Consent and Authorization Form

Principal Investigator: **Lilia Cervantes, MD**

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Study Title: Peer Navigator Study: Improving the well-being of Latinos on Hemodialysis

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study wants to know if a bilingual peer navigator can help improve your well-being by providing you with support with social and medical challenges. We are doing this study because we know that many Latinos on dialysis face social and medical challenges. We understand that peer support is important. We know that cultural values affect healthcare decisions so we designed this study with the support of Latinos from the community with kidney failure.

You are being asked to be in this research study because you have end-stage kidney disease, are Latino or Latina, and receive hemodialysis three times per week.

Up to 160 participants will be enrolled in this study.

What happens if I join this study?

If you join the study after providing consent, you will be placed in 1 of 2 groups. One group is control and the other group is intervention. The group you are placed in is selected by chance (like tossing a coin) and this is called "randomization". A computer decides which group you are put into. If you are in the INTERVENTION group, you will be asked to do the following:

- Participate in a short interview (may be audio-recorded) that will include questions about the social challenges you are facing, your mental health and symptom burden, as well as your quality of life.

- Participate in 5 visits with your peer navigator. The peer navigator will provide you with support with your social and medical challenges. This may include helping you understand information you received from your providers, helping you find resources in your community, and helping you make appointments. The locations of the meetings will be your choice (You can choose to meet during dialysis, in the waiting room, home, or other).

- The PN will attend the monthly meeting with the Dialysis Center staff for those participants in the intervention group.

- When you complete the study, we will invite you to participate in a short interview (may be audio-recorded). The interview will include questions about your experience with the

peer navigator and questions we asked at the time of consent about social challenges and quality of life.

- We will also look at your medical records. These records will include your hemodialysis center or hospital records.

- Your participation will last four to six months.

If you are in the CONTROL group, you will receive all of the above EXCEPT the Peer Navigator visits.

What Will Happen to my Recorded Information?
In this study we will be audio-recording your interviews. We will use an audio-recorder. We will keep this information secure and private. Audio recordings of the interviews will be stored in a secure, password protected server with limited access, once analysis is complete, these will be destroyed.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include emotional distress that may be felt when asked questions about your social needs. The Patient Navigator will notify dialysis staff and the dialysis Medical Director if your score is 10 or more in the depression questionnaire (PQH-9) so you can receive support. The research team will notify your nephrologist when you have joined the study so that they know you are part of this study. Answering the questions is your choice. You can choose not to answer the questions.

You may also become tired during the interviews. You may request to complete the interviews over separate days or take breaks.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed. Visits will only be recorded in a private and secure setting, therefore visits completed at the Fresenius centers will not be audio recorded.

The study may also include risks that are unknown at this time.

What are the possible benefits of the study?

Potential benefits include receiving additional social support from the Patient Navigator. This study is designed for the researcher to learn more about how to improve the well-being and care for Latino/Latina patients with end-stage kidney disease receiving hemodialysis.

Who is paying for this study?

This research is being paid for by the National Institute of Diabetes and Digestive and Kidney Diseases, which is part of the National Institutes of Health.

Will I be paid for being in the study? Will I have to pay for anything?

You or your insurance company may be billed for:

- Any standard medical care given during this research study.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor.

- You will receive up to $220 divided into separate payments during the study depending on which group you are placed into. For the first interview after providing consent, you will receive $60. You will then receive $20 for each of the five visits with the peer navigator (only if you are in the Intervention group). Finally, you will receive $60 when you complete the final study interview.

- Payments for taking part in this research study will be put onto a "ClinCard." ClinCard is managed by a company named Greenphire. ClinCard works like a gift card and can be redeemed where Mastercard is accepted. At a minimum, your name, date of birth and social security or tax identification number will be given to Greenphire in order for study payments to be loaded onto a ClinCard. Let the research staff know if you have concerns about using ClinCard. It is important to know that payments for participation in the study is taxable income. If you receive $600 or more from Denver Health & Hospital Authority in one tax year, you will be sent an IRS Form 1099 for tax purposes.

- You will only be compensated for the visits you completed.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study, the alternative to participation is to not participate.. If you choose to take part, you have the right to stop at any time. If you refuse or decide to stop your participation, you will not lose any benefits or rights to which you are entitled.

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have questions about injury related to the research, you may call Lilia Cervantes at 303-602-5075 and/or your private physician. Dr. Lilia Cervantes should be informed about any injury you experience while you take part in this study. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Lilia Cervantes. You may ask any questions you have now. If you have questions later, you may call Lilia Cervantes at 303-602-5075. You will be given a copy of this form to keep. You may have questions about your rights as someone in this study. You can call Lilia Cervantes and the research staff with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

Certificate of Confidentiality
This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.
These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

To those connected with the research,
If required by Federal, State or local laws,
If necessary for your medical treatment, with your consent,
For other scientific research conducted in compliance with Federal regulations,
To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Denver Health and Hospital Authority

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your

information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Lilia Cervantes, MD
777 Bannock Street, Mail Code 4000
Denver, CO, 80204

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institutes for Health who is the company paying for this research study.
- Officials at the institution where the research is being conducted (especially your nephrologist) and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Fresenius Dialysis Medical Care Centers and Frenova

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

- Some things we cannot keep private: If you tell us about child abuse or that you are going to physically hurt yourself or someone else, we have to report that to the state police or other agency. Also, if we get a court order to turn over your study records, we will have to do that.
- Audio Recordings. The recordings will be stored on the Denver Health firewalled, password protected virtual private network on a server accessible only to study team members. The recordings will be stored only to complete a fidelity check of the content and process of the intervention visit. Once the fidelity has been assessed, audio files will be destroyed.

You have the right to request access to your personal health information from the study doctor. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records from Fresenius that are relevant to this study, including but not limited to Diagnoses, History and Physical, laboratory studies, kidney transplantation visits, vital signs, and weight.
- Research Visit and Research Test records
- Surveys/questionnaires: Social determinants of health composite survey, social isolation survey, self-efficacy survey, and quality of life survey.

What happens to Data that are collected in this study?

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Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____ Date:_____

Print Name: _____

Consent Form explained by: _____ Date:_____

Print Name: _____

--------Witness Signature line (if patient is blind, illiterate, or has a reading limitation) ------

Witness Signature: _____ Date_____

Print Name: _____

Witness of Signature □

Witness of Consent Process □