RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Gut Microbiome and p-Inulin in Hemodialysis

Principal Investigator: [include name, clinical office address and office phone number]
(Study doctor)

Research Coordinator: [optional]

Emergency Contact:

ABOUT THIS CONSENT FORM

We are asking you to take part in a research study. Taking part in this study is voluntary. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. You can choose whether or not you want to be in this study. Before you can make your decision, you 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. We're going to talk to you about the study, and we will give you this consent form to read. You may also want to talk about it with your family, friends, or family doctor. If you decide not to be in this study, you will not be treated differently or lose any benefits that you are entitled to. Please ask us about anything that you don't understand. If you join the study, you may withdraw from the study at any time. There are no penalties for leaving the study.

BACKGROUND AND PURPOSE OF THIS STUDY

We are asking you to take part in this study because you have kidney failure and are being treated with maintenance hemodialysis. This study is about bacteria in the digestive system ("gut"). All humans have a very large amount of bacteria in their gut. Some of these are good bacteria and some are bad bacteria. In healthy people, good and bad bacteria are usually balanced and do not cause health problems. Kidney disease can change the balance of bacteria and this may have negative effects on health.

A prebiotic is a food ingredient that promotes the growth of good bacteria in the gut. Prebiotics have been shown to help balance good and bad bacteria. p-Inulin is a prebiotic that is found in vegetables with high fiber content such as sugar beets, leeks, onions, garlic, and asparagus.

We are doing this study to learn more about the gut bacteria in people with kidney disease, and whether p-inulin improves the balance between good and bad bacteria. We plan to study the gut bacteria before, during and after patients take p-inulin. This information will help us plan a larger research study to see if prebiotics can be used to improve the health of people with kidney disease.

Up to 20 participants at 4 hospitals will be enrolled in this study. **Insert site name* plans to enroll [**Insert expected range for site keeping in mind that you might need to make up for participants who do not provide the required samples*] participants.

WHAT HAPPENS IF YOU JOIN THE STUDY

You will be in this study for 28 weeks (about 7 months). There are three phases: no treatment, p-inulin treatment, and post-treatment. While you are in this study, we will collect information about your health, your diet and the medications you take. At each study visit, we will ask you about any important medical events that happened since the last visit such as emergency room visits or hospital admissions. You will bring us samples of your stool throughout the study, and we will collect weekly blood samples during dialysis. You will take p-inulin twice a day for 12 weeks (3 months).

While you are in this study, we would like you to continue to eat how you normally do. Please let us know if you plan to make a big change in your diet in the next 7 months. During the study, you must not eat yogurt take prebiotic or probiotic supplements, or drink beverages with prebiotics or probiotics (other than the p-inulin that we provide).

Screening and Baseline Visit(s)

Before you can be in this study, you will have a Screening Visit to see if you meet the study enrollment requirements. If you meet the requirements you will have a Baseline Visit. The Screening and Baseline Visits can take place together on the same day or on separate days, and they can take place at the dialysis unit

Screening activities include collecting the following information:

- Your age, sex, and race
- Your medical history
- Current prescription medications, over-the-counter products, herbal and dietary supplements
- Whether you've taken prebiotics and probiotics in any form including yogurt, supplements, tea, and beverages
- For women who are able to get pregnant, we will draw blood for a pregnancy test – you will not be able to participate if you are pregnant

Baseline activities include the following:

- A diet questionnaire about the foods you've eaten in the past 1 month
- A questionnaire about any gastrointestinal (GI) symptoms you may be having
- Blood collection: a little less than 3 teaspoons of blood will be collected. Because the blood will be obtained at dialysis through the dialysis tubing, this collection will not require a needle stick.
- Instructions on how to collect and package your stool samples

Throughout the 3 phases of the study you will have weekly contacts with the research team (in-person or by telephone) and study visits every 4 weeks at the dialysis unit. During the weekly contacts we will ask you whether you have started any antibiotics.

Pre-Treatment phase (Weeks 1-8)

- You will not take p-inulin during this phase.
- Stool sample collection: 1 time per week during Weeks 1-7 and 2 times during Week 8.
- Blood samples: 1 time per week during Weeks 1-8.
- GI symptom questionnaire will be done at Week 4 and Week 8.
- Diet questionnaire will be done at the end of this phase.

P-Inulin Treatment phase (Weeks 9-20)

- You will take p-inulin mixed in water or other beverage 2 times per day.
- Stool sample collection: 2 times during Week 9, 1 time per week during Weeks 10-19, and 2 times during Week 20.
- Blood samples: 1 time per week during Weeks 9-20.
- GI symptom questionnaire will be done at Week 12, Week 16, and Week 20.
- Diet questionnaire will be done at the end of this phase.

Post-Treatment phase (Weeks 21-28)

- You will no longer take p-inulin.
- Stool sample collection: 2 times during Week 21, and 1 time per week during Weeks 22-28.
- Blood samples: 1 time per week during Weeks 21-28.
- GI symptom questionnaire will be done at Week 24 and Week 28.
- Diet questionnaire will be done at the end of this phase.

Stool Collection

You will be given written instructions about how to collect and package your stool samples. We will give you stool specimen collection kits that contain the supplies you need to collect and package stool at your home. You will deposit your stool into a container that rests on your toilet

bowl. Each kit will have tubes with caps. The cap of each tube has a small spoon attached to it. You will scoop a small amount of stool, put it in the tube, and close the tube. You will do this for several tubes. You will have disposable gloves to wear while doing this.

You will put the closed tubes into a ziplock bag and then put the bag in a clean Styrofoam container with pre-frozen cold packs. You may also keep the container in your refrigerator. You will put the container in a box that you will bring to the dialysis unit for the research team to pick up.

Blood Collection
Your blood samples will be collected at dialysis just before your dialysis session begins. Because the blood will be obtained through the dialysis tubing, this collection will not require a needle stick. Each blood sample collection will be 13 milliliters (about 3 teaspoons). Before your blood is collected, we will check your most recent blood count. If it's too low, we will not collect your blood.

P-Inulin Treatment
At the beginning of the Treatment phase (Week 8) you will be given a 4-week supply of p-inulin and instructions on how to take it. The p-inulin comes in packets. You will mix 4 packets with ¾ cup (6 ounces) of water or other beverage. You will take 4 packets in the morning and 4 packets at night. You must keep all unused packets and bring them to your Week 12 study visit.

You will get another 4-week supply of p-inulin at your Week 12 study visit and at your Week 16 study visit. You will take the p-inulin in the same way and return your unused packets at Weeks 16 and 20.

POSSIBLE RISKS OR DISCOMFORTS
The common side effects of p-inulin include gastrointestinal symptoms such as passing gas, bloating, loose stools, and increased stool frequency. There may be side effects that are not known at this time.

Collecting and preparing the stool samples at home and bringing the samples to the dialysis center will require effort on your part and might feel burdensome. You will also need to bring in and take home supplies throughout your participation. Please think about whether you will be able to collect and prepare your stool samples for 7 months. It is important for this study that you give us stool samples, so we ask that you think carefully about what we are asking you to do.

Women of Childbearing Potential: You should not be in this study if you are pregnant, breastfeeding, or planning to become pregnant in the next 7 months. If you are able to become pregnant, you will have a pregnancy test before starting this study. If you do become pregnant

while you're in this study, tell us right away. You will no longer be in the study but we will contact you after your delivery to obtain information about your health, and the health of your baby.

During the study you need to take safety measures to prevent pregnancy by not having sex or by using a medically accepted method of birth control such as a diaphragm and spermicide, cervical cap and spermicide, latex condoms and spermicide, and hormonal contraception such as intrauterine devices (IUD), hormonal implants, injectable contraceptives, or birth control pills.

We will tell you as soon as possible if we learn new information that could cause you to change your mind about being in this study. A Data and Safety Monitoring Committee, which is an independent group of experts, will review the safety of this study while the study is being done.

POSSIBLE BENEFITS

You are not expected to benefit from being in this study. The information learned from this study will be used to plan larger studies of p-inulin that will help determine if it is beneficial for patients with kidney disease.

OTHER OPTIONS TO BEING IN THIS STUDY

If you decide not to take part in this study, you will continue to get dialysis-related care from your nephrologist and dialysis unit.

PAYMENT

[** insert site specific language describing payment milestones, whether SSN must be provided for payment and how ppts will receive payment]

COSTS

There will be no cost to you from participating in the study. p-Inulin will be given to you at no cost. There are no charges for blood tests that are done for the study, and supplies for the stool sample collections will be given to you.

RESEARCH RELATED INJURY

If you are hurt because of this study, we will treat your injuries. We may bill your insurance company for the costs of this care and you may also have to pay some costs.

There are no plans for **insert site name* to pay you or give you other compensation for injuries. You do not give up your legal rights by signing this form.

If you think you have been injured because you are in this study, tell us as soon as possible. Call Dr. **insert PI name* at **insert phone #*. **[*or insert site specific language in this section]**

VOLUNTARY NATURE OF THE STUDY

If you decide to be in the study, you are free to leave the study at anytime. Leaving the study will not affect how we care for you at **insert site name*. To withdraw, simply tell us that you no longer wish to take part. If you decide to stop for any reason, it is important to let us know as soon as possible so you can stop safely.

EARLY TERMINATION OF THE STUDY

This study is expected to end after all participants have completed all visits, and all information has been collected. We expect the study to be completed in about 15 months. This study may also be stopped at any time by us or the study sponsor without your consent because:

- We feel it is best for your health or safety. We will tell you if we do this and the reason why.
- The sponsor or the study Principal Investigator has decided to stop the study.

DATA AND SAMPLE STORAGE AND TESTING

Your blood and stool samples will be sent to central laboratories for testing at Baylor College of Medicine, University of California, Davis, and the University of Pennsylvania.

We are also asking you to allow us to give your leftover samples and related information to the National Institutes of Diabetes, Digestive and Kidney Diseases (NIDDK) Central Repository. After all tests have been done, your remaining blood and stool samples, and study data stored at the Data Coordinating Center at the University of Pennsylvania will be transferred to the NIDDK Central Repository to be stored for future research. The Repository collects, stores, and distributes biological samples and associated data from individuals with many kinds of conditions and from healthy people. The purpose of sending some of your samples to the Repository is to make samples available for future research by investigators who are not involved in the Microbiome study.

Investigators who use your samples will not have access to any of your personally identifiable information so they will not know who you are or be able to contact you. Neither you nor your physician will receive results of tests done on your samples. The stored samples will be used only for research and will not be sold. Cell lines will not be developed using your samples. The findings from this research may result in the future development of products with commercial value, although there are no plans for this. There are no plans to share with you any potential profits from the research.

If you agree to have your samples and data stored in the Repository, you can change your mind until the study ends. You can withdraw your permission to store your samples and information by sending a letter to Dr. **insert PI name* at the address on page 1. Your specimens and any information about you will be destroyed. After the study ends, you will not be able to

withdraw your samples or data because the Repository will not know which ones are yours. The data will stay in the Repository indefinitely.

You do not have to agree to have your samples sent to the NIDDK Repository in order to be in this study.

PROTECTING YOUR PERSONAL INFORMATION

Protecting your privacy and your personal health information is important to us. This section describes how your personal information will be used and protected. Protected Health Information (PHI) includes health information in your medical records and information collected during the research study.

The following PHI will be collected, used for research, and may be shared with others while you are in this research study:

- Name, address, telephone number, date of birth, gender
- Dialysis medical record information
- Medical history
- Current medications or therapies
- Information from the tests, questionnaires and visits described in this form
- Safety information such as adverse events
- Social Security number (to pay you) [*delete if not applicable at your institution]

Who may see, use, and share your health information:

- The study doctor and the study team doing this study
- Other authorized personnel at **insert site name*
- **insert site name* Institutional Review Board (the committee that oversees research on human research participants)
- The Data Coordinating Center (DCC) at the University of Pennsylvania
- Other doctors and study teams doing this same study at the other study sites
- The Translational Core Lab at the University of Pennsylvania will receive and analyze blood samples; and store stool samples
- West Coast Metabolomics Center at the University of California, Davis will receive and test stool and blood samples
- The Alkek Center at the Baylor College of Medicine will receive and test stool samples
- Data Safety and Monitoring Board for the study
- Representatives of government agencies, including The National Institutes of Health, the National Institute of Digestive, Diabetes and Kidney Diseases (NIDDK - the government agency sponsoring this study), the Office of Human Research Protections, and others who watch over the safety, effectiveness, and conduct of the research.

When your information is released outside of *_insert site name_*, you are not identified by name, *social security number, address, or any other direct personal identifier. You are identified by a unique ID number that is assigned to you for this study. The link between your name and code number is kept in a secure file and is not shared with anyone outside *_insert site name_*.

The Data Coordinating Center for this study stores study information from all research centers. All information that could identify you is removed at the research center and sent to the DCC by a secured Internet connection. The study information is stored in secure electronic files at the University of Pennsylvania. Only authorized members of the research study have permission to see these data.

At the end of the study, all data *(except for your Social Security information) will be sent from the DCC to the NIDDK Central Repository where it will be archived. Researchers who plan to use your data for future scientific study will be required to request and receive all of the necessary approvals or waivers from the NIDDK before using your data. Data will only be released to scientists who are qualified and prepared to conduct a research study.

We will do our best to make sure that your personal information is kept private. However, we cannot promise total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. You may withdraw or take away your permission to use and share your health information at any time and for any reason. You do this by sending a letter to Dr. *_insert PI name_* at the address on page 1. If you withdraw your permission, you will not be able to stay in this study.

Withdrawing from the study won't change the care you get for your kidney disease now or in the future. There are no penalties for leaving the study. If you decide to stop for any reason, it is important to let us know as soon as possible so you can stop safely.

Even if you withdraw your permission, we may still use your information that was collected before your written request if that information is necessary to the study.

If you decide not to give permission to use and give out your health information, you will not be able to be in this study.

A description of this clinical trial is on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website may include a summary of the results of the study. You can search this website at any time.

Electronic Medical Records and Research Results

[insert local IRB required language regarding including study related information in the EMR; contact DCC or your IRB if you have questions about language to use]

QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT

If you have questions, concerns or complaints about being in this study or if you have any questions about your rights as a research participant, please talk to Dr. **insert PI name* or the study team. If you can't reach us or you want to talk to someone who isn't a part of the study, please call the **name of IRB* at the **insert site name* at **phone number*.

Permission to Send your Blood Samples to the NIDDK Repository

Please respond to the following statements and CIRCLE either "YES" or "NO" and write your initials and today's date:

I give permission to store my blood samples at the NIDDK Central Repository for future use.

YES NO Initials: _____ Date: _____

I give permission to store my stool samples at the NIDDK Central Repository for future use.

YES NO Initials: _____ Date: _____

When you sign this form, you are agreeing to be in this study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting **insert site name* to use the health information that is collected about you for research purposes within our institution. You are also allowing **insert site name* to share and release that health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. Please print your name and then sign and write today's date.

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