Maimonides Medical Center
IRB/Research Committee

View xForm - IRB Application

This "IRB Application" xForm must be used when submitting a new study to the IRB. NOTE: This xForm must also be used for Maimonides research that will be overseen by an external IRB, so that the Maimonides IRB can assess other institutional requirements. (Version 9.2; Published 09.28.2015)

Application Data Entry
- Submitted 6/12/2017 2:58:29 PM ET by EL-Hennawy, Adel MD

Amendment Information

Study

2015-06-25

Project Title

Outcomes of the use of sodium bicarbonate (8.4%) solution as a catheter lock solution to prevent hemodialysis catheter loss due to lumen clot formation

PI

EL-Hennawy, Adel MD

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Submitting User

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INSTRUCTIONS: This copy of the IRB Application xForm should only be used to make an amendment to an IRB approved application. All changes and new attachments will be automatically tracked. You will be prompted to answer any new questions that have been added since the last revision of this IRB Application xForm.

IF ADDING STUDY STAFF:

Upon receipt of your IRB request, the IRB will verify whether or not the Investigators and key personnel involved in the study have submitted their Annual IRB COI Disclosure form within the past year. If any COI forms are not on currently on file, the study team/team member will be notified and asked to complete the form before approval of the study will be granted by the IRB.

All Investigators and Key Personnel conducting human subjects research must complete and submit a Conflict of Interest Disclosure Form ("Disclosure Form") in IRBManager. To do so, the user must be logged into IRB Manager, click "HOME", then click "START XFORM", select the "Conflicts of Interest" xform, complete the form, and click "SUBMIT".

If a co-investigator is an employee of another institution, they can provide the adjudication of conflict of interest from their institution in lieu of using the Maimonides Medical Center disclosure forms, provided their institution provides a statement to the IRB that their policy complies with the 42 CFR part 50, Subpart F. The Maimonides Medical Center IRB can require the Maimonides Medical Center COI disclosure forms, if requested.

If at any time after submitting a Disclosure Form, one or more Financial Interests or Leadership Roles of an Investigator or Research Official or of an Investigator's or Research Official's Immediate Family in any research or health care-related organization changes in any material way, the Investigator or Research Official must promptly notify the IRB or Research Integrity Officer, respectively, of that change by submitting an updated Disclosure Form. Investigators must submit an updated Investigator Disclosure Form to the IRB annually. If an Investigator discovers or acquires a new significant financial interest (e.g. through purchase, marriage or inheritance) during the award period, the Investigator must submit an updated Conflict of Interest Disclosure Form within 30 days to the IRB after discovery or acquisition. A new SFI is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a "new" SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

If at any time after making a disclosure of a potential research-related institutional investment or interest, an Investigator, IRB member, or Research Official becomes aware of any additional significant investments of the Medical Center, the Investigator, IRB member, or Research Official must promptly notify the Research Integrity Officer of their new knowledge.

IF ADDING STUDY STAFF:

-Completion of the CITI "Basic Human Subjects Basic Course for Investigators" ("Biomedical" or "Social & Behavioral") is required for each "investigator" and "key personnel".
-In addition, if the study is funded by the U.S. Public Health Service (PHS), the same individuals must also complete the CITI "Conflicts of Interests training for Research Involving Human Subjects" course.
-Each person must achieve a minimum overall passing score of 80% for the required training modules. The certificate (completion report) is only valid for a period of 4 years.

See: https://www.citiprogram.org/ or http://intranet.mmc/Main/EducationalRequirementsforResearch.aspx

THE IRB STAFF WILL CONFIRM WHETHER EACH REQUIRED CITI IS ON FILE AND VALID; IF THE IRB STAFF IS NOT ABLE TO VERIFY THE COMPLETION OF REQUIRED CITI, THE STUDY TEAM WILL BE INFORMED. THE IRB WILL NOT GRANT APPROVAL FOR INDIVIDUALS WHO HAVE NOT COMPLETED THE REQUIRED TRAINING.

Check the following items, if they will be modified in this IRB Application xForm:

No answer provided.

If this amendment is for a change in the PI or budget the application will automatically be routed for Department Chair approval.

If this amendment represents a change in the budget, finance will be notified.

Please provide a specific summary of the amendment.

Addition of Dr. Elena Frolova as sub-investigator.

If you are making any changes to personnel on the study, please specifically describe who is being removed from the study and who is being added.

Provide a brief summary of all other details that will be modified.

Alternatively, you may upload an attachment that summarizes the changes. If you upload an attachment, please write "see attached."

Please provide a reason for your amendment.

Conflict of Interested Form expired and she was removed. The form has been updated and resubmitted.

Alternatively, you may upload an attachment that includes the reasons for the changes. If you upload an attachment, please write "see attached."

Optional Attachment(s):

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu

No answer provided.

IRB, Study Title, and Principal Investigator

WARNING: PLEASE DO NOT CONDUCT HUMAN RESEARCH OR ANALYZE DATA WITHOUT FIRST RECEIVING AN IRB APPROVAL LETTER, IRB EXEMPTION, OR AN IRB DETERMINATION LETTER.

Please indicate which IRB will review and oversee the research at your site:

Maimonides Medical Center IRB

An external IRB may only be selected, if the Maimonides Medical Center IRB Chair has approved its use in advance and an IRB Authorization Agreement has been established. Otherwise, select Maimonides Medical Center IRB.

If you select an external IRB, the questions will be limited to those required by Maimonides Medical Center IRB (e.g., regarding Conflict of Interest, Training, HIPAA Waivers, Information Security, etc). When using an external IRB, please follow the procedures of the external IRB, including those for IRB approval and reporting requirements. Once the Maimonides IRB reviews the associated materials for a study that will be overseen by the external IRB, we will issue a letter to adjudicate any conflicts of interest and document training. We will also approve any HIPAA waivers or HIPAA Authorizations that the external IRB will not approve. If there are any information security requirements for the study, these will also be reviewed by the MIS IRB Members.

If the external IRB does not provide a date stamp on the informed consent documents or HIPAA Authorizations or Waivers, the Maimonides IRB will do this.

Copies of approval and determination letters from the external IRB must be promptly sent to the Maimonides IRB for tracking and follow-up, as applicable.

NOTE: If you are from Coney Island Hospital or Richmond University Hospital and wish to use an external IRB, do not use this xForm, but follow your hospital policies.

Project Title:

Outcomes of the use of sodium bicarbonate (8.4%) solution as a catheter lock solution to prevent hemodialysis catheter loss due to lumen clot formation

Provide Study Nickname or Community Name, if applicable:

Sodium bicarbonate lock solution

Please type in the e-mail address of the PI:

EL-Hennawy, Adel MD

Email: adel.el-hennawy@nychhc.org **Business:** 718-966-4864

The Principal Investigator (PI) oversees scientific, technical, and day-to-day management of the research. The PI must have applicable qualifications and experience and be in good standing with the Medical Center. Only a clinician can serve as a PI on a study that involves a clinical intervention.

The PI is responsible for the oversight of the study and any compliance issue.

A PI must be an Attending Clinician (e.g., Physician or Nurse Practitioner), an employee in an official Supervisory position, or a PhD level employee that is assigned to do research as part of their duties, as defined in their written job description. Clinicians that are not employed by the Medical Center but have an affiliation agreement may serve as Principal Investigators.

Clinicians enrolled in Maimonides' residency, fellowship or nursing training programs (i.e. "trainee") may not serve as Principal Investigators but may serve as Co-Investigators. Trainees must have a Faculty Sponsor who will serve as the Principal Investigator and provide adequate supervision and mentoring to the trainee. Non-supervisory employees, students and volunteers cannot be a Principal (Clinical) Investigator; however, they can be considered Co-Investigators or Key Personnel, or non-research staff.

Are you requesting IRB approval for the use of a Humanitarian Use Device (HUD)?

***Note:* Check "*Yes, for research purposes*" *if* the HUD activity includes BOTH research *and* clinical activities.**

NO

As defined in 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year." HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Although the use of a HUD within its approved labeling does not constitute research, the FDA requires IRB approval be obtained before a HUD can be used in a facility.

At which site is the Principal Investigator located?

For MMC Cancer Center, please select CC

Selected value *Coney Island Hospital* is no longer available.

MMC = Maimonides Medical Center

CC = Maimonides Medical Center Cancer Center

CIH = Coney Island Hospital

RUMC = Richmond University Medical Center

Is this is a study only conducted at Coney Island Hospital?

Yes

Enter "Yes" if the study is only conducted at Coney Island Hospital (CIH) or when CIH is the main site of a multicenter project that does not involve Maimonides.

Enter "No" if it is conducted at Maimonides, regardless of whether it includes other places.

Is the study only conducted at Richmond University Medical Center (RUMC)?

No

Enter "Yes" if the study is only conducted at Richmond University Medical Center (RUMC) or when RUMC is the main site of a multicenter project that does not involve Maimonides.

Enter "No" if it is conducted at Maimonides, regardless of whether it includes other places.

Is this study considered a case series/case report involving just a few individuals (up to 20 individuals)?

No

*Check **YES** if this involves **ONLY** a retrospective review of data for a case report/series of just a few individuals (e.g., review of symptoms, signs, diagnosis, treatment, without long term follow-up).*

The data reviewed may contain a demographic profile of the patient, but usually describes an unusual or novel occurrence.

Checking YES to this question will direct the IRB Robot to only require an abbreviated set of questions.

Does this project involve multiple sites?

No

Will this be a *retrospective* study, a *prospective* study, or will it be both *retrospective* and *prospective?*

You may choose more than one answer, if applicable.

A proposed research project is generally either *retrospective, prospective,* or both.

Retrospective

The IRB will need to know whether the data collection is retrospective and/or prospective to determine if certain exemptions or waivers can be applied to the research.

***Retrospective** means the data already exits; however, please also select **"retrospective"** if requesting a **prospective** chart review of medical records if they do not exist at the time of the study proposal, but will be reviewed **retrospectively** at the time that the research is conducted and at a time when the patients are not available (e.g., patients would not be in the hospital while the study is being conducted and will not be available for follow-up).*

***Prospective** means that the data does not yet exist.*

Provide a brief non-technical summary of the project:

Use non-scientific terms.

This must be understandable to a lay person or non-medical personnel.

The purpose of this study is to compare two types of lock solutions utilized in hemodialysis catheters to prevent the formation of clots. We aim to compare the effectiveness of sodium chloride lock solution (SCLS) and sodium bicarbonate lock solution (SBLS). Since there is no ideal catheter lock solution, it was reasonable to evaluate an alternative catheter lock solution. We selected sodium bicarbonate solution because it is has some anticoagulation property. Also, it is readily available and routinely used in a hospital setting. This is a prospective study for a defined period. Data will be compared to a retrospective cohort during the same year.

Protocol Description

PROTOCOL INFORMATION

Does this study involve the use or disclosure of information regarding alcohol or substance abuse treatment program that includes access or disclosure of any of the following data elements: 1) names, 2) addresses, 3) social security numbers, 4) fingerprints, 5) photographs, or 6) similar information by which the identity of a patient can be determined with reasonable accuracy and speed, either directly or by reference to other publicly-available information?

No

If "Yes" is selected, this must be a prospective study that involves obtaining a PHSA consent.

Note: The PHSA consent language can be merged with the informed consent, information sheet, or HIPAA Research Authorization, as applicable, if any of these documents are also required for the study.

Does this study involve access to psychiatry notes?

No

If "Yes" is selected, this must be a prospective study that involves obtaining a consent with HIPAA Research Authorization that specifically discloses which investigators will have access to the psychiatry notes.

Is the PRIMARY purpose of this activity considered a Health Care Operations (e.g., performance improvement, quality assurance, etc.)?

No

Describe the overall aim of the project:

Study Objective:

To compare two types of lock solutions used in hemodialysis catheters to prevent clot formation. We will compare the effectiveness of SCLS with SBLS in mitigating hemodialysis catheters malfunction due to occlusion or thrombosis.

Your description should paint the "big picture" of the project.

If applicable, describe the condition or patient outcome of interest.

If applicable, describe the expected impact: incidence and prevalence at your institution or geographic area.

Write 1-3 specific study objective(s).

-- OR (as an alternative)--

State the hypothesis (or hypotheses) of your study.

Hypothesis:

We hypothesize that SBLS will be more effective in preventing thrombosis-related catheter malfunction than SCLS as sodium bicarbonate has some anticoagulation properties (29). However, we could not find literature related to SBLS, and its anticoagulant principle still cannot be definitely explained. It can be speculated that it works by binding calcium and removing it from the many enzymes of the coagulation system that require it as a cofactor.

Objectives are the basic research question(s) that the study is designed to answer. They often relate to the effectiveness of a therapy or an intervention or to the relationship between a predictor and a clinical outcome. Each objective should be one sentence and include one of the outcomes that you are interested in researching and the variables/factors that affect or correlate with it.

Hypotheses are more detailed and deal with the specific direction of the change in outcome due to the intervention or to the correlation. Hypotheses are the tests you use to help answer the objectives. Hypotheses are more specific than objectives and are what you test statistically. In practice, objectives and hypotheses are not always easy to tell apart.

References:
1) http://www.consort-statement.org/consort-statement/2---introduction0/item2b_objectives 2) http://www.niaid.nih.gov/researchfunding/grant/strategy/Pages/stepswin.aspx

Provide a summary of the relevant background information and importance of the knowledge expected to result from this study:

Central venous catheters, originally introduced as vascular access for short-term dialysis, have become an acceptable form of permanent vascular access. Both non-tunneled, non-cuffed and cuffed, tunneled hemodialysis catheters are used for vascular access in HD patients who have no alternative access or are awaiting placement or maturation of AVF. One of the major causes of catheter loss is clot formation in catheter lumen. Clotted catheter accounts for 10%–42% of catheter malfunctioning depending on catheter site. Heparin is routinely used as a "locking" solution for preventing thrombosis-related catheter malfunction. Many other agents, such as warfarin, sodium citrate, low-molecular weight heparin, and concentrated sodium chloride have been studied for the same purpose.

The purpose of this study is to compare two types of lock solutions utilized in hemodialysis catheters to prevent the formation of clots. We aim to compare the effectiveness of sodium chloride lock solution (SCLS) and sodium bicarbonate lock solution (SBLS). Since there is no ideal catheter lock solution, it was reasonable to evaluate an alternative catheter lock solution. We selected sodium bicarbonate solution because it is has some anticoagulation property. Also, it is readily available and routinely used in a hospital setting. This is a prospective study for a defined period. Data will be compared to a retrospective cohort during the same year.

Describe the need, relevance and priority for the study. For example, osteoarthritis in post-menopausal women affects N women over the age of 50. Patient symptoms are characterized by… This study is needed because... (describe why your proposed study is important and fills any knowledge gap in the field).

Describe the scientific and medical data (e.g., results of observational studies and early clinical trials) that justifies the study, its design, and the intervention groups. Include any data from animal and human studies relevant to mechanism of action, effect size, and possible effects of the intervention on selected outcomes.

Name and describe the intervention regimen(s) and justify why the intervention(s) have been chosen. Describe and justify the route of administration, dosage regimen, intervention period, frequency and intensity, etc. Summarize the known and potential risks of the interventions.

Include a list of relevant references:

References:
1. Allon, M. (2009). Treatment guidelines for dialysis catheter-related bacteremia: an update. Am J Kidney Dis, 54(1), 13-17. doi: 10.1053/j.ajkd.2009.04.006
2. Allon, M., & Sexton, D. J. (2014). Tunneled, cuffed hemodialysis catheter-related bacteremia: UpToDate.
3. Ash, S. R., Mankus, R. A., Sutton, J. M., Criswell, R. E., Crull, C. C., Velasquez, K. A., . . . Ing, T. S. (2000). Concentrated Sodium Citrate (23%) for Catheter Lock (Vol. 4, pp. 22-31): Hemodialysis International.
4. Chen, F. K., Li, J. J., Song, Y., Zhang, Y. Y., Chen, P., Zhao, C. Z., . . . Yao, D. F. (2014a). Concentrated sodium chloride catheter lock solution--a new effective alternative method for hemodialysis patients with high bleeding risk. Ren Fail, 36(1), 17-22. doi: 10.3109/0886022X.2013.830207
5. Chen, F. K., Li, J. J., Song, Y., Zhang, Y. Y., Chen, P., Zhao, C. Z., . . . Yao, D. F. (2014b). Concentrated sodium chloride catheter lock solution--a new effective alternative method for hemodialysis patients with high bleeding risk. Ren Fail, 36(1), 17-22. doi: 10.3109/0886022X.2013.830207
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10. Duncan, N. D., Singh, S., Cairns, T. D., Clark, M., El-Tayar, A., Griffith, M., . . . Taube, D. (2004). Tesio-Caths provide effective and safe long-term vascular access. Nephrol Dial Transplant, 19(11), 2816-2822. doi: 10.1093/ndt/gfh467
11. FDA Talk Paper: FDA issues warning on triCitrasol dialysis catheter anticoangulant. (2000).
12. Group, H. A. W. (2006). Clinical practice guidelines for hemodialysis adequacy, update 2006. Am J Kidney Dis, 48 Suppl 1, S2-90. doi: 10.1053/j.ajkd.2006.03.051
13. Ishani, A., Collins, A. J., Herzog, C. A., & Foley, R. N. (2005). Septicemia, access and cardiovascular disease in dialysis patients: the USRDS Wave 2 study. Kidney Int, 68(1), 311-318. doi: 10.1111/j.1523-1755.2005.00414.x

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15. Klouche, K., Amigues, L., Deleuze, S., Beraud, J. J., & Canaud, B. (2007). Complications, effects on dialysis dose, and survival of tunneled femoral dialysis catheters in acute renal failure. Am J Kidney Dis, 49(1), 99-108. doi: 10.1053/j.ajkd.2006.09.014
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stenosis in haemodialysis: comparative angiographic study of 50 subclavian and 50 internal jugular accesses. Nephrol Dial Transplant, 6(10), 722-724.
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24. Stas, K. J., Vanwalleghem, J., De Moor, B., & Keuleers, H. (2001). Trisodium citrate 30% vs. heparin 5% as catheter lock in the interdialytic period in twin- or double-lumen dialysis catheters for intermittent haemodialysis. Nephrol Dial Transplant, 16(7), 1521-1522.
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29. Wong DW, J Pharm Sci. 1980 Aug; 69(8):978-80.Effect of sodium bicarbonate on in vitro conversion of fibrinogen to fibrin.

Please attach the Protocol (including appendices) or Project Description, if applicable for this project:

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

Research protocol for sodium bicarbonate lock solution _El-Hennawy_9-16-15.doc Protocol

Design and Methods

If you need assistance completing this section, please contact your research mentor or a statistician.

Resources:

Medical Center	***Department***	***Contact***
Maimonides Medical Center *Office of Research Administration* *Brooklyn, NY 11219*	*ALL*	***Dr. Theresa Jacob*** *Director of Research, Psychiatry* *Director, Clinical and Translation Research* *Phone: 718-283-7162* *TJacob@maimonidesmed.org* *Mr. Antonios Likourezos* *Research Manager, Department of Emergency Medicine* *Phone: 718-283-6896* *alikourezos@maimonidesmed.org*
Coney Island Hospital *2601 Ocean Parkway* *Brooklyn, NY 11235*	*ALL*	***Ms. Karen Hultberg*** *Associate Director, Medical Staff Affairs* *Phone: 718-616-5627* *Fax: 718-616-5195* *Karen.Hultberg@nychhc.org*
Richmond University Medical Center *355 Bard Avenue* *Staten Island, NY 10310*	*Medicine*	***Dr. Dennis Bloomfield*** *IRB Liaison* *Phone: 718-818-2707* *DBloomfield@RUMCSI.org*
	OBGYN	***Dr. Nisha Lakhi*** *IRB Liaison* *Phone: 718-818-2426* *NLakhi@RUMCSI.org*
	Pediatric	***Dr. Melissa Grageda*** *IRB Liaison* *Phone: 718-818-4636* *MGrageda@RUMCSI.org*
	Psychiatry	***Dr. Nida Khan*** *IRB Liaison* *Phone: 718-818-5007* *Nikhan@RUMCSI.org*
	Radiology	***Dr. Michael Mantello*** *IRB Liaison* *Phone: 718-818-2148* *MMantello@RUMCSI.org*
	Nursing	***Dr. Kathleen Dimauro*** *IRB Liaison* *Phone: 718-818-4387* *KDimauro@RUMCSI.org*

Describe the study design and methods.

Methods:
This quality improvement study.

Retrospectively, we will review medical records of patients who were admitted to Coney Island Hospital (CIH) in Brooklyn, New York that need dialysis via catheter over a six month period.

We will review the medical records of patients who were admitted during the study period at CIH to identify those who meet the inclusion criteria.

We will look at patients that were given sodium bicarbonate as a catheter lock solution admitted with a diagnosis of renal failure (acute or chronic failure) and requires hemodialysis treatment using a hemodialysis catheter (tunneled or non-tunneled catheter). Upon completion of hemodialysis treatment, each lumen of the catheter will be flushed with 17.5 mL of NaHCO3 8.4 % and locked with the 2.5 mL of locking solution. The catheters are monitored for thrombosis at each hemodialysis treatment. Thrombosis will be evaluated by resistance or complete occlusion to inflow or outflow of catheter ports before initiation of heparin free hemodialysis or during hemodialysis treatment if blood flow is less than 200 ml/min. Data will be collected from patients' EMR, nursing notes and Interventional radiologist reports and placed onto the data collection tool in Excel.

Data collection will be done by reviewing charts at a time when the patients are not available to the study team.

Data will be collected spanning a period of six months. In this group of patients, 0.9 % sodium chloride were used as a catheter lock solution and it was used in the same manner as sodium bicarbonate lock solution. Data from the sodium bicarbonate solution group will be compared to sodium chloride group to test our hypothesis. Locking solution will be infused in the catheter's lumen by trained hemodialysis nurse according to their policies and procedures. There will be no direct patient contact for purposes of this study.

Data on catheter malfunction due to thrombosis/occlusion, catheters retention rate, patients' hospital stay, complications due to catheters lock solutions, patients' demographic and laboratory results will be collected at conclusion of the study.

All dialysis patients will receive heparin free hemodialysis treatment. The duration of each

Indicate, in general terms, how the design will answer the question posed by the study.

Your description should provide enough information so that the reviewer can evaluate how you plan to address your study aims, understand what the study proposes to do and what participants will undergo. The description should be able to answer the following questions, if applicable to the study:
1. Type/design (e.g., placebo-controlled, double-mask, parallel design, open-label, dose escalation, dose-ranging, observational, cross-sectional, case control)
2. Specific statement of the primary and secondary outcomes (must be consistent with Study Objectives)
3. Study population and groups/arms including sample size (including a table, if appropriate)
4. Study location (e.g., in-patient or out-patient, clinic, community)
5. Approximate duration of enrollment period and follow-up (specify individual participant vs. entire trial)
6. Description of intervention and administration
7. Randomization, blinding and any stratification
8. Other protocol specific details, such as centralization of evaluations (e.g., central laboratory or central reading center for clinical scans)
9. You may attach diagrams or graphics to explain design complexities in the next question.

hemodialysis session will be 3 hours. The last sodium bicarbonate or isotonic saline lock solution will be removed and discarded before connecting hemodialysis catheter to machine. After hemodialysis treatment, the patient's blood will be rinsed back thoroughly with normal saline solution. The catheter will be flushed and locked with 20 ml in each port with either isotonic sodium chloride in isotonic sodium chloride lock group or NaHCO3 8.4 % solution in sodium bicarbonate group.

As per Dr. Frolova and Dr. El-Hennawy, the SCLS and SBLS are both options for locks solution. There is currently no set standard of care, and it is up to the discretion of the treating physician to order whichever lock solution he/she sees fit.

There is no policy/procedure change made for the research interevention, and there is no new policy that is being evaluated. What Dr. Frolova meant was that the physicians will have not direct patient contact during the catheter locks solution infusion because these are done by hemodialysis nurses.

Describe the statistical methods that will be used to analyze the data (chi square, t-test, correlation):

Analysis:

Basic characteristics (number of catheter malfunction due to thrombosis/occlusion in groups, catheters retention rate, number of hemodialysis treatments, patients' demographic and laboratory results) of all study patients will be collected and compared descriptively.

The incidence of catheters malfunction due to thrombosis/occlusion in both groups will be compared using Chi-square test. Also it was estimated that we need at least 72 patients in each group for 90% Power.

At CIH, the unique patient rate of catheter failure for normal saline is 16% while it is estimated that the rate will be 2% for sodium bicarbonate. As per Dr. Peter Homel, Maimonides Medical Center biostatistician, based on these estimates, we will need at least 72 patients per group to have 90% power with alpha=0.05 (72 patients who previously received saline, and 72 patients who get sodium bicarbonate). These will be non-overlapping patients – i.e., no patients who got both).

We will compare these two groups of patients utilizing chi square tests to test for the difference in the patient rate of catheter loss.

Who will do (or guide) the data analysis?

Dr. Peter Homel guided us in number of patients required for 90% power with alpha=0.05. NYC HHC biostatisticians Yingyi Xiao and Brian Altonen will assist the study team in data analysis upon completion of data collection.

What and how will you measure or collect data to test your hypothesis (or study objectives)?

Analysis:

Basic characteristics (number of catheter malfunction due to thrombosis/occlusion in groups, catheters retention rate, number of hemodialysis treatments, patients' demographic and laboratory results) of all study patients will be collected and compared descriptively.

The incidence of catheters malfunction due to thrombosis/occlusion in both groups will be compared using Chi-square test. Also it was estimated that we need at least 50 patients in each group to apply statistical test of significance.

A data collection sheet will be utilized.

Considerations:

Include specifics about the type of each measurable outcome (ie. nominal data like gender, continuous data like age or blood pressure).

How will the data be collected, by whom and how often? If tissue or blood samples are collected, please describe process for collection, storage, assays, shipping, bio banking, etc.

How will you ensure good quality or reliability of the information you are collecting (e.g., two readers for an x-ray or sonogram)?

Be sure to describe all data that are to be collected and all procedures to be done. Distinguish between what is done as part of standard of clinical care (if applicable) and what is done for research purposes. For studies that involve multiple visits, describe the schedule of what will be collected when. If possible, please provide this schedule information in a tabular format.

Attach any necessary graphic or diagram files related to the study methods:

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

No answer provided.

You may use graphics or diagrams to explain design complexities.

IRB manager will accept any type of file including graphic and video files; however, the IRB members must have access to the program to view the file, so it is best to attach files that are accessible in Microsoft or Adobe formats.

Describe where the research data will reside and who will have access to hold or maintain the data?

The PI and co-investigator will have access to the study data. All research data will be kept in a password-protected computer in the Nephrology Department at Coney Island Hospital.

Fully describe any data repository, data warehouse, file server, or database, including the location and institution and the expected duration of the storage.

Describe who will manage the data and any rules for how data can be released to others.

If coded data are stored, the specific details regarding coding agreements or who will have access to the code should be described.

Note: The informed consent or information sheet, when applicable, should describe the the protections in place for the research participants.

Describe precisely wherespecimens will be stored (e.g., physical site, building and room, etc.):

Enter "N/A" if the study does not involve a specimen storage.

N/A

Enter "N/A" if the study does not involve a specimen storage.

Describe where specimens will be banked including the location and institution and the expected duration of the storage.

Describe who will manage the repository and any rules for how specimens can be released to others.

If specimens are stored in a repository for future genetic testing, they must be totally stripped of identifying information or be coded.

If coded specimens are stored, the specific details regarding coding agreements or who will have access to the code should be described.

Note: The informed consent or information sheet, when applicable, should describe the specimen storage and the protections in place for the research participants.

Describe the methods that will be used to destroy data and/or specimens at the end of the research study life cycle.

Upon study closure, study data will remain in a secure location in the Research Administration Department, Room 1007, for a minimum of 8 years. Electronic data will be saved in password-protected computers in the Nephrology Department for a minimum of 8 years after closure.

Note: All research materials must be maintained in accordance with the information security and retained for the period of time outlined in policies regarding retention requirements.

Inclusion/Exclusion Criteria

PARTICIPANT INFO - Inclusion/Exclusion Criteria

List the inclusion criteria

- All patients admitted to Coney Island Hospital and needed hemodialysis treatment via hemodialysis catheter.
- All patients will receive heparin free hemodialysis treatment.

List the exclusion criteria

- Patients who are receiving Coumadin, Heparin drip or thrombolytic agents.
- Patients with abnormal PTT (> 35), PT (> 13.5) and INR (> 1.5).
- Patients with severe thrombocytopenia (< 40K).

These are not the opposite of the inclusion criteria, but are criteria such as comorbidities that may affect your outcomes.

Will participants be excluded if they are already enrolled in certain studies?

No

Demographics of Participant Population

Participant Information

Will any of the following populations be enrolled in the study for either an intervention or interaction?

Note: Check N/A if this study only involves data and there are not interventions or interactions (e.g. this is only a retrospective study).

N/A - No Vulnerable populations are enrolled or this study involves data only (no interaction/interventions)

You can choose multiple values for this answer.

Pregnant minors are considered children.

If prisoners, pregnant women, fetuses, or neonates will be included in the study, the study cannot undergo expedited review.

Check the gender(s) of the participants that will be in this study

Males
Females

Patient type:

In-patients

"Inpatient" means that the procedure requires the patient to be admitted to the hospital, primarily so that he or she can be closely monitored during the procedure and afterwards, during recovery.

"Outpatient" means that the procedure does not require hospital admission and may also be performed outside the premises of a hospital.

Indicate the age range of the participants:

18-99

Even if you are not recruiting and enrolling participants (data review only), please indicate the age range for the participants about whom their data pertains.

All ages over 89 and all elements of dates (including year) indicative of such age are considered to be identifiable information; unless such ages and elements are aggregated into a single category of age 90 or older. If you need to record the actual age of an individual over 89, this study does not meet the criteria for exemption category #4, unless the information is public; however, the study may qualify for expedited review.

Employees / Students

Participant Information

Does your research involve student education records or is it funded by the U.S. Department of Education (ED)?

No

If yes is checked, additional ED regulations [e.g., Family Educational Rights Protection Act (FERPA), Protection of Pupil Rights Amendment (PPRA)] and school policy may apply. Please contact the IRB for assistance.

Will the research be conducted in a NYC school or involve data from the NY Department of Education?

No

If yes is selected, the NYC DOE IRB must also approve the research.

Exempt Application?

Are you requesting an exemption for this study?

***Do not select YES** if you **are collecting** "Protected health information (PHI)," as used in Policy RES-19, consists of any patient (or employee) information, including very basic information such as their name or their age, that (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and (2) either identifies the individual, or could reasonably be used to identify the individual. Protected health information may be in any form, including spoken, written, or electronic form. Examples of protected health information include, but are not limited to, medical records, medical data on information systems, and applications for health or disability benefits.*

.

No

Answering "no" will allow you to skip the questions regarding exemptions. You will then be prompted to answer a series of questions to determine if the study qualifies for expedited review. If you select "yes," you will be prompted to select one or more of the exempt categories, in the next section.

The exemption categories are described below:

Exemption Category 1: *Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.*

Exemption Category 2: *Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. NOTE: Just because a study involves a survey, does not mean it is automatically exempt under category #2. To qualify for this exemption, the survey must not collect identifiable information or must not be risky in nature to the participants. If an intervention is also involved, the intervention must also meet one of the exemption categories for the entire study to me exempt.*

Exemption Category 3: *Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item #2 above, if: (1) The human subjects are elected or public officials or candidates for public office; or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.*

Exemption Category 4: *Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.*

NOTE: If you claim this exemption because information is recorded without identifiers, you must include your data collection sheet. The data collection sheet must not contain any identifiers, including the 17 HIPAA identifiers outlined in the RES-19 policy.

Exemption Category 5: *Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or service under those programs. NOTE: Exemption #5 only applies to research that is exempted from a Federal Department or Agency Head (e.g. Secretary of the US Department of Health and Human Services)*

Exemption Category 6: *Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.*

Determination of Eligibility for Expedited Review?

EXPEDITED REVIEW CONSIDERATIONS

Check the box if<u>any</u> of the conditions below are <u>true</u>. If checked, the research is not eligible for expedited review and the the application will skip to the next section.

<u>If none of the following apply, do not select anything; move to the next question.</u>

No answer provided.

Note: Even if the research is eligible for expedited review, the IRB may defer it to be reviewed at an IRB meeting.

A NSR device study that is not exempt from the IDE regulations is still considered an IDE study and cannot be expedited.

Expedited Review Categories?

Please check the boxes to indicate the categories of research that will be undertaken. This will help determine whether a project, involving no greater than minimal risk, is eligible for expedited review. All of the research can only involve procedures listed in one or more of the following categories, in order to be eligible for expedited review. Studies involving children may qualify for expedited review, unless otherwise indicated within the categories.

MORE THAN ONE CATEGORY MAY BE CHECKED IF NECESSARY.

IF THE RESEARCH DOES NOT QUALIFY FOR EXPEDITED REVIEW, GO TO THE "PREVIOUS" SCREEN AND CHECK THE BOX THAT STATES "The research does not meet any of the categories for expedited review"

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Expedited Review Category #1a/1b:
Does this study involve a clinical study of drugs or medical devices under either or both the following conditions?

No answer provided.

Check either or both a or b, as appropriate.

EXAMPLES:
(1)(a): The study compares different drugs that are approved by the FDA and is not done for the purpose of marketing or changing the label of the drug.
(1)(b): EXAMPLE: The study involves an FDA approved device (e.g., 510(k) cleared) that is used according to the labeling.

Expedited Review Category #2a/2b:
Does the research involve collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

No answer provided.

Check either or both a or b, as appropriate.

EXAMPLES:
(2)(b): The study involves blood collection within the specified limits above.

Expedited Review Category #3:
Does this study involve a prospective collection of biological specimens for research purposes by noninvasive means?

No answer provided.

EXAMPLE: The study involves a non-invasive biological specimen collection(s) such as:
(a) hair and nail clippings in a nondisfiguring manner;
(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction;
(d) excreta and external secretions (including sweat);
(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
(f) placenta removed at delivery;
(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
(j) sputum collected after saline mist nebulization.

Expedited Review Category #4:
Does the research involve the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

No answer provided.

Examples provided in the regulations:
(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the participants' privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

EXAMPLE: The study involves collection of data through FDA approved EKG equipment.

Expedited Review Category #5:
Does the research involve materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). This category includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. This category also includes research involving materials that will be collected solely for non-research purposes.

Yes

EXAMPLES:

- *The study involves collection of data from a clinical medical record, or the secondary use of research data from another study. (e.g., retrospective chart review that does not qualify for an exemption).*
- *The study involves transfer of specimens solely collected for a clinical procedure to a repository (e.g., waste tissue or excess tissue not needed for pathology diagnosis, provided that the extra tissue was not collected for the purpose of the research).*

Expedited Review Category #6:
Does the research involve collection of data from voice, video, digital, or image recordings made for research purposes?

No answer provided.

EXAMPLE: The study involves collection of data using a video tape or audio recording.

Expedited Review Category #7:
Is the research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

No answer provided.

EXAMPLE: The study involves use of a survey that is not exempt because it collects both identifiable and sensitive information or it involves children.

The following is confirmed:

All of the research involves only procedures/activities listed in the above expedited review categories.

If any of the research procedures or activities cannot be expedited, the study is not eligible for expedited review. In other words, all procedures and activities that are part of the research in this project must fit within one or more categories of expedited review.

DO NOT CHECK THIS BOX IF THERE ARE ANY PARTS OF THE RESEARCH THAT DO NOT FIT INTO ALL OF THE CHECKED CATEGORIES ABOVE. IF YOU ARE NOT ABLE TO CONFIRM, PLEASE CHECK THE BOX ON THE PREVIOUS PAGE TO INDICATE THE STUDY IS NOT ELIGIBLE FOR EXPEDITED REVIEW.

Participant Sample Size/Power Estimates

Note: There are reference tables, mathematical formulas, and online calculators that can be used to estimate the sample size you need to have a good chance of finding or getting significant results. This is called power analysis or sample size estimation. Also, please include estimated rates of refusal/ attrition on part of participants or rates of ineligible records which may require more participants to be contacted than will be actually enrolled in the study.

Local numbers:

Estimated number of eligible participants available at your recruitment site, if known:

100

This refers to the estimated number of eligible participants that might be available at your recruitment site. This number can be an estimate.

Estimated number of participants or participant records that need to be screened, prior to enrollment or inclusion, in your research project at your recruitment site:

100

This means the estimated number of participants or participant records that you think you will need to screen in total, in order to reach the desired enrollment number to achieve the study goal.

Sample Size (at local recruitment site):

144

Indicate the total number of eligible participants or participant records that will be included in the study at your local recruitment site. If this study is taking place at multiple centers, the total for all sites needs to be indicated in the next question.

When recruiting and enrolling research participants on a prospective basis, include the number that you plan to enroll.

When performing a a retrospective review of data, include the number of participants about whom their data will be reviewed.

Describe how the above numbers were determined (e.g., provide a power analysis, explain the pilot data, or reference prior studies).

This study is a pilot study to test sodium bicarbonate as a hemodialysis catheter locks solution in decreasing clot formation in the cather lumen when compared to isotonic sodium chloride solution use. There is currently no literature that compre sodium bicarbonate with other catheter locks solution in hemodialysis patients.

At CIH, the unique patient rate of catheter failure for normal saline is 16% while it is estimated that the rate will be 2% for sodium bicarbonate.

As per Dr. Peter Homel, Maimonides Medical Center biostatistician, based on these estimates, we will need at least 72 patients per group to have 90% power with alpha=0.05 (72 patients who previously received saline, and 72 patients who get sodium bicarbonate). These will be non-overlapping patients – i.e., no patients who got both).

We will compare these two groups of patients utilizing chi square tests to test for the difference in the patient rate of catheter loss.

*A power analysis **should** be provided to ensure the sample size is adequate and to avoid delays in application approval (e.g., to prevent a b error where there really is a difference, but your sample size is too small to detect it).*

You should ask a biostatistician for help describing the data analysis if you are not sure. If you need help in this section please contact Dr. Peter Homel, at x718-283-7193 or phomel@maimonidesmed.org

If a power analysis was not done, please explain why.

Retrospective

Retrospective Information

Indicate the date range (start and stop date) of the records that will be reviewed retrospectively?

Sodium Chloride (Saline) Group: May 1, 2014 - October 31, 2014
Bicarbonate Group: From study approval plus six months

Enter N/A, if not applicable

Study Time Line

Study Time Line

How many months will this study take place at the Medical Center?

6

This field is a numeric field.

This can be an estimate. Continuing review (progress reports) are always required on at least an annual basis or more frequently, if determined by the IRB.

Include in your timetable preparatory work needed to carry out the study (e.g. indicate 240 months for a ten year period).

Additional documents

Select any of the following types of documents, if they are to be used in this study:

DOCUMENTS

Select any of the following types of documents, if they are to be used in this study:

Data collection tools
Other

For exempt research for either category #2 or #4, please attach supporting documents to verify the criteria for the exemption category are met.

Attaching the CRFs for IRB review and approval in the next screen is only needed if a sponsor requires IRB review of these forms.

When attaching documents, please be very specific about the naming the file and selecting the types of the attachment. This exact file name that is used and the type of the document selected will be included in the final IRB approval letter.

Please attach data collection tools:

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

Data Collection Sheet_Cather Lock Solution Study.xlsx Data Collection Tool(s)

Please attach other documents to be reviewed by the IRB:

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

De-Code Sheet_Cather Lock Solution Study.xlsx Miscellaneous

Access to PHI, ePHI, PII, IIPD, ISI, PD

Does the research involve obtaining, accessing, using, reviewing, recording, or disclosing any of the following types of data (regardless of whether it is not recorded or eventually de-identified)?

- **Protected Health Information (PHI) (e.g., medical record)**
- **Electronic PHI (ePHI)**
- **Personal Identifiable Information (PII)**
- **Individually identifiable private data**
- **Identifiable sensitive information**
- **Personal data**

Yes

*"Protected health information (PHI)," as used in Policy RES-19, consists of any patient (or employee) information, including very basic information such as their name or their age, that (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, **and** (2) either identifies the individual, or could reasonably be used to identify the individual. Protected health information may be in any form, including spoken, written, or electronic form. Examples of protected health information include, but are not limited to, medical records, medical data on information systems, and applications for health or disability benefits.*

Information Security Risk Assessment

What technical safeguards will be used in this study to protected identifiable electronic data?

The study protocol states that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team
Email which contains Electronic Protected Health Information (EPHI), Protected Health Information (PHI) and Personal Identifiable Information (PII) is encrypted when communicating over an insecure network (i.e. Internet)
The data repository, data warehouse, file server and/or database that stores research data is in compliance with the MISPC-012-Institutional Systems Requirements Policy.
File transfers containing (EPHI), (PHI) and (PII) use a secure file transfer mechanism to ensure data security when in transit. These technologies include, but are not limited to, HTTPS secured websites, Secure File Transfer (SFTP) and Virtual Private Networks (VPN)
Research projects which contain EPHI, PHI and/or PII, in an electronic format will reside in a centralized secure location (i.e. network file share, SharePoint site or database). Sensitive information must not be stored on a local computer hard drive)
User credentials (i.e. network ID and password) are not shared.

Where will electronic data reside?

Other (described below)	*Electronic data must reside in a centralized secure location.* *Sensitive information cannot be stored on a local computer hard drive.*

If other was checked above, please explain.

In a password-protected computer at CIH.

If the research activities involve obtaining, accessing, using, recording or reviewing full or partial Social Security Numbers (SSNs), please provide the justification for doing so:

Enter "N/A" if SSNs are not obtained, accessed, used, recorded or reviewed.

N/A

Describe how private or sensitive identifiable data will be excluded from publication or presentation:

If this is not feasible, please explain why it is not feasible.

Do not state "no identifiers are recorded" if you are collecting "Protected health information (PHI)," as used in Policy RES-19, consists of any patient (or employee) information, including very basic information such as their name or their age, that (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and (2) either identifies the individual, or could reasonably be used to identify the individual. Protected health information may be in any form, including spoken, written, or electronic form. Examples of protected health information include, but are not limited to, medical records, medical data on information systems, and applications for health or disability benefits.

Patient identifiers will be coded.

Check all measures that will be used to maintain the confidentiality of participants' data.

<u>Do not select</u> "no identifiers are recorded" <u>if</u> you are collecting "Protected health information (PHI)," as used in Policy RES-19, consists of any patient (or employee) information, including very basic information such as their name or their age, that (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and (2) either identifies the individual, or could reasonably be used to identify the individual. Protected health information may be in any form, including spoken, written, or electronic form. Examples of protected health information include, but are not limited to, medical records, medical data on information systems, and applications for health or disability benefits.

Paper- based records will be kept in a secure location and only be accessible to only personnel involved in the study as listed on this IRB application.
Removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team.
Prohibit the use, or collection of, social security numbers as part of a study.
Computer-based files will be available to study personnel through the use of access privileges and passwords.
Whenever feasible, identifiers will be removed from study-related information.
Maintain access logs
Unnecessary identifiable information is excluded.
Unnecessary identifiable information is redacted.

Describe the types of mobile devices that are used in this study, and explain how they will be used:

<u>Mobile devices include, include but not limited to, laptops, tablets, USB drives, portable hard drives and smart phones</u>.

Enter "N/A" if mobile devices are not involved in the study.

N/A

Which technical security measures will be implemented to guard against unauthorized access to EPHI (Electronic Protected Health Information) that is being transmitted over an electronic network?

Secure Transmission of EPHI (Email/Secure FTP): HIPAA mandates that "A covered entity must implement technical security measures that guard against unauthorized access to EPHI (Electronic Protected Health Information) that is being transmitted over an electronic network".

Transmission Security (Email, Secure FTP).

Must use encryption when:
1. If the recipient is an employee or has a @maimonidesmed.org (or @nychhc.org for CIH; or @RUMCSI.org for RUMC) email account, you are required to use that email address when transmitting EPHI. There are no exceptions.

2. Email that is sent to an external recipient containing EPHI must be encrypted. This applies to either forwarding or replying to an email. The instructions for encryption can be found below.

3. If the unencrypted e-mail went to a personal e-mail account (such as Gmail, Hotmail, Yahoo, or any other), please immediately delete the e-mail from that mailbox.

4. Your account will be disabled if you continue to send unencrypted email.

The Medical Center provides the following technology to encrypt sensitive information:

Communication Method

	Description	Point of Control	How to guides and application links
Secure File Transfer	**Used to send large files securely**	**User initiated**	**http://intranet.mmc/Main/MMCemail.aspx** **(or hhtps://filetransfer.nychhc.org for CIH)** **(Check with Nancy Taronto for RUMC)**
Secure E-MAIL	**Used to encrypt EPHI within the body of e-mail**	**User initiated**	**http://intranet.mmc/Main/MMCemail.aspx** **(Check with Janina Sawyer for CIH)** **(Check with Nancy Taronto for RUMC)**
Secure E-Mail with an attachment	**Used to encrypt EPHI within body of e-mail and the file attachment**	**User initiated**	**http://intranet.mmc/Main/MMCemail.aspx** **(Check with Janina Sawyer for CIH)** **(Check with Nancy Taronto for RUMC)**

N/A -identifiable data will not be transmitted outside the hospital firewall or e-mail system.

How will data be accessed from remote locations?

Data will not be accessed from remote locations.

Acceptable Response Examples:

- *Data may be accessed through the Maimonides share-point site via an encrypted hospital owned lap top.*
- *Data will not be accessed remotely*

Benefits

Describe any potential benefits or outcomes to society.

If the hypothesis is true, we can use sodium bicarbonate locks solution in hemodialysis catheters to prevent clot formation. Sodium bicarbonate is cheap and readily available and mitigates bleeding complications due to use of anticoagulants in locks solution.

Indicate "n/a" if not applicable.

Consider any benefits to society, particularly if there is no direct benefit to the participant.

Protected Health Information (PHI)

HIPAA/HITECH REGULATORY CONSIDERATIONS

Are all members of the research team for this study also members of the patient's treatment team?

Research team = Investigator (PI), Co-Investigators (CO-I), Key Personnel

Treatment team = Physician or medical staff who provide treatment services to the patient regardless of research interventions.

If any member of the research team is NOT a member of the patient's treatment team, select "No".

Yes

Is a HIPAA Alteration needed for this research project?

No

A HIPAA Alteration permits the use of a Research Authorization that does not contain all of the required elements or statements, or that otherwise deviates from the format or process prescribed by the HIPAA regulations.

This may be useful, for example, when an Investigator is also seeking waiver of documentation of informed consent, when the only link of a participant to a study is their signature on a consent form and HIPAA Research Authorization, if it can be considered impracticable to the study's completion to obtain a signed Research Authorization form as such a requirement might prevent study completion.

There also may be other circumstances where a simplified consent and authorization document are appropriate given the nature of the patient population enrolling in the research and in that case a request to waive certain but not all elements or required statements of the authorization would be made.

EXAMPLE: This can be requested when a waiver of documentation (signature) of informed consent is requested when it is also impracticable to obtain a signature on a HIPAA Research Authorization, when the signature would create a document that adds a risk to the individual for a highly sensitive and risky research topic.

Will PHI be accessed by or disclosed to anyone outside the Medical Center *prior* to obtaining a HIPAA Authorization signed by the research participant?

N/A

If yes, "Accounting of Disclosure Forms" must be submitted to medical records, with each individual disclosure.

IC/Assent Waivers ?

INFORMED CONSENT/PARENTAL PERMISSION/ ASSENT

Please indicate whether informed consent (or parental/guardian permission), or pediatric assent will be obtained and documented or whether a waiver of any the requirements of informed consent (or parental permission/assent) is requested:

B4. Waiver of requirement to obtain informed consent or parental (or guardian) permission.

More than one box may be selected, if applicable, depending on the design of the study.
There are several types of waiver requests:

o A request to "waive informed consent for recruitment purposes" may be made when the research team needs to look at data such as medical records to gather information to contact a participant to see if they are interested in participating in a study. Once the participants are recruited, informed consent is usually obtained at the time of enrollment, unless waived or when the research is exempt.

o A request to "waive the documentation" (signature) of informed consent can be made when informed consent is obtained without documentation (e.g., signed informed consent). When this is requested, an information sheet should be provided to the participant and in general an information sheet will be required by the IRB. There are no regulatory requirements regarding the information that must be included in the information sheet; however, it is generally a best practice to include information that addresses all the required elements of informed consent. A template information sheet is available for guidance.

o A request to "waive informed consent (process)" may be made when the investigator wishes to waive the entire process of consent (including documentation). No information sheet is required if this is granted.

o A request to "waive some of the required elements" of the written informed consent document, can be requested when an investigator does not wish to include all the required elements of informed consent in the informed consent document.

Would you like additional guidance?

No

Clicking "Yes" will open more detailed guidance.

HIPAA Waiver Full

FULL HIPAA WAIVER REQUEST

Based on the previous responses, a FULL HIPAA Waiver is required for the retrospective portion of the study.

1. Brief description of the protected health information for which the study team is requesting access:

Please indicate the protected health information (PHI) for which you are requesting access:

All questions in this section must be completed by any researcher requesting a waiver of the authorization requirement under HIPAA

Please tailor the response to each question based on the individual research.

Do not select a response unless it is relevant to the specific project and accurately reflects the approach or process that will be used.

We wish to access PHI contained in patient medical charts for a retrospective chart review.
The data fields/elements that will be recorded or collected are listed on the attached data collection form based on the date range indicated in the IRB application.

When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

Please affirm the following:

The PHI described within this request is limited to the minimum necessary to accomplish the intended purpose.

2. Plans to protect the "identifiers" from improper use and disclosure:

Indicate which *actions* are part of the study team's plan to protect the "identifiers" from improper use and disclosure:

The details you include in your request should reflect accurately how you will protect identifiers and should be reasonable in relation to the risk to privacy posed by the study; you should not include any of the following plans if you will not actually be able to implement such protections,

PHI will not be disclosed to persons outside of the Medical Center.
Identifiable information will be stored in a secure manner (e.g., locked file cabinet, password protected database) accessible only to research study investigators.
Forms used for recording data for this study will not have any participant identifiers.
The study team will used coded information, which do not have any elements of PHI.
All labels and patient identifiers will be removed. Under no circumstances will PHI be revealed.
No photocopies will be made of any patient chart, lab or other clinical information.
A master record (log) will be maintained, which correlates patient record number and serial number in case there is a need to recheck data on the protocol sheet with the information in the chart. This log will be kept in a locked drawer or be secured by other similar means.
All research files will be locked while they are unsupervised.
We will use screen savers on computer monitors, shred excess copies of paper documents.
We will protect codes that link patients to their data and keep the code locked away when not in use.
We will keep electronic data stored in password protected files and will not e-mail any information unless it can be encrypted.
All PHI will be used only on site at MMC and will not be disclosed to any outside entity.

3. Plan to destroy the "identifiers" at the earliest opportunity or justification for retaining the identifiers:

Please indicate one of the following:

The study team has an adequate plan to destroy the "identifiers" at the earliest opportunity consistent with the conduct of the research

Describe the plan to destroy the identifiers at the earliest opportunity, after the conclusion of the research and record retention period. Include when and how identifiers will be destroyed. Be specific:

Identifiable data will be stripped of all HIPAA identifiers and the deidentified data will be stored safely and securely.

Specify which identifiers and information will be destroyed:

The de-coding sheet which contains the MR# and code for each patient will be destroyed upon the collection of all necessary study data. Any paper copies of will be placed in HIPAA waste bins for disposal, and electronic copies will be deleted from all CIH-password protected computers.

4. Affirmation statement:

Protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under Maimonides Medical Center's policy entitled "Use and Disclosure of Protected Health Information for Research Purposes" (RES-19)?

Specifically, the following is represented:

The PHI is to be used for the sole purpose of this research project and will not be disclosed to any other person or entity without prior authorization.
The PHI will not be disclosed to an individual's employer for employment decisions without the individual's authorization and any other pertinent assurances.

5. Reason the research could not practicably be conducted without the waiver:

The research could not practicably be conducted without the waiver *because* (specify):

We will be accessing confidential information about patient health and demographics in retrospective manner who would not be in the hospital while the study is being conducted
The participants for whom records would be reviewed are no longer followed or lost to follow-up (e.g., significant proportion of individuals relocated or died).
To practically conduct this research study requires that we be able to access and use patient PHI to identify prospectively our patients who meet study eligibility criteria and to focus our recruitment efforts at these patients.

6. Reason the research could not practicably be conducted without access to and use of the protected health information:

The research could not practicably be conducted without access to and use of the protected health information *because*:

It is not possible to conduct this research unless we are able to identify and recruit potential research participants.

(Please note: If a researcher can practicably use de-identified health information or a limited data set for a research study, a waiver of authorization should not be granted.)

HIPAA Waiver Approval

Investigators should click "NEXT" to move forward.

HIPAA Waver Approval (IRB Privacy Officer Designee use only).

Note: Only IRB Member can view questions in this section.

IC Waivers / Alterations

The questions below must be answered because you previously indicated a request for either:

- **B2. Waiver of the process of informed consent or parental (or guardian) permission for recruitment purposes only. Informed consent or parental (or guardian) permission will be sought from participant prior to enrollment,**
- **B3. Waiver of requirement to obtain child assent, when a child is capable of assenting for recruitment purposes only. Child assent will be sought from participant prior to enrollment;**
- **B4. Waiver of requirement to obtain informed consent or parental (or guardian) permission;**
- **B5. Waiver of requirement to obtain child assent, when a child is capable of assenting; and / or**
- **B6. Alteration of one or more specific elements of the informed consent process.**

Note:

If B2. B3. B4. or B5. were previously selected, you should select D1. below

If B6. was previously selected, you should select D2. below

Please select the type of waiver or alteration of informed consent or parental (or guardian) permission or requirement for child assent:

D1. Waiver of Informed Consent (all elements)

The questions below must be answered because you previously indicated a request for either:

- **B2. Waiver of the process of informed consent or parental (or guardian) permission for recruitment purposes only. Informed consent or parental (or guardian) permission will be sought from participant prior to enrollment,**
- **B3. Waiver of requirement to obtain child assent, when a child is capable of assenting for recruitment purposes only. Child assent will be sought from participant prior to enrollment;**
- **B4. Waiver of requirement to obtain informed consent or parental (or guardian) permission;**
- **B5. Waiver of requirement to obtain child assent, when a child is capable of assenting; and / or**
- **B6. Alteration of one or more specific elements of the informed consent process.**

NOTE:

If B2. B3. or B6. were previously selected, you should select D3. below.

Please indicate which set of criteria is met:

D3. The following criteria are met: i) The research involves no more than minimal risk to the subjects; ii) The waiver or alteration will not adversely affect the rights and welfare of the participants; iii) The research could not practicably be carried out without the waiver or alteration; and iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Discuss how the waiver will not adversely affect the rights and welfare of the participants:

The use of lock solution is a standard of care for hemodialysis patients.

Explain why the research could not practicably be conducted without the waiver or alteration:

Note: The emphasis must be placed on the impracticability to perform the research based on scientifically and ethically justifiable rationale; not just that it is impracticable to obtain consent. Practicability should not be determined solely by considerations of convenience or costs. Please see the examples provided in the guidance on HIPAA waivers.

The study team is not deviating from any current standards of care. Patients and/or their surrogates sign consents for hemodialysis treatment as per hospital policy and procedure.

Define the plan, when appropriate, to provide individuals with additional pertinent information after participation (e.g., debriefing plan):

Note: This typically only applies to when box D2 is checked (e.g. deception research)

Type N/A if not applicable

N/A

Informed Consent/Assent/Information Sheet

Does the study involve any of the following sensitive information, each of which may warrant additional provisions in the research consent form or an additional consent form altogether.

<u>If none of the following apply</u>, do not select anything; move to the next question.

No answer provided.

Is there any additional information that you would like to provide regarding consent or assent?

N/A

BAA or Decendent PHI

Check if any of the following are involved in the research:

None of the above

If a Limited Data Set(s) or Protected Health Information (PHI) will be released outside the Medical Center, a Data Use Agreement (DUA) or Business Associate Agreement (BAA) needs to be established, unless the release of information is described in a HIPAA Authorization or a HIPAA Waiver.

PHI in limited data sets may include the following: Addresses other than street name or street address or post office boxes, all elements of dates (such as admission and discharge dates), and unique codes or identifiers not listed as direct identifiers: Names; Postal address information, other than town or city, State, and zip code; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images.

If Decedent's PHI is involved, complete a Research Certification for PHI of Decedents, and attach below.

General Information

Submitting User

EL-Hennawy, Adel MD

Email: adel.el-hennawy@nychhc.org **Business:** 718-966-4864

Please click "Add contact" to provide the e-mail address for the Main Contact or Research Coordinator.

If a contact is NOT in IRB Manager, use the (new xForm) link below to create a new contact.
Remember to try to enter all possible emails of the contact before submitting a new contact.

Frolova, Elena MD

Email: Elena.Frolova@nychhc.org **Phone:**

This person will receive reminders for continuing reviews and other important communications.

Even if you are the PI on the study and the contact person, you must list yourself.

Multiple contacts may be added. If there are multiple contacts, you may indicate the "Primary Contact."

If a contact is NOT in IRB Manager, use the (new xForm) link below to create a new contact.
Remember to try to enter all possible emails of the contact before submitting a new contact.

User had the option to start a different form here.

Please select the Primary Department/Division where this research will be conducted.

(For MMC Dental, please select "MMC Surgery/Dental")

Coney Island Hospital/Medicine

The Department Chair (MMC and RUMC) or the Director of Service (CIH) will need to approve the IRB application before it is sent to the IRB.

Other notes regarding additional signatures:

- *If the research is conducted within the Pediatrics, Nursing, or Emergency departments of MMC, designated members of the department will need to review the application before the form can be e-signed by the Division Chief or Department Chair. The designated individuals will be informed automatically to review and e-sign.?*
- *If the research will be conducted within the Pediatrics, Medicine, or Surgery departments of MMC, the Division Chief / Department Director will need to approve the IRB application before it goes to the Department Chair. The Division Chief will automatically be notified to e-sign.*
- *If this study involves recruitment of patients from the MMC Emergency Department (ED), the ED needs to approve the research (if you select ED, the ED will automatically be notified to review and sign).*
- *If the study involves radioactive isotopes, the Office of Radiation Control and Radiology Department will need to approve the research (if you selected YES to the question related to radioactive isotopes, the Office of Radiation Control and Radiology Department will automatically be notified to review and sign).*
- *If the study involves radiation beyond the typical limits of clinical use (e.g., x-rays,CT scans, angiograms, and imaging studies), the Radiology Department needs to approve the research (if you indicated within the application that the study involves radiation beyond the typical limits of clinical use, the Office of Radiology Department will automatically be notified to review and sign).*
- *Based on how questions are answered within the IRB Application xForm, the appropriate Medical Center staff will be automatically notified for approvals before the IRB receives the application.*

Please select any other Department / Divisions (if not already selected above) that are required to review this application. This is required whenever the research involves or impacts more than one Department and / or Division.

WARNING: ***DO NOT RE-ENTER THE SAME DEPARTMENT OR DIVISION USED AS A RESPONSE TO THE PREVIOUS QUESTION, OR THE DEPARTMENT/DIVISION WILL RECEIVE DUPLICATE REVIEW REQUESTS, WHICH MAY SLOW DOWN THE REVIEW.***

Note: ***If the research does not involve or impact other departments and / or divisions, do not answer this question.***

No answer provided.

Examples:
1) The research involves collaboration or careful coordination with another Department (e.g., Radiology, Pathology, Pharmacy, etc).
2) The research will impact the budget, resources, or clinical care of patients in another Department.
3) Research Intervention/Interaction takes place in another Department
4) Patients/Employees are recruited in another Department

Each department representative will need to e-sign the IRB application, before it is submitted to the IRB. You can add multiple contacts.

CIH = Coney Island Hospital

MMC = Maimonides Medical Center

RUMC = Richmond University Medical Center

PI Qualifications

Please describe the qualification of the Principal Investigator to conduct this research study (e.g. previous experience with similar studies, list board certifications and licensures, if applicable to clinical interventions):

Dr. Adel El-Hennawy is the Director of Nephrology at CIH. He has extensive experience in conducting clinical trials and has many peer-reviewed publications.

Please attach a CV or bio sketch (NIH format) of the PI:

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

Adel EL-Hennawy-CV.doc	CV/Resume/BioSketch	*If CV or bio sketch was submitted to the IRB in the past and it has not substantial changed since the last submission, you do not need to attach a revised document for this submission.* *For clinical trials, please save the latest CV to the study binder. The PI should sign and date the CV before it is placed in the study binder.*

Is any additional training required of the PI?

No	*For example: List any specific training for a research intervention or training required by the sponsor.*

Study Staff

STUDY STAFF

All co-investigators and Key Personnel must be employees, residents, or fellows of the Medical Center (MMC, CIH, or RUMC), students covered by an affiliation agreement with the Medical Center, or a volunteer that has been cleared through the Medical Center volunteer office; otherwise, their institution's IRB must review the research, if they are conducting an activity which causes their institution to become engaged in human research.

Investigators or Key Personnel can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and one investigator is designated the "principal investigator" with overall responsibilities for the study.

NOTES:
1) If this is a multi-center project that is overseen by multiple IRBs, you DO NOT need to list the staff that are covered by another IRB, as their IRB is legally responsible for assuring their staff are trained and conflicts of interests are adjudicated.
2) If you wish to list individuals that are from another institution that does not have an IRB for a Non-Federally study, these individuals must become volunteers of the Medical Center (see above).
3) If this is a Federally funded multi-center project, employees from other institutions MUST be overseen by the IRB of their own institution.
4) Employees from other institutions should check with their institution and/or IRB, to determine if they must submit an IRB application to their own institution.

Co-investigators and Key Personnel include any individual performing tasks related to the conduct of human research or a clinical trial, such as:
1) recruiting or enrolling participants,
2) obtaining informed consent,
3) interacting or intervening with participants,
4) having access to identifiable private information or protected health information (PHI),
5) analyzing identifiable data, and/or
6) carrying out an activity that makes an institution engaged in human research, as defined in OHRP guidance:
http://www.hhs.gov/ohrp/policy/engage08.html

Research coordinators and assistants must be listed as a co-investigator if they will also conduct human research.

Please click "add contact" to add each Co-Investigator (this is email driven)

If a contact is NOT in IRB Manager, use the "create new contact" link below to create a new contact in IRB Manager. Once you finish with the "create new contact" xform, click the "add contact" button on this form to add the contact to this form.

Remember to try to enter all possible emails of the contact before submitting a "new contact" xform.

Frolova, Elena MD

Email: Elena.Frolova@nychhc.org **Phone:**

Hultberg, Karen

Email: Karen.Hultberg@nychhc.org **Business:** 718 616 5627

Research coordinators and assistants must be listed as a co-investigator or key personnel if they will conduct human research including any of the activities described above.

If a contact is NOT in IRB Manager, use the "create new contact" link below to create a new contact.

User had the option to start a different form here.

Please click "add contact" for each Key Personnel.

If a contact is NOT in IRB Manager, use the "create new contact" link above to create a new contact in IRB Manager. Once you finish with the "create new contact" xform, click the "add contact" button in this section to add the contact to this form.

Remember to try to enter all possible emails of the contact before submitting a "new contact" xform.

No answer provided.

The requirements for Conflict of Interest Disclosure and training certificates are identical to the Co-Investigators, even if an individual is designated as a Key Personnel.

Please list any Non-Research Staff (those who <u>are not considered</u> "Co-Investigators" or "Key Personnel") and will support this study.

If a contact is <u>NOT</u> in IRB Manager, use the "create new contact" link above to create a new contact in IRB Manager. Once you finish with the "create new contact" xform, click the "add contact" button in this section to add the contact to this form.

<u>Remember to try to enter all possible emails of the contact before submitting a "new contact" xform.</u>

Callejo, Fay P MPH

Email: Fay.Callejo@nychhc.org **Business:** 718-616-4298

Sawyer, Janina

Email: Janina.Sawyer@nychhc.org **Business:** 718-616-4298

For example, non-research staff may be individuals analyzing <u>de-identified</u> or <u>aggregate data</u>, individuals providing a clinical service to support the research, individual providing a non-research or healthcare operations activity, etc.; AND are not considered collaborators on the study.

IMPORTANT: Do not include anyone that is doing anything that meets the definition of an investigator (see above). For example, if someone has access to identifiable data or are obtaining informed consent for the purposes of the research, or doing an activity which makes their institution engaged in human research they cannot be listed here.

Describe the role of any <u>Non-Research Staff</u>:

Administrative support.

Examples:

- *Analyze coded, de-identified, or aggregate data.*
- *Provide clinical support.*
- *Conduct performance improvement activity*
- *Provide statistical analysis*
- *Draw routine clinical blood draw*
- *Provide radiology support; but not collaborate on the study*
- *Provide pathology support; but not collaborate on the study*

Please list the IRB designee for your department and any other persons that should have access to the study in IRB Manager (if not already listed as study staff).

Up to 10 valid contacts, may be listed; however, in order to have access, they also must apply for an IRBManager user name and password.

"Other persons" may include:

- **Department Chair (CIH, MMC, RUMC)**
- **Director of Service (CIH)**
- **Division Chief (MMC)**
- **Facility Research Coordinator (CIH)**
- **IRB Designee (see side-bar)**

Hupart, Kenneth MD

Email: Kenneth.Hupart@nychhc.org **Business:** 718-616-3786

IRB Designees

If this is a Coney Island Hospital study, please include: *Karen.Hultberg@nychhc.org*

If this is a Maimonides Medical Center study, please include the IRB Designee for your department:

Anesthesiology:
DFeierman@maimonidesmed.org

Cardiology:
GHollander@maimonidesmed.org

Emergency Medicine:
ALikourezos@maimonidesmed.org

Hematology/Oncology:
LCovolus@maimonidesmed.org

Medicine: *SKamholz@maimonidesmed.org*

Nursing: *TSmith@maimonidesmed.org*

Obstetrics/Gynecology: *TBD @maimonidesmed.org*

Orthopedic Surgery: *TBD @maimonidesmed.org*

Pathology:
JBalderacchi@maimonidesmed.org

Pediatrics: *MRojas2@maimonidesmed.org*

Performance Imp/Risk Management: *TBD maimonidesmed.org*

Pharmacy: *Pcaruso@maimonidesmed.org*

Population Health Management:
Kbhandarkar@maimonidesmed.org

Psychiatry: *TJacob@maimonidesmed.org*

Radiation Oncology:
LCovolus@maimonidesmed.org

Radiology: *SHonig@maimonidesmed.org*

Surgery: *TBD @maimonidesmed.org*

If this is a Richmond University Medical Center study, please include the IRB Liaison for your department:

Medicine: *DBloomfield@RUMCSI.org*

Nursing: *Kdimauro@RUMCSI.org*

Obstetrics/Gynecology:
NLakhi@RUMCSI.org

Pediatrics: *MGrageda@RUMCSI.org*

Psychology: *JaGarcia@RUMCSI.org*

Radiology: *MMantello@RUMCSI.org*

Are volunteers or students (other than Residents or Fellows) included as co-investigators/key personnel?

No

Students may be a co-investigator or key personnel. Students must be covered by an affiliation agreement with the Medical Center and complete all training requirements before conducting research.

Volunteers may be a co-investigator or key personnel. Volunteers must be processed through the volunteer office and complete all training requirements before conducting research.

Other Required Training

Is any additional training required of the Co-Investigators or Key Personnel (other than the CITI training required by the IRB)?

No

For example: List any specific training for a research intervention or training required by the sponsor.

Compliance with Laws

COMPLIANCE WITH LAWS

Have any of the investigators or key personnel been excluded from participation in, or otherwise sanctioned by, Medicare, Medicaid or any other federal, state or local health care program, or been otherwise barred from being a government contractor or subcontractor by any unit of the federal, state or local government?

No

Have any of the investigators or key personnel been found by the FDA or any other state or federal government agency or enforcement body to have violated any federal, state or local laws, rules or regulations relating to clinical investigations or human research?

No

Have any of the investigators or key personnel ever been or are currently under investigation by any government enforcement agency relating to clinical care, billing for clinical care, or research projects?

No

Sponsored Studies/Additional Costs

Will this be a sponsored study?

No

Check "Yes" if you are requesting or anticipating any types of support, funding, supplies, equipment, or labor from an entity that is external to the institution.

Check "Yes" if this is a trial that is part of an oncology group (e.g., Alliance, SWOG, ECOG, etc)

Sponsors will be invoiced IRB fees by the Office of Grants and Contracts; however, IRB fees do not apply to government agencies, oncology groups, internal departments, or the Maimonides Research and Development Foundation.

The IRB fee schedule is posted on the IRB SharePoint site.

CIH Questions

COSTS RELATED TO CIH STUDY

Are there any research costs to Coney Island Hospital or to the research participants?

No

Note: If a research participant must incur a research cost, this must be fully disclosed in the informed consent document.

CIH researchers should create a STAR account if they do not already have one; studies must be IRB approved before they will be reviewed in STAR.

Please acknowledge this requirement:

I understand that as a CIH researcher I should create a STAR account, if they do not already have one; studies must be IRB approved before they will be reviewed in STAR.	*STAR (System Approved Research): www.star.nychhc.org*

Additional Information

ADDITIONAL INFORMATION

Please provide any other relevant information for the IRB to consider.

N/A

Please attach any other relevant information for the IRB to consider.

NOTE: When attaching the file, be sure to indicate the "type" from the drop-down menu.

No answer provided.

INTERNAL IRB NOTES

PI Attestation (Self Submittal)

Is the Principal Investigator for this study the same as the Division Chief or Department Chair which oversees the department where this study will occur?

No

By signing this form below, I acknowledge the investigators responsibilities and attest that the information contained in this form and all of the attached materials are accurate and complete to the best of my knowledge. I understand that the IRB can require additional modifications or change the risk assessment of the study. I agree to fulfill the following responsibilities described in RES-7 policy. These responsibilities may include, but are not limited to the following:

- **Oversees scientific, technical, and day-to-day management of the research.**
- **Hold the lead responsibility for the research protocol, including oversight of its implementation and the activities of other Investigators and research staff, and management of any funding associated with the protocol and is held accountable for all compliance.**
- **Uphold professional and ethical standards and practices when conducting research.**
- **Will be guided by the ethical principles of the Belmont Report. When applicable to certain clinical trials, clinical investigators are guided by the principles of Good Clinical Practice (ICH E6) and the Declaration of Helsinki.**
- **Adhere to the Corporate Compliance Code of Conduct.**
- **Comply with all Federal and State laws and regulations, contractual obligations, and Medical Center policies.**
- **Submit accurate IRB application materials and conduct research according to all written approvals and applicable contractual obligations.**
- **Provide timely progress reports and associated materials for continuing review.**
- **Request amendments on a timely basis and in accordance to IRB procedures.**
- **Promptly report all required events or incidents to the IRB.**
- **Ensure proper study closure.**
- **Oversee and ensure qualified research staff.**
- **Ensure appropriate outreach and contacts with research participants.**
- **Prospectively obtain applicable consent and authorization documents from each research participant, using IRB approved stamped form(s).**
- **Securely maintain complete research records, in accordance with Federal timeframes and Medical Center policies.**
- **Co-operate with any audit, sponsor site visit, or government investigation.**
- **Disclose conflicts of interest on a timely basis.**
- **Ensure appropriate use and review of laboratory reports.**
- **Follow Medical Center billing practices.**
- **Follow policies for students and volunteers.**
- **Ensure adequate resources and obtain appropriate approvals of the research budget and contracts related to the research.**
- **Register all applicable clinical trials on www.clinicaltrials.gov and maintain updates based on the required frequency.**
- **Ensure all required IRB approvals are obtained, when the PI is the overall PI for a multisite study**
- **Notify the IRB of relocation of research activities**
- **Follow procedures when departing from the Medical Center.**
- **If there are any missing PI signature on attachments to this IRB application, this signature covers those attachments as well.**

Signed Monday, June 12, 2017 2:58:23 PM ET
by EL-Hennawy, Adel MD

By entering your password you are electronically signing this form and agreeing to the assurances.