Study Documents

for

eLearning for Suicide Prevention, ID: STUDY00013577, NCT05178121

Date: 9/17/23

Includes:

Study protocol, informed consent form (ICF), and statistical analysis plan (SaAP).

IRB APPROVAL OF APPLICATION

June 25, 2021

Dear Doyanne A Darnell:

On 6/25/2021, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Formative Evaluation of an eLearning Approach to Suicide Prevention Training
Investigator:	Doyanne A Darnell
IRB ID:	STUDY00013577
Funding:	Name: National Institute of Mental Health (NIMH), Grant Office ID: FA185626, Funding Source ID: K23MH118361-01A1 Funding Title(s): "Technologic Innovation to Enhance the Scalability and Sustainability of Trauma Center Provider Training in Suicide Safety Planning"
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved your activity.

- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**
- COVID NOTE: Researchers must comply with current infection control requirements and complete a self-assessment that activities fit within allowable research as described on the HSD website.
- Your application qualified for expedited review ("minimal risk"; Categories 6 and 7).
- Under the Revised Common Rule this IRB approval is valid until study completion. In other words, there is no expiration date and you are not required to submit Continuing Review Reports to maintain your approval. However, you are still required to (1) obtain IRB approval before making any changes (modifications) to your research, and (2) provide the IRB with any Reportable New Information such as breaches of confidentiality or unanticipated problems.
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.
- Your study automatically has a Certificate of Confidentiality (CoC), because you have NIH funding. A description of the CoC protections and responsibilities has been placed in your study's Documents section.

- If you plan to continue data collection past the expiration of your NIH funding and the CoC, contact the Human Subjects Division prior to the end of your funding. We will help you determine whether you need to apply for a CoC extension.

Determinations, waivers, and regulations

The IRB made the determinations and waivers listed in the table below. Note that any granted waivers of consent or parent permission do not override a subject's refusal to provide broad consent.

Requirement	Determination or Waiver
Documentation of consent	Waived

Location of documents
Use the consent form that was approved and stamped by the IRB. It can be downloaded from the Final column under the **Documents tab** in Zipline.

In addition, HSD has uploaded the following documents to the **Documents tab** in Zipline:
- Certificate of Confidentiality Acknowledgement Letter

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Jeff Love, IRB Administrator
206-543-2921, lovej2@uw.edu

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example **(1.1)** must be answered.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: Formative Evaluation of an eLearning Approach to Suicide Prevention Training

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP Use of the UW IRB**.*

University of Washington

1.2 Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[X] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

This study is a part of a series of studies to develop and pilot a technology-enhanced training in suicide safety planning that targets skill-building in general counseling skills to accompany a standard web-based didactic with skill demonstration in suicide safety planning. Other IRB applications related to this research are: STUDY00007344, STUDY00011507, STUDY00011259

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[X] **No**

[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

This study is part of preliminary and pilot research to develop a technology-enhanced eLearning training in suicide safety planning that targets skill-building in general counseling skills to accompany a standard web-based didactic with skill demonstration in suicide safety planning. The training is designed to support acute medical care nurses to engage patients at-risk of suicide in collaborative and empathic suicide safety planning. Skill-building technologies include a chat bot called "Client Bot Emily" and an automated computer-based coding and computer-generated feedback report through a platform called Lyssn. This study is a formative evaluation of the technology-enhanced or eLearning approach. It includes assessment of training acceptability and engagement with the training components and technologies and the conduct of an end-of-evaluation focus groups with study nurses. Findings will be used to inform iterations to improve the acceptability of the training as well as to inform the implementation of the training and implementation of suicide safety planning with patients in a larger trial.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

The study is an evaluation of an eLearning training approach that utilizes a pre-post training longitudinal design.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

Descriptor	
1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).	☐
2. Part of an institution, organization, or program's own internal operational monitoring.	☐
3. Improve the quality of service provided by a specific institution, organization, or program.	X
4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.	X
5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.	☐
6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.	☐
7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.	☐
8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)	☐
9. Expanded access use of a drug or device not yet approved for this purpose	☐
10. Use of a Humanitarian Use Device	☐
11. Other. Explain:	☐

1.8 Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

Suicide prevention training is required for nurses in Washington State and nurses currently screen for suicide risk on acute care units at Harborview Medical Center. The Joint Commission, which oversees services at hospitals, recommends also having patients receive a brief intervention known as suicide safety planning to help support their ability to cope with suicidality after discharge. Current trainings in suicide prevention rely primarily on didactics without opportunities to practice skills, and nurses are not yet routinely trained in skills for suicide safety planning. This project is designed to develop training methods in suicide safety planning that can be further studied in a large trial. Additionally, procedures for a larger trial will be piloted. The training methods incorporate technologies that can efficiently and feasibly help nurses build skills needed in suicide safety planning. Future studies would test the effectiveness of the training on patient outcomes.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

We have conducted focus groups to explore nurses' interest in and opinions about suicide safety planning training and suicide prevention as well as using eLearning and computer technology for this purpose. We have conducted usability testing for the technologies involved. We have also been working with Harborview's Nursing Clinical Inquiry Council, a committee that oversees nursing research, education, and quality improvement initiatives. These activities indicate it will be feasible and appropriate to engage nurses in acute care in this formative evaluation.

1.9 Supplements. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified	SUPPLEMENT Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	SUPPLEMENT Devices
☐	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT Multi-site or Collaborative Research
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT Non-UW Individual Investigators
☐	**Other REDCap Installation Attestation for Electronic Consent** The research will use a non-UW installation of REDCap for conducting and/or documenting informed consent.	SUPPLEMENT Other REDCap Installation
☒	None of the above	

1.10 Confirm by checking the box below that you will comply with these basic COVID infection and risk control measures, OR that you have an exception granted by the HSD Director: (a) the only in-person interactions are essential for the study; (b) study team members and participants will wear face coverings throughout all procedures; (c) all study staff and participants will be screened for COVID-19 just prior to each research visit; and (d) no participants over the age of 85 years will be enrolled if their in-person participation is not connected with a clinical visit. See this webpage for details, including what "screening" means.

Review the HSD website for current guidelines about which in-person research activities are allowable.

[X] **Confirmed**

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Up to 20 nurses will be recruited from Harborview Medical Center acute care units serving patients admitted for medical, surgical, or traumatic injury reasons.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Nurses working on acute care units at HMC.

b. Exclusion criteria. Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Nurses unable to complete research activities remotely will be excluded. Remote training and research activities require the use of laptop, computer, or smart phone with internet access.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection that will continue with prisoner subjects

2.4 Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

*For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the **GUIDANCE Prisoners** for the definition of "prisoner", which is not necessarily tied to the type of facility in which a person is residing.*

[X] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and their location(s):

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research is funded by one of these federal departments and agencies (Health & Human Services; Energy; Defense; Homeland Security; CIA; Social Security Administration), and/or will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole or pardon decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole or pardon.

[ ] **Confirmed**

2.5 **Protected populations**. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
[ ] Fetuses in utero	WORKSHEET Pregnant Women
[ ] Neonates of uncertain viability	WORKSHEET Neonates
[ ] Non-viable neonates	WORKSHEET Neonates
[ ] Pregnant women	WORKSHEET Pregnant Women

a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

N/A

2.6 Native Americans or non-U.S. indigenous populations. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**

[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

2.7 Third party subjects. Will the research collect private identifiable information about *other individuals* from the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

[X] **No**

[ ] **Yes** → If yes, these individuals are considered human subjects in the study. Describe them and what data will be collected about them.

2.8 Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

☒ **Yes** → If yes, for each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research ***Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100***
Nurses at HMC	20

2.9 COVID-19 Screening. If there will be any in-person interactions with the subjects, describe how you will screen them for COVID-19 symptoms within the 24 hours before the interaction. Also, describe the COVID-19 screening procedures for the study staff who will interact with the subjects.

Acceptable procedures include some type of symptom check or attestation, or a SARS-CoV-2 test with quick access to results. Symptom attestation involves an individual reviewing a list of symptoms and declaring the presence or absence of those symptoms. HSD strongly encourages adapting this Washington State Department of Health Screening Tool https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Employervisitorscreeningguidance.pdf or the UW EH&S Example Symptom Self-Attestation in this document: https://www.ehs.washington.edu/system/files/resources/guidance-symptom-monitoring-COVID-19.pdf. If you will test for the virus, you must also describe here whether the testing lab is CLIA-certified and how the results will be reported to the subjects.

N/A – all research activities will be remote.

3 NON-UW RESEARCH SETTING

Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1 Reason for locations. Describe the reason(s) for choosing the locations.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

N/A

3.2 Local context. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

N/A

3.3 Location-specific laws. Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A

3.4 Location-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

N/A

3.5 If the PI is a student: Does the research involve traveling outside of the US?

☒ **No**

☐ **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes.

Participants will be identified and recruited in several ways:
1) Nurse managers/administrative staff will be invited to announce the study at staff meetings and post a flyer in work areas for nurses with information about the study and who to contact to find out more about the study / sign up. The PI/research staff may also announce the study at staff meetings.
2) The PI may reach out directly to nurses via an email list provided by nurse managers/administrative staff
3) An advertisement about the study may be included in an internal newsletter received by nurses
4) Flyers advertising the study may be posted in nurse working areas and common areas near or on the hospital campus where nurses frequently take breaks (e.g., local coffee shop).

Nurses who are interested in the study will be provided an email address to contact the PI/research staff. The PI/research staff will contact interested nurses to provide more information about the study.

4.2 Recruitment materials.

a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

The recruitment materials will include talking points for staff meetings, emails, and flyers. Descriptions are uploaded in Zipline (see Attachment: Recruitment Materials).

b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter. The text of these letters and emails must be uploaded to ***Zipline*** (i.e., a description will not suffice).

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

X	**No**
	Yes → If yes, describe the nature of the relationship.

4.4 Payment to participants. The IRB must evaluate subject payment for the possibility that it will unduly influence subjects to participate. Refer to GUIDANCE Subject Payment when designing subject payment plans. Provide the following information about your plans for paying research subjects in the text box below or note that the information can be found in the consent form.

- The total amount/value of the payment
- Schedule/timing of the payment [i.e., when will subjects receive the payment(s)]
- Purpose of the payment [e.g., reimbursement, compensation, incentive]
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include all of the above-listed information about payment, including the number and amount of payments, and especially when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Nurses are remunerated for all study activities, including completing training activities, surveys, skill assessments using standardized patient role-plays, and end-of-study focus groups. All activities take place outside of work hours; therefore nurses are provided remuneration in exchange for their time, effort, and to offset any potential costs to them for participating (e.g., child care). The total amount of remuneration, $450, is detailed in the Attachment: Nurse Study Activities & Remuneration.

4.5 Non-monetary compensation. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

N/A

4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[X] **No** → If no, skip the rest of this section; go to question **5.1**.

[ ] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

4.7 Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[X] **No** → If no, skip the rest of this section; go to question **5.1**.
[ ] **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the **recruiting and screening procedures**?

[ ] **No** → If no, describe the information that will be provided during the consent process and for which procedures.

[ ] **Yes, written** → If yes, and a **written** signature will be used to document consent:
- Upload the consent form to ***Zipline***.

[ ] **Yes, electronic** → If yes, and an **electronic** signature will be used to document consent:
- Upload the consent form to ***Zipline***.
- **If the eSignature process or method for recruiting and screening is different than for the main study procedures**, use the questions about electronic consent in Section 8.3 and 8.4 to differentiate between recruiting/screening and main study electronic consent. **If electronic consent will be used for recruiting/screening but not main study consent**, use 8.3 and 8.4 to describe eConsent and note that it is only for recruiting/screening.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*
*Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** on the Seattle Children's IRB website.*

Nurses will be recruited to participate in a formative evaluation of an eLearning training in suicide prevention that includes participating in virtual training activities, completing surveys, completing training outcome assessments of skills using standardized patient role-plays, and participating in end-of-evaluation focus groups.

All study activities are detailed in Attachment: Nurse Study Activities & Remuneration.

There are 3-4 hours of training activities and 3 hours of research activities.

Training activities include 1 hour of didactics that includes reading material and watching video material, including skills demonstrating of suicide safety planning. Then, nurses practice skills of asking a virtual suicidal patient open-ended questions and making reflective statements using a chat bot (i.e., Client Bot Emily). The chat bot also provides feedback on skills practice. The third type of training activity is to practice suicide safety planning with a patient actor and receive feedback on general counseling skills used during the role-play through a computer program and feedback platform (i.e., Lyssn).

The training and technologies are further depicted/described in the Attachment: eLearning Approach.

Research activities include completing surveys about knowledge, skills, motivation, and confidence in engaging patients around suicidality in general and safety planning in particular. Surveys will also include acceptability of and interest in using the technology for training. Standardized patient role-plays are also used to evaluate skills learned through the training process. End-of-evaluation focus groups of about 5 nurses each will provide insight into implementation barriers and facilitators of completing the training and of potentially doing safety planning with patients.

5.2 Recordings. Does the research involve creating audio or video recordings?

☐ **No** → If no, go to question **5.3**.
☒ **Yes** → If yes, verify that you have described what will be recorded in 5.1 and answer question **a**.

a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

☐ **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

☒ **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No** → If no, go to question **5.4**.
☐ **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

- ☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
- ☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
- ☐ CHN Center for Human Neuroscience MRI Center (Arts & Sciences research facility)
- ☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
- ☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
- ☐ SCCA Imaging Services
- ☐ Northwest Diagnostic Imaging
- ☐ Other: identify in the text box below:

c. Personnel. For MRI scans that will be conducted at the DISC, CHN or BMIC research facilities: Indicate who will be responsible for operating the MRI scanner by checking all that apply.

- ☐ MRI technician who is formally qualified
- ☐ Researcher who has completed scanner operator training provided by a qualified MRI operator

5.4 Data variables. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

Measures & Variables

Nurse training and technology acceptability will be assessed using the System Usability Scale (SUS), open-ended questions, and a modified version of the Client Satisfaction Questionnaire-8 (CSQ-8) to assess nurse satisfaction with the training.

Nurses will complete demographic questions (e.g., gender, race/ethnicity, age) and asked about their length of current employment, training background, and experience with suicide prevention and other behavioral interventions.

Nurse training targets will include use of the technology and nurse motivation for training and delivery of safety planning. Self-report surveys at post-training and the 6-month follow-up will include questions to assess whether and when nurses used the Client Bot and Lyssn feedback system and how they used it in their training and practice. Use data will also be collected by Client Bot and Lyssn systems, which will consist of how often nurses accessed the program, times of day of use, how long nurses spent on the program, and features used. A measure of nurse motivation to use the training materials, including the technology, will be asked at each survey time point. This will include variables such as nurse interest in the material, technology, and willingness to persist when challenged by practicing skills and getting corrective feedback. Motivation to use the general counseling skills to conduct collaborative safety planning with patients (i.e., transfer of training) will be assessed by adapting measures from the Theoretical Domains Framework (TDF; e.g., beliefs about capabilities and consequences, behavioral intentions, negative emotions).

Nurse training outcomes of general counseling skill quality and quality of safety planning will be assessed using standardized patient assessments. Nurses will complete four 30-minute role-plays over the course of the evaluation. These will be conducted by research staff/patient actors via Zoom, recorded, and assessed for general counseling skill quality using the Lyssn system. Pre- and post-training and follow-up role-plays will be assessed for fidelity to the safety planning intervention by the PI. Self-reported perception of skills will be assessed via survey at baseline, post-training and 6-months post-training using methods modified from training clinicians in evidence-based psychotherapy. Nurses will also complete **knowledge quizzes** of what is safety planning and how to do it.

Implementation barriers and facilitators will be assessed for both engaging in the training and using the skills learned with patients via nurse surveys at baseline, post-training and 6-months post-training as well as end-of-study focus groups. Questions will be designed using the TDF (e.g., beliefs about consequences, role & identity, environmental context & resources).

5.5 Data sources. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

1. REDCap surveys

Research Electronic Data Capture (REDCap) is a HIPAA-compliant data capture system used by the UW and supported by UW's Institute of Translational Health Sciences. It will capture self-report survey data for this study, which are completed at baseline, post-training, and 6 months post-training.

2. Standardized patient role-play recordings & quality assessment

Nurses will be asked to complete four standardized patient role-plays with research staff or paid actors. These role-plays will be recorded. The Lyssn system will score the role-plays for general counseling skills. The PI will score the role-plays for quality of suicide safety planning. The results of scoring of role-plays will be kept on UW Medicine servers and in de-identified format.

3. Focus group recordings & transcripts

Nurses will be invited to participate in a 1-hour focus group with other study nurses to gather qualitative data about their experiences in the training and perceptions of implementation barriers and facilitators of other nurses utilizing the training and skills taught in safety planning. Transcripts of these focus groups will be made and de-identified.

4. Technology use data

The technologic innovations under study, including Client Bot and the Lyssn system will gather use data. Nurses will be provided access to the technologies in a fashion that allows use to be tracked internally by the systems.

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

a. Will you or any members of your team have access to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

Nurses will be identifiable on Zoom audiovisual recordings. We will have names and email addresses to send remuneration. REDCap will house a link between email address and data but data will be downloaded in de-identified format. A tracking log to follow nurses over time will include names and email addresses, and any other contact information they provide.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

  This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

b. Will you or any study team members obtain any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

See 5.6 a

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

  This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

☒ Identifiers will be stored with the data. Describe the data to which this applies:

Zoom audio/video recording will be stored on UW Medicine servers and accessible only by the research team.
REDCap will store data with an email address, which is used to send out a survey link; however, downloaded data will be de-identified.

☒ Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Names and contact information will be stored separately from study data and will be maintained on UW Medicine servers. Nurses will have a study ID that is associated with their name in this file and then used to link study data in de-identified datasets.

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

No

5.7 Protected Health Information (PHI). Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

☒ **No** → If no, skip the rest of this question; go to question **5.8**

☐ **Yes** → If yes, answer all of the questions below.

a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

b. Is any of the PHI located in Washington State?

☐ **No**
☐ **Yes**

c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

Confirm by checking the box that the UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access, obtain, use, or disclose any UW Medicine PHI.

☐ **Confirmed**

e. Will you obtain any HIPAA authorizations electronically (i.e., e-signature)?

☐ **No**
☐ **Yes**

If 'Yes', confirm by checking the box that you have read and understand the 'Special Considerations' section of the **GUIDANCE Electronic Informed Consent** for information regarding the use of electronic signatures and HIPAA authorizations.

☐ **Confirmed**

f. For which PHI will HIPAA authorization NOT be obtained from the subjects?

Provide the following assurances by checking the boxes.

☐ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will the research obtain or generate genomic data?

☒ **No**

☐ **Yes** → If yes, answer the question below.

a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**

☐ **Yes** → If yes, complete the **SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**

☐ **Yes**

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

☒ **No**

☐ **Yes** → If yes, answer all of the questions below.

a. Describe <u>what will be stored for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

b. Describe <u>what will be shared with other researchers or with a repository/database/registry</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

c. Who will oversee and/or manage the sharing?

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

e. Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

☐ **No**

☒ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

☐ **No**

☒ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

N/A

g. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them

☒ **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

The research team will communicate with participants for enrollment, follow-up, and to conduct standardized patient role-play assessments. These will include things like going over study procedures, checking in to see how the study is going for them as it progresses, to ensure we have correct contact information for them, and to schedule role-plays. We will communicate with participants to email remuneration and thank them for participation. Participants will be encouraged to contact the PI or research team at any time with questions or concerns or help troubleshooting technology. We will provide a contact phone number and email for the PI/research team.

5.12 Future contact with subjects. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

☐ **No**
☒ **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

The study team will retain contact information only accessible by the study team to inform participants of potential future studies.

5.13 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

☒ **No**
☐ **Yes** → If yes, describe the alternatives.

5.14 Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples**: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

1. Standardized patient role-plays
   Nurses will be invited to participate in 4 total 30-minute standardized patients role-plays. These role-plays are designed to provide opportunities to practice skills in suicide safety planning using general counseling skills and as assessments of skills for evaluation purposes. Scenarios will be of patients hospitalized for medical/surgical/trauma reasons of varying adult ages. Nurses will receive feedback from the Lyssn system on one of the role-plays as part of the training. The PI will also assess the quality using a measure of suicide safety planning as part of the formative evaluation on pre and post-training role-plays. The computer coded and human coded data will be maintained in study records ongoing in a de-identified format and used for evaluation and refinement of the training program.

2. REDCap surveys
   Nurses will be asked to complete 15-20 minute REDCap surveys prior to starting training activities, at the end of training activities, and at 6 months after training activities. These will provide opportunities to observe self-reports of knowledge, skills, confidence, and motivation to engage patients in suicide safety planning and motivation for engaging in the training. Post-training and follow-up surveys will also assess self-report use, satisfaction, and acceptability of the training technology and any barriers to using it. Nurses will also be asked whether they used any skills learned with patients on their units. We will also collect demographic information, such as nurses age, gender, race/ethnicity, years at the hospital and since completing their graduate training, and unit they work on.

3. End-of evaluation focus groups
   Nurses will be invited to participate in a virtual 1-hour focus group with other study nurses to gather qualitative data about their experiences in the training and perceptions of implementation barriers and facilitators of other nurses utilizing the training and skills taught for safety planning. These focus groups will be transcribed and de-identified.

5.15 SARS-CoV-2 testing. Will the subjects be tested for the SARS-CoV-2 coronavirus?

If the only testing is to screen the subjects (question 2.8), you do not need to answer this question

[X] **No**
[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

5.16 Research equipment and COVID-19. Does you research involve any equipment that will be used on more than one subject that is not part of a clinical facility?

Examples: a computer tablet, a portable research ultra-sound device).

[X] **No**

[ ] **Yes** → If yes: confirm by checking the box below that the disinfection and cleaning of the equipment will meet the enhanced UW Environmental Health & Safety requirements described here: https://www.ehs.washington.edu/system/files/resources/cleaning-disinfection-protocols-covid-19.pdf

[ ] **Confirmed**

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will parental permission be obtained for:

[ ] All of the research procedures → Go to question **6.2b.**

[ ] None of the research procedures → Use the table below to provide justification, and skip question 6.2b.

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both boxes are checked, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

6.4 UW Office for Youth Programs Development and Support. If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with **UW Administrative Policy Statement 10.13** and the requirements listed at this website. This includes activities that are deemed to be Not Research or Exempt. It does not apply to third-party led research (i.e., research conducted by a non-UW PI). Information and FAQs for researchers are available.

This point is advisory only; there is no need to provide a response.

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will assent be obtained for:

☐ All research procedures and child groups	→ Go to question **7.2.**
☐ None of the research procedures and child groups	→ Use the table below to provide justification, then skip to question **7.6**
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why assent will not be obtained

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

7.3 Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

7.4 E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

7.5 Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups	→ Use the table below to provide justification, then go to question **7.5.b**
☐ All of the research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of the research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse the answer across the groups and/or procedures.*

a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe the plans (if any) to re-obtain assent from children.

b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

7.7 Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.

CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ Not ask or appear to ask subjects to waive their rights

PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which the answers in this section apply.

[X] Adult subjects

[ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which consent will not be obtained?

[X] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all groups, collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

Nurses interested in participating will be provided the consent form for the study, which will allow nurses time to review what the study entails before meeting with the PI/research staff or starting training/research activities. Nurses will be offered the opportunity to have a phone call or videoconference session with the PI or research staff to go over the study procedures and ask any questions before agreeing to participate. Nurses will also have the opportunity to continue participation without this session. They will be encouraged to contact the research team any time with questions about the study and using the materials. There will be instructions provided virtually also as part of each step in the process.

Nurses willing to participate will receive a unique link to a REDCap survey to review the consent form and indicate consent by typing their name into a field in the survey. This is followed by an orientation to the study activities, a demographic survey, and the baseline survey. Nurses will have access anytime through a study website and/or REDCap informational survey to the orienting information about the study and instructions for completing each part of the training and research activities.

At each standardized patient role-play, the actor will orient the nurse to the role-play, its purpose, and remind participants that their participation is voluntary.

c. Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Nurses have at minimum a high school diploma, with most having some amount of college or a bachelor's degree or above. Nurses are expected to have a 12th grade reading level. We will provide nurses with an opportunity to ask questions about the study during the consent process.

d. Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☐ **No**

☒ **Yes** → If yes, describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

Nurses may perceive that participating in the research is a required part of their job. The PI/research staff will communicate that the research is voluntary and will not report back to supervisors about the participation or degree of study completion by any one nurse (whether the study reaches the requested sample size may be communicated to assist with advertisement of the study again to nurses).

e. Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE Key Information for Consent Materials**.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

I have experience conducting research with nurses providing services to hospitalized patients at Harborview and at hospitals in Washington and other U.S. states. This research includes training nurses in brief behavioral health interventions and asking them to complete research surveys and standardized patient role-plays.

f. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

The study includes training and research activities that occur over multiple occasions. Some activities are scheduled with the research team, such as the standardized patient role-plays. Nurses will be reminded that they may opt out of participating at any point. They will be encouraged to contact the PI or research team by phone or email anytime with questions or concerns or to stop participating. Nurses will be reminded that there is no consequence for withdrawing their participation and they will receive remuneration for attempted activities (e.g. they will receive remuneration for partially-completed surveys).

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE Electronic Informed Consent for information about electronic consent requirements at UW.

[ ] **No** → If no, skip to question 8.4
[X] **Yes** → If yes, answer questions **a** through **e**

a. Describe the electronic consent methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

Nurses will be provided with a pdf version of the consent form in an email when they express interest in the study. To enroll, the consent form information will be presented in a REDCap survey.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

Nurses will navigate using the REDCap system and indicate consent by typing their name into a text box and clicking a button to submit the response.

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

Nurses will be provided the consent form ahead of being provided a link to a web-based orientation and pre-training survey. Nurses will be invited to schedule a call or session with the PI/research staff to go over the consent but this will not be required. Nurses will be given contact information to talk with the PI/research team at any point to get help or ask questions about the study.

d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

Nurses will have access to the consent methodology as they will need to use the same technology to participate in all portions of the study and will have basic skills for using this technology as a routine part of their work environment.

e. How will the research team ensure continued accessibility of consent materials and information during the study?

Nurses will be emailed copies of the consent form ahead of time and will be provided a link to a website/REDCap survey that has all needed study information. They will be provided contact information for the PI/research team.

f. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

The technology being tested is already in use elsewhere with other healthcare providers. No known adverse effects of interacting with the technology have been noted. Should any information arise that would affect risks to participants, the PI/research team will notify participants by email and add content about this to the beginning of any future surveys or next interaction with the research team.

8.4 Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Is written documentation of consent being obtained for:

[X] None of the research procedures	→ Use the table below to provide justification then go to question **8.5.**
[ ] All of the research procedures	→ Do not complete the table; go to question **8.4.b.**
[ ] Some of the research procedures	→ Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? YES	NO
Nurses	All procedures	[X]	[ ]
		[ ]	[ ]
		[ ]	[ ]
		[ ]	[ ]

☐ ☐

Table footnotes

1. *If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *See the GUIDANCE Electronic Informed Consent for information about options (including REDCap e-signature and the DocuSign system) and any associated requirements.*
- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☐ **No**

☐ **Yes** → If yes, indicate which methodology will be used.

- ☐ **UW ITHS REDCap**
- ☐ **Other REDCap installation** → Please name the institutional version you will be using (e.g. Vanderbilt, Univ. of Cincinnati) in the field below and provide a completed **SUPPLEMENT Other REDCap Installation** with your submission.
- ☐ **UW DocuSign**
- ☐ **Other** → Please describe in the field below and provide a signed **TEMPLATE Other E-signature Attestation Letter** with your submission.

b.1 Is this method legally valid in the jurisdiction where the research will occur?
NOTE: UW ITHS REDCap and UW DocuSign have been vetted for compliance with WA State and federal laws regarding electronic signatures.

☐ **No**

☐ **Yes** → If yes, what is the source of information about legal validity?

b.2 Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE Electronic Informed Consent for information and examples

☐ **No** → If no, provide the rationale for why this is not required or necessary to protect subjects or the integrity of the research. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** → If yes, describe how subject identity will be verified, providing a non- technical description that the reviewer will understand.

b.3 How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if written documentation of consent is not being obtained for any part of the research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

N/A

8.7 Deception. Will information be deliberately withheld, or will false information be provided, to any of the subjects?
Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

[X] **No**
[ ] **Yes** → If yes, describe what information and why.

Example: It may be necessary to deceive subjects about the purpose of the study (describe why).

a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

[ ] **No**
[ ] **Yes**

b. Will subjects be debriefed later? (Note: this is not necessarily required.)

[ ] **No**
[ ] **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[X] **No** → If no, go to question **8.9**.
[ ] **Yes** → If yes, answer the following questions.

a. Rationale. Provide the rationale for including this population.

b. Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **GUIDANCE Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

8.9 Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the

woman and the person who obtains the informed consent.

8.10 Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

The research team will take steps to protect nurses' privacy. We will not share whether they enroll or complete study procedures with anyone outside the research team. The study team will ensure data is collected and transferred securely and de-identified when possible. All data is stored securely in UW's REDCap instance and on a UW Medicine network drive accessible by the PI and research staff. Recordings of standardized patients will be necessarily identifiable. These will not be shared outside of the study team and will be stored on the secure UW server. REDCap survey data will be downloaded and stored in deidentified format. Focus groups will be recorded, transcribed, and transcriptions maintained in de-identified format. During the informed consent process for all project focus groups, we will inform participants that we cannot guarantee confidentiality in the focus groups as other participants can break confidentiality by disclosing what other participants discuss during the session. We will request at the start of all focus groups that participants not share what has been discussed in the focus groups with persons who did not participate in that focus group session.

9.2 Identification of individuals in publications and presentations. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[X] **No**

☐ **Yes** → If yes, will subject consent be obtained for this use?

☐ **Yes**

☐ **No** → If no, describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

9.3 **State mandatory reporting.** Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

☒ **No**

☐ **Yes** → If yes, the UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 **Retention of identifiers and data.** Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

☒ **Confirm**

9.5 **Certificates of Confidentiality**. Will a federal Certificate of Confidentiality be obtained for the research data?
NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.

☒ **No**

☐ **Yes**

9.6 Data and specimen security protections. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the **GUIDANCE Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

Level 2: These data have relatively little sensitivity except possibly short-term embarrassment or psychological discomfort if the data were disclosed.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Ensure applicable risk information from any Investigator Brochures, Drug Package Inserts, and/or Device Manuals is included in your description.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Potential Risks:

Confidentiality. Nurses may be concerned that performance on the standard patient role-plays and responses to study surveys and focus group questions may be shared with colleagues or supervisors.

Observation/assessment burden. Completing training and research tasks may be perceived as burdensome and nurses may experience some performance-related anxiety on the standardized patients. Nurses may experience some frustration interacting with the technology, which may depend on nurse computer technology literacy.

Distress related to talking about suicide. Nurses in Washington State are expected to have some experience talking about suicide and working with patients at-risk of suicide. They are required to take six continuing education hours of suicide prevention training for their license and routinely screen acute care patients for suicide risk. However, interacting with a standardized patient in a role-play about suicide and suicide safety planning may be novel. Reporting on or discussing experiences nurses have had with suicidal patients may be associated with anxiety, sadness, or other emotional distress.

Coercion. There is a risk that nurses may feel coerced to participate in the study.

Plans to Minimize Potential Risks

Confidentiality. The study team will ensure data is collected and transferred securely and de-identified when possible. All data is stored securely in UW's REDCap instance and on a UW Medicine network drive accessible by the PI and research staff. Recordings of standardized patients will be necessarily identifiable. These will not be shared outside of the study team and will be stored on the secure UW server. REDCap survey data will be downloaded and stored in deidentified format. Focus groups will be recorded, transcribed, and transcripts will be deidentified. During the informed consent process for all project focus groups, we will inform participants that we cannot guarantee confidentiality in the focus groups as other participants can break confidentiality by disclosing what other participants discuss during the session. We will request at the start of all focus groups that participants not share what has been discussed in the focus groups with persons who did not participate in that focus group session. No presentation or publication arising from this research will use participant names or other information that would allow participants to be identified.

Observation/assessment burden. To manage potential performance anxiety related to the standardized patient role-plays, nurses will be reminded that the assessments will be used only for the research study and will not be shared with their supervisor or others who may use the information in an evaluative way. We will remind nurse participants that the purpose of our project is to develop effective training methods, not to evaluate them as professional nurse providers. Nurses will be reminded that all activities are voluntary, including the training activities. They will be allowed to quit using any of the training technology, end the session with the standardized patient, skip survey questions, and leave the focus group early or not answer questions if they choose. Nurses will have an opportunity to debrief with the research staff after the standardized patient. Nurses will be able to schedule the standardized patient to occur at their convenience.

Distress related to talking about suicide. Nurses will be allowed to end specific training or research activities if feeling distressed. The PI will be available to debrief nurses' experiences with training and research activities and nurses may reach the PI at her cell phone during the workday or the PI will return calls the following day. The PI will routinely reach out to nurses enrolled in the study and check in about their experience. The PI is a licensed clinical psychologist who routinely supervises and consults with mental health providers on managing distress associated with patient care. Dr. Comtois has expertise in suicide prevention trials and training clinicians in suicide prevention and treatment and will also be available to consult with the PI on these issues.

Coercion. Nurses will be recruited by the PI/research team. The PI/research team will post advertisements, attend staff meetings, ask the unit nurse manager to send out a recruitment email, or email potential nurse participants directly to invite them to participate in the study. Nurses will be reminded that they can opt out of any part of the training and research activities and that whether they complete the activities is documented for research purposes and not reported to fellow nurses or supervisors. Remuneration was designed to balance adequate compensation for time and effort without being too large of an amount to be coercive.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?

10.3 MRI risk management. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

b. Who will (1) calculate the dose of GBCA; (2) prepare it for injection; (3) insert and remove the IV catheter; (4) administer the GBCA; and (5) monitor for any adverse effects of the GCBA? Also, what are the qualifications and training of these individual(s)?

c. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

d. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

☒ **No**
☐ **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

☒ **No**
☐ **Yes** → If yes, check all the boxes that apply.

☐ Administration of any drug for research purposes

☐ Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes

☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery

☐ Administration of a radio-isotope for research purposes**

☐ Implantation of an experimental device

☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

See Attachment: Formative Evaluation DSMP

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Nurses will have the option to withdraw from participation in the study. There is no anticipated reason why a nurse would be withdrawn without their consent. To withdraw, nurses will inform the PI/research team by phone, Zoom, or email that they would like to no longer be involved in the study. There is no option for

partial withdrawal. The PI/research staff will keep track of withdrawals and identify a reason if one is given.

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Nurses may benefit from receiving training in suicide safety planning; learning skills that they value and may find useful with patients who are at-risk of suicide. They may find some of the training technology interesting and engaging.

10.10 Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

[X] **No**

[ ] **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

a.2. Explain which of these results will be offered to subjects.

a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

b. Is there a plan for offering subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

[X] **No**

[ ] **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[ ] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[ ] **No**

[X] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

The technology being used is an existing commercial product. There is no remuneration or compensation offered outside of what nurses receive for participating in the study activities.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, residents, fellows, or post-docs.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/

[X] **The CV will be uploaded.**

12.3 UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:

Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.
Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.
Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.
Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Research Coordinator: Review consent and study procedures with nurses, send surveys and follow-up with nurses, check study emails, conduct standardized patient role-plays, enter data, participate in focus groups, transcribe audio data, assist in presentation and manuscript preparation.
Co-Investigators: Co-Investigators will help interpret study data, check the quality of study data, and support the PI with addressing an participant concerns. They will help write relevant manuscripts.

12.4 Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The PI is responsible for training all study team members in the research procedures. All research team members will have completed CITI or human subjects training as also required by the funding agency (NIH).

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

The PI is credentialed to deliver services at Harborview Medical Center as a psychologist and sees patients there routinely. The PI will work with nursing leadership/research oversight committee regarding recruitment advertisement and engagement with nurses. The PI has a HIPAA-compliant Zoom account through UW that can be used for data collection and private discussions.

13.2 Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**
☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination

☐ **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.

UNIVERSITY OF WASHINGTON
CONSENT FORM

Formative Evaluation of an eLearning Approach to Suicide Prevention Training

Researchers: Doyanne Darnell, PhD (Lead) Psychiatry 206-744-9108
Andria Pierson, MEd

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

PURPOSE OF THE STUDY

We are evaluating an eLearning training for nurses in suicide safety planning that uses innovative technologies to provide nurses with opportunities to practice and get feedback on their skills. Findings will be used to inform iterations to improve the training and help guide future efforts to implement the training within a larger trial.

STUDY PROCEDURES

All study procedures are done virtually. The study includes participation in eLearning training and training evaluation activities.

Training Activities (3-4 hours over 1 month)

The eLearning training includes a 1-hour didactic component with information about suicide safety planning and how to do it along with video demonstration of suicide safety planning being done. You will be able to complete this at any time that works for you prior to using the two technologies below.

The training also includes using two novel technologies:

1. A conversational agent or chat bot that allows a person to practice general counseling skills with a computer-simulated person. The computer will be designed to act as a suicidal patient.
2. An interactive, confidential report generated by a computer with feedback on a person's use of general counseling skills in an interaction with another person. The feedback will be based on one of your standardized patient role-plays done as part of the study.

   The training includes completing two standardized patient role-plays in which you will practice the suicide safety planning skills learned in the didactic portion. The role-plays will be audio and/or video recorded and the second will be uploaded into a web-based platform that generates the computerized feedback on your use of general counseling skills in the session.

Training Evaluation Activities (3 hours over 6 months)

1. The study includes 3 brief (15-20 minute) surveys. One is completed prior to the training, one is completed after completing training activities, and one is completed 6 months later. These surveys are completed using the online survey system REDCap. The first survey includes demographic questions like your age, gender, professional degree, work-shift, and years working at the hospital. The surveys will ask questions about your experience working with suicidal patients and interest, confidence, and motivation to do suicide safety planning with patients and get training in suicide safety planning. The surveys will also assess your experience using the technologies being evaluated and your opinions about this training and the potential for using skills learned with patients.

   You may refuse to answer any question.

2. We will ask you to complete 2 standardized patient role-plays that are used entirely for research purposes – one after you complete the training and one 6 months later. The role-plays will be audio and/or video recorded. No feedback is provided on these.

3. At the end of the evaluation (6 months after the training), we will invite you to participate in a focus group with 3-5 other nurses to reflect on your experience with the training and your perspective on implementing this training with other nurses at Harborview as well as doing suicide safety planning with patients. The focus groups will be held by video conference using Zoom technology. The focus groups are led by the lead researcher and, possibly, another research team member. You may decide not to respond to any researcher questions or comments from other nurses in the focus group. The focus groups will be recorded and transcribed for use in data analysis.

RISKS, STRESS, OR DISCOMFORT

There are risks to participating in the study.

The training tasks involve simulated conversational interactions about suicidality. The research surveys and focus groups include questions your experiences in your work place about the potentially sensitive topic of working with suicidal patients. You may experience psychological or emotional discomfort thinking and/or talking about suicidality.

You may feel frustration interacting with the technology. You may feel discomfort receiving feedback on your role-play.

The lead researcher will be available to talk with you at any point in the study and following focus group sessions if you would find it helpful to debrief your experience. You may email or phone the lead researcher or research team at any time.

In focus groups, all efforts will be made to limit discussion of personal stories that may be distressing to group members in focus groups. We will remind participants not to share what is said outside of the group.

You will be welcome to skip parts or take breaks at any time.

There is a risk that the data collected and stored by the research team could be improperly accessed. The research team will take steps to protect your data. Survey data will be stored on UW's REDCap, which is HIPAA-compliant. Data will also be stored on secure UW Medicine

servers and password-protected. All data will be presented in group format and will not identify you individually.

Efforts will be made to schedule standardized patient role-plays and focus groups at convenient times for you.

BENEFITS OF THE STUDY

You may not benefit directly from this study. It is possible that you will enjoy interacting with the novel technologies under study and learning about suicide safety planning. The potential benefit to future patients and society of this research is finding feasible ways of training nurses in skills for suicide prevention with patients at-risk of suicide.

SOURCE OF FUNDING

The study team and the University of Washington is receiving financial support for this research from the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

The information you share will be confidential. The transcripts created from the audio-video recordings will be de-identified. Only the research team will have access to your role-plays with standardized patients, audio-video of focus groups, and data associated with the novel technologies being studied. You will be assigned a study ID. This ID will be associated with your demographic information, survey responses, standardized patient role-play skills report, and focus group transcripts. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must take steps to help you or others stay safe.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;

- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 6/30/23. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION AND SPECIMENS

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You will receive up to $450 for participating in this study. You will receive a Visa cash card emailed to you for each part of the study.

Orientation = $25
Training activities = $100
Each standardized patient role-play = $50 ($200 total)
Each survey = $25 ($75 total)
Focus group = $50

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact the lead researcher, Doyanne Darnell, at 206-744-9108, cell: 770-329-3059, or darnelld@uw.edu. Expect 24 hours for a response if you leave a message or email.

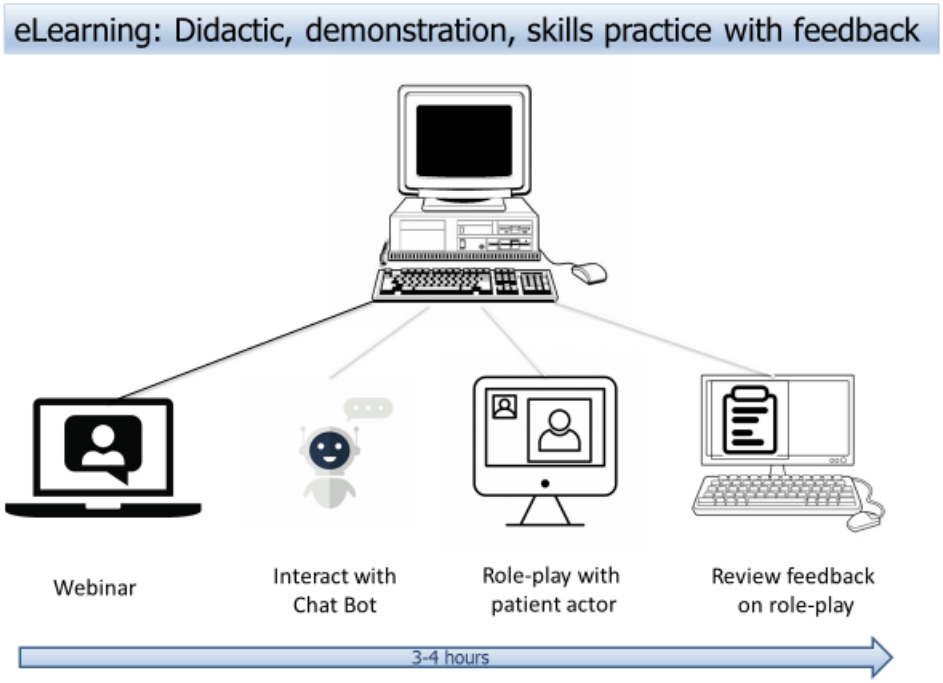
Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject



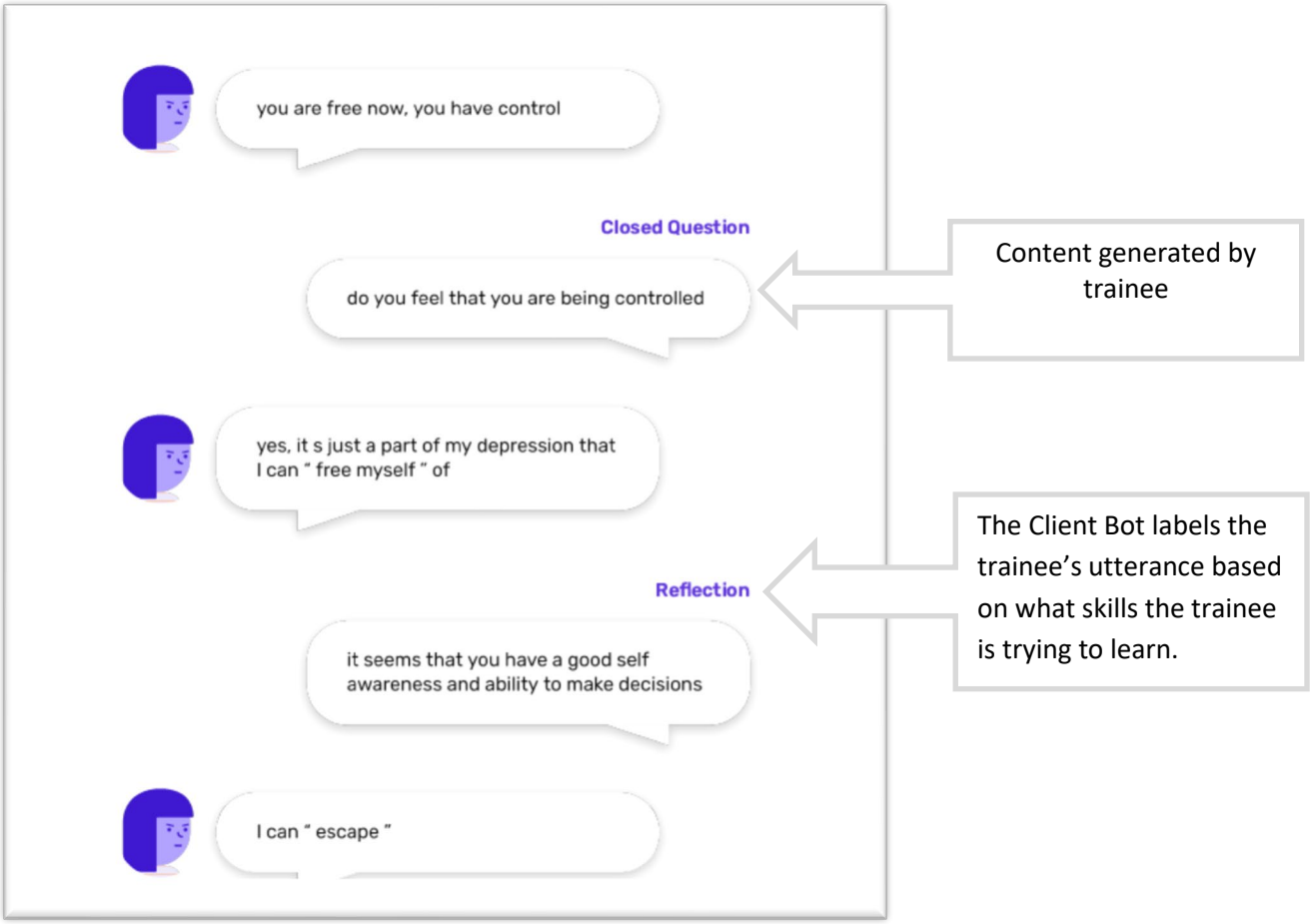
The eLearning approach in this study includes evaluation of two technologies used for skill-building in general counseling skills, after engaging in didactic content that explains and demonstrates suicide safety planning. The two technologies are:

1. Client Bot (see example page 3)
   This technology uses machine learning and artificial intelligence to portray a client or patient in an interactive text format, providing a trainee the opportunity to practice general counseling microskills (e.g., reflective statements of what a patient says or means; open-questions to elicit a patient's perspective and interests) and receive real-time feedback on performance and coaching on use of these skills. The computer-simulated patient will have the persona of a suicidal patient.

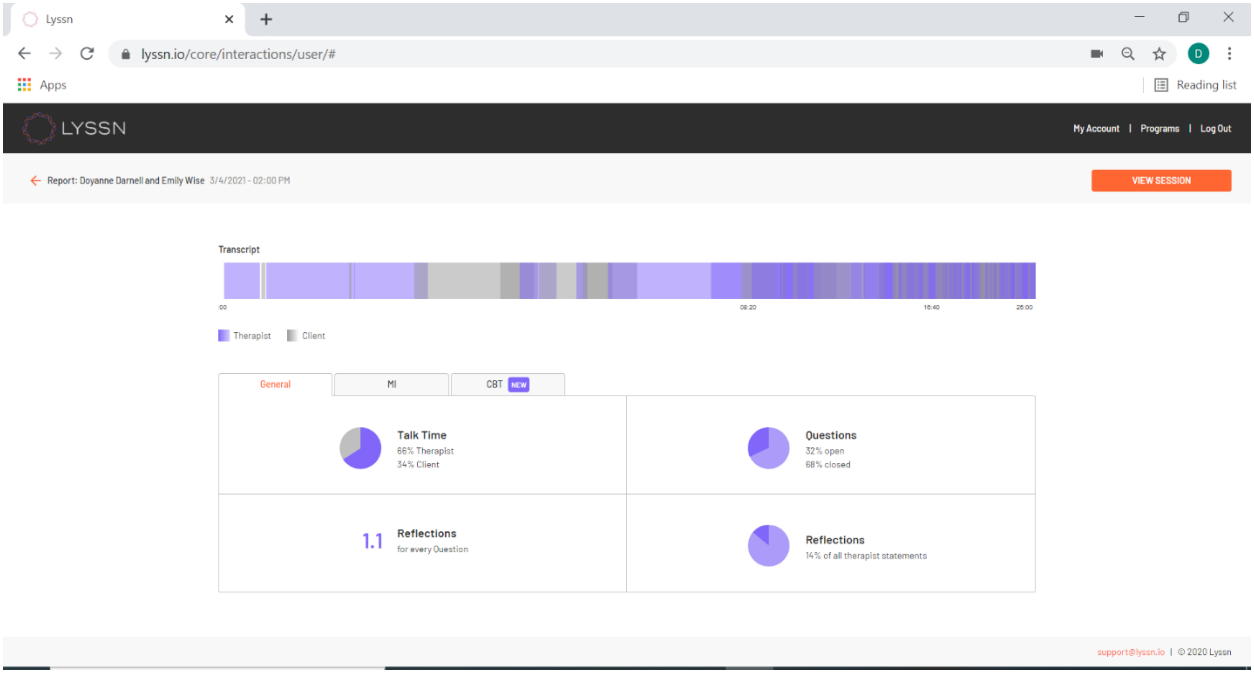
2. Lyssn (see example page 4)
   The Lyssn platform is a system utilizing speech signal and natural language processing as well as machine learning to assess the quality of general counseling skills (common in Motivational Interviewing). Lyssn has three main functions: a) it securely captures audio or video data from counseling sessions, using a HIPAA-compliant, cloud-based platform; b) it processes and analyzes this information; and c) it provides end-users access to the raw data (i.e., recording) and quality measures to give trainees feedback on their skills and monitory quality assurance. An interactive web report includes an automated speech-to-text transcript of the session and counseling quality statistics such as the provider's level of empathy, collaborative style, how many reflective statements the provider makes relative to questions they ask, and how many

questions are open-ended (encourages patients to talk more). In addition, there is a timeline of the entire session, where each talk-turn is linked to the transcript of the session to facilitate review and study of specific exchanges within the session. Each talk-turn includes predicted counseling quality indicators based on the machine learning engine and a visual representation of vocally-encoded arousal of the speaker.

Client Bot Emily - Example



Lyssn Platform - Snapshot of a Feedback Report



Attachment: Nurse Study Activities & Remuneration

	Research Activities	Training & Research Activities					Research Activities				
Activities	**1** 30 min Study orientation & baseline survey	**2** 60 min Web-based didactic & demonstration	**3** 30 min Standardized patient role-play	**4** 30 min Interact with Client Bot Emily	**5** 30 min Standardized patient role-play	**6** 15 min Review Lyssn feedback report	**7** 30 min Post-training standardized patient role-play	**8** 15 min Post-training survey	**9** 30 min 6-month follow-up standardized patient role-play	**10** 15 min 6-month follow-up survey	**11** 60 min End-of-study focus group
Data collection	Demographics, pre-training TDF constructs	Embedded knowledge questions	Post-web training knowledge & skills	Tech use data	Post-Client Bot knowledge & skills	Tech use data	Post-Lyssn knowledge & skills	TDF constructs, tech use, acceptability	6-months post-training knowledge & skills	TDF constructs, skills use, acceptability	Implementation barriers & facilitators
Remuneration	$50	$100	$50	Included with #2	$50	Included with #2	$50	$25	$50	$25	$50
Week	1	1-2	2-3	3	3-4		5		30		

Attachment: Recruitment Materials

This study is part of developmental research for a technology-enhanced suicide prevention training for nurses working with patients at Harborview Medical Center.

Recruitment efforts may include flyers posted in work areas and places on and off the hospital campus frequented by nurses during breaks (e.g., local coffee shop), announcements at staff meetings, emails sent directly to nurses through a mailing list obtained from nurse managers or through nurse managers who can distribute the advertisement, and an advertisement in an internal newsletter that goes out to nurses. The advertisements will explain that the study team is looking for volunteers to participate in an evaluation of an eLearning suicide prevention training and engage in research activities to inform improvements to the training program and how to study the program in a larger trial.

<u>Talking points for staff meetings, emails, and flyers</u>

- Purpose of the study
- The importance of suicide prevention activities with hospitalized patients (many patients at-risk and hospitalization provides an opportunity to help patients; Joint Commission recommendations for suicide risk assessment and suicide safety planning in this setting)
- Study procedures (see Attachment: Nurse Study Activities & Remuneration)
    i. Engage in 3-4 hours of training activities virtually over the course of 1 month.
        1. Most can be done at any time of day
        2. 30-minute standardized patient role-plays are scheduled with the patient actor
    ii. Engage in 3 hours of research activities completed virtually over the course of 6 months
        1. Complete 3 research surveys
        2. Participate in an end-of-evaluation focus group
        3. 30-minute standardized patient role-plays scheduled with a patient actor
- Remuneration for study activities
    i. Up to $450
- Contact information for the PI and/or research staff

Data and Safety Monitoring Protocol

Darnell K23 K23MH118361

Technologic Innovation to Enhance the Scalability and Sustainability of
Trauma Center Provider Training in Suicide Safety Planning

Aim 3: Conduct a formative evaluation of the technology-enhance training in suicide safety planning.

1. Entities Responsible for Monitoring the Trial

Study Team

The PI and primary mentor Dr. Comtois will provide oversight of Aim 3 data and safety monitoring. Other mentors and consultants will advise as needed. The PI and Dr. Comtois meet monthly, at which time they will engage in routine monitoring activities. They will communicate as needed for more immediate issues as described below. The PI will be responsible for ensuring compliance with reporting requirements to NIMH and the UW IRB.

UW Human Subjects Division – Institutional Review Board

The study will be monitored by the University of Washington IRB. The PI and research staff are responsible for ensuring compliance with the approved procedures and fulfilling reporting requirements to the IRB as detailed below.

2. Summary of the Study Protocol

Overall purpose of the K23 research

The K23 includes developmental and pilot research for a technology-enhanced training in suicide safety planning that targets skill-building in general counseling skills to accompany a standard web-based didactic with skill demonstration in suicide safety planning. The training is designed to support acute medical care nurses to engage patients at-risk of suicide in collaborative and empathic suicide safety planning. Skill-building technologies include a chat bot called “Client Bot” and an automated computer-based coding and computer-generated feedback report through a platform called Lyssn. Aims 1 and 2 include qualitative and user-centered design research to inform technology adaptation and the elucidate the implementation context.

Purpose of Aim 3

Aim 3 includes assessment of training acceptability and engagement with the training components and technologies and the conduct of an end-of-evaluation focus groups with study nurses. Findings will be used to inform iterations to improve the acceptability of the training as well as to inform the implementation of the training and implementation of suicide safety planning with patients in a larger trial.

Setting and Participants

Up to 20 nurses will be recruited from Harborview Medical Center acute care units serving patients admitted for medical, surgical, or traumatic injury reasons. Recruitment will target those units for which patient-level data is also collected.

Procedures
Nurses will be recruited on an ongoing basis, which is expected to take about two months. Nurses will engage in 3-4 hours of training that is expected to take about one month to complete. Enrolled nurses will also engage in evaluation activities that will take 3 hours total. In the first month, this includes several standardized patient role-plays of suicide safety planning and survey measures. Six months after the training is completed, nurses will be asked to complete a 6-month standardized patient role-play, 6-month follow-up survey, and participate in an end-of-study 1-hour focus group. Some role-plays will serve dual purposes as part of the training as well as to collect training outcome data.

Primary Outcomes
Acceptability. Nurse training and technology acceptability will be assessed using the System Usability Scale (SUS), open-ended questions, and a modified version of the Client Satisfaction Questionnaire-8 (CSQ-8) to assess nurse satisfaction with the training.
Training outcomes. Nurse training outcomes of general counseling skill quality and quality of safety planning will be assessed using standardized patient assessments. Nurses will complete four 30-minute role-plays over the course of the evaluation. These will be conducted by research staff or paid actors via Zoom, recorded, and assessed for general counseling skill quality using the Lyssn system. Pre- and post-training and follow-up role-plays will be assessed for fidelity to the safety planning intervention by the PI. Self-reported perception of skills will be assessed via survey at baseline, post-training and 6-months post-training using methods modified from training clinicians in evidence-based psychotherapy.

Secondary Outcomes
Training targets. Nurse training targets will include use of the technology and nurse motivation for training and delivery of safety planning. Self-report surveys at post-training and the 6-month follow-up will include questions to assess whether and when nurses used the Client Bot and Lyssn feedback system and how they used it in their training and practice. Use data will also be collected by Client Bot and Lyssn systems, which will consist of how often nurses accessed the program, times of day of use, how long nurses spent on the program, and features used. A measure of nurse motivation to use the training materials, including the technology, will be asked at each survey time point. This will include variables such as nurse interest in the material, technology, and willingness to persist when challenged by practicing skills and getting corrective feedback. Motivation to use the general counseling skills to conduct collaborative safety planning with patients (i.e., transfer of training) will be assessed by adapting measures from the Theoretical Domains Framework (TDF; e.g., beliefs about capabilities and consequences, behavioral intentions, negative emotions).

Other Variables of Interest
Nurse demographics. Nurses will complete demographic questions (e.g., gender, race/ethnicity, age) and asked about their length of current employment, training background, and experience with suicide prevention and other behavioral interventions.
Knowledge of safety planning. Nurses will complete brief quizzes to assess knowledge of what safety planning is and how to do it.
Implementation barriers and facilitators. Implementation barriers and facilitators will be assessed for both engaging in the training and using the skills learned with patients via nurse surveys at baseline, post-training and 6-months post-training as well as end-of-study focus groups. Questions will be designed using the TDF (e.g., beliefs about consequences, role & identity, environmental context & resources).

Plan of Analysis
Quantitative data will be viewed graphically and analyzed descriptively. Qualitative open-ended responses to questions will be summarized into common themes or content analyzed, as appropriate. Acceptability of the training will be supported by scores above 24 (indicates average of 3) on the CSQ-8 provider-version, above 67 on the SUS, and responses to open-ended questions based on relevant TDF constructs. Feasibility of the training will be supported by nurse use statistics collected by the computer technology and completion of all training parts (web-based didactic, Client Bot, and Lyssn feedback). Focus group qualitative data will be content analyzed according to TDF constructs.

3. Human Subjects Considerations

Inclusion/exclusion Criteria
All nurses working on participating units will be eligible for participation. There are no exclusion criteria. Nurses will opt into the study based on interest and willingness, including willingness to utilize a computer and the internet to participate in the web-based training activities.

Informed Consent
Informed consent may occur in person, by phone, or by videoconference. The PI/research staff will send the informed consent document to nurses ahead of time and then meet to go over and explain the study, review the consent form, and answer any questions. We will obtain a waiver of documentation of informed consent to facilitate virtual consent procedures. Nurses are expected to be literate in English at the high school level. They are also expected to be able to use computer, internet, REDCap technology as they routinely use these or similar systems in their routine work.

Risks Associated with Study Participation
Confidentiality. Nurses may be concerned that performance on the standard patient role-plays and responses to study surveys and focus group questions may be shared with colleagues or supervisors.
Observation/assessment burden. Completing training and research tasks may be perceived as burdensome and nurses may experience some performance-related anxiety on the standardized patients. Nurses may experience some frustration interacting with the technology, which may depend on nurse computer technology literacy.
Distress related to talking about suicide. Nurses in Washington State are expected to have some experience talking about suicide and working with patients at-risk of suicide. They are required to take six continuing education hours of suicide prevention training for their license and routinely screen acute care patients for suicide risk. However, interacting with a standardized patient in a role-play about suicide and suicide safety planning may be novel. Reporting on or discussing experiences nurses have had with suicidal patients may be associated with anxiety, sadness, or other emotional distress.
Coercion. There is a risk that nurses may feel coerced to participate in the study.

Plans to Minimize Potential Risks
Confidentiality. The study team will ensure data is collected and transferred securely and de-identified when possible. All data is stored securely in UW's REDCap instance and on a UW Medicine network drive accessible by the PI and research staff. Recordings of standardized patients will be necessarily identifiable. These will not be shared outside of the study team and will be stored on the secure UW server. REDCap survey data will be downloaded and stored in deidentified format. Focus groups will be recorded and transcribed. Transcripts will be deidentified. During the informed consent process for all project focus groups, we will inform participants that we cannot guarantee confidentiality in the focus groups as other participants can break confidentiality by disclosing what other participants discuss during the session. We will request at the start of all focus groups that

participants not share what has been discussed in the focus groups with persons who did not participate in that focus group session. No presentation or publication arising from this research will use participant names or other information that would allow participants to be identified.
Observation/assessment burden. To manage potential performance anxiety related to the standardized patient role-plays, nurses will be reminded that the assessments will be used only for the research study and will not be shared with their supervisor or others who may use the information in an evaluative way. We will remind nurse participants that the purpose of our project is to develop effective training methods, not to evaluate them as professional nurse providers. Nurses will be reminded that all activities are voluntary, including the training activities. They will be allowed to quit using any of the training technology, end the session with the standardized patient, skip survey questions, and leave the focus group early or not answer questions if they choose. Nurses will have an opportunity to debrief with the research staff after the standardized patient. Nurses will be able to schedule the standardized patient to occur at their convenience.
Distress related to talking about suicide. Nurses will be allowed to end specific training or research activities if feeling distressed. The PI will be available to debrief nurses' experiences with training and research activities and nurses may reach the PI at her cell phone during the workday or the PI will return calls the following day. The PI will routinely reach out to nurses enrolled in the study and check in about their experience. The PI is a licensed clinical psychologist who routinely supervises and consults with mental health providers on managing distress associated with patient care. Dr. Comtois has expertise in suicide prevention trials and training clinicians in suicide prevention and treatment and will also be available to consult with the PI on these issues.
Coercion. Nurses will be recruited by the PI/research team. The PI/research team will post advertisements, attend staff meetings, ask the unit nurse manager to send out a recruitment email, or email potential nurse participants directly to invite them to participate in the study. Nurses will be reminded that they can opt out of any part of the training and research activities and that whether they complete the activities is documented for research purposes and not reported to fellow nurses or supervisors. Remuneration was designed to balance adequate compensation for time and effort without being too large of an amount to be coercive.

4. Quality Assurance Procedures

Data quality assurance includes monitoring data collection to ensure they are accurately and reliably collected and monitoring the storage of data to ensure they are stored securely and appropriately. Effective data quality assurance procedures involve proper training of staff in data collection procedures, use of appropriate data collection tools, and periodic review of adherence to data collection, transfer, and storage procedures as well as data completeness and accuracy.

The PI will develop manuals and procedures for data collection and storage, receiving guidance from mentors and consultants as appropriate, and will train research staff in these procedures.

Sources of Material
This study includes four primary sources of data collected for research purposes:

a) Standardized patient role-play recordings
   Nurses will be asked to complete four standardized patient role-plays with research staff or paid actors. These role-plays will be recorded. Quality assessment scores will be generated by Lyssn as well as the PI coding of some of the role-plays as outcome assessments for suicide safety planning adherence.

b) REDCap surveys

Research Electronic Data Capture (REDCap) is a HIPAA-compliant data capture system used by the UW and supported by UW's Institute of Translational Health Sciences. It will capture self-report survey data for this study, which are completed at baseline, post-training, and 6 months post-training.

c) Focus group recordings & transcripts
Nurses will be invited to participate in a 1-hour focus group with other study nurses to gather qualitative data about their experiences in the training and perceptions of implementation barriers and facilitators of other nurses utilizing the training and skills taught in safety planning.

d) Technology use data
The technologic innovations under study, including Client Bot and the Lyssn system will gather use data. Nurses will be provided access to the technologies in a fashion that allows use to be tracked internally by the systems.

Data Confidentiality

a) Standardized patient role-play recordings
Neither the recordings of standardized patient role-plays nor the individual quality assessment scores based on the role-plays will be shared outside of the research team. Scores will be maintained in de-identified format once downloaded from Lyssn or after PI coding of safety planning.

a) REDCap surveys
REDCap survey data will be stored in identifiable format in REDCap to facilitate tracking of survey completion and participant remuneration; however, the data will be de-identified upon download and stored on secure UW Medicine servers.

b) Focus group recordings & transcripts
Audio/video files of focus groups will be stored on secure UW Medicine servers. Transcripts will be made in de-identified format and also stored on secure UW Medicine servers.

c) Technology use data
Technology use data is stored securely on the Client Bot and Lyssn systems. This data will be transferred in de-identified format using secure email from Lyssn to UW or downloaded by the PI/research staff and then de-identified for storage. Data will be stored on a secure UW Medicine server.

Data Security

d) Standardized patient role-play recordings
Audio/video files of standardized patient role-plays will be stored on secure UW Medicine servers and the Lyssn platform. Lyssn provides a high level of security, is HIPAA-compliant, and meets standards of UW Medicine. There will be no real patient interactions recorded.

e) REDCap surveys
REDCap is a HIPAA-compliant secure data capture system that requires a log-in and password through an associated UW account. Accounts are only provided by REDCap staff. The research team will keep their log-in information private.

f) Focus group recordings & transcripts
Audio/video files of focus groups will be stored on secure UW Medicine servers. Transcripts will be made in de-identified format and also stored on secure UW Medicine servers.

g) Technology use data
Technology use data is stored securely on the Client Bot and Lyssn systems. This data will be transferred in de-identified format using secure email from Lyssn to UW or downloaded by the PI/research staff and then de-identified for storage. Data will be stored on a secure UW Medicine server.

Data Integrity

a) Standardized patient role-play recordings
Standardized patient role-play scenarios will be developed by the research team for the purposes of the study. The PI will train research staff/standardized patient actors, in the scenarios. The PI will review standardized patient role-plays and provide feedback and re-training to staff/actors as needed. Research staff will test audio/video recording equipment prior to use. Audio/video recordings will be checked immediately following the role-play session for recording quality and any problems addressed prior to the next session.
The PI has been trained in coding of suicide safety planning for quality and will ensure accurate downloading of Lyssn data and entry of quality assessment data.

b) REDCap surveys
All REDCap data collection surveys will be pilot tested by the research team. The surveys will be designed to reduce potential for human error in data entry or unintentionally skipping items. The PI and/or research staff will periodically review the survey data to ensure the tools are functioning properly.

c) Focus group recordings & transcripts
Research staff will test audio/video recording equipment prior to use. Audio/video recordings will be checked immediately following the focus group for recording quality and any problems addressed prior to the next session. The PI will review transcripts to ensure their quality.

d) Technology use data
The PI will work with technology consultants to ensure the technologies are accurately capturing usability data. The PI will ensure the data is transferred properly to the research team and is prepared appropriately for analysis. The PI and/or research staff will periodically review the technology use data captured to ensure the tools are functioning properly.

5. Event Reporting

The study team will follow procedures for reporting reportable events required of both the UW IRB (Guide to Reporting New Information - UW Research (washington.edu)) as well as NIMH (NIMH Reportable Events Policy).

The following Office of Human Research Protection (OHRP) Definitions will be used to meet reporting requirements:

Adverse Event (AE). An adverse event (AE) is any untoward medical occurrence in a participant temporally associated with participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these.

Serious Adverse Event (SAE). A serious adverse event (SAE) is any adverse event that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- An important medical event that may jeopardize the participant's health and may require medical intervention to prevent one of the other events listed above (based upon appropriate medical judgment)

Unanticipated Problem. Unanticipated problems include 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 (in this guidance document, 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)
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

AE and SAE Identification

Nurses may experience emotional or psychological distress talking about suicide with other nurses, answering questions about working with suicidal patients, or role-playing suicide safety planning with a patient actor. There are no other known AEs or SAEs that are expected to occur through participation in the study. The study team may become aware of AEs or SAEs through survey responses or during attempts to engage nurse participants in study activities.

Event Reporting Table

The following table details reporting requirements for the UW IRB and NIMH.

Event	UW IRB	NIMH
AEs	Unexpected AEs - Report within 10 business days	For all AEs and SAEs that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the annual progress report.

Event	UW IRB	NIMH
Deaths related to study participation	Unexpected SAEs - Report within 10 business days	Deaths must be reported immediately (no later than within 5 business days) of the principal investigator first learning of the death.
Other SAEs	Unexpected SAEs - Report within 10 business days	Unexpected SAEs - Reported to the NIMH PO within 10 business days of the study team becoming aware of the SAE. For all SAEs that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the annual progress report.
Unanticipated problems	Breach of confidentiality: Report within 24 hours Inappropriate access or use of protected health information (PHI): Report within 24 hours All others: Report within 10 days	Report to the NIMH PO within 10 business days of the investigator learning of the event.
Protocol violation/deviation	Report within 10 business days	With the annual progress report.
Serious non-compliance or continuing non-compliance	Report within 10 business days	Reported to the NIMH PO within 10 business days of IRB determination - Reported by the institution
Changes to risk/benefits	Report within 10 business days	N/A
Premature suspension or termination of some or all of the research by the sponsor, researcher, or institution	Report within 10 business days	Any suspension or termination of approval must include a statement of the reason(s) for the action and must be reported promptly to the NIMH PO within 3 business days of receipt. Must be reported by both the regulatory or monitoring entity and Investigator
Audit, inspection, compliance or safety-related inquiry from a federal agency including initial notification of an upcoming audit or inspection	Report within 10 business days	N/A

Event	UW IRB	NIMH
Complaint from a subject or other person about the study, which cannot be resolved by the research team	Report within 10 business days	N/A

6. Trial Stopping Rules

   There are no stopping rules for this pilot study.

7. Management of Incidental Findings

   N/A

8. Conflict of Interest

   K23 consultant David Atkins, PhD, is Chief Executive Officer for Lyssn. K23 consultant Michael Tanana, PhD, is Chief Technology Officer of Lyssn. Lyssn products and Dr. Tanana's consultant time are provided at cost. Dr. Atkins' time is offered in-kind.

Statistical Analysis Plan for eLearning for Suicide Prevention, ID: STUDY00013577, NCT05178121

We will examine descriptive statistics for all outcomes, including frequencies for categorical variables and the mean, standard deviation, and confidence intervals based on the standard error of the mean for variables observed across timepoints.