Improving Delirium Screening and Detection for Older Adults Presenting to the Emergency Department (ED): A Novel ED Delirium Screening and Detection Program

Research Protocol Document

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Northwell Health

RESEARCH PROTOCOL

Protocol Title:	Improving Delirium Screening and Detection for Older Adults Presenting to the Emergency Department (ED): A Novel ED Delirium Screening and Detection Program
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Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
- Do not use this template if:
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1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain:

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in **language intelligible to a moderately educated, non-scientific layperson**.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Delirium occurs in up to 20% of older adults presenting to the Emergency Department (ED) and is associated with poor outcomes. Failure to identify patients with ED delirium not only prevents initiation of mitigation strategies, but is also a barrier to advancing the field in terms of evaluating management and clinical outcomes. This project studies the potential of an ED Delirium Detection Program (ED-DDP), developed to address the need for consistent and accurate ED delirium detection.

This research will have two objectives: **Aim 1 will conduct a pilot stepped wedge cluster randomized trial (SW-CRT) of the ED-DDP across 3 diverse EDs to determine preliminary efficacy of the detection training program** and **Aim 2 will use a mixed methods approach to assess RE-AIM implementation outcomes (Reach, Efficacy, Adoption, Implementation, and Maintenance) of the training program**. Aim 1 will consist of a multicomponent 1-day delirium champion workshop where the training is delivered, real-time direct observation/training of champions via telehealth, and practical training of nurses throughout each ED by champions. In Aim 2 we will assess implementation outcomes using training logs, tele-observation, interviews with champions and nurses, and electronic medical record screening.

The overarching aim of this proposal is to determine the preliminary efficacy of the training program for improving ED delirium screening, detection, and management in older adults, while also evaluating implementation outcomes of the program for champions/nurses. We will use findings from this study to inform a full-scale SW-CRT to evaluate the impact of the program on patient outcomes at Northwell Health. The long-term goal of this study is to implement and disseminate a

comprehensive ED-DDP that will improve screening, detection, and management of ED delirium in older adults.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

Over 23 million older adults present to the Emergency Department (ED) each year in the United States, and up to 20% will experience delirium while in the ED. Yet, it is estimated that over 75% of ED delirium cases are missed. Failure to systematically screen and detect ED delirium affects clinical management (e.g., use of chemical and physical restraints) and outcomes (e.g., increased mortality and dementia).

Despite the use of traditional educational programs (online modules, didactics), integration of validated delirium screening tools (e.g., brief Confusion Assessment Method, bCAM) into the electronic health record (EHR), and screening prioritization, existing ED delirium programs have only demonstrated improvement in screening rates, while consistently failing to improve delirium detection. These repeated failures necessitate a comprehensive training program that can address the known barrier of wide-ranging knowledge deficits, and improve consistent and accurate delirium screening.

Known barriers to ED delirium detection consist of a lack in screening tool use, competing priorities, and wide-ranging knowledge deficits. Even when validated screening tools (e.g., brief confusion assessment method, bCAM) are prioritized and integrated into nursing workflow, they are rarely used consistently or accurately in clinical practice, leading to lack of delirium detection. Our long term goal is to implement and disseminate a comprehensive ED Delirium Detection Program (ED-DDP) that will improve screening, detection, and management of ED delirium in older adults.

Our innovative ED-DDP builds on EHR integration and screening prioritization (resulted in delirium detection rates of <3%), with a “train-the-trainer” model, consisting of a multicomponent one-day workshop for delirium champions, nurse training by champions, and real-time bedside training via telehealth (delirium tele-training). Tele-delirium training is used, not only to provide direct training/feedback on screening tool use and management strategies, but also to assess screening accuracy by nurses (tele-observation). By addressing wide-ranging delirium knowledge deficits and lack of real-world bedside delirium screening tool

use, the ED-DDP has the potential to change practice and improve ED delirium screening, detection, and management.

This study will be the first to evaluate accurate delirium screening. Previous ED delirium programs have only been able to demonstrate improvement in delirium screening adherence, while consistently failing to improve detection.14,32,33 Accurate delirium detection is essential, not only to initiate management strategies, but also to inform future research on improving patient-centered outcomes (e.g., mortality and dementia).4

This study is also one of the first interventions to go beyond traditional education programs (online modules, didactics) and EHR integration of a validated delirium screening tool (e.g., bCAM), which have both failed to improve ED delirium detection in real-world clinical practice.4,25,32 The innovative components of the ED-DDP ("train-the-trainer" model, 1-day training workshop for champions, tele-training using direct observation and feedback), will overcome barriers by: explaining the significance of delirium as a disease process; and teaching, monitoring, and reinforcing appropriate screening tool use and management strategies.

This will be one of the first studies to utilize the RE-AIM framework to evaluate implementation outcomes of a training program to improve delirium screening and detection, which will enhance future sustainability, generalizability, and the potential for broad dissemination.4,19,33 The use of an established Implementation science framework, combined with a broad-based mixed-methods approach, represents a substantive departure from extant research on ED delirium.

Our group has previously developed and tested the innovative DDP in the intensive care unit (ICUDDP) within the Northwell Health system. The ICU-DDP utilizes a "train-the-trainer" model, which consists of: 1) a multicomponent one-day delirium champion training workshop; 2) real-time direct observation, training, and reinforcement via telehealth (tele-delirium training); and 3) practical training of nurses by champions. The ICU-DDP improved delirium detection from 9.1% to 30.1% ($p = 0.005$).

Given the success of the ICU-DDP, we refined the ICU-DDP for the ED (ED-DDP). In order to accomplish this, we obtained informal feedback from ED stakeholders who indicated that participation in the ED-DDP was of high priority, acceptable, and feasible.

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*

- *The goals and the hypothesis to be tested should be stated.*

The objectives of this proposal are to: 1) conduct a pilot stepped wedge cluster randomized trial (SW-CRT) of the ED-DDP across 3 diverse EDs to determine preliminary efficacy of the EDDDP to improve ED delirium detection, screening, and management; and 2) use a mixed-methods approach to assess RE-AIM implementation outcomes of program Reach, Efficacy, Adoption, Implementation, and Maintenance.

Aim 1: Conduct a pilot stepped-wedge cluster randomized trial (SW-CRT) across 3 ED sites to determine the preliminary efficacy of the training program for improving delirium screening, detection, and management in older adults presenting to the ED. We will enroll 3 diverse EDs (based on setting and patient demographics), and randomize them to receive the intervention at 3-month intervals over a 15-month period (control—standardized delirium screening [bCAM]; intervention—standardized delirium screening [bCAM] + ED-DDP). The primary outcome will be delirium detection (proportion of positive bCAM documentation among those with delirium via validated chart review). Secondary outcomes will be delirium screening (proportion of older adults with bCAM documentation among eligible older adults) and management strategies (e.g., use of restraints).

Table 1. Stepped Wedge Cluster Randomized Trial (SW-CRT) Design

ED Site Crossover Sequence	Period 1 (3 months)	Period 2 (3 months)	Period 3 (3 months)	Period 4 (3 months)	Period 5 (3 months)
A	Control	*Implementation	Intervention	Intervention	Intervention
B	Control	Control	*Implementation	Intervention	Intervention
C	Control	Control	Control	*Implementation	Intervention
*No chart review will occur during Implementation Periods					

The primary objective will be to assess the preliminary efficacy of the ED-DDP and to estimate the effect size and intraclass correlation coefficient (ICC) information needed for a future full-scale SW-CRT. ICC is critical to capture because as ICC increases, the design effect (and hence the sample size needed) decreases. Currently no known estimate of the ICC exists, so it is important to conduct this preliminary trial to obtain a rough estimate of the ICC.

Aim 2: Use a mixed methods approach to conduct implementation outcome assessments of the ED-DDP for champions and nurses. A multimodal approach, using training logs, tele-observations, and EHR data, will assess quantitative outcomes during implementation/intervention periods: Reach (training completion), Efficacy (accurate screening tool use), Adoption (screening rates), and Implementation (fidelity/time of program delivery). We will conduct semi-structured interviews (intervention period) to assess and explain: successes and challenges of training completion (Reach) and Adoption of delirium screening;

adaptations made to ED-DDP delivery (Implementation); and plan for Maintenance.

Table 2. Mixed-Methods Approach to Assess Implementation Outcomes of ED-DDP Delivery to Champions and Nurses

RE-AIM Framework	Measures – Implementation Period	Measures – Intervention Period
Reach	Training Logs (Quant): Proportion of champions who complete training at each ED site (workshop + 3 tele-training sessions); Proportion of nurses who complete at least 1 training session with a champion at each ED site (Goal: 80%)	Interviews of nurses/champions (Qual): Program participation (why/why not?)
Efficacy (Accurate Delirium Screening)		Tele-Observations using a validated spot check tool (Quant): Proportion of nurses (10 at each ED site) who score at least 80% accuracy on bCAM use in Intervention (Goal: 80%)
Adoption		EHR (Quant): Proportion of nurses who screen 80% of eligible patients (Goal 80%) Interviews (Qual): Adoption of delirium screening by nurses (why/why not?)
Implementation	Training Logs (Quant): Proportion of training components (e.g. workshop, tele-training sessions) that adhered to ED-DDP protocol (Fidelity; Goal: 80%) Training Logs (Quant): Time required to train champions and nurses (Time; Goal: 80% of champions/nurses complete training during Implementation Period)	Interviews (Qual): Adaptations to ED-DDP (Adaptations)
Maintenance		Interviews (Qual): Degree to which the ED-DDP and delirium screening has become institutionalized; Plans to continue/discontinue training by champions and delirium screening by nurses

Emergency Department Delirium Detection Program (ED-DDP); Quantitative (Quant); Qualitative (Qual); Electronic Health Record (EHR)

We will use a mixed-methods concurrent parallel design, collecting and analyzing separately the implementation and intervention data, as well as the quantitative and qualitative data. Then, we will analyze and interpret the data together to triangulate results. We will use a matrix and data transformation approach to mix the data and lead to a final set of findings.

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

The study team has prior experience implementing the same program customized to, and delivered in, an intensive care unit, and previously demonstrated high recruitment/retention rates of champions. Preliminary data demonstrates high levels of "buy-in" among ED stakeholders. Further, we obtained informal feedback from ED stakeholders (nurses, physicians, leadership, patients/caregivers), which revealed that participation in the ED-DDP was of high priority, acceptable, and feasible. The program was refined to be low burden to staff through tactics such as nurse training occurring during work hours, ability to implement training without additional resources, and strong hospital leadership support.

The three participating Emergency Departments were chosen based on stakeholder commitment to the program as well as setting, patient diversity, and participation in national collaboratives (e.g., Geriatric ED Collaborative). The first ED is located in the most diverse urban county in the country (Long Island Jewish Forest Health) within a 312-bed hospital; the second ED is located in a highly diverse region in NY within a 284-bed hospital (South Shore University Hospital); and the third ED is located in a suburban area of NY, within a larger 371-bed hospital, and serves as the primary site of co-I Dr. Barnaby (Huntington Hospital). These 3 ED sites have between 50-60 full-time nurses and 2019 (pre-COVID) annual volumes of 14,051, 16,917, and 17,333, respectively.

All individuals on the study team will be required to attend weekly meetings with the PI to discuss the study protocol, timelines, and issues as they come up in real-time.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

In Aim 1, site champions will be identified by emergency department leadership at Long Island Jewish Forest Hills, Huntington Hospital, and South Shore University Hospital or they will self-identify by expressing interest to their ED leadership. Once identified, the study team will contact the potential participant to confirm

their eligibility and interest in volunteering as a site champion. Although leadership will identify champions who qualify for participation, there will be no requirement by ED leadership to participate. The voluntariness of participation will be made clear during the recruitment process.

For Aim 2, training logs from Aim 1 will be used to contact ED staff trained by champions to invite them to participate in semi-structured interviews during the intervention period. The study team will also invite trained champions to participate in these interviews.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Aim 1 (ED-DDP Champions)

Inclusion Criteria

- Nurse educators, managers or bedside nurses self-identified or recommended by ED leadership to volunteer as a program site champion
- Primarily working at Long Island Jewish Forest Hills, Huntington Hospital, or South Shore University Hospital
- Commitment to program participation

Exclusion Criteria

- Unable to meet program requirements, including attending champion workshop, agreement to observation and training via telehealth, and commitment to train department staff
- Does not primarily work in the emergency department

Aim 2 (Participant Interviews)

Inclusion Criteria

- Champion trained through the ED-DDP program or
- Staff member trained by ED-DDP Champion
- Currently working at Long Island Jewish Forest Hills, Huntington Hospital, or South Shore University Hospital

Exclusion Criteria

- Does not primarily work in Emergency Department

Eligibility for Chart Review

- Aged 65 years or older
- Presenting to a participating study site ED during control or intervention periods
- Survival to ED discharge or to hospital admission

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

This study will enroll at least 5 and up to 10 clinical staff Champions at each of 3 Northwell ED sites (up to N=30 total). During Aim 2, the study team will conduct 5-10 interviews of a mixed sample of champions and champion-trained nurses until saturation is reached at each site (approximately N=15, or until saturation, no more than N=30).

For the primary outcome of delirium detection: Every three months, with the exception of when a site is in their implementation period, we will randomly select 250 patients per participating ED for chart review, totaling N=1,000 patients per ED ant N=3,000 patients overall. Thus, chart reviews will take place during control periods and intervention periods only. No patient data will be collected during implementation periods.

For the secondary outcomes of delirium screening and management strategies, we will include all charts of all older adults (greater than 65 years of age) presenting to the ED to survive to hospital admission or ED discharge (in both control and intervention periods) in analysis.

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

Aim 1

Retrospective in-depth chart reviews will be conducted during the control period which will occur prior to implementation at each site. The implementation period will take place in a 3-month period at each ED site. During the implementation

period, participant Champions will be asked to attend a one-day workshop and participate in two 15-minute tele-training and one 15-minute Champion-nurse observation sessions with a study investigator during their normal work hours. These activities will take approximately 1 month to complete. Participant Champions will also be asked to train all additional unit staff via additional 15-minute training refreshers on standard of care practice.

Aim 2
Semi-structured participant interviews will last approximately 30-minutes.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

The primary endpoint will be delirium detection, calculated by proportion of positive bCAM documentation among those with delirium via validated chart review.

Secondary endpoints will be delirium screening (proportion of older adults with bCAM documentation among eligible older adults) and ED delirium mitigation and management strategies (proportion of eligible patients who receive safety precautions [fall, aspiration, or wandering], and proportion of eligible patients who receive physical and chemical restraints (benzodiazepines, antipsychotics, diphenhydramine) for behavioral symptoms.

11. RESEARCH PROCEDURES

1. *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
2. *Include any screening procedures for eligibility and/or baseline diagnostic tests*
3. *Include procedures being performed to monitor subjects for safety or minimize risks*
4. *Include information about drug washout periods*
5. *If drugs or biologics are being administered provide information on dosing and route of administration*
6. *Clearly indicate which procedures are only being conducted for research purposes.*

- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

Aim 1: Conduct a pilot stepped-wedge cluster randomized trial (SW-CRT) across 3 ED sites to determine the preliminary efficacy of the ED-DDP for improving delirium screening, detection, and management in older adults presenting to the ED.

The study has identified 3 sites with strong commitment from emergency department leadership at Long Island Jewish Forest Hills, Huntington Hospital, and South Shore University Hospital to participate in study activities.

Control Period

- All nurses working in the emergency department receive a 20-minute ilearn training module on an integrated electronic health record (EHR) delirium screening tool (bCAM) as part of their standard job preparedness training. The study will begin by assessing baseline adherence to standard of care screening and associated outcomes for all three sites. During the control period, trained study staff members will conduct retrospective in-depth chart reviews to assess presence of delirium in eligible patients with visit records at each participating site, as well as any corresponding delirium documentation, including the bCAM and delirium mitigation and management strategies employed during the patient's ED visit. These chart reviews will take place every 3 months a site is in the control period, and will assess 250 randomly-selected charts that meet eligibility requirements for delirium screening. Charts will be pulled based on dates the participating site is within their control period. Eligible patients are defined as those aged 65 years or older, presenting to a participating study site ED who survive to ED discharge or to hospital admission.

Eligible patient data will be collected using a HIPAA-compliant REDCap database. Data collected include:

- Total number of adults aged 65 and older presenting to the ED site
- Total number of eligible older adults presenting to the ED site
- Eligible patient demographics:
    - Age
    - Gender
    - Race
    - Ethnicity
- Eligible patient clinical presence:
    - Baseline function
    - Chronic conditions (based on Charlson Comorbidity Index)
    - Severity of acute illness (based on Modified Early Warning System (MEWS)
- Eligible patient dementia-related documentation
    - Presence of dementia
    - All bCAM documentation, and corresponding result (positive, negative, unable to assess)
    - ED delirium safety strategies (e.g. orders for fall, aspiration, or wandering safety precautions)
    - ED management of behavioral symptoms associated with delirium (e.g. orders for benzodiazepines, antipsychotics, diphenhydramine, or restraints)
- Proportion of nurses that screen eligible patients

Two delirium experts (Dr. Sinvani and Dr. Makhnevich) will perform chart checks and adjudicate any uncertain cases.

In conjunction with the 3-month retrospective chart review (control period), the study team will begin implementing the ED-DDP program one site at a time in a stepped-wedge cluster randomized trial design (Table 1). Every 3 months, the study team will implement the ED-DDP program at one new site until all 3 sites have received the intervention. ED sites will remain in the control period and have their data retrospectively reviewed until they enter the implementation period.

Table 1. Stepped Wedge Cluster Randomized Trial (SW-CRT) Design

ED Site Crossover Sequence	Period 1 (3 months)	Period 2 (3 months)	Period 3 (3 months)	Period 4 (3 months)	Period 5 (3 months)
A	Control	*Implementation	Intervention	Intervention	Intervention
B	Control	Control	*Implementation	Intervention	Intervention
C	Control	Control	Control	*Implementation	Intervention
*No chart review will occur during Implementation Periods					

Implementation Period

The implementation period will last three months for each site and consist of three parts. No chart review will occur during a site's implementation period.

1. **Delirium Champion Workshop:**
   ED leadership at each site will identify 5-10 champions, consisting of nurse educators, managers, or bedside nurses to participate in a one-day train-the-trainer workshop. ED leadership will be instructed to select champions based on their interest in delirium and their commitment to participate in the program. The workshop will include additional education regarding the presence and clinical significance of delirium and a review of the appropriate use of the bCAM screening tool, delivered via patient testimonials, small group discussions, delirium and screening tool use (didactics) and role-playing.

2. **Real-time direct observation/training:**
   Following workshop participation, all champions will receive 3 tele-training sessions. The first 2 tele-training sessions will provide direct observation and feedback from one of the co-investigators while the champion performs a bedside delirium screen. The final tele-training session will consist of direct observation and feedback of the champion by one of the co-investigators while the champion is providing training to a nurse. During each training session, Drs. Sinvani and Makhnevich will use a validated Spot Check Form to determine baseline delirium screening activities before training takes place.

3. **Training of nurses by champions:**

Upon successful completion of the Delirium Champion Workshop and 3 tele-training sessions, champions will be asked to provide bedside delirium trainings for all ED nurses at their site. Champions will be provided with training logs and asked to submit completed logs to the study team.

Intervention Period

During the intervention period, ED nurses will be assessed for their use of the bCAM delirium screening tool during their initial assessment of all older adults presenting to the ED. At the beginning of the intervention period, Drs. Sinvani and Makhnevich will observe a random sample of nurses (N=30, 10 at each ED site) performing a delirium screening using validated Spot Check Form to determine baseline delirium screening activities post-implementation period.

Trained study staff will conduct retrospective in-depth chart reviews to assess presence of delirium in each site and any corresponding delirium documentation, including the bCAM and delirium mitigation and management strategies employed. These chart reviews will take place every 3 months a site is in the intervention period, and will assess 250 randomly-selected charts that meet eligibility requirements for delirium screening. Charts will be pulled based on dates the participating site is within their intervention period. Eligible patients are defined as those aged 65 years or older, presenting to a participating study site ED who survive to ED discharge or to hospital admission.

All data will be collected using a HIPAA-compliant REDCap database:

- Total number of eligible older adults presenting to the ED
- Eligible patient demographics:
    - Age
    - Gender
    - Race
    - Ethnicity
- Eligible patient clinical presence:
    - Baseline function
    - Chronic conditions (based on Charlson Comorbidity Index)
    - Severity of acute illness (based on Modified Early Warning System (MEWS)
- Eligible patient dementia-related documentation
    - Presence of dementia
    - All bCAM documentation, and corresponding result (positive, negative, unable to assess)
    - ED delirium safety strategies (e.g. orders for fall, aspiration, or wandering safety precautions)
    - ED management of behavioral symptoms associated with delirium (e.g. orders for benzodiazepines, antipsychotics, diphenhydramine, or restraints)

As in the control period, two delirium experts (Dr. Sinvani and Dr. Makhnevich) will perform chart checks and adjudicate any uncertain cases.

Aim 2: Use a mixed methods approach to conduct implementation outcome assessments of the ED-DDP for champions and nurses

Aim 2 will gather quantitative and qualitative data collected during implementation and intervention periods to assess and explain the reach, efficacy, adoption, implementation, and plan for maintenance using the RE-AIM framework.

Data assessed from the implementation period include training logs to determine proportion of champions who complete training, proportion of nurses who are trained by a champion, proportion of training components adhered, time required to train champions and nurses, and proportion of nurses who scored at least 80% accuracy on bCAM use during the tele-observation sessions in Aim 1.

Data assessed from the intervention period include all data derived from the retrospective chart review, including proportion of nurses who screen eligible patients.

In addition to assessing data collected during Aim 1, the study will incorporate semi-structured interviews in Aim 2 to provide additional context to reach, adoption, and implementation of the ED-DDP program and to help plan for program maintenance. The study team will conduct 6-9 interviews of a mixed sample of champions and champion-trained nurses until saturation is reached at each site (minimum of N=18, up to N=30). Interviews will be 30-minutes in length and will be scheduled by a research coordinator at a mutually beneficial time for the participant and study team member. All interviews will be recorded and transcribed before being analyzed with NVivo software. Interview participants will receive $50 compensation for their time via ClinCard mailed to an address they provide the study team.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

The primary objective will be to assess the preliminary efficacy of the ED-DDP and to estimate the effect size and intraclass correlation coefficient (ICC) information needed for a future full-scale SW-CRT. ICC is critical to capture because as ICC increases, the design effect (and hence the sample size needed) decreases. Currently no known estimate of the ICC exists, so it is important to conduct this preliminary trial to obtain a rough estimate of the ICC.

Primary Outcome: Delirium detection defined as the proportion of positive delirium screens (positive bCAM documentation), among those with delirium (based on validated chart review).

Secondary outcomes:

- Delirium screening, defined as proportion of eligible patients (65+, presenting to the ED) screened for delirium (EHR bCAM documentation)
- ED delirium mitigation and management strategies:
    - Proportion of older adults with any order for safety precautions (fall, aspiration, or wandering)
    - Proportion of older adults receiving benzodiazepines, antipsychotics, diphenhydramine, or restraints for behavioral symptoms.

Primary and secondary outcomes will be assessed at study completion.

Analysis of the outcome delirium detection will be conducted solely to calculate estimates needed to complete a sample size calculation for a subsequent full-scale SW-CRT. Effect size and intraclass correlation coefficient (ICC) estimates obtained will be used to compute the sample size needed for a full-scale SW-CRT using methodology outlined by Hemming and Taljaard, 2016. ICC is critical to capture because as ICC increases, the design effect (and hence the sample size needed) decreases (Woertman, 2013). There is currently no known estimate of the ICC so it is important to run this preliminary trial to obtain a rough estimate of what the ICC will be.

Analysis of delirium detection will be based on the proportion of patients with documented delirium in their chart among those with who truly had delirium. True cases of delirium will be identified retrospectively by expert chart review using a standardized protocol. This is essentially the sensitivity of delirium detection. Analysis of delirium detection will be conducted on patients with true delirium among a randomly sampled population of 3000 patients (1000 patients per ED or 250 patients per ED per data collection period), see sample size considerations below.

To estimate the intervention effect, we will use a generalized linear mixed effect model (GLMM) to account for the hierarchical structure of the data (patients nested within EDs) using PROC GLIMMIX in SAS Studio version 3.8. GLMMs are an extension of linear mixed models and will be used to allow for the binary primary outcome. For GLMM, we define a basic model as: $gg(pp) = XXkkkk\theta\theta + aakk + \beta\beta kk + eeiiiiii$, where pp represents the probability of $YYiiiiii$ taking on the value of 1, and $YYiiiiii$ is an indicator variable of the response from individual ii in cluster kk at time period tt (1=delirium detected, 0=delirium not detected) $XXkkkk$ is an indicator variable of the intervention assignment of cluster kk at time period tt (1=intervention, 0=control). $\theta\theta$ represents the fixed effect for the

intervention, $aakk$ represents the random effect for cluster kk, $\beta\beta tt$ represents the random effect for time period tt, and $eeiiiiii$ represents within-cluster error. The GLMM will use a logit as the link function, represented by gg. Estimates obtained will be used to compute the sample size needed for a full-scale SW-CRT.

Exploratory moderator and mediator analyses will be conducted. Moderator analyses will explore if patient characteristics, specifically age, Modified Early Warning System (MEWS) score, and presence of dementia, moderate the intervention effect (i.e., there is a differential effect of the intervention on delirium detection based on the value of the moderator). In the GLMM model, separate interaction terms of the intervention group and age, MEWS score, and presence of dementia will be added. Any interaction term that is statistically significant ($p<0.05$) will be included in the final model so that independent effects of the intervention and corresponding moderators can be determined. Mediator analyses will explore if implementation outcomes (see Aim 2), specifically the proportion of nurses who complete at least 1 training session with a champion, the proportion of nurses who score at least 80% on bCAM accuracy, and the proportion of nurses who screen 80% of eligible patients, mediate the intervention effect (i.e., are on the causal pathway between the intervention and delirium detection). Each potential mediator will be assessed as a continuous variable at the ED level. Mediator analyses will be carried out by assessing the difference between the direct effect of the intervention in a model with vs. without the mediator. The significance of the mediated effect will be tested via bootstrapping. Mediators will first be tested separately, and mediators found to be significant will be included in the final model. Exploratory analyses will also adjust for the following covariates: gender, race, marital status, baseline function, and chronic conditions (CCI).

Sample size considerations (Aim 1):
We will randomly select 250 patients per ED per each of the 4 periods of data collection per cluster. This equates to 1000 patients per ED or 3000 patients overall and is a feasible number of medical charts for the expert chart reviewer to abstract and review. Additionally, based on 2019 data, the smallest estimated available sample size of eligible subjects (aged 65 years and older presenting to the ED) per ED per period is >14,000, indicating that this is an achievable number of patients for each ED. If 3000 patients total are included, we conservatively estimate that 300 true cases of delirium will be detected, assuming that the prevalence of delirium is 10%. We expect the sensitivity of delirium detection to be 80%, where the precision of the 95% CI will be approximately ± 5% with a sample size of 300. Table 2 shows precision of estimation for delirium detection sensitivities of 50%, 65%, and 80%.

Table 2. Precision of Estimation for Delirium Detection

Sample Size with True Delirium	Sensitivity of Delirium Detection	Precision of the 95% CI
300	50%	±5.66%
300	65%	±5.40%

300	80%	±4.53%

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

N/A

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

The researchers take the issue of privacy very seriously. Study information will be stored in a Northwell-approved database drive to store PHI (e.g. SharePoint and REDCap), and it will only be accessible to research staff listed on the approved IRB protocol. Names or other identifying information will not be shared with those outside the research team, except for the purposes of sending research communications. Phone numbers and email will only be used for study-related communications. Any phone calls or emails will be sent to participants through the respective study site's secured server and calls made at each study location in a secured area. Along with the organizational administrative, technical and physical safeguards and IRB approved measures, data privacy and security procedures will include: (1) training staff on data sensitivity and protocols for safeguarding confidentiality; (2) scanning any potential hardcopy (e.g. training logs) with PHI into an approved electronic database (i.e. SharePoint) (3) shredding hardcopies once scanned into the secure electronic database;

(4) Destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed (Disposal Policy for Protected Health and Confidential Health System Information – policy no 800.47);
(5) capturing and storing assessments in REDCap, a secure web-based HIPAA compliant application designed to support data capture for research studies; and
(6) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

This research is funded by the NIH, thus a Certificate of Confidentiality has been issued for this research. Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

On June 17, 2021 NIA released NOT-AG-21-029: NIA Announces New Policy and Procedures for the Reporting of Human Subject Enrollment Data for NIA Clinical Research Trials/Studies. The new policy applies to all NIA grants, contracts, and cooperative agreements that are active as of July 1, 2021 and support human subjects research as defined by the National Institutes of Health (NIH). In addition to NIH reporting requirements for study enrollment, NIA investigators will be required, on a monthly basis, to electronically submit participant enrollment data into the secure NIA Clinical Research Operations & Management System (CROMS) for all human subjects enrolled in their trials/studies. This information will be provided for Nurse Champions and interview participants ONLY. Enrollment information about individuals whose charts are reviewed for this research will NOT be transferred to NIA/NIH.

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

Part I – this part should be completed for all studies that require a DSMP.
Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*
- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

The Principal Investigator, Co-Investigators, and research team members will be responsible for monitoring the scientific integrity and data safety for the full duration of the study. They will meet on a weekly basis to discuss the progress of the study.

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

Oversight Responsibilities:
The PI will be responsible for ensuring participants' safety on a daily basis. Study procedures involve record reviewing, delirium training, observation of training and screening and interviews. The PI will supervise the research, ensure that each individual engaged in research is qualified to do so by virtue of education, training and experience to perform the delegated task. She will protect the rights, safety and welfare of participants by ensuring that the research is conducted in accordance with all federal regulatory requirements, state law, and Northwell Health policies (including IRB SOPs), and is conducted in accordance with the IRB-approved plan, and ensure the accuracy, security and integrity of the research data and data analysis.

Monitoring Responsibilities:

- Study data are accessible at all times for review by the PI and named co-investigators. The PI and study team will meet weekly. Reportable events (unanticipated problems, deviations, violations, etc.) will be reviewed by the PI in real-time and reported to the IRB in a timely manner and in accordance with Northwell IRB Policy.

Should an unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk, the event will be reported in a timely manner but not more than five (5) working days after discovery by the PI.

The PI, as well as the IRB and other oversight committees, have the authority to stop or suspend the study or require modifications.

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Should a participant choose to withdraw from research, they will be instructed to email the study team to withdraw. Participants will be contacted by a member of the research team confirming their study withdrawal, and to answer any questions they may have. All data up until the receipt date of the email will be included in the research study.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to results*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

We do not expect any adverse events directly attributable from this study. Delirium screening is a standard of care and should be performed on all older adults presenting to the ED. The training is meant to improve accurate delirium screening. The outcomes (delirium detection, screening rates, and management) of this study will be obtained retrospectively through EHR data and a chart review process. The research poses no more than minimal risk to subjects.

The primary potential risk of this study is loss of confidentiality. Measures to mitigate risks to loss of confidentiality are detailed in Section 14 “Data Management and Confidentiality” above.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

Research-related injuries are not expected for this no greater than minimal risk project. .

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

This research is designed to determine the preliminary efficacy of the proposed ED-DDP for improving ED delirium screening, detection, and management in older adults, as well as to evaluate outcomes for champions/nurses. Although there will be no direct benefit to research participants, their contributions to this study will inform a full-scale SW-CRT to evaluate the impact of ED-DDP on patient outcomes, and will eventually scale to a comprehensive program to improve delirium management and outcomes in the emergency department.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

The study will be introduced by a study team member after individuals first self-identifies as interested in participating as a champion to ED leadership, and/or after ED leadership first solicits interest in participation. Participants will be encouraged to ask questions at any time during the research. Should questions arise, research personnel will ensure that the individual is in a private location for open conversation to protect the privacy interests of the individual. All study-related

communications will be delivered via a secure, Northwell email or via the Northwell approved e-platform.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

This research study is funded by the National Institutes for Health (NIH). All study related equipment, services will be provided to participants at no cost. Patient insurance will not be billed.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

Those participants who successfully complete 30-minute semi-structured interviews in Aim 2 will be provided a $50 ClinCard.

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*
- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

Aim 1
Participant champions will receive an information sheet describing their involvement in research prior to attending the one-day training workshop. The information sheet will be delivered electronically via REDCap, a web-based platform capable of recording electronic signature. The information sheet will contain all of the elements required by applicable federal regulation for the protection of human subjects, and will begin with a concise and focused presentation of the key information that is most likely to assist participants in understanding the reasons why he/she might or might not want to participate in the research. Included in the electronic information sheet will be contact information to reach a consenting coordinator to answer any questions a potential participant may have before continuing with the research. Both the research phone and email inbox will be monitored daily by consenting coordinators.

This study does not propose to collect information about the patient receiving the delirium screen at bedside for any of the tele-training sessions. As such, we do not consider the patient a secondary subject. Patients will be informed in advance that the Champion and trainee will be observed as part of the training program; any patient who expresses concern with observation will still have the delirium screen administered as part of the program, but their Champion and Nurse Trainee will not be observed.

Aim 2
Participant champions and trained nurses invited to take part in a semi-structured interviews during the intervention period will also receive an information sheet describing their involvement in research. Similar to the information sheet given to champions before the training workshop, the information sheet will be delivered electronically via REDCap and will contain contact information to reach a consenting coordinator to answer any question a potential participant may have before continuing with the interview.

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*

- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.*

N/A

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

The study is committed to enrolling a racially and ethnically diverse population. Given that the study is focusing on recruitment of Northwell employees, we anticipate that most employee participants will have the competency to comprehend study materials produced in the English

language at a 6th grade level, particularly when explained by trained clinical research coordinators.

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS ☐ N/A

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *Explain why it is not possible to conduct this research without using the information or biospecimens in an identifiable form*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

We request a waiver of consent under 45 CFR 46.116 for record review to establish the control cohort and to assess the training program. Record review procedures involve no more than minimal risk to participants and the waiver will not adversely affect their rights or welfare. The primary risk of record review is loss of confidentiality; we have mitigated this loss by establishing sound data protection procedures to maintain privacy and confidentiality. We propose to review 3,000 records. As such, it would not be practicable to perform the record review, as it has been defined in this study, if consent was required for these reviews which use identifiable private information.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

We are requesting a waiver of documentation of consent. We will provide an information sheet to participants that explains the training program and procedures, and document verbal agreement to proceed given the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

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25. WAIVER OF HIPAA AUTHORIZATION ☐ N/A

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

We request a waiver of authorization for record review during both Aims. The description of the PHI for which use or access is requested is as follows: • Eligible patient age (if over 89 years of age) • Medical record number or encounter number • Location of service • Elements of date of related admission, encounters, orders, and discharge, including, but not limited to:

Collection of this information is necessary to establish our control cohort and assess the training program. The use of this protected health information involves no more than a minimal risk to the privacy of individuals, based on our adequate plan to protect the identifiers from improper use and disclosure as described above.

The health information collected for the described purpose will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study. The research could not practicably be conducted without the waiver or alteration. In addition, the research could not practicably be conducted without access to and use of the protected health information.

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*
- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☒ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☐ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

This study will recruit eligible employees of the health system to participate in an ED-DDP program aimed to increase delirium screening and improve patient outcomes.

Individuals with a supervisory relationship over an employee will not enroll any individual who reports to them in this study. Employee participation or non-participation in this study will have no bearing on an individual's position at Northwell Health. The voluntariness of participation will be made prominent during the recruitment process.

We are not intentionally targeting minorities, but expect minorities to be part of those eligible for participation.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

N/A

28. REFERENCES/BIBLIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.