# **Durham VA Healthcare System**

Department of Veterans Affairs

Consent For Clinical Treatment/Procedure

## A. IDENTIFICATION

1. Patient name, Social Security Number, and Date of Birth:

**PatientSSN** 

- 2. Decision-making capacity:
- 3. Name of the treatment(s)/procedure(s):

Chronic Dialysis (Hemodialysis, Home Hemodialysis and Peritoneal Dialysis) for End Stage Kidney Disease

- **4. Part of the body on which the treatment/procedure will be performed:** (Correct site includes the correct side [i.e., left or right] and the precise anatomical part, such as a specific finger. DO NOT ABBREVIATE.)
- 5. Practitioner obtaining consent:
- **6. Supervising practitioner:** (if applicable)
- **7. Additional practitioner(s) performing or supervising the treatment/procedure:** (if not listed above)

#### **B. INFORMATION ABOUT THE TREATMENT/PROCEDURE**

8. Reason for treatment/procedure (diagnosis, condition, or indication):

You have developed kidney failure that is not expected to get better (End Stage Kidney Disease, ESKD). As a result, your kidneys are not able to do their usual functions of removing waste products, salt, and fluid from your blood. The treatment for ESKD is kidney replacement therapy which can be given as dialysis or kidney transplantation. Dialysis is done to remove the waste products, salt and fluid that build up in your blood when your kidneys cannot work to limit the symptoms of kidney failure. Dialysis is given on an ongoing basis, or until you receive a kidney transplant. You can also choose to end dialysis as any time, but, since dialysis is a life sustaining treatment, if you do stop dialysis, you will develop symptoms of kidney failure and die from complications.

9. Brief description of the treatment/procedure:

Dialysis involves cleaning your blood of toxins and removing extra fluid from your body that build up when the kidneys are damaged. Dialysis is performed in many ways for the treatment of end stage kidney disease.

Hemodialysis: The most used form of chronic dialysis is hemodialysis. In these treatments, blood is drawn out of your body with care at a controlled speed from a special surgically crafted blood vessel in your arm or leg (fistula or graft) or through a catheter (small tube) placed into a large vein in your neck or leg. The blood is passes through a dialysis machine and then returned to your body. Waste products that have built up in your blood are removed. Extra fluid that you have collected may also be removed. The blood sometimes is kept from clotting as it passes through the dialysis machine using blood thinners.

In-Center Hemodialysis: Hemodialysis is often done in a dialysis clinic (in-center hemodialysis) that you would need to go to many times per week. The plan for dialysis would be decided by your kidney doctor (nephrologist). Treatments are usually given three times per week (Monday-Wednesday-Friday or Tuesday-Thursday-Saturday). These treatments last from 3 to 5 hours each time.

Home (Self-Care) Hemodialysis: Hemodialysis can also be given at home. You will be trained to carry out the treatment for yourself. All the equipment and supplies will be given to you. Many schedules are used for home hemodialysis treatments. These range from 2 hours to 8 hours per treatment performed 3 to 7 days per week. You and your kidney doctor will decide the best plan for you together. After completing training, you would perform your hemodialysis treatment and would only need to be seen in clinic monthly. If problems come up that change your ability to do your hemodialysis at home, you might need to switch to in-center hemodialysis on a temporary or permanent basis.

Home (Self-Care) Peritoneal Dialysis: Dialysis is also offered by placing a catheter into your abdomen (belly) to allow sterile fluid (peritoneal dialysate) to flow into and out of the space around your bowels. This fluid has salts, sugar, and other additives. This is called peritoneal dialysis (PD). The toxins that collect in your blood, extra salt and water are drawn into the clean peritoneal dialysate (sterile fluid) and drained out of the catheter. It is then replaced with clean dialysate. This procedure is done many times over the course of the day, either by hand or by using a machine. The details of treatment may change over time, based on your condition and how well you respond to treatment.

If you choose peritoneal dialysis, you will be taught how to give the treatment to yourself. All the equipment and supplies will be given to you. After you have completed training you would carry out your peritoneal dialysis treatments at home and would only need to be seen in clinic monthly. If problems come up that change your ability to do the treatment, you might need to switch to in-center hemodialysis on a temporary or permanent basis.

Inpatient Dialysis: If you are hospitalized, your dialysis will be provided during your hospital stay.

Medical Management without Dialysis: You may choose to not start on dialysis. Understand that without dialysis, you may feel much worse with symptoms over time and die of kidney failure. If you do not choose to start dialysis, you will be offered medical management to help lessen your symptoms and keep your quality of life as long as possible.

Selection of Type of Dialysis: The type and details of your dialysis treatment will be decided by your kidney doctor after talking with you. Your treatment may change as your condition changes. This includes problems of treatment, or if your choices about your treatment changes.

This may mean switching between home (self-care) and in-center (staff-assisted) dialysis, switching between peritoneal dialysis and hemodialysis. It may also involve the use of prolonged or continuous kidney replacement therapy if you are hospitalized. You can choose to end dialysis at any time if you feel that it is not giving you adequate quality of life and no longer agrees with your wishes for your medical care.

The first type of dialysis that will be used will be [select one]:

- \* In-center hemodialvsis
- \* Home hemodialysis (with in-center hemodialysis as back-up)
- \* Peritoneal dialysis (with in-center hemodialysis as back-up)

Decisions to change the form of dialysis will be made between yourself, your kidney doctor, and your dialysis treatment team. These decisions will be documented in your dialysis long-term care plan or some other part of your medical record. Completing another informed consent form will not be needed for each change in your treatment. We will ask you to complete a separate consent form for placement of the vascular access (fistula, graft, or catheter) for hemodialysis, or for placement of the catheter in your abdomen for peritoneal dialysis.

This consent is for the start of chronic dialysis. Your dialysis treatment is expected to carry on indefinitely. This consent is valid until there is a major change from the first treatment plan, or if there is a change in your health or diagnosis that would be expected to alter this consent form.

### 10. Potential benefits of the treatment/procedure:

Dialysis is a life-sustaining treatment for kidney failure. All the forms of kidney replacement therapy (dialysis) are done to remove poisons and impurities from the blood that cause symptoms of kidney failure. These are lowered brain function (sleepiness, confusion, coma), loss of appetite, nausea and vomiting. Kidney dialysis helps fix chemical imbalances that happen during kidney failure. These are high potassium levels (hyperkalemia) and a buildup of acid in the blood. All the forms of dialysis can be used to remove extra fluid from the lungs, blood stream, and other areas which may be adding to having swelling and shortness of breath.

# **11. Known risks and side effects of the treatment/procedure:** (Include potential problems related to the recuperation.)

Known risks of this treatment include, but are not limited to:

The risks of dialysis differ with the form of treatment. Risks that are common to both hemodialysis and peritoneal dialysis include:

- \* Fever.
- \* Heart attack.
- \* Heart rhythm disturbances.
- \* Stroke.
- \* Greater sensitivity to cold.
- \* Infections due to bacteria.
- \* Leg pain or cramping.
- \* Very low or high blood pressure.
- \* Risk of spreading hepatitis (liver infection), human immunodeficiency virus (HIV), and other viruses.
- \* Sepsis (infection in the blood).

\* Death.

Risks that are seen only with hemodialysis include:

- \* Air bubbles going into the bloodstream.
- \* Allergic response to the solution used to sterilize the dialyzer (machine).
- \* Bleeding.
- \* Clotting.
- \* Damage, blockage, or sudden closing of blood vessels.
- \* Infection of the catheter, fistula or graft used to reach your blood.
- \* Blockage of the catheter, fistula or graft used to reach your blood.

Risks that are seen only with peritoneal dialysis include:

- \* Infection in your belly (peritonitis).
- \* Blockage of the catheter in your belly.
- \* Damage to your bowel by the catheter in your belly.

#### Additional risks discussed:

### 12. Alternatives to the treatment/procedure:

- \* Watching and waiting with your doctor to see if your kidney function stabilizes or improves and if you can delay when you start dialysis.
- \* Being listed for a kidney transplant. If you do not have a medical contraindication, kidney transplantation is an option that can be considered instead of dialysis. If you wish to get a kidney transplant, you need to talk about being evaluated and referred with your doctors. If you need to start dialysis right away, a kidney transplant is not an option. You can get a transplant after you have been on dialysis. If you get a transplant and it is successful, you will be able to end dialysis treatments.
- \* Choosing not to be treated with dialysis (see Medical Management without Dialysis, above). You may choose to not be treated with dialysis. As your kidney function gets worse, you will become sicker, experience more symptoms, and in the end, die of kidney failure. If you choose to not start dialysis, you will be given medical care to help lessen your symptoms and keep up your quality of life for as long as possible.

#### 13. Anesthesia / Moderate Sedation:

No, neither anesthesia nor moderate sedation will be used in this treatment/procedure.

#### 14. Blood products:

It is not expected that blood products will be used in this treatment/procedure.

#### 15. Additional information

I understand that VA hospitals are teaching facilities, and trainees may participate in or observe this treatment/procedure.

#### 16. Comments

17.	Imag	e(s)	if s	ele	cted:
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C. SIGNATURES

# **Practitioner obtaining consent:**

- All relevant aspects of the treatment and its alternatives (including no treatment) have been discussed with the patient (or surrogate) in language that s/he could understand. This discussion included the nature, indications, benefits, risks, side effects, and likelihood of success of each alternative.
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this treatment.
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

 Date/Time:

# Patient or surrogate:

By signing below, I attest to the following:

- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment/procedure could help me, and things that could go wrong.
- Someone has told me about other treatments or procedures that might be done instead, and what would happen if I have no treatment/procedure.
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment/procedure. If I do refuse or change my mind, I will not lose my health care or any other VA benefits.
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure.

Data/Times
Date/Time:

**Witnesses:** No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

By signing below, I attest to the fact that I have witnessed the patient (or surrogate) and the practitioner sign this consent form.

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Date/Time:
No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.
Date/Time:
If the conversation is not audio taped a second practitioner, or other VA employee, must witnes the conversation.
Date/Time:
[ ] The employee witness is not located with the provider signing this form and will provide separate documentation that s/he witnessed the conversation (witness will not sign this form)