NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form (Ultrafiltration Rate)

Title of Study:	Reducing Arrhythmia in Dialysis by Adjusting the Rx Electrolytes/Ultrafiltration - RADAR S18-01324
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to evaluate heart rhythms in patients who are being treated with hemodialysis. We want to see how these heart rhythms are affected with changes in the dialysis ultrafiltration rate. We will be using an implantable cardiac monitor called the Reveal LINQ to track heart rhythm. We want to find out if changing the dialysis ultrafiltration rate (UFR) can better help the heart rhythms of people with kidney failure who are being treated with chronic hemodialysis. The ultrafiltration rate controls how much fluid is removed from the body during dialysis treatments. We want to closely watch the effect that these ultrafiltration rate changes have on your heart rhythm and fluid status. We also want to find out if changing the UFR is safe to do without causing too many side effects.

Hemodialysis is the most common way to treat advanced kidney failure. In hemodialysis, a machine filters wastes, salts, and fluid from your blood when your kidneys are no longer healthy enough to do this work.

The U.S. Food and Drug Administration (FDA) has cleared the Reveal LINQ for use in patients who are at risk for having abnormal heart rhythms, or in whom a doctor suspects an abnormal heart rhythm.

You have been asked to take part in this study because you are on maintenance hemodialysis for end-stage renal disease.

3. How long will I be in the study? How many other people will be in the study?

It will take you about 4 months to complete this study. During this time, we may ask you to make up to 4 visits to NYU Langone Health for the Reveal LINQ implant/explant procedure and some wound check visits if necessary.

About 60 subjects will take part in this study in up multiple centers. Other subjects who take part will undergo changes in their electrolytes while being monitored with the Reveal LINQ.

4. What will I be asked to do in the study?

If you decide to take part in this study, you will get a Reveal LINQ device surgically implanted under your skin. The device is less than half the size of a AAA battery. This device is an insertable cardiac monitor (ICM). Information collected by this device can help doctors closely check heart rhythms. ESRD (end-stage-renal-disease) patients are more at risk for abnormal heart rhythms because their kidneys are not able to remove fluid and electrolytes from their blood as they would if the kidneys were working properly.

The hemodialysis sessions that you are scheduled to have as standard treatment are not part of this research study. You would have hemodialysis even if you were not in this study. The implantation of an insertable cardiac monitor to watch for abnormal heart rhythms will be done for research purposes. We will monitor your usual dialysis care for one month following the implant of the Reveal LINQ device. After that month of observation, we will try two different treatment strategies for controlling your UFR during dialysis.

There are two UFR treatment strategies that we are testing in this study. You will rotate every week (back and forth) through both groups for a period of 8 weeks. The study doctor will not know what treatment group you are in. Below are the two groups:

a) Restricted UFR; UFR ≤10 ml/kg/hr
   We will limit the amount of fluid per hour that the dialysis machine takes off during each dialysis treatment.
b) Standard of Care/ Unrestricted UFR; UFR as needed
   There will be no limit in the amount of fluid per hour the dialysis machine is allowed to remove during each dialysis treatment.

The study doctors will only make the above changes to your dialysis care. Due to your medical condition and the type of data that will be collected about you and your heart rhythms as part of this study, the study doctors may identify health conditions that require changes to your dialysis or general medical care such as

- how often you will have dialysis,
- changes to your dialysis prescription
- changes to your medications

- performing heart tests or procedures

Your study doctors will not make any of these changes as part of this study, but they will explain the findings to you and your doctor so that you and your doctors can decide on the best plan.

Study Visits:

Screening (Visit 1): You will be screened and asked to sign the consent form before any study procedures take place. If you agree to be in this study, the kidney doctor and study coordinator will collect information about you and your medical and surgical history to confirm your eligibility. If coagulation labs (labs that analyze your risk of bleeding with a procedure) are not clinically available, then these labs may be drawn. . If a blood pregnancy test is required, then a sample will be collected at this time and sent to the local lab for processing. This visit is expected to take about an hour and will take place at the dialysis unit, Lower Manhattan Dialysis Center located at 323 E 34th St, New York, NY 10016. Starting at this visit, the research team will start recording any new symptoms you may experience until visit #11 or a week after visit #9 depending on whether or not you choose to keep the LINQ device.

Baseline (Visit 2) & Reveal LINQ: This visit will take place at NYU Langone Health and will last 2-4 hours. As needed, the procedures required to complete this visit may take place on more than 1 calendar day. During the Baseline visit, the following will be done:

- You will have a physical exam
- We will collect information about your health and the medications you are currently taking.
- We will collect any other information in your medical records related to your condition or treatment that may relate to your being able to take part in this study.
- Due to COVID-19 safety precautions, you may be provided with a COVID-19 nasal swab test as part of this visit.
- Reveal LINQ device placement
- We will check your coagulation lab values within 72 hours of your Reveal implant procedure. If you are taking certain novel oral anti-coagulants (NOAC) you will need to hold them for 24 hours before and after the implant procedure. If you are not taking any NOACs, the coagulation lab values may be obtained up to 96 hours prior to the Reveal implant procedure. If necessary, we will check your platelet count at the same time as your coagulation labs.
- You may receive up to 24 hours of an antibiotic around the time of your Reveal placement in order to further decrease the risk of an infection at the insertion site.

Choice of antibiotic may be determined by your allergies and any history you have of prior infections. Antibiotics used may include vancomycin, clindamycin, nafcillin, or cefazolin.
During this visit a study cardiologist will give you a numbing shot in the area where they plan to insert the device. If the study cardiologist thinks it is best, they may insert an intravenous catheter and inject medications to help you relax during the procedure. They will then make a small incision, less than 1cm, in the skin over your chest. Using a specially designed tool, the LINQ is and inserted just under the skin. Once in position, the tool is removed and the incision is closed with steri-strips (surgical tape strips). Following the insertion, the study team will schedule regular, automatic data transmissions to take place during the time that you usually sleep. You will be given a monitor/charger and a Patient Care Assistant which you will be required to keep for the duration of your participation in the study. You may be asked to manually transmit the data on one or more occasions during the study. This will require holding the monitoring device over your chest and staying near the transmitter for several minutes until the transmission is completed. The study team will walk you through this process.

Procedure for Missed Dialysis Treatments Prior to Visit 3 (Baseline Period):
If over half of the treatments (7 or more) have been missed during this time, an extension of one or two weeks will be needed to complete the observation period. This will begin on the first Monday or Tuesday after you return to dialysis and we will delay start of dialysate/bicarbonate visits accordingly.

Week 1 Reveal (Visit 3) (+/- 3 days): Wound check visit at dialysis unit or NYU Langone Health. The study team will review labs from your medical record and ask you about any changes in health or medications.

Week 4 Reveal (Visit 4) (+/- 3 days): This visit will also serve to review events and data from the baseline month of usual dialysis care 30 days after the procedure. You will be randomized to a treatment arm (either a or b) and will start study treatment on the next Monday or Tuesday.

Ultrafiltration Rate Treatment Visits: These visits will take place every other week at either the dialysis unit or on the phone. Your dialysis unit records will be reviewed at least monthly.

Week 5 (Visit 5) (+/- 3 days): Visit to take place either at dialysis unit or by phone. You will be asked about any changes in health or medications and the study team will also review your dialysis records.

Week 7 (Visit 6) (+/- 3 days): Visit to take place either at dialysis unit or by phone. You will be asked about any changes in health or medications and the study team will also review your dialysis records.

Week 10 (Visit 7) (+/- 3 days): Visit to take place either at dialysis unit or by phone. You will be asked about any changes in health or medications and the study team will also review your dialysis records.

Week 12 (Visit 8) (+/- 3 days): Visit to take place either at dialysis unit or by phone. You will be asked about any changes in health or medications and the study team will also review your dialysis records.

Procedures for Missing Dialysis Treatments during Treatment Periods:
If more than half the treatments are missed (7 or more) during any of the 4 month-long treatment groups we will have you make up the missed study treatments upon your return to your dialysis unit. This will be done by extending the treatment period for that group for 2-4 additional weeks so that you continue receiving the assigned intervention for an additional 1-2 weeks until you have completed at least 6 treatments with that intervention. You will not be required to undergo any extra dialysis.

If you miss outpatient dialysis for more than 6 consecutive weeks (for example due to a long hospitalization) the study team will evaluate you in order to decide whether it is safe for you to continue in the study before resuming your assigned treatments.

End of Treatment (Visit 9):
You will be asked about any changes in health or medications and the study team will also review your dialysis records. At this visit, you may elect to participate in Study A. If you are screened and eligible, you will not need to redo the Week 1 Reveal insertion follow-up visits, since you already have a device. There will be a 1 week washout period, and then a 1 month observation period where you will receive standard of care dialysis at the dialysis prior to starting the intervention for the Study A. If you elect not to screen for Study A or are not eligible, you may keep the device implanted. If you elect this option, collection of changes in your health and medication will conclude one week after this visit. If you elect to remove the device, we will schedule the explanation procedure.

Reveal LINQ explant (Visit 10):

Following completion of the Week 23 visit, you will be given the option to come back to NYU Langone Health for device removal. Due to COVID-19 safety precautions, you may be provided with a COVID-19 nasal swab test as part of this visit. Following the device removal there will be a 1-week wound check visit either at NYU Langone Health or the dialysis unit. If you choose not to have the device removed it will stay in place and continue to record your heart rhythm. The principle investigator or other member of the study team will contact your doctors to let them know how to obtain results of any recordings.

You will be asked about any changes in health or medications and we will review or check your coagulation lab values within 72 hours of your Reveal explant procedure. If you are taking certain novel oral anti-coagulants (NOAC) you will need to hold them for 24 hours before and after the implant procedure. If you are not taking any NOACs, the coagulation lab values may be obtained up to 96 hours prior to the Reveal explant procedure. If necessary, we will check your platelet count together with your coagulation labs. During this visit a study cardiologist will give you a numbing shot in the area where they plan to remove the device. If the study cardiologist thinks it is best, they may insert an intravenous catheter and inject medications to help you relax during the procedure. They will then make a small incision, less than 1cm, in the skin over your chest. Using a specially designed tool, the LINQ is removed and the incision is closed with steri-strips.

The study doctor may have to take you out of the study for your own safety. This may happen because of infection, serious heart arrhythmias, high fluid volumes in your body, or other harmful effects.

Explant Follow Up (Visit 11):

This is an optional wound check visit at dialysis unit or NYU Langone Health after the implant has been removed. Collection of changes in your health and medications will conclude at this visit.

5. What are the possible risks or discomforts?

Possible risks and discomforts associated with having a Reveal LINQ system implanted include:

- The risks associated with use of antibiotics such as vancomycin, clindamycin, nafcillin, and cefazolin include the risk of allergic reactions including rashes or more severe reactions that may include symptoms of wheezing, severe shortness of breath and low blood pressure. Other risks include the risk of developing antibiotic associated diarrhea or the development of an infection resistant to the antibiotic you receive.
- Rejection of the device by your body (including local tissue reaction):
  It is possible that your body will react to a having a foreign object inserted. If this happens we will offer you the care to treat the problem and remove the LINQ if necessary.
- Movement of the device from its implant location
  If the LINQ moves too much we may open your incision to relocate and reattach the device. This is common and happens in less than 1 out of 100 cases.
- Pain and/or bruising at the implant location
- Itching, swelling, redness, discharge or other irritation at or near the implant location
- Slow healing incision/wound
- Missed cardiac signals or too many signals collected by the Reveal LINQ device
- The battery for the Reveal LINQ stops working earlier than expected.
- Loss of Privacy and Confidentiality

Possible risks associated the Carelink System include:

The Carelink system is used to transmit information from your Reveal LINQ device to the study doctor. It will contain information on the serial number used by Medtronic to identify your Reveal LINQ device, the information on your heart rhythm recorded at each session, and the date that information was transmitted using the Carelink system. This information will be stored on a secure server. When your Reveal LINQ device is surgically implanted (inserted), Medtronic will also receive your name and date of birth along with the serial number of your device. This information is kept by Medtronic in separate, secure location, which is accessed only if Medtronic needs to contact you or your doctors because of problems with the device.

Medtronic takes steps to protect the privacy of the health information sent to the secure Medtronic server over the Internet. However, Medtronic cannot guarantee the health information is protected against unauthorized interception. This means that in a rare case, someone who is not associated with the study may see your information.

Risks of Ultrafiltration Rate Change:

The best and safest way of prescribing the dialysis ultrafiltration rate is unknown and it is possible that the current standard of care may partly account for the high risk of abnormal heart rhythms in dialysis patients. The study is designed to test whether different strategies for prescribing the ultrafiltration rate can improve the safety of dialysis by reducing the risk of abnormal heart rhythms and cardiac events such as heart attacks and cardiac arrest. Although both of the randomized strategies for prescribing the ultrafiltration are consistent with the usual ways dialysis is performed, it is possible that one or more of the strategies could increase the risk of abnormal heart rhythms, cardiac events or cardiac arrest.

Risks of Collecting Extra Fluids ("Volume Overload"):

In addition, you may accumulate extra fluid during the weeks when the ultrafiltration rate is restricted. Restricting your ultrafiltration rate means that your rate will not go above a certain amount. As a result, the machine may not remove all the extra fluid that your body has collected since your last dialysis session. If you gain too much fluid you may have swelling in your legs or shortness of breath. If you have too much fluid in your body, then clinicians may make the dialysis session run for a longer time or you may need to have an extra dialysis session during the week. The study staff will review your dialysis treatment sheets to look at the difference between your dry weight and your post dialysis weight.
In severe cases, you would need to be hospitalized or to have an extra dialysis session to remove the extra fluid and make your breathing better.

Infection:

Because of your kidney disease and your hemodialysis treatments, there may be a chance that you might experience additional risks. Because of your hemodialysis treatment and frequent needle sticks into your fistula or catheter, you may be at higher risk that your device might get infected. If it does get infected, your study doctor may ask you to have another surgical procedure to remove the device.

Risks of Conscious Sedation:

If you undergo conscious sedation during the implant procedure, there may be a chance that you could experience allergic reactions to the medications or have a drop in blood pressure that could cause fainting or light-headedness. You might also experience difficulty breathing during or immediately following the procedure. In severe cases, this could require the use of other medications to reverse these problems or the insertion of a breathing tube to help your breathing.

Risk of Blood Draw:

You may experience some discomfort from the blood drawing. Any time blood is drawn there is a risk of bleeding, bruising, or infection. Rarely, people faint when their blood is drawn. If this happens we can treat the problem. The total amount of blood that will be collected during this study is about 4 tablespoons.

Risk of COVID-19 Nasal Swab:
You may experience mild discomfort from the nasal swab.

Abnormal Heart Rhythms:
There may be a chance that your Reveal LINQ device may not detect or may over detect abnormal heart rhythms. This may be related to the amount of fluid that collects in your body between hemodialysis sessions and the amount of fluid that is removed during a hemodialysis session.

6. Can I be in the study if I am pregnant or breastfeeding?

Because taking part in this study may harm an embryo, fetus, or breastfeeding baby, you should not become pregnant, breastfeed a baby, or father a child while participating in this study. Other risks may not yet be known.

If you are currently pregnant, you will not be able participate in the study. You should not become pregnant while you are participating in this study. If you are able to become pregnant, you will be required to use a medically accepted method of birth control while you participate in the study:

- Hormonal methods like birth control pills, patches, vaginal rings or implants,
- Barrier methods such as condoms or a diaphragm used with spermicide (a foam, cream or gel that kills sperm),
- Intrauterine device (IUD),
- Abstinence (no sex).

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons. The principal investigator may ask you to provide information about the outcome of your pregnancy and the health of your baby.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you.
This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

You may not benefit from taking part in this study. It is possible that by seeing information from your Reveal LINQ device about your heart rhythms, your doctor may be able to better treat any known or unknown heart conditions, but this is not guaranteed.

We hope that what we learn from this study may benefit other patients in the future.

9. What other choices do I have if I do not participate?

You do not have to be in research study to find out if you have abnormal heart rhythms. You can choose to continue receiving standard hemodialysis treatment and not have the study device implanted. Other methods in standard use for detecting abnormal heart rhythms include electrocardiograms and holter monitors. These technologies or the Carelink system can be used by your doctor outside of the study if he or she believes tests of your heart rhythm are necessary.

10. Will I be paid for being in this study?

We will pay you for the time and the effort spent coming in for all study visits. These visits are listed below. For each visit that you complete, we will pay you as follows:

Week 4 Reveal Visit 4: $150
Week 12 Study Visit 8 (or Reveal explant visit, whichever comes first): $150

We will pay you up to a total of $300

In order for you to receive a payment check, you need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

You will not be responsible for the cost of the Reveal LINQ, its implantation, any prescription changes that are required for the sole purpose of the study, nor any study visits.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the study sponsor, or the Food and Drug Administration (FDA) without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, the Food and Drug Administration (FDA) or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Please make sure to notify the study team if you wish to drop out from the study. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

There are no specific tests that are required before you leave the study. We may ask you to come in for a final visit where your kidney and/or heart doctor may discuss whether your device should remain implanted or whether it should be removed. All of your health data collected for the study will be used as described in this form.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without

your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).
The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- NYU Langone Medical Center research staff involved in this study
- The sponsor: National Institutes of Health (NIH).
- Medtronic, the company that provides the Reveal LINQ device.
- Other researchers and medical centers that are part of this study and their ethics boards
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research
- People from organizations that provide independent accreditation and oversight of
- hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers,
- and lawyers

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

16. Financial Disclosure

The NYU Langone Health maintains a financial disclosure process by which researchers must disclose any personal financial interest that may be related to the research. This study involves medical devices manufactured by Medtronic. One or more of the investigators involved in this study has or has had a financial relationship with Medtronic for work or an activity that is not part of this protocol. This may include consulting, advisory boards, equity, or writing reports. If you would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4079.

17. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. _____ Subject Initials

18. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

19. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the

Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date