Screening Evaluation (Adult)

General Instructions

The Screening Evaluation form should be completed at the screening visit, which should take place up to, but no more than, 6 weeks prior to the Baseline visit (Day 0/randomization).

This form captures information on co-existing conditions, medications, and minimal physical assessment items obtained via patient interview and medical record review. When information in the medical record conflicts with information provided by the patient, the medical record is normally considered to be the accurate source, although there may be instances when the information provided by the patient is more up to date or accurate. In this instance, the information from the patient may be used.

The coordinator is responsible for obtaining the information recorded on this form. In non-English speaking patients, the interview may be performed through a certified interpreter. While a trained translator is preferred, a family member or friend of the patient (who speaks fluent English and the native language of the patient) may be acceptable for this role as determined on an individual basis.

Specific Instructions

Patient ID**:** Record the Patient ID in the top right hand corner of each page.

Date of Evaluation: Record the date (month/day/year) that corresponds to the protocol visit.

Section I: Coexisting Conditions

Check "Yes", "No", or "Unknown" for each condition listed to indicate whether or not the patient has been diagnosed or told by a doctor that they have the condition, or is receiving treatment for the condition.

Diabetes: Juvenile (Type 1) or Type II onset diabetes, regardless of treatment (e.g. diet, exercise, oral medication, insulin).

Hypertension: is normally diagnosed when a blood pressure of ≥ 140 systolic or ≥ 90 diastolic is noted on two separate occasions, or if the patient is currently on antihypertensive medication.

Hyperlipidemia: blood level elevation of lipids such as cholesterol, cholesterol esters, phospholipids and triglycerides, or on medication to lower these levels.

Thyroid dysfunction: includes hyperthyroidism or hypothyroidism. Hyperthyroidism, or overactive thyroid, is a condition in which the thyroid gland produces too much of the hormone thyroxine. Hypothyroidism, or underactive thyroid, is a condition in which the thyroid gland does not produce enough of certain hormones.

Other: any other coexisting condition present at the time of the visit

Section II: Medication History

Prescription Medications: Check "Yes" or "No" to indicate if the patient is currently taking any prescription medications. Prescription medications are defined as those medications prescribed by the patient's medical provider(s). Record any prescription medication that the patient is currently taking on the Concomitant Medication Log. Instruct the patient to bring a complete list of medications or the prescription pill bottles to all protocol visits.

Herbal/natural medications:	Check “Yes” or “No” to indicate if the patient is currently taking any herbs, herbal or natural medicines. Check “Unknown” if it is not known whether the patient is taking any herbs, herbal or natural medications.
Vitamins and minerals:	Check “Yes” or “No” to indicate if the patient is currently taking any vitamins or minerals. Items are to be taken as a separate supplement and may be in pill or liquid form. If yes, check the appropriate type. Check “Unknown” if it is not known whether the patient is taking any vitamins or minerals. Multi-vitamin: a supplement containing three or more vitamins or minerals but no herbs, hormones, or drugs. Common brand names include but are not limited to Centrum or One-a-Day. There are also multi-vitamins available as generic and store brands or prenatal vitamins. Vitamin D: supplement specific to vitamin D and may be in combination with calcium. Do not include if part of a multi-vitamin supplement. Common vitamin D and calcium combinations include but are not limited to Os-Cal, Viactive, and Caltrate+D. Record vitamin D and calcium combinations as both Vitamin D and Calcium supplements. Vitamin E: supplement specific to vitamin E. Do not include if part of a multi-vitamin supplement. Folate: supplement specific to folate. May also be referred to as folic acid or vitamin B_9. Do not include if part of a multi-vitamin supplement. Iron: supplement specific to iron. Do not include if part of a multi-vitamin supplement. Calcium: supplement specific to calcium and may be in combination with Vitamin D. May be noted as calcium citrate, calcium carbonate, or calcium lactate. Do not include if part of a multi-vitamin supplement. Common vitamin D and calcium combinations include but are not limited to Os-Cal, Viactive, and Caltrate+D. Record vitamin D and calcium combinations as both Vitamin D and Calcium supplements. Other: a vitamin or mineral other than those listed, and not part of a multi-vitamin supplement.

Section III: Physical Assessment

Height:	Record the patient’s height at the time of the physical exam. Ask the patient to remove shoes prior to obtaining the measurement. Check “inches” or “cm” (centimeters) to indicate which unit of measure was used. If height was not measured then check “Not done”. If for any reason (e.g. wheelchair-bound, equipment failure, etc.) a standing measurement is not obtained, record “Not done”.
Weight:	Record the patient’s weight at the time of the physical exam. Check “lbs” (pounds) or “kg” (kilograms) to indicate which unit of measure was used. If weight was not measured then check “Not done”.

Blood pressure: Record the patient's systolic and diastolic blood pressure in mmHg. Blood pressure should be obtained after the patient has been seated with both feet flat on the floor for at least 5 minutes. If blood pressure was not measured then check "Not done".

Section IV: Biospecimens

Samples obtained: Check "Yes" or "No" to indicate if samples were obtained at this visit.

If yes, check "NIDDK Repository", "Central lab", "Genetics", or "Immunology study" to indicate which samples were obtained.