ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Mentee

INTRODUCTION:

You are being asked to participate in a research study entitled: “Peer mentorship to improve outcomes in patients on maintenance hemodialysis”. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say “no” now or at any time after you have started the study. If you say “no,” your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the “Principal Investigator.” Her name Ladan Golestaneh. You can reach Dr. Golestaneh at:

3411 Wayne Avenue- Suite 5H
Bronx, NY, 10467
718-920-5442

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by The National Institute of Diabetes, Digestive and Kidney Diseases.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and MontefioreMedicalCenter has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., BelferBldg #1002
Bronx, New York10461

Why is this study being done?

The purpose of this research is to test the effect of offering at-risk hemodialysis patients the opportunity to talk regularly with specially trained peer mentors, who are themselves hemodialysis patients with special training on the health and sense of well-being of patients receiving the mentoring. The trained hemodialysis patients will talk regularly to participants (potentially you) about being on dialysis, what to drink and not to drink, what to eat and not to eat and the importance of coming regularly to dialysis sessions. We will study whether participants who talk to the peer mentors will have fewer hospitalizations and visits to the emergency department compared to participants who do not talk to peer mentors.

Why am I being asked to participate?

You are being asked to participate in this study because you are on hemodialysis, you have one or more hospitalizations or emergency department visits in the previous month or missed more than one treatment or have 2 shortened dialysis treatments in the last month, you started dialysis recently, or have used a catheter as only access. You have been asked to participate because the dialysis staff has recommended you to the study.

How many people will take part in the research study?

You will be one of about **200** people who will be participating in this study to receive mentoring. The study will be conducted at 1 other location outside of Montefiore Medical Center/Albert Einstein College of Medicine

How long will I take part in this research?

It will take you about 3 months to actively engage in this study but your clinical information will be gathered for an additional 15 months after that. The study staff will not collect any data other than what is gathered as part of your routine care.

What will happen if I participate in the study?

If you decide to enroll in the study, you will be randomized (like flipping a coin) to either the group of mentees (those who will get the phone call) or the usual care group. All participants will get an informational pamphlet on fluid and dry weight and continue with their regular dialysis visit which is within the scope of usual care practices. All participants will be asked to fill out questionnaires at 3 study visits; one when you join the study, another one after active peer mentoring (if you are assigned to that group) and the last one at the end of the study period.

If you are randomized to the peer mentorship group, you will be assigned to a mentor. The mentor will call you to talk to you and help you understand your care better. A cell phone will be provided to you (or if you insist on using your personal cellphone or landline telephone and understand the implications of using your minutes and associated costs is fine as well), and you will speak to your mentor every week for 3 months. You will also be invited to social events monthly which you can attend if you want to. Everything you record will be kept confidential.

After the three months you will be asked to complete questionnaires about your feelings about the study and what you may have learned. You will then be asked to fill out the questionnaires again after 15 months. The questionnaires should take about an hour to complete and can be

filled out during your dialysis treatment.

In addition, if you have been in the emergency room or have been hospitalized at Montefiore Medical Center and/or outside of Montefiore Medical Center within the time you were enrolled in the study, we will request that you give us a copy of your hospital discharge summary. We may need for you to sign a release that will allow us to request records from outside Hospitals.

Will there be audio and/or video recording?

During the intervention time, (the 3 months you will be speaking on the telephone to a mentor), the study staff will listen to approximately 1 telephone conversation per month that your assigned mentor recorded at their home with a handheld recorder that was provided to them by the study. The content that will be recorded will be about being on dialysis, what to drink and not to drink, what to eat and not to eat and the importance of coming regularly to dialysis sessions. We expect the calls to last between 2 and 25 minutes. Some may take longer. You will be asked to keep a log of each phone call with how long you talked and what you talked about. Everything you record will be kept confidential. The tapes will be destroyed 2 years after the study has ended.

Genetic Testing

This study will not involve genetic research or genetic testing.

Information Banking (Future Use and Storage)

We will store information about you in a “bank”, which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____I consent to have my information used for future research studies.
_____I do NOT consent to have my information used for future research studies.
Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

Yes, you will be paid for some parts of the study. You will receive a total of $50 for each of 3 study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.You will be reimbursed for travel to these assessments (Metrocard). If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed. In addition, you will receive For those mentees randomized to the intervention, you will receive $15 per hour for telephone

calls you complete with your mentor. Any call lasting between 3 minutes and 30 minutes will be treated as ½ hour and any call over thirty minutes to 1 hour will be treated as a full hour, for purposes of calculating your pay. The study will pay only up to 2 hours of telephone time per week. For the duration of the 3 months of intervention you may get paid up to $360.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. Transportation and some food will be provided to monthly social events and to your 3 study visits. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Ladan Golestaneh (718) 920-5442. If you become pregnant at any point during the study you must let a member of the study staff know.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable

- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Certificate of Confidentiality
As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the certificate to attempt to legally refuse to provide it. This is rare—in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information**.**

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Questionnaire
You may feel uncomfortable answering questions about things you may feel are personal or intrusive about your lifestyle or the people around you. You can choose not to answer questions that make you feel uncomfortable.

Other Risks
There may be other risks or discomforts if you take part in this study. Other potential risks of study participation could be the additional time it will take to receive mentoring and complete questionnaires, but there is no reason to suspect that any serious adverse events will occur due to the intervention.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include an improved experience with hemodialysis, a sense of accomplishment in helping future patients and a small monetary reward.

What choices do I have other than participating in this study?

You can decide not to participate in the study. You will continue to be provided with appropriate medical care by your doctor.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if we find out that you have breached the confidentiality of other participants in the study. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date
_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date