Dr. Jager-Hyman.

Participants will complete baseline surveys (30 min) and measures of SSAI use via chart-stimulated recall (CSR) (15 min) at T1 and then receive either IAU or EBIS. T2 assessment will comprise surveys (30 min) and will take place immediately after training in both arms. At T3 and T4 (two- and twelve-week follow-ups), clinicians will complete brief questionnaires (30 min), a CSR to measure SSAI use (15 min), and a role play to index SPI fidelity (45-60 min). At T4, clinicians will also complete a qualitative interview (30 min). We anticipate it will take clinicians approximately 17 hours to complete study procedures over 12 weeks (6 hours for training, 6 hours for expert consultation, and ~5 hours for research assessments across T1-T4).

Note: As Aim 3 activities meet the NIH definition of a clinical trial, Aim 3 activities are registered on ClinicalTrials.gov as a condition of award (NCT05172609).

2. Data Collection:
Not applicable.

3. Genetic Testing:
Not Applicable

4. Use of Deception:
No deception will be used in this project.

5. Statistical Analysis:

Quantitative analyses This pilot feasibility trial is not intended to be adequately powered to detect significant effects.[94,95] Findings will provide key preliminary data to support the feasibility of EBIS and study procedures for a fully powered R01 (e.g., frequency of suicidal ideation over the 8-week follow-up period). Qualitative analysis of interview transcripts and mixed methods analysis will supplement quantitative analyses.

Preliminary Analysis. Data screening and missing data analysis will be conducted in accordance with best practice recommendations.[96] Prior to conducting main analyses, we will examine the psychometric properties of all scales used to assess constructs of interest (e.g., coefficient alpha) to confirm adequate performance. We will conduct analyses of baseline variables as a randomization check to ensure comparable baseline characteristics for clinicians in EBIS and IAU. Any differences will be controlled for in subsequent analyses.

*Hypothesis 1***:** *EBIS will be an acceptable and feasible implementation strategy.* We will calculate descriptive statistics on the AIM and FIM measures and compare scores between EBIS and IAU. We will also evaluate EBIS feasibility by calculating the proportion of clinicians randomized to EBIS who complete all exposure tasks.

*Exploratory Hypotheses 1 and 2***:** *EBIS will engage target implementation mechanisms of clinician anxiety and self-efficacy better than IAU; clinicians randomized to EBIS will show improved SSAI adoption and fidelity relative to clinicians randomized to IAU***.** We will examine the effect of condition over time on target mechanisms (anxiety and self-efficacy) and implementation outcomes (mean CSSRS screening frequency across encounters, proportions of appropriate encounters in which clinicians conduct follow-up assessment with the CSSRS and SPI use, as measured by CSR, and average SPI fidelity scores on role plays) using repeated measures analysis of covariance (ANCOVA), controlling for organization (given the small sample size and that we will recruit from only a small number of organizations for this pilot, we do not anticipate the need for multilevel analysis).

Qualitative and Mixed-Method analyses. Qualitative analysis of interviews will complement quantitative data to better understand: (1) the efficacy of EBIS to reduce clinician anxiety and bolster self-efficacy, (2) processes by which EBIS does or does not faciliate SSAI use, and (3) contextual factors in clinicians' settings that are not addressed by EBIS. Interviews will be transcribed and analyzed via qualitative software, guided by an integrated approach[97] which uses an inductive process of iterative coding to identify recurrent themes, categories, and relationships. A structured codebook will be developed. We will code for a priori attributes of interest (i.e., the extent to which EBIS engages our target mechanisms of anxiety and self-efficacy) and also use modified grounded theory,[98] which provides a systematic and rigorous approach to identifying codes and themes (e.g., to identify additional barriers that arise to SSAI use). Using the qualitative software program, Dr. Becker-Haimes and a postdoctoral fellow will separately code three transcripts and compare their application of the coding scheme to assess its reliability and robustness. Any disagreements will be resolved through discussion and the codebook refined and applied to all transcripts. Code reliability will be monitored via bi-weekly meetings to ensure $\kappa \geq .85$. After coding, we will read through all codes to examine themes and produce memos of examples and commentary. Mixed methods will analyze themes as a function of quantitative data to identify patterns of responding, following NIH guidelines for best practices in mixed methods.[99] We will first use findings from quantitative data to identify patterns in qualitative data by entering quantitative findings into analysis software as participant attributes. Quantitative attributes will categorize and compare important themes among subgroups. For example, we may categorize clinicians into two groups: those with high and low SSAI use on CSR data. Then, if clinician anxiety emerges as a theme from interviews, we can query instances when anxiety is discussed among clinicians with low and high SSAI use; this will allow us to identify patterns and make interpretations across groups based on quantitative data. Dr. Becker-Haimes is experienced in mixed-methods implementation research[42,100] and will oversee these analyses.

RISK/BENEFIT ASSESSMENT:

1. Risks:

Potential harm to participants is minimal as we are testing two ways of training clinicians in gold-standard suicide prevention practices, not testing the use of a new suicide prevention practice. There are no known physical, financial, or legal risks to participating in the study. However, there is a risk of loss of confidentiality in all research. We will minimize this risk by using secure, encrypted servers to host all data and conduct the analysis. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and study staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. Data will be stored, managed, and analyzed on a secure, encrypted server behind the University of Pennsylvania Health System (UPHS) firewall. All study personnel that will use this data are listed on the IRB application and have completed training in HIPAA standards and the CITI human subjects research. All data analyses will be performed using participants' identification numbers rather than names to minimize the circle of study team members who know the identity of the research participants. In addition, risk of loss of confidentiality will be minimized by storing completed paper surveys and copies of the signed informed consent forms (separate from one another) in locked file cabinets in locked offices accessible only to trained study staff.

We will minimize the risk of coercion by making clear in the consent process that participation in the study is truly voluntary and will not affect participant employment in any way. Our experience conducting similar research protocols is that therapists who are not interested in participating in the research decline freely. Managers/leadership will not be present when study staff describes the study to potential participants, enabling participants to choose not to participate without having to do so in the presence of leadership. In addition, we will provide participants with ample time to ask questions or have family/friends ask questions about their participation. To ensure no participants (potential or actively participating) feel coercion to participate in any of the study aims, we will work closely with our IRB, Advisory Board, and stakeholders to ensure that our study is not coercive. In our previous work, we have ensured that all data provided by clinicians are confidential and never shared with peers, supervisors, clinic leadership, or the payer in an individual or identified manner. We will continue to take this approach in the proposed work.

Self-reported questionnaires, role-plays, CSRs, and semi-structured interviews could lead participants to feel temporarily uncomfortable. Importantly, exposure-based treatments upon which the EBIS implementation activities are based, are generally well-tolerated with few to no side effects. To minimize discomfort, we will follow established procedures used in multiple studies executed in the proposed settings by the study investigators. Specifically, a licensed clinical psychologist or physician from the research team will be available to speak with any participants who feel unduly distressed and will make appropriate referrals. Participants are made aware of their ability to discontinue participation at anytime without penalty.

Although we will not be asking participants about their own suicidal thoughts or behaviors, if a participant spontaneously discloses suicidal thoughts, plans, or behaviors to a member of the research team, we will follow the High Risk Management Protocol used routinely in the Penn Center for the Prevention of Suicide (CPS) IRB-approved research studies. Co-Investigator Shari Jager-Hyman, Ph.D. from CPS will train all study staff in these procedures.

In the event that a clinician mentions child abuse/neglect or a patient's imminent suicidality/homicidality during qualitative interviews, or if suicidality/homicidality is otherwise observed while study staff are embedded in the clinical settings, we will follow established protocols from similar studies carried out by our team. Specifically, a clinically-trained member of the research team will consult with the patient's treatment team to ensure that any information about child abuse/neglect or intent to harm self or others has been reported to the appropriate parties, as required by law. A licensed clinical psychologist or physician with extensive experience assessing risk (Drs. Oquendo, Becker-Haimes, or Jager-Hyman) will be available for consultation at all times that researchers are conducting study assessments.

2. Benefits:

There are no direct benefits to participants; however, participants may find satisfaction in sharing their ideas and experiences with research staff. Clinician participants may indirectly benefit from participation by receiving free training and consultation on the use of suicide prevention screening, assessment and the SPI with their patients. This may contribute to clinicians providing more effective care for treatment-seeking individuals and/or increase their understanding of key concepts or strategies involved in psychosocial treatment. The benefit to the clinical community is that the results may ultimately help improve the quality of care. The ratio of risks to benefit is positive, considering that we do not think that the study poses any risks and the scientific yield from the study could be greatly beneficial.

3. Subject Privacy:

Privacy will be given utmost consideration and is highly valued in the proposed research. Research staff will exercise caution in ensuring privacy within the constraints of the research setting (clinicians' work environment). For participants in Aims 2 and 3, research staff will ensure that all study questionnaires and interviews and are administered in private places where no one can overhear the content. Research staff will ensure that participants are comfortable proceeding with the interview in their environment prior to beginning.

4. Subject Confidentiality:

How will confidentiality of data be maintained? Check all that apply.

X Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

X Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.

X Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

X Whenever feasible, identifiers will be removed from study-related information.

☐ A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

☐ A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

X Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

X Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

☐ Other (specify):

The only data will be collected from mental health clinicians interacting with the strategies being refined and tested. No identifying patient information will be collected. All project staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations. When results of the research are presented at scientific meetings or published, no identifying information will be included. Only authorized persons from Penn and their associated Institutional Review Board will have access to review research records. Below we outline how we plan to ensure confidentiality specific for all study related activities.

To ensure confidentiality across all aims, we will be using the following methods for protection of data living on Center for Mental Health (CMH) servers. All data will be de-identified and subject identity will be masked using numeric codes and password-protected master lists and will not be linked in any way to the participant's names. Identifiable data will be entered and stored into password-protected files on password-protected drives on the CMH encrypted server or on REDCap, and files for analysis will only be identified with subject numbers, and will not contain any identifying

information. Given that only the study research team will have access to the identities of the participants, and all appropriate safeguards are in place, it is unlikely there will be a breach of confidentiality.

We will only store and use the data at the following locations: 1) Password-protected PCs in locked offices at Penn; 2) The desktop computer that will access the data will be part of the CMH domain, with Windows Active Directory group policies in place to distribute and enforce best-practice desktop security policies. Security and software updates are pushed through the system in a timely manner using desktop management tools (Tivoli/BigFix and Windows Automated Update Service).; and 3) A server at the University of Pennsylvania within the facilities managed room in the data center.

Physical copies of any data will be encrypted while at rest and will be held in a locked cabinet within the CMH office. Additionally, all data hosted on the server will be accessed over an encrypted (Value-Added Network) VAN connection. Individually identifiable or deducible data will not be transmitted by unsecured telecommunications. Any data transfer will be sent via secured communications, which include secure Penn Medicine email servers or SecureShare, a web-based application for secure, encrypted file exchange available to Penn faculty, staff, and students. Further, the data will not be physically moved or transmitted in any way from the CMH servers or secured desktop(s) without written approval.

Brief qualitative interviews and role plays will be audio-recorded during Aims 2 and 3. All trainings and consultation sessions will be video recorded. These audio and video recordings will be directly uploaded into REDCap and subsequently transcribed and de-identified using HIPAA compliant vendors. All transcripts will be double checked to ensure that no identifying information remains. This means if a participant mentions someone's name or specific location (e.g., clinic, street name) in the recording, the identifying information will be removed and replaced with a description of the information (e.g., [NAME], [LOCATION]). The recordings will be destroyed after the transcription process is completed. The de-identified transcripts will be stored in password-protected files in the CMH encrypted server or on REDCap, and the deidentified data will be loaded into qualitative software for data management and analysis.

During the clinical trial phase of the study (Aim 3), quantitative surveys may also collected using pen-and-paper hard copy, depending on participant preference; study staff will enter any pen-and-paper data directly into REDCap. All study participants will be given an ID number for identification purposes. A document with participants' names and identification numbers will be electronically stored in a separate REDCap file. Only the research team will have access to this file. All data will be protected at the file-level and operating system level. All data for analysis will have personal identifiers removed and the data will be aggregated through qualitative analysis. Field notes will be taken and immediately encrypted. Any paper materials related to the study will be stored in a locked file cabinet in a locked office at CMH. Only research staff will have access to this locked cabinet.

Individually identifiable or deducible data will not be transmitted by unsecured telecommunications., Any data transfer will be sent via secured communications, which include secure Penn Medicine email servers, or SecureShare, a web-based application for secure, encrypted file exchange available to Penn faculty, staff, and students. The data will ultimately be transferred to CMH encrypted servers and all precautions above will be taken.

The master list linking ID numbers and names will be kept on password protected computer files accessible only to the study investigators. Tracking information will be housed in a locked file cabinet within a locked office at Penn and this master list will only be used for the coordination of data collection and participant payment. All research staff will sign confidentiality statements and be trained in the protection of human subjects by the PIs and through the Collaborative IRB Training Initiative (CITI) course. Participants will be notified that the alternative to participation is to not participate, they can withdraw their participation at any time without penalty, and their decision to participate will not affect services or employment.

All data, including the master list linking identifiers to the ID number and notes will be retained for the length required by federal guidelines. After this time period has lapsed (three years from the date of the final Federal Financial Report), the master list linking identifiers to ID numbers and notes will be destroyed.

5. Protected Health Information

The following PHI will be collected

- Name
- Address
- Electronic mail addresses
- Telephone numbers
- Biometric identifiers, including finger and voice prints

Name, address, electronic mail address, and telephone numbers will be collected for the purpose of contacting participants about research activities and compensation only. Additionally, PHI (voice prints) will be collected via audio recording and will be maintained on REDCap, a HIPAA-compliant server.

6. Compensation:

Aim 1: N/A, no human subjects activities.

Aim 2: Clinicians will be compensated $75 for all Aim 2 activities (engaging with the EBIS prototype and completing follow up interviews and surveys) and will receive continuing education credits for training received in the CSSRS and the SPI.

Aim 3: Clinicians will receive up to $250 for completing study assessments: $50 compensation for completing study activities at T1, $25 for T2, and $75 for T3 and $100 for T4 study activities. Clinicians also will receive continuing education credits for training received in the CSSRS and the SPI.

7. Data and Safety Monitoring:

The NIMH-funded P50 Penn INSPIRE Center has convened a 3-member DSMB from distinguished faculty outside of Penn and the INSPIRE advisory board. The DSMB includes identified experts by the INSPIRE MPIs and consists of an independent group of experts charged with reviewing study data for data quality and integrity, adherence to the protocol, participant safety, study conduct and progress, and making determinations regarding study continuations, modifications, and suspensions/terminations. DSMB members are independent from any professional or financial conflict of interest with the research project or study investigators. The DSMB will meet at least once for the duration of the project.

As noted above, this study is considered minimal risk to participants, as it consists primarily of observations and quality improvement practices. There is no direct interaction with patient populations. Clinician participation in the study does not create or increase the risk of completed suicide for the patients with whom they work. However, it is possible that study staff may learn that a patient is at high risk of suicide and that appropriate safeguards have not been enacted to ensure that patient's safety. In the event this occurs, we will follow this risk management protocols described above (see *Risks*) that we have applied successfully in other studies.

8. Investigator's Risk/Benefit Assessment:

There are no direct risks to participation. Some strategies may interface with patients, but no new interventions will be introduced, as the goal is to increase the use of established SSAIs supported by the City of Philadelphia within routine clinical practice. Providers will maintain complete autonomy with respect to patient care.

The benefit to the clinical community is that the results may ultimately help enhance the implementation of suicide prevention practices. The ratio of risks to benefit is positive, considering that we do not think that the study poses any risks and the scientific yield from the study could be greatly beneficial. Participants will be adequately compensated for their participation throughout all aspects of the project.

INFORMED CONSENT:

1. Consent Process:

Aim 1 does not involve collection of research data and, therefore, there is not a consent process for this phase.

Aim 2. Prior to beginning data collection for Aim 2, members of the research team will provide a verbal description of the study to clinicians. Clinicians will then be asked to electronically sign consent forms in REDCap (using REDCap's established e-consent signature option) that thoroughly describe the procedures to be followed in the study and the type of assessments involved. Clinicians will be informed that all information they provide will be kept confidential (unless it is determined that it must be reported as required by law), within the study personnel. No information gathered as part of this research will be shared with agency executive directors or supervisors (unless it is determined that information must be reported as required by law). Clinicians will also be informed that participation is voluntary and there is no penalty for declining to participate or withdrawing from the study at any point. We anticipate all clinicians will be competent to provide informed consent.

Participants will be provided with copies of signed consent forms while original copies of the signed consent forms will be stored electronically in REDCap or kept in locked files at Penn, which no one will have access to other than the research team.

Aim 3. We will obtain agency leadership approval to recruit clinicians from organizations before consenting any participants. Prior to participation, Dr. Oquendo, Becker-Haimes or another member of the research team will verbally provide a full description of procedures to be followed and the type of assessments involved to all clinicians. Participants will also be informed at this point that all information they provide will be fully kept confidential allowable by law. No identifiable information gathered as part of this research will be shared with a recruited clinicians' agency executive director, supervisor, or local regulatory department. Participants will be asked to electronically sign a consent form through REDCap that thoroughly describes the procedures to be followed in the study and the type of assessments involved. There will be no consequences for individuals who elect not to enroll in the study. Clinicians will also be informed that they can withdraw from the study at time of their choosing point without penalty. Informed consent will be completed by study staff by phone or in person. We anticipate all clinicians will be competent to provide informed consent.

Given that we are recruiting practicing mental health clinicians, we do not anticipate recruiting any participants under the age of 18; thus, assent procedures will not be necessary.

2. Waiver of Informed Consent:

We are not requesting exemption or alteration of written informed consent documentation

RESOURCES NECESSARY FOR HUMAN RESEARCH PROTECTION:
Study investigators include MD and PhD-level researchers with expertise in suicide prevention (Oquendo, Jager-Hyman), exposure therapy (Becker-Haimes), and implementation science (Becker-Haimes, Jager-Hyman). A postdoctoral fellow and clinical research coordinator will be thoroughly trained in the study protocol and will facilitate all data collection. Given that study activities constitute a clinical trial, all study staff will complete Good Clinical Practice (GCP) training. Regular meetings among study team members will ensure that research staff are adequately informed of the protocol and their research-related duties. We are confident that the size of the research team will be adequate to carry out the proposed project.

For Aim 1, we additionally will bring together an Advisory Board of clinicians, administrators, suicide prevention experts, implementation scientists, and exposure theorists to refine the EBIS implementation strategy. Dr. Becker-Haimes has close relationships with local community mental health clinics which will facilitate recruitment of Advisory Board members.

The Department of Psychiatry at the University of Pennsylvania's Perelman School of Medicine will provide the research infrastructure, physical accommodations, and resources necessary to ensure the project's success. The study team members have dedicated office space with password protected computer systems. Researchers will have the necessary word processing and statistical software for the project.

Acronym	Description

SSAIs	suicide screening, assessment, and interventions
EBIS	exposure-based implementation strategy
CSSRS	Columbia Suicide Severity Rating Scale
SPI	Safety Planning Intervention
IAU	Implementation as Usual
EBPs	evidence-based practices
RA	research assistant
CSR	Chart Stimulated Recall
SPIRS	Safety Planning Intervention Rating Scale
ASI-3	Anxiety Sensitivity Index
PI	Principal Investigator
co-PI	Co-Principal Investigator
REDCap	Research Electronic Data Capture
CRCU	Clinical Research Computing Unit
CITI	Collaborative IRB Training Initiative
UPHS	University of Pennsylvania Health System
CPS	Center for the Prevention of Suicide
CMH	Center for Mental Health
PCs	Personal Computers
VAN	Value-Added Network
PHI	Protected Health Information
INSPIRE	Penn Interdisciplinary Network for Scientists Promoting Inclusion, Retention, and Equity
DSMB	Data and Safety Monitoring Board
GCP	Good Clinical Practice