Informed Consent Cover Page

Official Title: Controlling Hypertension Through Education and Coaching in Kidney Disease

NCT Number: NCT04087798

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY
(INTERVENTION GROUP CONSENT)

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study IRB Name: Improving Outcomes in Kidney Disease Using Systems-Driven Education and Coaching HUM00136011 *(Also referred to as Controlling Hypertension through Education and Coaching in Kidney Disease, CHECK-D)*

Company or agency sponsoring the study: National Institutes of Health (NIH)

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Julie Wright Nunes, MD, MPH, Department of Internal Medicine-Nephrology, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Behavioral intervention study

This research is studying whether education and coaching impact healthy behaviors and have an impact on blood pressure. **This research will provide education about kidneys and blood pressure, and for patients in intervention clinics, also provides free health coaching to help support healthy blood pressure.** Your health-related information, survey responses, and blood and urine samples will be collected for this research study.

This study involves a process called randomization. This means that the intervention you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate

groups, based on chance (like the flip of a coin), to compare different treatments or procedures. Patients are randomized depending on the clinic they are seen in. **Your clinic is randomized to the intervention, and you will be in the intervention group based on this.** Patients, providers and clinics are not 'blinded' to which group you are in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include pain with the needle stick for blood draws or psychological distress due to a better understanding of kidney disease, blood pressure and behaviors needed to keep you healthy. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by giving education and health coaching intervention that may help you and other patients with CKD better manage their health.

We expect the amount of time you will participate in the study will be 12 months.

You can decide not to be in this study. Alternatives to joining this study include continuing with your usual medical care. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Kidney disease affects 20 million people and may put people at risk for complications like worsening kidney disease or heart problems. Early management to improve blood pressure may decrease the risks. The purpose of this study is to test the effect of an education and coaching intervention on blood pressure control and other health and patient-reported outcomes in patients who have kidney disease and blood pressure that is not always optimally controlled.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You can be part of this study if you are age 21-85, have kidney disease, and have high blood pressure that is not always at goal. You are not able to be in this study if you are pregnant, on dialysis, have had a kidney transplant, or have severe cognitive impairment. You may also not participate if you do not speak or read in English.

3.2 How many people are expected to take part in this study?

We are expecting about 350 patients to participate: About 280 from the University of Michigan clinics and 70 from the Detroit Medical Center / Wayne State University clinics. We may increase the target enrollment number to 450 depending on the drop-out rate.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You may have received an informational handout about your kidneys and kidney disease today or in the past.

If you agree to be in this study, you will receive an at-home blood pressure monitor, and we will ask you to complete four study visits as well as 4 to 6 health coaching phone calls over the next 12 months. The exact number of health coach calls will be based on your schedule and individual needs. The first study visit will take place at enrollment. The other study visits will take place one month, six months, and 12 months after enrollment. All of these study visits may take place in-person or by telephone.

If you choose to enroll in the study, the following study activities will take place at enrollment:

1. Your blood pressure will be checked by you with the at-home monitor. If study visits take place in-person, a study team member will check your blood pressure.
2. We will ask you to provide a blood sample and urine sample into a urine cup to measure your kidney function. The volume of blood obtained will be about 4 tablespoons.
3. We will schedule your first phone call with a health coach, which will take place within 7 days after enrollment.
4. We will ask you to complete several short surveys, including a usability survey to evaluate the education worksheet. None of your answers will be shared with any of your medical providers. We will also collect some information from your medical record about you and about your chronic kidney disease.

At months 1 and 6, the following study activities will take place:

1. Your blood pressure will be checked by you with the at-home monitor. If study visits take place in-person, a study team member will check your blood pressure.
2. We will ask you to complete several short surveys about your medical care experience, your management of your chronic kidney disease, and your knowledge about your diagnosis. As before, none of your answers will be shared with any of your medical providers. We will also collect some information from your medical record about you and about your chronic kidney disease.

At month 12, the following study activities will take place:

1. Your blood pressure will be checked by you with the at-home monitor. If study visits take place in-person, a study team member will check your blood pressure.
2. We will ask you to provide a blood sample and urine sample into a urine cup to measure your kidney function. The volume of blood obtained will be about 4 tablespoons.
3. We will ask you again to complete several short surveys about your medical care experience, your management of your chronic kidney disease, and your knowledge about your diagnosis. As before, none of your answers will be shared with any of your medical providers. We will also collect some information from your medical record about you and about your chronic kidney disease.

Health coaching:

In addition to the study activities above, we will ask you to complete a total of 4-6 health coaching sessions over the phone. The first coach call will take place within about 7 days of your enrollment visit, and the last coach call will take place about 10-11 months after your enrollment visit. Depending on your preference and coaching needs, you and your coach will decide together when to schedule the 2-4 sessions between the first and last coach calls. Coach calls are not confidential. Coach calls will be recorded for quality assurance and coach training/feedback purposes. This data will be kept in a secure electronic file, which only the coaches and researchers will be able to access through a website. In addition, information pertaining to your health coach calls will be faxed to your primary care provider on file. **If you do not agree to be audio recorded, you cannot take part in the study.**

As stated previously, this study involves a process called randomization. This means that the intervention you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. Patients are randomized depending on the clinic they are seen in. **Your clinic is randomized to the intervention, and you will be in the intervention group based on this.** Patients, providers and clinics are not 'blinded' to which group you are in.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments and report any adverse reactions you may have during the study.

Collection for unspecified future research:

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your medical information collected in the main study so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your medical information, we may not be able to take the information out of our research.

We may share your medical information with other researchers so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Risks of allowing your data to be used in future research may include a very small chance of breach of confidentiality of medical records. Other risks are unknown. Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your medical information. Allowing us to do future research on your medical information will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
Each of the four study visits will take approximately 1 to 1.5 hours for a total of 4 to 6 hours. It may be a little more or less depending on individual needs. Each coach call will take approximately 30 to 45 minutes for a total of 2 to 3 hours for the minimum of four calls (you and your coach may decide to complete an additional one or two 30- to 45-minute coach calls depending on your schedule, preferences, needs, and coaching needs). Total estimated time to take part in this study is 6 to 9 hours assuming you complete four coach calls.

Each of the four study visits will take approximately 1 to 1.5 hours for a total of 4 to 6 hours. It may be a little more or less depending on individual needs, but we do not think it will on average ever take more than 1.5 hrs.

4.3 When will my participation in the study be over?
Your participation in this study will be over when you have completed all study activities. Participation will last approximately 12 months.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with the study sponsor, the National Institutes of Health (NIH).

Preparation and handling of specimens will follow local UM and DMC/WSU laboratory procedures. Assays are processed and reported at local labs. Lab results will be entered into your health record.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
Overall expected risks of participating in this study are minimal. However, possible risks include:

- Pain with the needle stick during blood draws. This pain is typically mild and goes away very quickly. Some people get a bruise after a blood draw. This is mild and also goes away in a few days. Rarer risks resulting from blood draws include fainting and infection at the needle stick

site. To minimize this risk, blood draws will be completed by an experienced technician when blood samples are obtained from your veins.
- Breach of confidentiality of medical records
- Risk of psychological distress from a survey related to answering questions about patient-provider communication and medical diagnosis **or related to receiving health coaching aimed towards improving health behaviors**
- Potential distress because of a better understanding about kidney disease and blood pressure
- As with any research study, there may be additional risks that are unknown or unexpected

The researchers will try to minimize these risks by keeping all data from this study in locked cabinets and on password protected servers that only members of our study team will be able to access. You are free to skip any survey questions or study measures if you want. Your treatment at the University of Michigan or Detroit Medical Center / Wayne State University will not be affected if you decide you do not wish to participate.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or concerns, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems or concerns that you have during this study. If you become sick or hurt during the time you are participating in the study, we will ask if you would like to stop. If this happens, you can choose not to continue your participation or we can schedule another time for you to participate in study activities.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

The benefits of this study are:
- You may receive information and participate in study measures that ultimately may help you become more informed, activated, and engaged in your health care
- You will receive free health coaching aimed to support motivation for healthy behaviors related to blood pressure
- Possible benefits to society includes that this may benefit future patients who have kidney disease and high blood pressure

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information. If you

are a woman of childbearing age, and become pregnant during the study, you need to let the study PI or study team contacts know, because this study excludes pregnant women. This is because your blood pressure and kidney management would need to be carefully guided by doctors and the education and self-care behavior needs are outside the scope of this study.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

There may be other ways of educating patients about kidney disease and blood pressure. You can get education and care as usual through your doctors. Participation in this study is completely voluntary.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

You can choose to leave the study at any time. There is not any known danger to doing so, you will simply stop participating in the study and study activities. Our study team must be notified however, so that they do not continue to reach out regarding follow up for study activities. Contact information is found in Section 10.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.
- If you change your primary care provider to be outside of the health system.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the contact telephone number listed in Section 10.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care

- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive $25 for completing each phase of the study as follows:
1. Immediately after you complete the enrollment and its study measures.
2. After you complete one-month study measures.
3. After you complete 6-month study measures.
4. After you complete the final (about 12-months after enrollment) study measures.

Thus, for completing all phases of the study and its measures, you will receive $100 in total. This compensation will be given to you in the form of gift cards. You need to provide specific information in order for the study staff and sponsor to ensure that you have been given the gift cards. You do not have to accept the gift cards if you do not want to. If you decide to stop participating in the study, your compensation will be pro-rated. This means you do not have to give up any compensation incentives that you have already received, but you will not get future incentives because you will not have completed future phases of the study.

You will also be able to keep the at-home blood pressure monitor at the end of the study, but we ask that you only use it for research purposes while participating in this study.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your hardcopy (on paper/printed) research information will be stored in a locked cabinet and will not be made a part of your regular medical record. Any information stored electronically will be in secure

servers in password protected files. **However, coach call logging, tracking and data accumulation will be kept on a secure electronic password protected server. Information that coaching was done will be faxed to a primary care provider on file. Motivational text messaging will be available from the coach to you, if you wish to receive it on your own cell phone, the number of which you provide. In addition, coach calls may be recorded for quality assurance and coach training/feedback purposes but will not be used to analyze any participants on an individual level. This data will be kept in a secure electronic file, to which only the coaches and researchers will have access.** If the researcher orders any tests, the order and results may become part of your regular medical record. Otherwise, research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Only researchers will be able to access links to your de-identified study ID and you, and these links will be separate from study measures collected from you.

Because this study is NIH-funded this research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens 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, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Health coach counseling notes
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- The researchers may need to information to determine if there is an association between clinical aspects of patients or demographics and the outcomes measured by the study
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record or your DMC/WSU medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Julie Wright Nunes, MD MPH
Mailing Address: 311 Simpson Memorial Institute, 102 Observatory, Ann Arbor, MI 48109
Telephone: 734-764-5178
Email: ContactCHECK-D@umich.edu

Project Manager: Chiao-Li Chan
Mailing Address: North Campus Research Complex, 2800 Plymouth Road, Bldg. 14, G016
Ann Arbor, MI 48109-2800
Telephone: 734-615-0506
Email: ContactCHECK-D@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?
You will receive a copy of the signed and dated informed consent.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document.

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to audio recording solely for purposes of this research

This study involves audio recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep my identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my data for future research.

_____ No, I do not agree to let the study team keep my data for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name:

_____

Title:

_____

Signature: _____

Date of Signature (mm/dd/yy): _____