Local IRB # 1910-001 **IRBNet #1505531**

BUTLER HOSPITAL
INSTITUTIONAL REVIEW BOARD
PROTOCOL

1.) Project

Title of Project: Development of an Adjunctive Video-Based Suicide Prevention Intervention Immediately Following Psychiatric Hospitalization

Principal Investigator (PI): Lisa Uebelacker, Ph.D.

Other Investigator(s): Brandon Gaudiano, Ph.D., Sarah Arias, Ph.D., Ivan Miller, Ph.D., Lauren Weinstock, Ph.D.

2.) Description of Study

A. Specific Aims

1) **Phase 3**: We will conduct a pilot RCT (n=40) of hospitalized patients (including people enrolled in a partial hospital program) with a recent suicide attempt/plan who will receive treatment as usual (TAU) plus *LifePlans* vs TAU only. We will examine *LifePlans* feasibility and acceptability (video viewing, engagement, satisfaction, recruitment/retention), treatment differences (within relevant confidence intervals) on outcomes (e.g., suicide behaviors), and change on potential mechanisms.

B. Background

Suicide and attempted suicide are major public health issues in the U.S., accounting for almost 45,000 deaths in 2016, and over 1 million attempts each year. Although recent years have seen significant advances in our knowledge of efficacious treatments for many psychiatric disorders, the suicide rates in the U.S. have been increasing since 2000. Even with increased efforts in recent years, there still has been a relative paucity of research devoted to developing or testing innovative interventions directly targeting suicidal behavior to reach those most in need. Some treatments (e.g., cognitive behavior therapies) have been found to reduce rates of suicide attempts, but these interventions require substantial training and are lengthy and costly to administer. On the other hand, minimally intensive interventions (e.g., follow-up letters, postcards) have shown mixed results. More efficient and effective "middle ground" interventions developed to prevent suicidal behavior are clearly needed. We urgently need interventions based on evidence-based principles that decrease suicidal behavior and are feasible to deliver to large numbers of patients at times when their risk for suicide is high.

Narrative communication is an alternative strategy for disseminating behavior change principles that has shown efficacy for improving health behaviors. Our own pilot work suggests it may be useful for treating depression. Narrative methods refer to people with lived experience talking about both their struggles and successful ways of coping. Narrative strategies are consistent with social learning theory: people learn by observing others like themselves. An advantage of narrative communication that it is often viewed as more engaging by patients (than didactic communication) and, with the help of video, is easier to disseminate than traditional interventions delivered by clinicians. Narrative communication interventions can be designed to promote key principles from evidence-based psychotherapies.

In this treatment development project, we propose to develop and test a narrative-based video intervention for people with suicidal behavior or plan (with or without intent) being discharged from psychiatric hospitalization. The period immediately following discharge, and the entire year after discharge, is a time of

substantially increased risk for suicidal behavior. In response to the need for treatment over this transition, we previously developed a psychosocial intervention, Coping Long Term with Active Suicide Program (CLASP), in which clinicians deliver up to 15 in-person and telephone sessions with patients and families starting during a hospitalization and continuing for 6 months post-discharge. CLASP targets risk factors associated with suicidal behavior (coping strategies, social support, adherence, hopelessness) in order to reduce subsequent risk. Initial research on CLASP is promising, with a 40% reduction in suicide attempts compared to controls over 6 months follow-up.

In this project, we propose to develop a new intervention, called *LifePlans*, based on the CLASP model but using an easily disseminable video-based format in which real patients discuss their history of suicidal behavior and the coping strategies that they used to stay safe. *LifePlans* will consist of 5, 30-min episodes that highlight patients' experiences consistent with the CLASP model. Episodes will cover these topics: 1) developing a personalized "Life Plan" to stay safe and restrict means, 2) clarifying valued life domains and related goals to improve hopefulness, 3) using informal problem solving to cope better with illness, 4) improving communication with family/friends to increase social support, and 5) adhering to primary treatments including pharmacotherapy and psychotherapy to promote illness management. To aid in video content development and planning, we will also conduct qualitative interviews of clinical stakeholders regarding their perspectives on the video series.

C. Experimental Method

C1. Brief Description of Subjects

Phase 3: Participants currently psychiatrically hospitalized or enrolled in a partial hospital program with suicide plan (with or without intent) or attempt (n=40) will be randomized to receive TAU vs TAU + LifePlans starting during their hospitalization and continuing after discharge.

C2. Study Design

Screening Process and Recruitment (phases 2 and 3)

Our team has developed effective procedures for recruiting from the inpatient milieu (during Phases 2 and 3) as well as the partial hospital milieu (only during Phase 3). We will obtain a Protected Health Information (PHI) waiver for review preparatory to research. Then, we will screen electronic medical records at Butler Hospital to identify potentially eligible participants. Patients meeting inclusion criteria that can be assessed via chart review (i.e., criteria 1, 3, 5), and after obtaining attending physicians' permission, will be approached by research staff. Patients will be approached in-person on the units or if they are attending a partial hospital program virtually, they will be contacted by phone using the number provided in their chart. Staff will provide a description of the study and invite patients to participate in additional screening to determine study eligibility. Those consenting and meeting all inclusion criteria will be invited to participate in the study.

Research Assessments (phases 2 and 3)

Assessments will be conducted: 1) to assess feasibility and acceptability, uptake, transportation, and understanding of key messages; 2) to assess inclusion criteria; or 3) to pilot outcome measures or potential mediators for the eventual large-scale RCT. See the table below for the purpose of each instrument and the assessment schedule. A trained research assistant will conduct all assessments. After the baseline assessment, we will conduct assessments at 1- and 6-months post-discharge. We will also administer weekly post-video surveys in order to assess completion and acceptability ratings.

Treatment acceptability/feasibility. Intervention credibility and patient expectations for intervention success after viewing the first episode will be measured with the Credibility Expectancy Questionnaire (CEQ).[6] The Client Satisfaction Questionnaire (CSQ-8)[7,8] will be used post-treatment to assess satisfaction with interventions. We will also use qualitative responses to a detailed post-treatment interview to gain participants'

feedback about interventions and research procedures, including whether there was any contamination between arms, with participants in LifePlans sharing videos or video content with participants in the treatment as usual arm.

We will ask participants to complete additional assessments reflecting the content of LifePlans. Participants will complete video completion surveys of the time that they spend watching the video and the particular sections watched. If they did not watch the videos, participants will answer questions on any barriers that prevented them from watching. To assess transportation/engagement, we use a modified version of the Transportation Scale [9] (11 items) we previously developed that is appropriate for watching a video. Sample items include: "The [video about XX] affected me emotionally" or "I found my mind wandering while [watching the video about XX.]" Items are rated from 1 "not at all" to 7 "very much." The total scale score is calculated by taking the average of all items**.** In addition, participants will complete a Video Acceptability Scale, which is adapted from a 7-item Likert-scale measure (1=not at all and 7=very much) designed for technology-assisted interventions by Ondersma et al.[10] that assesses how participants feel about their experience: overall liking, interesting, ease of use, understandable, respectful, or annoying. To assess message understanding, we will use a Message Scale, which consists of questions designed to: 1) enhance the impact of the intervention; and 2) provide data to us about their reactions to the video. The questionnaire includes these questions: 1) What did you like about this video? What did you not like about this video?; 2) What was the main message that you got from watching this video?; 3) Does this video have any relevance to your life? What relevance does it have to your life?; and 4) What might you do differently as a result of watching this video? We will use qualitative data analysis techniques to analyze participants' responses.

Research Assessments – Open Trial and Pilot RCT (phases 2 and 3)		
	Purpose	Timepoints
Treatment Acceptability, Feasibility, Uptake, Transportation		
Credibility Expectancy Questionnaire	P	BL
Client Satisfaction Questionnaire	P,O	M1
Qualitative Interview	P	M1
Video Completion Surveys	P	W1, W2, W3, W4
Transportation Scale	P	M1*
Video Acceptability Scale	P	M1*
Message Scale	P	M1*
Psychiatric Symptoms and Functioning		
Columbia Suicide Severity Rating Scale	O**	BL, M1, M6
Modified Scale for Suicide Ideation-	O	BL, M1, M6
PROMIS-29	O	BL, M1, M6
PROMIS Depression Short Form***	O	W1, W2, W3, W4
Hospital chart review	I,O	BL, M6
Psychosis Screening Questionnaire	I	BL
Mental Help Seeking Attitudes Scale	O	BL, M1, M6
Personal Suicide Stigma Questionnaire (self-blame subscale only)	O	BL, M1, M6
Potential Mechanisms (CLASP Targets)		
Multidimensional Scale of Perceived Social Support	Med	BL, M1, M6
Brief COPE	Med	BL, M1, M6
Valuing Questionnaire	Med	BL, M1, M6
Treatment Utilization		
Treatment History Interview		BL, M1, M6
Outpatient and Hospital Chart Review		BL, M1, M6
Note. Purpose: P=Pilot study target outcome; O=Outcome in large-scale RCT; I=Inclusion criteria; O**=Primary outcome in large-scale RCT; C=Characterize sample; Med=Potential mediator in a larger scale RCT. Timepoints: BL=baseline; W1, W2, W3, W4=Week 1, 2, 3, and 4 of the intervention. M1 and M6=Month 1 and 6. M1*=M1 during the pilot RCT, but weekly during the open trial.*** The PROMIS Depression Short Form was added for the pilot RCT.		

Suicidal Behaviors. The Columbia Suicide Severity Rating Scale (C-SSRS) [11] will be used to assess suicide ideation, intent, plans, and behavior. C-SSRS interviews will be conducted by trained research staff supervised by Dr. Uebelacker with consultation from Drs. Miller and Weinstock. Training procedures consist of: a) review of written materials, b) didactic instruction; c) practice interviews with review and feedback from senior staff; and 4) continued practice, training and feedback until high agreement with established consensus ratings are met

(e.g. 3 consecutive C-SSRS ratings are within 2 points of our consensus ratings). We will assess interviewers' reliability in an ongoing manner. Following initial training, interviewers and senior staff meet on a monthly basis to review tapes, address questions/issues, and monitor interrater reliability.

To ensure that we capture as much suicide-related data as possible, we will utilize procedures that have been developed for current ongoing large-scale suicide prevention clinical trials led by Dr. Miller (RO1 MH101129) and Dr. Weinstock (U01 MH106660). We obtain releases of information from patients at study start to conduct chart reviews throughout the study covering the two major healthcare systems in RI (CNE and Lifespan) and their corresponding EDs and inpatient units. We also collect treatment utilization data via self-report (THI) during follow-up assessments, and, at that point, we can ask participants for releases of information to request discharge summaries from additional hospitals that the patient may report attending. Consistent with previous studies, we scrutinize all hospitalizations or ED visits with any of the following characteristics: evidence of self-injury, mental health concerns, ingestion/overdose, and traumatic injury. Staff then read the discharge summary to determine if there is any evidence of current or recent intentional self-harm ideation or behavior, including whether any injury is sustained. Staff also use carefully developed definitions of suicide ideation and suicide attempt (from C-SSRS criteria) to determine whether there is evidence of either event in the medical record.

If the patient dies, staff record the death and whether there was any evidence of intentional self-injury leading to the death. As we have done in previous studies, if we are unable to locate a participant at follow-up, we will state or national death registries to ascertain whether he/ she died, and if so, cause of death. Thus, suicide outcomes will be determined using all data collected during the study from all possible sources, including follow-up assessments (C-SSRS), b) hospital chart reviews, c) and community clinician reports. Data from all sources will be reviewed by two research team members for congruence. Note that we will obtain releases of information from patients at study start to conduct chart reviews throughout the study covering the two major healthcare systems in RI (CNE and Lifespan) and their corresponding EDs and inpatient units. Disagreements between raters will be reviewed and adjudicated by Drs. Gaudiano (MPI) and Arias (Co-I). All reports will be classified using C-SSRS criteria. In a larger-scale clinical trial, our primary outcome will be a composite: a) suicide attempts or b) suicides.

Other Symptoms. We will use the following self-report scales: the Modified Scale for Suicide Ideation (MSSI)[13] which provides a score indicating overall severity of suicide ideation; and the PROMIS-29, which assesses pain intensity on seven health domains (physical function, fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles and activities, and sleep disturbance). We will also have participants in both study conditions complete the PROMIS Depression Short Form each week of the intervention to assess depressive symptoms. In addition, we also will assess the change in distress and perceived helpfulness during each week of the intervention for those assigned to LifePlans: 1) how distressed participants felt while watching the videos (5 point scale from "more distressed" to "less distressed"), 2) how distressed they felt after watching the videos (5 point scale from "more distressed" to "less distressed"), and 3) how helpful they felt the videos were (5 point scale from "very unhelpful" to "very helpful"). In order to ascertain inclusion criteria, we will use chart review and the Psychosis Screening Questionnaire[31] to screen out people at baseline. Finally, we will use the self-blame subscale on the Personal Suicide Stigma Questionnaire (PSSQ) which is a self-report measure that has been found to be reliable and valid for assessing stigma in persons who have suicidal behaviors.

Potential Mediators. Potential mechanisms will be assessed using the following self-report scales: the Multidimensional Scale of Perceived Social Support (MSPSS)[21], which is a reliable and valid measure of 3 aspects of social support (family, friends, and significant other); the Brief Cope[22], which assesses strategies used for coping in response to negative life experiences ; and the Valuing Questionnaire (VQ) which is a reliable and valid measure that assesses the extent to which a person lives by their values.

Potential Moderators. We have identified several potential moderators of CLASP effects in our previous research that we believe may also be relevant to the proposed project, which we will consider testing in future, larger-scale studies. The manuscript describing these results is currently in preparation. The following factors were found to moderate the effects of CLASP in the previous ED-SAFE study (U01 MH088278) and are also potentially relevant to LifePlans: marital status (CLASP more effective for those not married) and number of previous psychiatric hospitalizations (CLASP more effective for those with more hospitalizations). We will also consider whether recent suicide attempt status and lifetime suicide attempt status moderates outcome.

Treatment utilization. We have adapted a brief, structured Treatment History Interview (THI)[25] which allows us to collect information about other depression treatments such as inpatient hospitalization or psychotherapy, including any care that happens outside of the CNE system. We will combine this with information from the outpatient chart review (i.e., from the Providence Center) and inpatient chart review (from Butler Hospital) to gain a full picture of treatment utilization.

Clinical stakeholder interviews. Basic demographic information will be collected from all participants using a short self-report measure. These data will include age, gender, ethno-racial background, education level, duration of employment in current position, and duration of employment in the field. Participants will complete a 30-minute individual interview by telephone or videoconference. Prior to the interview, we will send participants a brief description of the video series and sample content. This interview will be scheduled at the participant's convenience and will be audio or video recorded. Stakeholder interview agendas will assess: : a) barriers to patients' medication/appointment adherence, b) how the field can use a video intervention to support aftercare, c) challenges patients face upon return to the community post-discharge, d) challenges faced by clinicians/organizations treating individuals with suicidal thoughts and/or behaviors. Questions will be delivered in an open-ended format to allow participants to share their opinions.

Retention and Adherence

We will use several strategies to increase retention for assessments. Research staff will remind participants about appointments, maintain a list of locator contacts for each participant, reach out to contacts as needed, schedule assessments regardless of intervention participation, and have flexibility in when assessments are scheduled. Finally, we will provide transportation if needed for appointments.

Phase 3: Pilot RCT

The aim is to conduct a pilot RCT (n=40), with participants randomized to treatment as usual (TAU) or TAU + LifePlans. We will enroll hospitalized patients with a suicide plan/attempt prior to admission in the past month (see full inclusion criteria below). Methods will be similar to those described in the open trial (see previous section for Phase 2), with only the differences noted below. We will continue to focus on acceptability and feasibility, including an evaluation of the proposed research design.

Phase 3: Control condition description and rationale

The control condition will be TAU, which, as noted above, will include Hospital Safety and Discharge Planning as part of inpatient care, followed by outpatient care at a CNE outpatient site. In choosing TAU as a control condition, we considered the nature of the LifePlans intervention. LifePlans is designed to be adjunctive to TAU and in fact to encourage adherence to outpatient treatment plans developed in the hospital. We did not choose a more robust control condition because LifePlans is designed to be a lower-intensity intervention (thus increasing its potential reach) and not to replace existing treatments (but, in fact, to enhance them).

Phase 3: Randomization

Participants will be randomized using a 1:1 ratio to either TAU or TAU + LifePlans. Randomization will be stratified by: a) gender (male/ female/ non-binary) and b) suicide attempt vs. plan prior to admission. Treatment arm assignments will be blocked in blocks of 4 or 6 participants (randomly ordered). A staff member with no other study responsibilities will set up randomization tables in REDCap, and other research staff will not have access to the tables. Participants will be randomized following the baseline assessment using the randomize feature in REDCap. This ensures allocation concealment.

C**3. Specific Procedures or Treatments**

See C2. Study Design.

C**4. Data Analysis**

This pilot study has the primary aims of refining interventions and research procedures for a subsequent RCT to test the efficacy of LifePlans. In the past, researchers have used pilot data to estimate an effect size to assist in future power calculations. Kraemer et al.[26,27] emphasized the limitations of this practice due to the likelihood of large standard errors surrounding effect size estimates, and the concern that RCTs should be powered to detect a difference between groups that is considered to be a minimally clinically significant difference. In light of these concerns, we propose the following analysis plan.

Target treatment development outcomes

We will use descriptive statistics to summarize all variables. At the end of the open trial, and midway and at the end of the pilot RCT, we will examine acceptability and satisfaction outcomes for LifePlans and for the overall study. When the outcome is not met, the research team will investigate and discuss the issue, and depending on the perceived reasons for the discrepancy, may modify relevant research procedures to address the issue. For example, if uptake is low, we will try to modify instructions to participants in order to increase uptake.

D. Material Inducements

Phase 3: Similar to Phase 2, for the pilot RCT (n = 40), we will pay participants for assessment interviews: $20 for baseline, and $40 for Month 1 and 6 assessments (up to $100). We will also pay participants $5 for each weekly survey they complete (up to $20 total). Therefore, they may receive up to $120 total for their participation. We will also provide transportation if needed for appointments.

E. Training of Research Personnel

All study staff will have undergone mandatory online education in human research participants' protection. PIs and research assistants will have training in Good Clinical Practice via an online program. All study staff will undergo specific training relevant to their study roles and responsibilities. Training will be documented via collection of training certificates.

3) Human Subjects

A. Subject Population

Phase 3: Participants (n=40) will be randomized to receive TAU vs TAU + LifePlans starting during their hospitalization and continuing after discharge.

Participants must meet the following criteria (same as Phase 2):

1. *Current psychiatric hospitalization with recent (past month) suicide plan (with or without intent), or a suicide attempt within 48 hours prior to hospitalization,* as indicated on the hospital chart and confirmed by administration of the C-SSRS [11]. Specifically, on the C-SSRS, this is operationalized to a "yes" on item 3, 4, OR 5, AND/OR a "yes" to suicide attempt/ interrupted attempt/ or aborted attempt.
2. *Ability to speak, read, and understand English well enough to complete the procedures of the study.*
3. *Aged 18 or older.*
4. *Regular access to a means of watching videos*(i.e., a smartphone, tablet, computer, or DVD player) *in the place they expect to live after discharge*.
5. *No current psychotic symptoms* (based on chart review and the Psychosis Screening Questionnaire)
6. *Plan to continue outpatient treatment.*

No minors, prisoners, fetuses/neonates, or decisionally/ cognitively impaired individuals will be recruited.

B. Recruitment and Consent Procedures

Phase 3: With a HIPAA waiver (see below) we will screen medical records at Butler Hospital to identify potentially eligible participants. Patients meeting inclusion criteria that can be assessed via chart review (i.e., criteria 1, 3, 5), and whose attending physician does not mark as ineligible for research, will be approached by research staff. Patients will be approached in-person on the units or if they are attending a partial hospital program virtually, they will be contacted by phone using the number provided in their chart. Staff will provide a description of the study and invite patients to participate in screening to determine study eligibility. Those consenting and meeting all inclusion criteria will be invited to participate in the study.

For the clinical stakeholder interview during Phase 2, we will consult with our investigator team to identify appropriate clinical stakeholders to approach about study participation. Once identified, Drs. Gaudiano or Uebelacker or another member of the research team will contact the stakeholder directly to introduce the study. If interested, the participant will be mailed or emailed (via REDCap link) a copy of the Stakeholders Informed Consent form in addition to a brief description of the video series. The participant will then be consented over the phone or via videoconferencing. The consent process will be documented either through audio or video recording or via electronic REDCap signature.

For **Phase 3**, some patients attend the partial hospital programs remotely and cannot be consented in person. With the participant's verbal permission (see attached "Verbal Consent (by Phone) for Use of Email and Videoconferencing"; answers to questions in script will be recorded in REDCap), we will send them a link for videoconferencing (i.e., video meeting on the HIPAA compliant online platform). In addition we will send a REDCap link that will bring them to a copy of the Phase 3 consent form that they will be able to use to follow along as we conduct the consent process with them at the beginning of that meeting. If we schedule a phone call, we will send them a copy of the Phase 3 consent form via email REDCap link. At the start of the meeting, we will conduct an informed consent process for this study, reviewing the consent document that we sent the participant. Participants will answer the questions and electronically sign the consent form in REDCap.

C. Potential Risks

Potential risks include coercion, discomfort or increased distress due to study procedures, suicide ideation or behavior, and breach of confidentiality. See information below about risk level and impact to subjects.

D. Protection of the Subject

D1. Measures to Minimize Potential Risks

Coercion

Description. Participants could feel that they must participate in the study or, once enrolled, continue to participate.

Risk Level and Likelihood. This is a serious risk but the likelihood of it occurring is judged to be minimal.

Minimization. The risk of coercion will be minimized by following standard procedures for obtaining informed consent. We will fully explain the study procedures, risks, benefits, and alternatives to all patients. Also, patients who do not consent or who withdraw at any time will receive usual clinical treatment with no prejudice. Participant remuneration will be set at modest monetary levels as used in similar studies. In Phases 2 and 3, we will obtain permission form the patient's treating physician to ensure that approaching the patient for research participation is clinically appropriate.

Discomfort or increased distress due to study participation

Description. Some participants may find that they feel discomfort or distress in response to completing study assessments or interviews, or when watching LifePlans videos.

Risk Level and Likelihood. This may occur for some participants. Based on our previous experience with this population, we believe that any distress that occurs is likely to be minor and transient.

Minimization. During assessments, research staff will remind participants that they may refuse to answer any question or take a break at any time. Participants will also be reminded that they can choose not to watch a video if they find it too distressing. We will encourage participants to inform research staff if a study procedure is distressing. Finally, we will also encourage participants to talk with their outpatient mental health providers if they find that they are experiencing increased distress for any reason. We will provide referrals to outpatient providers if any participants would like them.

Suicide ideation or behavior or psychiatric hospitalization

Description. Participants may reveal active suicide ideation/ plan/ intent/ or behavior during the course of a research interview.

Risk Level and Likelihood. These events may occur in a portion of enrolled participants, particularly in Phases 2 and 3. However, it is very unlikely that these events will be related to study participation.

Minimization. Suicide ideation and behavior, and psychiatric hospitalization, will be monitored via assessment interviews and chart reviews. In assessments, study staff will inquire about suicidal ideation and behavior using the C-SSRS. If any patient reports suicidal ideation, plans, or behavior during the study assessments or other study contacts, the action we will take is dependent on whether the participant is inpatient or he/ she is being treated as an outpatient. If the patient is inpatient, research staff will notify the treating clinician on the inpatient unit, so he/she is aware of the risk reported by the patient. If the patient is outpatient, at the time that suicidality and/or clinical deterioration is identified, a study clinician will immediately evaluate the participant. In such cases, research staff will immediately contact one of the Principal Investigators, Drs. Uebelacker or Gaudiano, or one of the Co-Is, Drs. Miller or Weinstock. All are licensed clinical psychologists; one of the MPIs or Co-Is will be on call at all times. The clinician will conduct a suicide risk assessment. Depending upon the specific situation, steps taken to ensure a participant's safety may involve: (1) escorting the patient to the hospital's ER for evaluation by an independent clinician and possible hospitalization, (2) alerting inpatient staff to the patient's level of risk, (3) notifying the patient's outpatient clinician(s) at CNE for whom we have releases of information, or (4) calling the appropriate police departments. We will follow the protocol outlined in the DSMP for reporting SAEs to the IRB and other monitoring entities.

D2. Measures to Ensure Confidentiality

Throughout this protocol, we use the term "secure, CNE-compliant location" for storage of electronic files. This refers to the following options:

- CNE research server
- CNE instance of REDCap
- CNE instance of HIPAA-compliant Box
- CNE computer (i.e, password-protected)

- Password-protected, encrypted (128 AES bit or higher) storage device (e.g., audiorecorder, hard drive)

Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff from this study trained to deal appropriately with sensitive clinical issues. All information will be treated as confidential material and will be available only to research and clinical staff. All data collected will be kept in a CNE-compliant location. Patient identifying information will be stored in a separate database and will be password protected. Any paper files with any identifying information will be kept in a locked filing cabinet. No subject will be identified in any report of the project.

In Phase 1b, which includes work with professional videographers, at the earliest possible time after capturing video and/or audio content concerning a research subject or subjects, we will move the content from the camera's memory, storage, SD Cards, etc. to a secure, CNE-compliant location. Once moved, the content will be immediately deleted from the camera's memory, storage etc. This should usually occur within 48 hours of obtaining the content. Audiorecorders and videocameras will be kept in a locked location (e.g., drawer, filing cabinet) except when being used or transported.

Audio/video recordings will be stored on a secure, CNE-compliant location as defined above. Video recordings collected by videographers (consultants) in Phase 1b will be stored on a secure external storage device that is encrypted and password protected per CNE standards (128 bit AES encryption or higher). Once the videographers have completed their work, this storage device will be given to the study investigators. External consultants (videographers) will receive education in Human Subjects (e.g., CITI training) and will also sign a Business Associates Agreement. At the conclusion of the project, any video footage not used in the final product will be destroyed.

Participants in Phase 1 who are chosen to be filmed to be part of the LifePlans videos will be re-consented immediately prior to the time when the raw footage will be shot. Participants will be informed that once the final product is completed and made available to study participants or patients via a web-hosting site on the internet, CNE will no longer have complete control over the video. After the raw footage is shot and edited, participants will have an opportunity to view any footage of them that may be used in the final LifePlans video. At that point, they may request that part or all of the footage not be used in the LifePlans videos, and we will respect their wishes and not use that footage. If participants wish for their videos to be withdrawn at a later date, i.e., after they are hosted on a website, we will make every effort to withdraw those videos from the website. However, in the consent process, we will make it clear that we cannot guarantee that the video has not been copied by an external party, as the copying could occur even though we will take available measures to prevent it.

D3. Data Safety Monitoring Plan

A. Data safety and storage.

Please see section D.2 above.

B. Data access.

Only study staff will have access to data. No confidential information may be released outside Butler Hospital without the express written consent of the study participants, unless mandatory for child and elder abuse and in situations in which the risk of suicide or homicide is imminent.

C. Educational training.

Please see section on training of research personnel above.

D. Adverse events and unexpected problems.

The MPIs and Co-Investigator Dr. Arias will be responsible for monitoring and reporting adverse events. They will meet with staff weekly to review any adverse events.

Definitions

Serious Adverse Events. An adverse event (AE) is any untoward medical occurrence in a subject during participation in the clinical study or with use of the experimental agent being studied. A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred; includes a suicide attempt or drug overdose)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

In this study, we will monitor and report on the following SAEs:

- Suicide behavior
- Inpatient hospitalizations that are:
    - Suicide-related or
    - Psychiatric in nature or
    - Due to substance use or overdose
- Death for any cause

Unanticipated Problems (UPs). The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

SAE Monitoring and Reporting

Given that we are recruiting a hospitalized sample with suicide risk and possible substance use disorders, we expect serious adverse events to occur, including suicide attempts, non-suicidal drug overdoses, and psychiatric rehospitalizations,. However, given the nature of the study, it is unlikely that SAEs will be related to the study procedures. If any of these adverse events occur, or any other unanticipated problems are identified, the following procedure will be activated: the research staff member who observes or is notified of an adverse event (e.g., suicide attempt) will notify the MPIs or their designee immediately. All study staff will be educated on the definition of SAEs and UPs so that they may report them to the MPIs as soon as possible after becoming aware of the occurrence of an SAE or UP. We will systematically assess for adverse events throughout the course of the trial (for Phase 2 and 3) via patient interview (C-SSRS, THI) and chart review at Baseline, Month 1, and Month 6. In addition, if a patient reports one of the above SAEs at any time, we will record and review it. The MPIs or their designee will complete an Adverse Event Form for each event that will include a level of severity and determine attribution (intervention-related or not). Reporting timeframes will vary by SAE type. Please see the table below for more details.

Data type	Frequency of review	Reviewer
SAEs (expected OR unrelated, including psychiatric rehospitalizations and suicide attempts)	Per occurrence	MPIs (within 72 hours) Reported to SMC in bi-annual reports Reported to NIH in annual progress reports
SAEs (related)	Per occurrence	MPIs (within 72 hours) Reported to IRB and SMC within 10 days Reported to NIH in annual progress reports
All deaths	Per Occurrence	MPIs (within 72 hours) Reported to IRB, SMC, NIH within 5 days
UPs	Per Occurrence	MPIs (within 72 hours) Reported to IRB and SMC within 10 days Reported to NIH in annual progress reports

Interim Analysis and Stopping Rules

There is no interim analysis planned.

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

Safety Monitoring Committee

We will appoint a Safety Monitoring Committee (SMC) for trial monitoring. This will be composed of three independent experts with relevant experience. They will receive reports and convene meetings for this study on a twice-yearly basis. They will also receive reports per occurrence of SAEs as described in the table above.

E. Potential Benefits

Phase 3: For all participants in Phases 2 and 3, we will conduct research assessments 1-month and 6-months post-hospitalization. If we identify risk for suicide at those assessments, we will work with participants to ensure that they receive appropriate treatment. Benefits to the participants receiving the LifePlans intervention may include education about and increased motivation for use of coping skills in the following areas: identification of life values and implementing values-consistent behavior; problem-solving strategies; communication with family, friends, and treatment providers; treatment adherence and engagement; and safety planning and means restriction.

All phases/ knowledge to be gained: This study will allow us to develop and pilot test a video-based self-help intervention for use at the high-risk time period of transition from psychiatric hospitalization to community outpatient treatment. We will assess acceptability, feasibility, and safety of this intervention. The proposed project, including the open trial and pilot RCT, will prepare us to conduct the next study in this line of research, i.e., a full-scale effectiveness study. Ultimately, we hope this will result in another tool to be used for suicide prevention in a high-risk clinical group.

F. Risk-Benefit Ratio

Phase 3: The risks to participants are judged to be acceptable relative to the anticipated benefits. Serious risks related to study participation are unlikely to occur. Benefits may include education if receiving the LifePlans intervention, and risk assessments and assistance obtaining appropriate treatment if needed at follow-up assessments.

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5) CRITERIA FOR WAIVER OF AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION (PHI)

5A. Does the requested use of PHI involve more than minimal risk to privacy?

☐ **YES *[if " YES," project is not eligible for PHI Waiver]***

☒ **NO *[if "NO," address 1-3 below]***

1. **Plan to Protect Patient Identifiers from Improper Use and Disclosure:**

Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All research personnel will receive training in research ethics and be approved by the institution to conduct research. All

information will be kept in locked files. Electronic data will be stored on encrypted drives/servers and password protected. Data will be available only to authorized personnel and subject codes will be used to store information in databases. No subject will be identified in any report of this project.

2. **Plan to Destroy Identifiers or Justification for Retaining Identifiers:**
PHI will be destroyed upon study completion plus 1 year.

3. **Assurances that the PHI will not be Re-used or Disclosed:**
Information collected will only be used for the purposes described below and will be treated as confidential material as described above.

5B. Could the research be practicably conducted without a waiver? ☐ **YES** ☒ **NO**
5C. Could the research be practicably conducted without access to and use of the PHI? ☐ **YES** ☒ **NO**
5D. PHI is only needed for activities preparatory to research ☒ **YES** ☐ **NO**

6) DESCRIPTION OF PHI TO BE COLLECTED UNDER WAIVER

Chart reviews of new patients will be routinely conducted by study staff to determine if they are likely to meet inclusion/exclusions criteria for the study as described above. PHI to be obtained: patient demographic and contact information (name, address, telephone numbers, gender, age, race, marital status, occupation status) and patient psychiatric/treatment history (diagnoses and suicide history, past and current psychological and/or pharmacological treatments, current mental health provider contact information, lab results).

7) ADVERTISEMENTS

Document attached.

8) INFORMED CONSENT FORM (ICF), ASSENT OF MINOR & PARENTAL PERMISSION FORM

Indicate number of consent(s): 9

Identify each consent (i.e., Main, Screening, DNA):

- Verbal Consent for email and videorecording prior to enrollment
- Phase 1A – Written consent
- Phase 1A-- Verbal consent
- Phase 1B- Consent for use of videos in LifePlans intervention
- Phase 1B – HIPAA release; media release; materials release; COVID risk acknowledgment
- Phase 2 – Main - Written consent
- Phase 2 – Stakeholders – Written consent
- Phase 3 – Written consent
- Phase 3 – Email/Videoconferencing verbal consent