General Instructions

The Baseline Evaluation form should be completed at the baseline visit. The patient should be randomized on the date of the baseline visit, after the patient is present.

This form captures information on adverse effects, concomitant medications, study 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: Adverse Effects

Check "Yes" or "No" for each adverse effect listed to indicate whether or not the patient reports that he/she currently has any of the signs, symptoms, or conditions, or has been told by a doctor that he/she has the condition.

Adverse Effects:

Fatigue: Defined as a lack of energy, weariness, or chronically tired. Characterized as prolonged weakness or tiredness that is not relieved by adequate rest, sleep or by the removal of other stressful factors. The patient may feel rested but with daily activity feel tired or feel tired after awakening and throughout the day a lack of energy or weariness or chronically tired.

Trouble sleeping: The inability to fall asleep, remain asleep throughout the night, or awake feeling refreshed.

Headache: Pain in the head that requires medical intervention and medication on a regular basis, such as migraines.

Dizziness: Refers to an impairment in spatial perception and stability, including but not limited to vertigo, disequilibrium, or lightheadedness.

Depression: Defined as having extreme feelings of sadness, dejection, lack of worth, and emptiness. There may be a loss of sense of pleasure in normal activities, decreased energy, change in sleeping habits, and feelings of hopelessness. Clinical definition of depression is the presence of these symptoms for at least a two week period. Information provided by the patient should be used in conjunction with results from the CES-D.

Weight loss: **Unintentional** loss of weight.

Decreased appetite: a loss of desire to eat even though you may not have eaten enough to supply your body with its basic caloric requirements.

Vision problems: Any type of visual disturbance including but not limited to blurred vision, halos, blind spots, or floaters.

Nausea: Uncontrolled persistent nausea and needed to seek medical intervention.

Upper abdominal pain: Pain in the upper abdominal area.

Breathing problems: Difficult or uncomfortable breathing.

Joint aches: Characterized as pain or stiffness in one or more joints.

Diarrhea: Frequent or loose bowel movements of unformed, watery stools

Vomiting: Uncontrolled or persistent vomiting.

Upset stomach: An unsettled stomach, indigestion, or a condition of impaired digestion.

Muscle pain: Any pain in the muscles. Do not include pain that is due to recent overuse or exercise.

Rash: eruption or breaking out of the skin, an inflammation of the skin.

Skin irritation: Skin redness or any other type of irritation of the skin, not including rash.

Flu-like symptoms: These may include but are not limited to fever, cough, headache, muscle aches, chills, sweating, fatigue, congestion, sore throat, nausea, diarrhea, and loss of appetite.

Hair loss: temporary or permanent loss of hair not associated with hereditary loss of hair that occurs with aging.

Other: any other sign, symptom, or condition that the patient reports as currently experiencing.

Adverse Events:

Check “Yes” or “No” to indicate if the patient experienced any adverse events since the screening visit. If “Yes”, also report the event on the Adverse Event Log. At a minimum, the following criteria should be used as a guide for recording events on the Adverse Event Log. These guidelines are not all inclusive and the recording of events remains at the discretion of the investigator. A symptom or condition that is present but does not reach one of these levels may still be recorded as an adverse event.

1) A symptom or event that requires discontinuation of study medication.
2) A newly diagnosed symptom or event that requires a written prescription for treatment.
3) A newly diagnosed symptom or event that results in a referral to another provider.

4) Any grade 3 or 4 event according to the NCI Common Toxicity Criteria.

If the adverse event meets the criteria of a Serious Adverse Event then complete the MedWatch form too.

Section II: Concomitant Medications

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). If the patient is currently taking prescription medications, update the Concomitant Medication Log to add or remove any medications that the patient started or stopped taking since the screening visit. 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: Study Medication

Study drug should be dispensed on the day of the baseline visit, with instructions to begin taking the study drug that same day.

Adherence counseling: Check "Yes" or "No" to indicate whether or not the patient was counseled on adherence to the study drug regimen, including the discussion of barriers to adherence, strategies to overcome barriers, and goals for adherence to therapy.

Study drug dispensed: Check "Yes" or "No" to indicate whether or not study drug was dispensed to the patient. If "Yes", complete the Study Drug Log to capture the amount of study drug dispensed. As a guideline, the amount of study drug needed to get to the next in-person protocol visit plus a few extra days of study drug should be dispensed. If study drug is not dispensed for some reason, complete the Off Protocol form.

Section IV: Physical Assessment

Height: **A height measurement must be obtained pre-treatment.** If height was not completed at the Screening Visit, 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 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 V: Bone Mineral Density

Test performed: Check "Yes" or "No" to indicate whether or not the patient has a bone mineral density test performed as standard of care within the last 3 years. Bone density tests should be performed according to standard of care when clinically indicated.

Potential indications for testing include:

- history of osteopenia or osteoporosis
- history of prior fracture
- history of malabsorption
- thyrotoxicosis, anorexia nervosa
- hyperparathyroidism
- women ≥65 years of age
- men ≥70 years of age
- postmenopausal women under age 65 with risk factors for osteoporosis
- women with premature menopause (<50 years) or long periods of amenorrhea

- vitamin D level < 30 ng/mL
- Asian race
- Type 2 diabetes
- tobacco use
- BMI < 23
- family history of osteoporosis, medications
- alcohol excess (≥2 drinks per day)
- minimal weight-bearing exercise

If Yes, complete the following information.

Date of test: Provide the date of the most recent test performed since the last protocol visit. If any piece of the date is unknown, record "Unk" [-3] in that field.

Evidence of Osteopenia: Check "Yes" or "No" to indicate if there was any evidence of osteopenia, defined as a decrease in the amount of calcium and phosphorus in the bone that can cause bones to be weak and brittle, and increases the risk for broken bones.

Evidence of Osteoporosis: Check "Yes" or "No" to indicate if there was any evidence of osteoporosis, defined as the thinning of bone tissue and loss of bone density over time.

Section VI: Biospecimens

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

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