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Northwell Health

RESEARCH PROTOCOL

Protocol Title:	Nudging Provider Adoption of Clinical Decision Support
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IRB Number:	18-0714

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:
  - Your study involves an FDA regulated product. In this case, use the *Clinical Trial Protocol Template.*
  - Your study has a protocol from a sponsor or cooperative group. In this case, use the *Protocol Plus*.
  - Your study is a registry or repository for data and/or samples, In this case, use *Protocol Template – Registry Studies.* .
- If a section of this protocol is not applicable, please indicate such.
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- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title as listed on the application.
  - Investigator: include the principal investigator's name as listed on the application form
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
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↓ Continue to next page to begin entering information about this study ↓

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*

United States citizens receive only half of recommended medical care[1] and a third of the care received is unnecessary[2]. The disparity between usual and evidence based clinical practice is responsible for a third of hospital deaths[3] and waste estimated at 380 billion dollars each year[4]. Computerized clinical decision support (**CDS**) attempts to close the gap by bringing meaningful and relevant evidence to health care providers at the point of decision making. Providers, policymakers, experts and consumers have identified these as key tools to revolutionize health care.[5-7] However, the moderate improvements in care seen with CDS [8-14] have been significantly limited by consistently low provider adoption, estimated at 10% [15,16]. Thus, there is a critical need to identify strategies to increase provider adoption of CDS.

The central hypothesis of this proposal is that the addition of a theory-informed "nudge" to a CDS tool will address identified behavioral barriers to use and significantly improve adoption by providers. Nudges are applications of behavioral science, defined as positive reinforcement and indirect suggestions that have a non-forced effect on decision making[17]. For example, default options for organ donation consent lead to striking differences in enrollment.[18] Previous studies on the impact of nudges on provider behavior have demonstrated exceptional results (i.e. decreased inappropriate antibiotic prescribing from 20% to 4%[19]) but have not examined their impact on provider adoption of CDS. We propose to use a behavioral theory-informed process to develop a new CDS tool that includes a nudge that addresses barriers to adoption.

We designed a CDS tool (**PE CALC**) to reduce unnecessary computed tomography pulmonary angiography (**CTPA**) testing for pulmonary embolus (**PE**) that is efficacious (37% reduction among tool adopters) when used. However, its overall impact is limited by low provider adoption (15%). Users identified low *social opportunity* ["my colleagues don't use the tool"], *reflective motivation* ["good

doctors don't need the tool"], *automatic motivation* ["the tool annoys me"] and *psychological capability* ["too many alerts to address"] as primary barriers to adoption on a survey based on the Capability Opportunity Motivation Behavior (**COM-B**) model [*specifies that changing behavior requires changing capability, opportunity and/or motivation*][20]. We have identified nudges to address each of these barriers. The overall objective of this training application is to develop and evaluate the feasibility and preliminary efficacy on provider adoption of adding a behavioral theory-informed nudge to PE CALC. By conducting interviews with ED providers, we will develop a prototype of a new tool, "PERK", which will include nudges to PE CALC. We will then perform "Think Aloud" and "Near Live" usability testing. Based on the results of these tests, we will develop PERK and test it in a six month pilot trial in the Emergency Departments (ED) at North Shore University Hospital (NSUH) and Long Island Jewish Medical Center (LIJMC). Our studies will provide us with information about the feasibility, acceptability, and preliminary efficacy of "PERK", as well as broader knowledge of the impact of including nudges in CDS tools to increase provider adoption and decrease unnecessary patient testing.

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*

Clinical decision support (CDS) has been shown to improve quality of care. Meta-analyses of the effect of CDS have shown that providers who use decision support are more likely to order appropriate treatments and provide preventive care services.[8,21-23] Extensive study of these tools has shown a morbidity decrease of 10 to 18%, placing CDS at the top of the spectrum of quality improvement interventions.[24] The expectation of CDS to improve the practice of medicine was communicated with the unprecedented federal resources ($30 billion) committed to supporting the use of EHRs through the HITECH Act of 2009, where "meaningful use" requirements demand the use of CDS.[25] These tools have great potential to improve quality ofcare.

In spite of the clear benefits of using CDS, meta-analyses have found provider adoption of these tools to be low[26] with up to 96% of CDS being overridden[27]. There is clear evidence of providers not using well thought out CDS, undermining potential clinical impact.[28] A systematic review of randomized controlled trials of CDS impact, found four system features to be independently predictive of successful clinical practice improvement.[29] Each of these factors improve provider

adoption (automatic triggering, including specific recommendations, workflow integration and computer based support). Improving provider adoption of CDS can help these tools reach their potential to improve quality ofcare.

One potential method for increasing provider adoption is through the inclusion of nudges. Nudges are defined as positive reinforcement and indirect suggestions that have a non-forced effect on decision making[17]. Recent studies have shown that nudges can be effective in influencing provider decision making. For example, a recent large randomized controlled trial evaluating behavioral interventions found a social comparison "nudge" decreased provider antibiotic prescribing for upper respiratory infections from 19.9% to 3.7%.[19] These results were durable at 3 months.[31] Another study used a simple poster with the clinicians signature committing to antibiotic stewardship to decrease inappropriate antibiotic prescribing by 20% relative to control.[30] Even simply changing the grouping of treatment options has demonstrated the ability to significantly impact provider behavior.[32]

In our study, we will assess the impact of adding nudges to an existing CDS tool on efficacy provider adoption. We previously developed a tool, PE CALC, to reduce unnecessary imaging in the diagnosis of pulmonary embolism (PE) in the emergency department (ED). One common test for PE, computerized tomography pulmonary angiography (**CTPA**), is sensitive and specific for PE; however, it is associated with a median of 10 mSV of radiation, the equivalent of 137 chest x rays.[33] A recent study including 2.5 million Medicare emergency visits found utilization to have increased fivefold between 2000 and 2009 with diagnostic yield declining.[34] It is now thought that 1.5% to 2% of all future cancers in the United States may be the result of medical radiation.[35] Surveyed emergency providers said that about a fifth of all imaging studies ordered are medically unnecessary,[36] with factors including fear of missing a low-probability diagnosis and fear of litigation. Clinical prediction rules address these concerns. Clinical prediction rules are validated tools that quantify the contributions the history, physical and laboratory results make towards a diagnosis, prognosis or treatment response.[37] They classify patients into low, intermediate and high probability of PE based on key elements of the history and physical exam, establishing pre-test probability before imaging.

Each CTPA carries a 14% risk of contrast induced nephropathy[38] and a lifetime malignancy risk that can be as high as 2.76%[39]. Incidental findings requiring diagnostic follow up are found in 24% of tests, increasing both costs and harms from repeat imaging.[40] The use of clinical prediction rules to assess pre-test probability before CTPA reduces testing by 25% without any missed PEs.[41,42] Their routine use by providers would result in 600,000 fewer scans, 84,000 fewer cases of contrast induced nephropathy and prevent 3,000 malignancies as well as 2,000 cancer deaths in the United States every year[39].

We based PE CALC on provider preferences, using a well-validated clinical prediction rule perceived as "most useful" by providers surveyed at Northwell Health (the Well's Score for PE). We implemented this tool in the EDs of NSUH and LIJMC and found that the tool was efficacious when used, with an increase in CTPA yield from 8% to 12% (a 37% reduction in unnecessary CTPAs) among adopters. However, it did not increase CTPA yield for the ED as a whole, as it was only used by 15% of providers. The goal of this study is to add nudges to PE CALC to develop a new tool, which we will call Pulmonary Embolism Risk Kalculator, or PERK. To our knowledge, our study will be the first to use behavioral theory to illuminate the impact of nudges on provider adoption of CDS. We hope that the results of our study will include not only a new CDS tool with higher adoption rate and efficacy than our previous PE CALC, but also new insight into the effects of nudges on provider adoption of CDS tools.

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 central hypothesis of this proposal is that the addition of a theory-informed "nudge" to a CDS tool will address identified behavioral barriers to use and significantly improve adoption by providers. Nudges are applications of behavioral science, defined as positive reinforcement and indirect suggestions that have a non-forced effect on decision making. For example, default options for organ donation consent lead to striking differences in enrollment.[18] Previous studies on the impact of nudges on provider behavior have demonstrated exceptional results (i.e. decreased inappropriate antibiotic prescribing from 20% to 4%[19]) but have not examined their impact on provider adoption of CDS. We propose to use a behavioral theory-informed process to develop a new CDS tool that includes a nudge that addresses barriers to adoption.

We designed a CDS tool (**PE CALC**) to reduce unnecessary computed tomography pulmonary angiography (**CTPA**) testing for pulmonary embolus (**PE**) that is efficacious (37% reduction among tool adopters) when used. However, its overall impact is limited by low provider adoption (15%). Users identified low *social opportunity* ["my colleagues don't use the tool"], *reflective motivation* ["good doctors don't need the tool"], *automatic motivation* ["the tool annoys me"] and *psychological capability* ["too many alerts to address"] as primary barriers to adoption on a survey based on the Capability Opportunity Motivation Behavior (**COM-B**) model [*specifies that changing behavior requires changing capability, opportunity and/or motivation*][20]. We have identified nudges to address each of these barriers. The overall objective of this training application is to develop and

evaluate the feasibility and preliminary efficacy on provider adoption of adding a behavioral theory-informed nudge to PE CALC. We will address this with the following Specific Aims:

AIM 1: To develop nudges designed to address identified behavioral barriers to adoption. We will create four nudges designed to address four identified barriers of tool use, using on our survey results and COM-B as a framework.

AIM 2: To conduct iterative usability testing on an evolving prototype of a new tool, "PERK". This will involve both qualitative and quantitative assessments of ease of use of "PERK". We will perform "think aloud" and "near live" testing to develop a prototype that will be revised and evaluated.

AIM 3: To evaluate the feasibility, acceptability and preliminary efficacy on provider adoption of a new tool compared to the current tool, in a pilot trial. We will conduct a 6 month pre-post analysis of "PERK" by comparing it to retrospective data from the first 6 months of PE CALC. Our primary feasibility outcome is post-pilot provider satisfaction. Secondary outcomes include stakeholder acceptability. ***H1:*** *PERK will demonstrate higher rates of provider satisfaction as compared to PE CALC.* Our primary efficacy outcome is increased provider adoption. Secondary outcomes include increased CTPA yield [*% of positive tests*], and decreased CTPA ordering. ***H2:*** *"PERK" will demonstrate higher provider adoption as compared to PE CALC.*

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 will collect data from the Emergency Departments (ED) of both North Shore University Hospital (NSUH) and Long Island Jewish Medical Center (LIJMC). Eligible participants for all three aims will be medical doctors and physician assistants working full time in either of these Emergency Departments (86 eligible at NSUH; 63 eligible at LIJMC). We will recruit from within this pool for AIM 1 and AIM 2. For AIM 3, all eligible providers will be automatically enrolled, as we will be collecting data from the EHR regarding the use of PERK.

All persons assisting with the trial will review the research protocol and be informed of their specific duties prior to the commencement of any research activities. We will also hold a study launch meeting for all involved in the research.

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*

Eligible subjects for all three aims of this study will be medical doctors and physician assistants working full time at NSUH or LIJMC. This includes residents in the Emergency Medicine/Internal Medicine program.

For AIM 1, potential subjects will be identified using the Electronic Medical Records (EMR) based on PE CALC use. We will contact participants via our secure email system. We will inform participants about the study, offering a $50 reimbursement for their time.

In addition, we will contact department heads at NSUH and LIJMC, as well as administrators, attendings, chief residents, administrative residents, and head PAs, and request names of potential participants for Aims 1 and 2. We will email the identified providers, mentioning the person who recommended that they might be interested in participating, and asking if they would like to participate in our study. Alternatively, we will ask department heads, administrators, or other faculty or staff to email potential participants and inform them of our study. We may also present our study at ED faculty meetings and/or resident meetings to raise awareness of our study. Alternatively, we will ask department heads, administrators, or other faculty or staff to present our study in information sessions to promote participation.

For AIM 2, eligibility and recruitment methods will be the same as for AIM 1, as indicated in the previous paragraph. We will contact participants using the health system email. We may also ask department heads, administrators, or other faculty or staff to distribute and/or display flyers to promote our study. The flyer may also be distributed through the physician Teams chat. We will inform potential participants and solicit interest, offering a $50 reimbursement for their time. There may be one follow-up phone call.

For AIM 3, full time ED providers will be eligible. We will conduct a pilot trial of PERK among 150 Emergency Medicine providers at NSUH and LIJMC. We expect 150 providers who meet the inclusion criteria to be in each of the pre- and post-groups.

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.*

Eligible subjects for all three aims of this study will be medical doctors and physician assistants working full time at NSUH or LIJMC. Participants will not be excluded by gender, race, or ethnicity. The providers in this study are expected to reflect the gender and racial/ethnic composition of the Emergency Department providers at North Shore University Hospital (NSUH) and Long Island Jewish Medical Center (LIJMC), who are approximately 35% women, 55% non-Hispanic White, 32% Asian, 6% Hispanic/Latino (of any race), 3% Black, and 4% multiracial/other. As this study focuses on adult medical providers, children will not be included. We anticipate adult participants age 25-70.

For AIM 1, we expect to recruit 12 participants to complete semi-structured interviews; however, we will recruit until thematic saturation is achieved.

For AIM 2, we expect to recruit 10 participants (5 for "Think Aloud" testing; 5 for "Near Live" testing); however, we will recruit until thematic saturation is achieved.

For AIM 3, we expect to include 150 providers who meet the inclusion criteria in the prospective cohort pilot study, and 150 in the retrospective cohort control group.

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*

For AIM 1, we expect to recruit 12 participants to complete semi-structured interviews; however, we will recruit until thematic saturation is achieved.

For AIM 2, we expect to recruit 10 participants (5 for "think aloud" testing; 5 for "near live" testing); however, we will recruit until thematic saturation is achieved.

For AIM 3, we expect to include 150 providers who meet the inclusion criteria in the prospective cohort pilot study, and 150 in the retrospective cohort control group.

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*

Enrollment will occur on a rolling basis throughout the testing period for AIM 1. Interviews for AIM 1 will take place during the first six months of Year 1, beginning in January 2019. Each participant will be interviewed for a 20-30 minute period, during which they will also be consented. It is possible that participants will be contacted again during the six month interview period for clarification; however, we do not anticipate contacting most providers outside of their interview sessions. Following the interview period, we will develop a "PERK" prototype in the second half of Year 1.

Enrollment will occur on a rolling basis throughout the testing period for AIM 2. For AIM 2, usability testing and iterative revision of the prototype will take place during Year 2 of the grant. Each participant will take part in a usability testing session approximately 20-30 minutes in duration, during which they will also be consented. Participants will also be given the option to fill out the pre-session questionnaire, consent form, and Audio Visual Authorization form on REDCap prior to their session. It is possible that participants will be contacted again during the one year period of usability testing sessions for clarification; however, we do not anticipate contacting most providers outside of their usability sessions.

During the first half of Year 3, we will develop the new PERK tool. In the second half of Year 3, we will recruit for the pilot clinical trial in AIM 3. The new PERK tool will be active for 6 months, and all full-time employed providers working in the emergency department at NSUH and LIJMC will be eligible for participation. We will perform the pilot trial in Year 4. The clinical decision support tool will be integrated into the electronic medical record and will be accessible for all full-time employed emergency department providers (n=150). Providers will be trained on using the tool through 30 minute sessions delivered during emergency department grand rounds. Additional education sessions will be delivered to continue participant engagement over time. In the second half of Year 4, to assess feasibility, providers will be contacted by email to participate in a post-pilot satisfaction survey. Reminder emails to complete the survey will be sent out up to five times. To assess acceptability, providers will be contacted by email to participate in one-time stakeholder interviews. A follow up phone call will be conducted with providers to provide participant information and solicit interest. The pilot trial will end in June 2022. We will complete our analyses in the first quarter of Year 5. The anticipated end date for this grant is August 31st, 2023.

10. ENDPOINTS

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

The endpoint of this study is provider adoption of the PERK tool. Secondary outcomes include increased CTPA yield [% of positive tests], and decreased CTPA ordering.

Our primary feasibility outcome is post-pilot provider satisfaction.

11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *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*

In AIM1, we will conduct semi-structured interviews with low, intermediate, and high users of the current tool, PE CALC (n=12 total, 4 each, continuing until data saturation) to refine our understanding of barriers to tool use and receive feedback on nudges' acceptability and ability to address identified barriers. Guided by our preliminary survey data and the COM-B framework, we will develop an interview guide. The interview will have three goals: 1) refinement of the four most prevalent barriers, 2) assessment of how well each nudge addresses the behavioral barrier, and 3) acceptability of the nudge. Dr. Safiya Richardson will conduct structured interviews at NSUH, LIJMC, 600 Community Drive, Manhasset, and other clinical sites including 257-07 Union Tpke, Glen Oaks with Dr. Katherine Dauber, PhD, an experienced researcher. The interviews will be audio recorded (using two digital voice recorders; one for backup in case of technical failure) and professionally transcribed. The guide will be revised based on the ongoing analysis of interview data.

In AIM 2, we will perform iterative usability testing of an evolving prototype of "PERK". We will build the prototype into the wireframing tool, Axure. The PERK prototype will add 4 small nudges to PE CALC. Usability of the prototype will be tested in two steps, "Think Aloud" and "Near Live" (n=5 participants each). During "Think Aloud" testing, participants verbalize their thought processes while interacting with the prototype. Participants will be given written clinical scenarios with low, intermediate, or high probability PE cases and asked to complete the specific steps necessary to use the tool. During

"Near Live" testing, participants will interact with a standardized patient pretending to have a low, intermediate, or high probability of PE. Participants will use the tool as they would during a real patient encounter to highlight higher level workflow usability issues.

All five participants for each round of testing will interact with the prototype at each step. The tool will be modified after "Think Aloud" and again after "Near Live" based on testing results. Before every session participants will be asked to complete a questionnaire to gather demographic information. They will be given a laptop with the PERK prototype and screen capture software. After every session they will complete a questionnaire to collect retrospective impressions of the tool, and a quantitative survey, the System Usability Scale. Each session will be audio-taped and Morae usability testing software will be used to screen-capture record all human-EHR interactions.

AIM 2 participants will be tested either in person or remotely via videoconferencing (such as with Microsoft Teams). Participants being tested remotely will fill out consent forms, the Audio Visual Authorization Form, and the surveys on REDCap. Participants being tested in person will be given the option to fill out these forms on REDCap or on paper. Audio and screen capture recordings (using Hypercam, Teams, or Morae) will be taken for each session. Prior to or at the beginning of each session, participants will fill out the Usability Pre-session Questionnaire. At the end of each session, participants will verbally answer questions from the Post-session Interview and PERK Tool (Feedback Survey Aim 2) documents; they will also fill out the System Usability Scale (on REDCap for remote testing, on paper or REDCap for in-person testing).

In AIM 3, we will conduct a pilot trial to evaluate the feasibility, acceptability, and preliminary efficacy on provider adoption of the new tool, "PERK", compared to the current PE CALC tool. This will consist of a six month prospective cohort pilot study with a retrospective cohort control group. All full time ED providers at NSUH and LIJMC will be eligible for participation. Training on PERK use will be conducted as a presentation during ED Grand Rounds. This will be led by Dr. Safiya Richardson and a research coordinator. It will last about 30 minutes with three basic components: 1) overview of the evidence supporting tool use, 2) hands-on session to practice using the tool, and 3) question and answer session. Similar educational training was conducted before launching the current tool, PE CALC.

For the pilot study, we will use EHR reporting data to generate a PERK monitoring dashboard. The dashboard will include trigger rates (percentage of ED patients for which the tool triggers), adoption rates (the percentage of times the provider completes the calculator once the tool is triggered), CTPA order rates (percentage of total ED patients for which a CTPA is ordered for the evaluation of PE), and CTPA yield (the percentage of tests ordered to evaluate for PE that are positive for PE).

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 uForsed.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

For AIM 1, we will perform qualitative analyses of our semi-structured interviews. We will use NVivo software (QSR International, Inc.) for qualitative data storage and organization. Use of computer-assisted techniques improves procedure standardization, enhances completeness, and permits greater flexibility in revising the analysis process. We will code and analyze the transcripts using a modified grounded theory informed by COM-B. In grounded theory, themes are not specified prior to analysis, but our modified approach will use the framework of COM-B to organize emergent themes (e.g., psychological capability, social opportunity). Dr. Dauber and Dr. Richardson will develop a codebook reflecting emerging themes after iteratively reading the transcriptions so that triangulation can be assessed and a broader and more complex understanding of the data attained. Using the constant comparative method, additional readings of the transcriptions will lead to the consolidation of these coding schemes until no further refinement is required. Coding discrepancies will be resolved by consensus. Coder agreement will be calculated with Cohen's kappa. In order to improve accuracy, validity, and transferability of the results, respondent validation will be implemented. Participants will be shown an analysis summary and asked to provide feedback if it conforms to their responses during interviews ensuring that the participant meanings and perspectives are accurately represented.

For AIM 2, we will perform qualitative analyses of our "Think Aloud" and "Near Live" usability testing. After all usability testing, the audio recordings of subjects will be transcribed verbatim and linked to screen capture videos. Two independent coders will read the annotated transcripts and watch the corresponding video for each case. All discrepancies in the coding will be resolved by discussion to achieve a consensus. Each coded segment of the transcribed text will be categorized for: (a) the CDS components involved, (b) usability/workflow issues as conveyed through providers' verbalizations and actions, (c) type of commentary provided by the subject (i.e. "positive", "neutral" or "negative" commentary). We will perform a thematic analysis of the transcribed audio recordings as recommended by Boyatzis.[69] Frequencies of codes will be tabulated for each subject. Morae software allows annotation of each of the components being used, time of use and usability theme. During "Near Live" usability testing the onscreen video recordings will be reviewed for time to CDS completion and time spent in workflow components. We will use NVivo software (QSR International, Inc.) for qualitative data storage and organization. We will code and analyze the transcripts using a modified grounded theory informed by COM-B. In grounded theory, themes are not specified prior to analysis, but our modified approach will use the framework of COM-B to organize emergent themes (e.g., psychological capability, social opportunity). Dr. Richardson and a trained research assistant develop a codebook reflecting emerging themes after iteratively reading the transcriptions. Using the constant comparative method, additional readings of the transcriptions will lead to consolidation of these

coding schemes until no further refinement is required. Coding discrepancies will be resolved by consensus.

For AIM 3, we will determine the feasibility of PERK using post-pilot provider satisfaction surveys, where mean scores for each response on a Likert scale will be reported with standard deviations and 95% confidence intervals. Acceptability will be determined from post-pilot stakeholder interviews with providers, nurses and the ED chairs at both institutions. Preliminary efficacy will be assessed by comparing provider adoption of PERK to provider adoption for the first six months of PE CALC. Providers in the pre- and post- groups will be summarized using descriptive statistics. Provider age, gender, race and type (attending vs. resident vs. physician assistant) will be compared between the two groups using two-sample t-test or Wilcoxon Rank Sum test for continuous variables and Chi-squared or Fisher's exact test for categorical variables. Since the variability of the adoption rate of PERK for each provider depends, in part, on the number of encounters, providers with larger numbers of encounters should carry more weight. Therefore, a weighted two-sample t-test will be used to test the difference in the weighted means of adoption rates between the groups. Weighted least squares linear regression with number of encounters as weight for each observation (provider) will be performed, to see whether there is difference in the adoption rate between the two groups after controlling for provider age, gender, race, type and other confounding variables.

Power Calculations: We expect 150 providers who meet the inclusion criteria to be in each of pre- and post- groups. We also assume the mean adoption rate of the pre group to be 15% with the standard deviation of 10% based on the historical data, and the mean adoption rate of the post- group to be 20%, 25% and 30% with equal standard deviation. With the sample size of 150 in each group, there will be at least 99% power to detect the difference of 5%, 10% and 15% in the mean adoption rates using a two-sided two-sample t-test at a significance level of 0.05. We are aware that the weighted two-sample t-test should be used to calculate the power. However, due to the lack of information about weights, the unweighted two-sample t-test was used instead.

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.*

Data obtained for this study include the audio/video recordings of interviews, as well as "Think Aloud" and "Near Live" usability testing. We will also be extracting EHR data. We plan on storing study data on the health system's encrypted shared drive. Data will be stored for 7 years following the completion of the study, which is the minimum allowed by our institution's the IRB. Only study team members that are on the Institutional Review Board (IRB) approved protocol will have access to the data that will be saved on a secured Northwell Health drive, Northwell REDCap, and/or Northwell OneDrive. Research team members will also be responsible for the transmission of data. They will meet the minimum and mandatory requirement to access the identifiable information as per the standards set by Northwell Health. Access and use of the data will be strictly monitored by the Principal Investigator (PI) and the research team. Northwell Health's Administrative Policy and Procedure Manual policy number 800.42 titled Confidentiality of Protected Health Information particularly addresses the access and use of the ePHI.

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.*

Please see APPENDIX A: Data Safety Monitoring Plan (DSMP).

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.*

n/a

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.*

For AIM 1 and AIM 2, we will explain to providers at the time of consent that their participation is voluntary and they are able to withdraw at any time. To withdraw, participants will need to notify the PI in writing of their withdrawal. There is no consenting, and therefore no withdrawal, for AIM 3.

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 result.*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

Providers participating in this study will be at minimal risk. We do not expect any adverse events directly attributable to the interviews, usability testing, or pilot study. Although adverse events associated with behavioral protocols such as ours are highly unlikely, in order to protect the safety of participants, all are provided with numbers for NWH's Emergency Rooms and referrals to the Department of Social Work.

A risk of potential breach of confidentiality of study data exists but the study team has put measures in place to prevent a breach from occurring; we plan on storing study data on the health system's encrypted shared drive. Data will also be stored on Northwell OneDrive and in Northwell REDCap, Only study team members that are on the Institutional Review Board (IRB) approved protocol will have access to the data that will be saved on a secured Northwell Health drive. They will meet the minimum and mandatory requirement to access the identifiable information as per the standards set by Northwell Health. Access and use of the data will be strictly monitored by the Principal Investigator (PI) and the research team. Northwell Health's Administrative Policy and Procedure Manual policy number 800.42 titled Confidentiality of Protected Health Information particularly addresses the access and use of the ePHI.

Throughout the development of the CDS, we will ensure the highest levels of security and HIPAA compliance. All communications will be encrypted during transit and all data will be encrypted at the system level.

We do not anticipate any significant physical, psychological, or social risk to the study providers. All risks and benefits of participation will be explained to providers and included in the written informed consent forms. It will also be explained to providers that their participation is voluntary and they are able to withdraw at any time.

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.*

We do not expect any adverse events directly attributable to the interviews, usability testing, or pilot study. Although adverse events associated with behavioral protocols such as ours are highly unlikely, in order to protect the safety of participants, all are provided with numbers for NWH's Emergency Rooms and referrals to the Department of Social Work.

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*

Participants will not directly benefit from taking part in this study. This study will improve our understanding of how to develop clinical decision support that is adopted by providers. Improved provider adoption of clinical decision support helps to close the gap between usual and evidenced based clinical care, reducing morbidity, mortality and health care waste. Adoption of this particular clinical decision support tool will decrease unnecessary testing for pulmonary embolism with computed tomography with contrast, reducing contrast induced nephropathy and malignancies from radiation exposure.

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).*

All participants will be given Subject Numbers by which they will be identified. The names of participants will not be associated with the participants' responses.. For AIM 1 and AIM 2, a member of the research team will obtain informed consent from providers at the time of enrollment. Providers will be informed of the study's risk and benefits. Researchers will explain to each participant that they have the ability to opt out of the study at any time. Whether or not they choose to participate in the study will have no effect on their employment or compensation. For HIPPA privacy purposes, providers will be informed that their names are not attached to study documents. Before being consented, providers will have the opportunity to ask

the researcher any questions to clarify inquiries or concerns. Documents given to providers will contain telephone numbers of appropriate personnel, if further questions about the study arise. Providers will also be asked separately to give consent to be audio taped. As per Northwell Health policy 100.47, clinical providers will also be asked to sign an Audio/Video recording authorization form. Audio recordings and other PHI will be stored on the health system's encrypted shared drive and/or Northwell OneDrive and will only be accessible by the study team.

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.*

There is no cost subjects.

22. PAYMENT TO SUBJECTS

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

Participants who complete the semi-structured interview in AIM 1 or the usability testing in AIM 2 will be reimbursed $50. Payment will be made directly to participants as an addition to their regular paychecks. There will be no payment to subjects in AIM 3.

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.*

For AIM 1 and AIM 2, informed consent will be obtained for all testing at the Emergency Departments at NSUH and LIJMC. A member of the research team will obtain informed consent from patients and surrogates at the time of enrollment. Providers will be informed of the study's risk and benefits. Researchers will explain to each participant that they have the ability to opt out of the study at any time. Whether or not they choose to participate in the study will have no effect on their employment or compensation. For HIPPA privacy purposes, providers will be informed that their names are not attached to study documents. Before being consented, providers will have the opportunity to ask the researcher any questions to clarify inquiries or concerns. Documents given to providers will contain telephone numbers of appropriate personnel, if further questions about the study arise. Providers will also be asked separately to give consent to be audio taped. As per Northwell Health policy 100.47, clinical providers will also be asked to sign an Audio/Video recording authorization form.

AIM 2 participants being tested remotely will fill out consent forms, the Audio Visual Authorization Form, and the surveys on REDCap. AIM 2 participants being tested in person will be given the option to do this online or on paper.

For AIM 3, we will collect pilot data from the EHR on the use of PERK. All providers at NSUH and LIJMC will be automatically enrolled. There will be no consenting for AIM 3; however, we hold an information session for providers on how to use PERK prior to launching the tool.

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*

n/a

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*

n/a

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS

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*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

For AIM 3, in which we will collect pilot data on the feasibility, acceptability, and preliminary efficacy on provider adoption of the PERK tool, we are requesting a waiver of informed consent. A waiver of informed consent will be necessary in order to have the PERK tool activated in the EMR profiles of the providers.

The research involves no more than minimal risks to the subjects: The study as described in the proposal would be considered a minimal risk study because it involves collection of de-identified aggregate data from the EHR at the NSUH and LIJMC Emergency Departments.

The waiver or alteration will not adversely affect the rights and welfare of the subjects: Due to the functionality of the tool, providers will be offered the tool and have the ability to dismiss the tool. Use of the tool will not affect employment status of the providers at the clinical site/hospital/health system. We will hold an information session for providers regarding the research study and their participation.

The research could not practicably be carried out without the waiver: The primary objective of AIM 3 is to assess the feasibility, acceptability, and preliminary efficacy on provider adoption of PERK compared to the current PE CALC tool in a pilot trial. In order to study this, all patients assessed for PE must be included. The decision support is completely computerized and will be done in real time. It would not be possible or practical to obtain consent from every provider in the Emergency Departments of NSUH and LIJMC prior to their use of the PERK.

Whenever appropriate, the subjects will be provided with additional pertinent information after participation: While providers will not be consented, we will hold an information session explaining how to use PERK prior to its incorporation into the EHR. Providers will be trained on using the tool through sessions delivered during emergency department grand rounds. Recruitment and training will be led by Dr. Richardson and a research coordinator. Training will last about 30 minutes with three basic components: 1) overview of the evidence supporting tool use, 2) hands-on session to practice using the tool and 3) question and answer session. Additional education sessions will be delivered to continue participant engagement over time.

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.*

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25. WAIVER OF HIPAA AUTHORIZATION x 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.

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*
X☐ *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.

Employees, residents, fellows, etc.: In order to protect subjects from undue influence in joining this study, employees/residents/fellows will not be consented to the study by any personnel who hold a supervisory position over them. Potential participants will be informed that their participation (or non-participation) will have no effect on their employment at the clinical site/hospital/health system, or future employability/opportunities at that site. All data will be kept confidential.

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/BIBIOGRAPHY

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.

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APPENDIX A: Data Safety Monitoring Plan (DSMP)

The principal investigator (PI), mentors, collaborators and research coordinator will be responsible for monitoring the scientific integrity and participant safety for the full duration of the study. They will meet weekly to discuss the progress of the study.

We will be responsible for maintaining our data and maintaining security. We will use standard IRB-approved and HIPAA-compliant measures to maintain confidentiality, privacy and data security. Data privacy and security procedures will include: (1) training staff on data sensitivity and protocols for safeguarding confidentiality, (2) storing and processing sensitive hardcopy in a secured, centralized location, (3) securing sensitive hardcopies in locked files when not in use, (4) removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for patient tracking and then using encrypted codes for subsequent identification of participants, (5) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed, (6) capturing and storing follow-up assessments in REDCap, a secure web-based HIPAA compliant application designed to support data capture for research studies, and (7) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis. Since protected health information (PHI) data will be collected and transmitted to the HIE hosted by Northwell Health, we have developed a clear and concise privacy and security plan. Northwell is well suited to develop such a plan as we are currently engaging in similar health technology projects that secure the electronic submittal of health information from patient to health system. The Office of the Chief Informatics Officer (OCIO) and HIE have set in place policies and procedures to ensure the security and privacy of the participants' PHI and will be advisors on our grant to ensure the clinical decision support system (CDSS) solution and underlying platform also meets Northwell security requirements.

Monitoring the progress of trials and the safety of participants.

The proposed project is a low-risk study. The risk of minimal fatigue using the tool will be monitored and participants may dismiss the tool at any time. The study team will review the data on a weekly basis. The work will be conducted with approval from the Program for the Protection of Human Subjects (PPHS).

As per Northwell Health (NWH) PPHS policies, the PI is required to notify the PPHS promptly of any unanticipated problems involving risks to subjects or others that might occur. The PI will monitor the progress of the study and safety of participants on an ongoing basis. The procedures of this study, such as regular meetings with research staff, will ensure discussion and reporting of all possible outcomes including any, though unlikely, adverse events. If the adverse event is due to the study and is unexpected, the PI will draft a safety report and send a copy to the PPHS. The PPHS committee will serve as an objective review mechanism. This policy/procedure means that any potential conflict of interest inherent in the PI being the sole reviewers of serious adverse advents is avoided.

Plans for assuring adherence with requirements regarding the reporting of adverse events (AEs).

All serious AEs (e.g., medical occurrences resulting in death) that occur during the study defined by the given protocol, regardless of the relation to the research, must be reported to the PPHS by telephone, e-mail, or fax within 24 hours of the investigator's awareness of the occurrence of the event. The PI will report SAEs to the PPHS and will disseminate information to other agencies as necessary. These initial reports are followed by a safety report which is a written account of the serious AE determined by a sponsor/investigator to be both related to the treatment under investigation and to be unexpected in nature. Serious AEs will be summarized annually in the PPHS application for continuation or termination of research.

All expected non-serious AEs that occur at a greater frequency or severity than anticipated and all unexpected non-serious AEs will be reported to the PPHS within 15 working days of the investigators becoming aware of the event. These AEs are also summarized annually in the PPHS application for continuation or termination of the research.

Plans for assuring that any action resulting in a temporary or permanent suspension of funded study is reported to the grant program director responsible.

Tiffany Chapman, Assistant Director, Grants Management Office at The Feinstein Institute at NWH, will provide prompt written notification of any action resulting in a temporary or permanent suspension of this protocol to the NIH grant program director responsible for the grant.

Plans for assuring data accuracy and protocol adherence.

The PI will follow procedures outlined under Elements 1 and 2 above which serve as part of the quality control procedure. The PI will meet with the mentors and research coordinator on a regular basis to ensure data accuracy and protocol adherence. Quarterly meetings (either in person or via phone) with the entire study team will also ensure protocol adherence. To ensure the validity and integrity of study data, the PI will also oversee all data management responsibilities. The PI will discuss all data management issues with the study team at NWH.