

Baseline

Subject criteria

Aged 18 years old or older.

Receiving regular hemodialysis for 3 months or more.

Capable of giving informed consent.

Exclusion criteria are active malignancy, pregnant women, prisoners, persons with significant mental illness.

Consent process

Confirm that the patient meets the inclusion criteria BEFORE consenting

Review consent form with the patient and answer any questions.

- Provide overview of what patient is being asked to do
- Advise of the minimal risks, the need to obtain protected health information (PHI) and uses that will be made of this information as summarized in the informed consent
- Explain how patients may withdraw from the study at any time or revoke their authorization for use of their PHI, including blood samples. Advise that there are no costs to patients for participating in the study
- Assure patient that withdrawal from the study will not affect in any way the patient's current or future dialysis care
- Ask patient to sign three (3) copies of consent form and give one copy to patient and one copy to clinic
- Give copy of revocation letter to patient
- Write Study ID# and SSN on the colored Research Office copy of the consent form

Get contact phone number from patient to use for appointment reminder.

Complete Demographic Form

Ask patient to sign Release of Medical Information form(s) for hospital and/or physician office records

Assign Study ID on Patient Enrollment Log with patient's name.

Data Collection

Physical Performance Form: *Must be completed pre-dialysis*. Patients may use any needed assistive devices during the physical performance tests and must be closely monitored for safety during these tests.

Grip strength:

- Ask patient to sit and to hold the dynamometer with the elbow bent and squeeze as hard as he/she can and then let go.
- Record the measurement in kilograms (if needle is between two marked lines, record the value between the two, e.g. between 28 and 30, record 29)
- Ask patient to repeat after a 15-second break
- Complete three trials
- Repeat procedure for the other hand

Gait speed: Measure and mark off 15 feet in hallway or area where timed walk can be conducted

- Using protocol script, ask patient to walk the course at a normal pace
- Repeat for second trial

Standing balance: (use protocol script)

- Ask patient to stand with feet together, side by side, for 10 seconds
- Ask patient to stand with feet in semi-tandem position for 10 seconds
- Ask patient to stand with feet in tandem position for 10 seconds

Chair stand: (use protocol script)**Single chair stand**

- Ask patient if he/she feels that it is safe to stand without help
- Ask patient to cross arms over chest and stand

Repeated chair stand (only if patient successfully completed single chair stand)

- Ask patient if he/she feels that it is safe to stand five times
- Ask patient to cross arms over chest and stand five times, using no more than 60 seconds

Body Composition Form:

These measures may be completed any time.

Height:

- Ask patient to take shoes off
- Ask patient to stand with his/her back against the measuring rod and with feet together
- The back must be straight
- The head must be straight with an imaginary horizontal line from the ear to the eyes
- The caliper gauge is pushed on the head so that the measuring tongue rests without sagging
- Measure patient's height to the nearest tenth of a centimeter and record (round up to nearest tenth cm if necessary)

Waist circumference:

- Measure while patient is standing. If patient is unable to stand, ask patient to lie back in the dialysis chair and then measure. Do not measure while patient is in a sitting position.
- Place the tape measure around the bare abdomen just above the hip bone then bring it around level with the navel
- Be sure that the tape is snug, but does not compress the skin, and is parallel to the floor
- Ask patient to stand up straight and exhale
- Measure to the nearest tenth of a centimeter and record
- Repeat a second time and record.

These measures must be completed when patient has had a treatment no more than 2 days prior, usually patient's second or third dialysis session of the week; measurement must be made immediately prior to BIS analysis.

Weight:

- Ask patient to remove shoes and to empty pockets before being weighed by dialysis staff
- Record patient's pre-dialysis weight measured to a tenth of a kilogram by dialysis staff

BIS:

- Calibrate the machine at the beginning of each use
- Confirm that patient does not have a pacemaker or defibrillator—do not conduct test if has either
- Ask patient location of access currently in use (right side or left side)
- Use non-access side for testing, but if patient has catheter and access that are on different sides, use catheter side
- Ask patient to remove jewelry on side being measured (except rings and earrings)
- Ask patient to remove cell phone, keys, other metal objects (except coins) from pockets and to remove belt if the buckle is large
- Clean electrode sites with an alcohol prep pad and allow to dry completely before placing electrodes
- Follow Imp SFB7 Instructions for Use

Patient Questionnaire: *may be completed at any time*

Medical History and Questionnaire: *may be completed at any time*

- Complete form by abstracting data from any available clinic medical records, including chart notes, dialysis flow sheets, hospital records, physician records, lab reports
- Make a copy of patient's medication list
- Make a copy of the patient's CMS Form 2728
- Request hospital and/or physician office records, if needed (for example, H&P)

Review all study forms for completeness and accuracy. **All questions must have a response recorded.**

Return completed consent form and data forms to research office.