Northwell Health

RESEARCH PROTOCOL PLUS

Protocol Title:	Evaluation of Synthesized 18-Lead ECG in the Emergency Department
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IRB Number:	17-0936

Guidelines for Preparing a Research Protocol Plus

Instructions:

- This document should be completed if your research study has an existing protocol from a Sponsor, Lead Site, etc.
- Respond to each item, even if to indicate not applicable (N/A0.
- Do not delete any of the text contained within this document.
- Please make sure to keep an electronic copy of this document. You will need to use it, if you make modifications in the future.
- Start by entering study information into the table above, according to these rules:
  - Protocol Title: Include the full protocol title.
  - Investigator: include the principal investigator's name
  - IRB Number: Indicate the assigned IRB number, when known. At initial submission, this row will be left blank.
- Once the table information is entered, proceed to page 2 and complete the rest of the form.

↓ 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 no more than ½ page*

This study, sponsored by Nihon Kohden, aims to determine the sensitivity and specificity of synthesized 18-lead electrocardiogram (ECG) in the diagnosis of posterior-lateral and/or right-ventricular ischemia, using actual 18-lead ECG as the gold standard. The synthesized 18-lead ECG calculates six extra leads of information from the standard 12-lead ECG done in the Emergency Department (ED). Nihon Kohden has created synECi18 Technology, which can mathematically synthesize and display the extra leads.

A standard 12-lead ECG records electrical information primarily from the left side of the heart, both anterior and inferior. A 12-lead ECG is commonly performed in the ED to detect abnormal heart rhythms and is the standard of care for patients with chest pain or suspected cardiac ischemic conditions. An 18-lead ECG records the same information as the 12-lead ECG, in addition to six leads that record the electrical information from the right and posterior sides of the heart. 12-lead ECGs are generally considered poor at recording electrical information from the right and posterior sides of the heart.

The patient population (n=300) will consist of patients who present to the North Shore University Hospital or Long Island Jewish Medical Center ED with a chief complaint of chest pain, chest pressure, or chest discomfort. These patients will be receiving a standard 12-lead ECG as part of their routine clinical care. Patients with ST-Elevation Myocardial Infarction (STEMI) will be excluded from the study as they need to be immediately sent to the cardiac catheterization lab and approaching these patients for informed consent to participate in this study would interfere with patient care. Additionally, patients with a known positive troponin value will also be excluded as they also require immediate clinical care.

Trained ED study technicians will use ECG machines provided by Nihon Kohden to obtain two consecutive 15-lead ECGs. The 15-lead ECG consists of a traditional 12-lead ECG and an additional three leads on the right side of the body. The first 15-

lead ECG will have an additional three electrodes/stickers on the right side of the chest and the second 15-lead ECG will have an additional three electrodes/stickers on the posterior side. This means the patient will have a total of six extra electrodes/stickers placed on their body—three on the right side of the chest and three on the back. Each ECG takes about 15 seconds to obtain, of which 10 seconds are recorded by the machine. The two 15-lead ECGs are then saved onto the ECG machine identified by a patient ID number and printed.

The saved information will later be input into an algorithm to calculate the synthesized 18-leads. This will occur towards the end of the study, and the patient will not be involved in this process. In other words, the device will take the actual information from the standard 12-leads and synthesize the six extra leads. The actual 18-leads (composed of the two 15-leads conducted in the ED) will be compared with the synthesized 18-leads produced by the synECi18 technology. A study cardiologist will evaluate the actual 18-lead ECGs and synthesized 18-lead ECGs and determine whether there is posterior-lateral and/or right-sided ventricular ischemia. The cardiologist will be blinded to the type of waveform they are analyzing (synthesized versus actual). There will only be one cardiologist who will evaluate ECGs for this study in a blinded fashion. The actual 18-lead ECGs will be used as the reference for comparison. The synthesized 18-lead ECGs will be compared with the actual 18-lead ECGs to calculate sensitivity and specificity.

The study will not interfere with patient care or treatment, however, the two 15-lead ECGs done in the ED will be shown to the physician who can determine whether or not to order an official 18-lead ECG in the hospital's electronic medical record system.

We hypothesize that the synECi18 synthesized 18-lead ECGs will provide high sensitivity and specificity for diagnosing posterior-lateral and/or right-ventricular ischemia, with the actual 18-lead ECGs being used as the reference for comparison.

3. 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*

In 2016, there was an average of 686 patients per month who presented to the Long Island Jewish Medical Center (LIJMC) ED and the North Shore University Hospital (NSUH) ED combined with a chief complaint of chest pain. Conservatively estimating that 10% of these patients would not be eligible due to out exclusion criteria, there will be approximately 618 eligible patients per month. Given that we will be obtaining a convenience sample (i.e. between the hours of

9am and 5pm when study ED technicians are available), we are allowing 6 months to enroll 300 patients.

All Academic Associates and study ED technicians participating in this study will be trained by Nihon Kohden representatives on how to operate the ECG machines provided by Nihon Kohden.

4. 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*

Academic Associates, full-time research assistants in the emergency department, will screen the ED status board for patients with a chief complaint of chest pain, chest discomfort, or chest pressure and will use the triage note and a conversation with the attending physician to determine if the patient qualifies for the study. If the patient qualifies, the Academic Associate will explain the study to the patient and, if interested, obtain informed consent from the patient to participate in the study.

Once informed consent is obtained, the Academic Associate will inform a trained study ED technician that the patient has been enrolled in the study. At a time that is convenient for the ED technician and that does not interfere with the patient's care, the ED technician will perform two consecutive 15-lead ECGs on the study patient and fill out the patient entry form (see attached).

Inclusion criteria:

- Subjects with a chief complaint of chest pain or chest discomfort or chest pressure
- Troponin test has been ordered (unknown positive at time of recruitment)
- Subjects are capable of providing informed consent
- English speaking

Exclusion criteria:

- STEMI patients
- Patients who have not had a troponin test ordered
- Pregnant women
- Patients under 18 years of age
- Prisoners

STEMI patients will be excluded from this study, as STEMI patients require immediate intervention. Approaching STEMI patients for participation in this study would interfere with clinical care.

Pregnant women will be excluded from this study because it would be uncomfortable to ask pregnant women to turn on their sides or back in order to place the additional electrodes/stickers on the right side of their chest and back.

Prisoners will be excluded because correction/police officers will be with them. Approaching prisoners for participation would interfere with correction/police officers as they do their job.

5. 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*.

The first phase of the study will be a pilot study, which will consist of enrolling 10 subjects to pilot test our data collection procedures and operations outlined in this protocol, as well as to troubleshoot issues that we did not expect. After our data collection procedures and operations are pilot-tested, the study will move onto the next phase for data collection.

The pilot study phase may take approximately two weeks to enroll 10 subjects. The main phase of the study will be the data collection phase, which is estimated to take 6 months. The data collection phase will consist of enrolling the remaining 290 subjects in the ED at NSUH or LIJMC.

6. 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*

The study will require obtaining two 15-lead ECGs on all enrolled patients. Each ECG takes approximately 30-seconds to complete. Placing the additional six electrodes/stickers on the patients will take less than five minutes. This means that the study ECG procedures should only take less than approximately 8 minutes. The consent process length will depend on the questions the patient has about the study. As stated, the patient will be left with the consent form for about 10 minutes to read it over in private. Taking into account this time, the consent time, and the study itself, we expect each patient enrollment will take 25 to 30 minutes.

The full study is expected to last approximately 9 months and will consist of three total phases. The first phase will be a pilot study conducted on 10 subjects to pilot test our procedures and operations of data collection outlined in the protocol. After we pilot test our procedures and operations, the study will move onto the data collection phase. This pilot study phase, which requires enrolling 10 subjects, will take approximately two weeks.

The main phase of the data collection period is expected to take about 6 months. This phase requires the enrollment of 290 subjects at NSUH ED and LIJMC ED. It is estimated that target patient enrollment could be 5 subjects per day per hospital, allowing the study to collect 50 patient ECG data sets per week. It is expected that data collection may be complete sooner than 6 months, however, some delays are taken into consideration. The study will begin at NSUH ED and once it is running well there, it will begin at LIJMC ED.

The evaluation phase of the study is expected to take 3 months. This phase will consist of analyzing all of the data.

Table of timeline:

Pilot Study Phase (Month 1)	**Main Data Collection Phase** (Months 2-6)	**Evaluation Phase** (Months 7-9)
• Pilot trial with up to 10 subjects	• Subject enrollment (290 subjects) • Data collection	• ECG analysis • Data report

7. RESEARCH PROCEDURES

- *Provide a description of any procedures that differ from what is described in the main study protocol.*

1) Identification: Patients will be screened for the study upon arrival to the ED by an Academic Associate (AA) who will be scanning the ED status board on Sunrise. The patients will be identified via chief complaint and triage notes as well as results to confirm there is no positive troponin result. The AA will speak to the physician and then the patient to determine if the patient is eligible for the study. This will be tracked through a screening log to ensure patients are not approached twice (screening log attached). Information on the screening log will be entered into REDCap at the end of the day, and the paper screening log will be destroyed.
2) If the patient is eligible, the AA will explain the study and consent form to the patient. The AA will also answer any questions the patient may have regarding the study.
3) The AA will allow the patient 5-10 minutes to review the consent form in private.
4) The AA will allow time for the patient to ask any new questions regarding the study or the consent form.
5) If the patient is interested in continuing with the study, the AA will obtain informed consent.

6) The AA will inform a study ED technician that a patient has been enrolled as well as the patient's location.
7) At a time that is convenient for the ED technician and that does not interfere with patient care, the ED technician will complete the patient entry form and obtain two consecutive 15-lead ECGs using the Nihon Kohden 15-lead ECG study machine. Only the patient ID will be entered into the machine. The patient will only be identified by their MRN on the patient entry form, which will be stored in a locked cabinet in the AA office. No identifiers will be stored in the study ECG machine. The AA will be with the ED technician when the 15-lead ECGs are being performed, to collect the patient entry form.
8) The two 15-lead ECGs will be printed out and shown to the physician. Then, the printed ECGs will be saved in the AA office in a locked cabinet identified only by the subject ID. The ECG results will not be used directly for any clinical decision making. The physician will decide if they would like to order an official 18-lead ECG after seeing the printed results from the study. The study ECGs will not be used for any clinical decisions.
9) Following the patient's ED visit, an AA will use the MRN and the ECG date from the data entry form to obtain test results for the patient obtained during their ED stay. These include troponin test, CAGs, CTA, stress echos, or nuclear stress tests. This data will be entered directly into the REDCap database (see attachment 2). Only IRB approved study personnel will have access to this database. At the end of the study, NKC, the sponsor, will be provided with the de-identified version of the data sheet (i.e. all points included in attachment 2 except the MRN).
10) All ECGs (synthesized and actual) in this study will be assigned a random code by the Academic Associate on this study, Martina Brave, and only she will have access to this code. The ECGs will be coded randomly with numbers provided by the randomization tool in Excel. The file with the random codes will be saved onto Northwell Health servers and a password will be placed on that document. Once coded, the ECGs will be put in numerical order to avoid ECGs from the same patient being back to back. The study cardiologist will analyze the ECGs in that numerical order and determine whether or not the ECG shows evidence of ischemia. This coding will shuffle the ECGs from all patients and all dates. The study cardiologist will not know which ECGs are synthesized vs. actual. The study cardiologist will record the random code on the ECG and their interpretation for that ECG on a form (form attached). The form will be provided to the Academic Associate, who will decode the ECG and enter the data into REDCap. Given that there will only be one study cardiologist, there will be no need to evaluate inter-rater reliability.
11)

8. STATISTICAL ANALYSIS

If the protocol you are submitting has a statistical plan within it, please confirm here, by checking the box ☐

If the protocol does not contain a statistical plan, please address these points:

- *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.*

Descriptive statistics, including frequencies, proportions, means, standard deviations, medians, and interquartile ranges, will be used to describe the study sample.

The aim of this study is to determine the sensitivity and specificity of synthesized 18-lead ECG in the diagnosis of posterior-lateral and/or right-ventricular ischemia, using actual 18-lead ECG as the gold standard. Accuracy, positive predictive value, and negative predictive value will also be calculated. A 2x2 table will be created as shown below:

		Actual 18-lead ECG (Gold Standard)		
		Positive	Negative	
Synthesized 18-lead ECG	Positive	A	B	A + B
	Negative	C	D	C + D
		A + C	B + D	Total

Sensitivity will be calculated by using this formula: A / (A + C)

Specificity will be calculated by using this formula: D / (B + D)

Accuracy will be calculated by using this formula: (A + D) / (A + B + C + D)

Positive predictive value will be calculated by using this formula:

[(Sensitivity)(P)] / [(Sensitivity)(P) + (1 – Specificity)(1 – P)]

Where P = prevalence of outcome

Negative predictive value will be calculated by using this formula:

[(Specificity)(1-P)] / [(Specificity)(1 – P) + (1 – Sensitivity)(P)]

Where P = prevalence of outcome

Based on a review of data from the North Shore University Hospital's Emergency Department, the prevalence of our outcome is estimated to be 10%. Our study will

enroll 300 patients; therefore, we estimate that 30 of these patients will have our outcome of interest and 270 will not. Based on a previous study by Tamura et al. published in the American Journal of Cardiology in 2014, sensitivity is estimated to be 83% and specificity is estimated to be 99%. Therefore, among the 30 patients with our outcome, the proportion of test positive by the synthesized 18-lead ECGs is estimated to be 83% with a corresponding 95% CI of 65% to 94%. Among the 270 patients without our outcome, the proportion of test negative by the synthesized 18-lead ECG is estimated to be 99% with a corresponding 95% CI of 97% to 100%.

No formal sample size calculations were performed for this study. Data collected from this study will allow us to perform a formal sample size calculation for future studies.

9. 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 data will be recorded on paper forms and then entered into a REDCap database. The paper forms will be stored in a locked cabinet in the Academic Associates office. Only Northwell study personnel will have access to the REDCap database. De-identified data only will be sent to the sponsor, Nihon Kohden, upon completion of the study.

Information on screening logs will be entered into REDCap at the end of each day, and the paper screening logs will be destroyed.

All data obtained in the study will be used exclusively for the purposes of the proposed research, which are clearly outlined in the informed consent signed by the patient. Ongoing protection of confidentiality will be adhered to throughout the study period and thereafter.

In addition, the PI, Dr. Timmy Li, will meet with the study staff on a regular basis to ensure data accuracy and protocol adherence.

10. RISKS TO SUBJECTS

- *Describe any potential risks which are not discussed in the protocol, their likelihood and seriousness. As a reminder, risks may be physical, psychological,social, legal or economic*
- *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.*

Undergoing two additional 15-lead ECGs may be physically uncomfortable for the patient because additional electrodes/stickers need to be placed on the subjects. Some patients report the leads are uncomfortable to remove as they require the small square of sticker/electrode. However, in order to minimize discomfort, we will be using the same electrodes/stickers placed on the patient for the standard 12-lead ECG. This means only 6 additional electrodes/stickers need to be placed on the patient.

There is only theoretical risk to privacy breach for patients in this study as we plan to use an encrypted and password protected database, REDCap, to collect and store all data. The paper data collection and consent forms will be stored in a locked cabinet in the AA office. Only IRB-approved study personnel will have access to data with PHI. In addition, all IRB-approved study personnel will have completed HIPAA training and are able to maintain patient confidentiality. All transmitted data will be sent over the secure Northwell Health network server.

11. 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.*

When unconnected tips or electrodes form the ECG machine touch an item which is not equipotential grounded, the patient may receive an electrical shock. However, all of the study ED technicians performing the ECGs are trained and licensed ED technicians. Additionally, the technicians were provided additional study training specific to performing 15-lead ECGs on the Nihon Kohden machines.

12. 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).*

Patients will only be approached about the study in a private area. Information will be stored on paper files in a locked cabinet and on the encrypted REDCap database. No follow-up communication is required as a part of this study.

13. DATA AND SAFETY MONITORING

- *If not provided in the main protocol, please indicate here the plan to monitor the safety of this study.*
- *If the protocol has a data and safety monitoring plan, please indicate the page number on which the plan can be found.*

We do not anticipate any adverse events, but in the case of a study-related adverse event, in accordance with Northwell Health guidelines, the study team will alert the IRB of any and all reports of adverse events and inform all members of the study team of any and all reports of adverse events. If three or more adverse events are reported, the study team will assess potential causes of the adverse events and, if the events are clearly linked to study participation, discontinue the study.

14. 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 study is financed through a grant from Nihon Kohden. There is no foreseeable cost to subjects. Both of the 15-lead study ECGs will be performed on Nihon Kohden machines provided specifically for this study and will not be billed to the patient.

15. PAYMENT TO SUBJECTS

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

Subjects will not receive payment for participation.

16. 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.*

Informed consent shall be obtained under the conditions set forth in 21 CFR Part 50: a)the subject shall have sufficient opportunity to consider participation in the study, b)informed consent shall be obtained without coercion or undue influence, c)informed consent shall be written in the native language of the subject and administered by approved personnel who speak the native language of the subject, d)a subject cannot be led to believe that they are waiving their rights as a subject or the liability of the sponsor or investigator.

If the patient qualifies, the Academic Associate will explain the study to the patient and summarize the consent form either in a private area of the waiting room or in a patient's room (depending on the time of identification). If the patient is interested, the Academic Associate will leave the patient with the consent form to read through and return 10 minutes later to see if they have any questions about the consent form or the study process. If the patient would like to move forward with enrollment, the AA will consent the patient using the standard consent form attached to this submission. A copy of the consent form will be given to the patient and the original will be kept in a binder in a locked cabinet in the AA office.

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

17. 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*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

N/A

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 <u>OR</u> 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.*

N/A

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.*

N/A

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18. 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.*

N/A

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)*

N/A

19. 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.

N/A