Manual of Procedures (MOP)
Section 6. Screening

Table of Contents

6.1 OVERVIEW

At most sites, the screening and informed consent process are staged into 2 parts, a *Pre-screening* phase followed by a formal *Screening* visit. Each site, based on its prior experience, has developed a detailed site-specific recruitment plan (based on MOP section 5) that includes a pre-screening recruitment strategy to identify individuals at increased risk for type 2 diabetes who will be invited to the in-person screening visit. Active recruitment will take place year round at regular rates of enrollment to ensure equal exposure of randomized participants to UV-B.

The target for the screening process is to have a screened-to-randomization ratio close to 3:1 or better.

6.2 PRE-SCREENING

The goals of the pre-screening phase are to: 1) identify potentially eligible participants; 2) initiate the informed consent process; 3) conduct a preliminary verification of eligibility; 4) promote efficiency by pre-selecting candidates with high likelihood of eligibility after screening; 5) allow sites flexibility in their approach of recruiting participants, while maintaining a study-specific set of inclusion/exclusion criteria.

The pre-screening phase is site-specific and is based on what has worked well previously at the site. Pre-screening takes place in one, two, or more stages that may include an additional visit (e.g. identification of potential participants through databases [pre-screening stage 1], followed by over-the-phone pre-screening [pre-screening stage 2], followed by a visit [pre-screening stage 3]).

Sites will employ a variety of sources including electronic databases (e.g. electronic medical records and research volunteer databases), community-based advertising (e.g. hospital newsletters and specific local newspapers), targeted outpatient hospital clinics (e.g. primary care, cardiology), mailings to primary care physicians in the metropolitan area, social media (e.g. Craigslist), and study press releases to local news media to recruit potential participants (see MOP section 5).

6.2.1 Pre-Screening Procedures

The following are examples of pre-screening approaches that sites may follow. Identifying people who are more likely to meet the pre-diabetes criteria at the screening and baseline visits is the most important aspect of the pre-screening process.

6.2.1.1 Over the Phone

When a person calls to inquire about D2d, first impressions are important. Introduce yourself and explain your role in the study (Research Coordinator, Recruitment Coordinator, etc.) to the caller. Phone inquiries about the study are a great way to assess the effectiveness of the site-specific recruitment strategies, so it is important to ask interested volunteers where and how they heard about the study or what prompted them to call.

The research staff reads a simple script (see Appendix) to callers providing a brief overview of the study, informing them that they will be asked questions to determine preliminary eligibility and that, if

eligible, they will be invited to the research site for an in-person screening visit. The caller will then be asked if she would like to continue with the call and if she agrees; the research staff will continue with the Pre-screening Questionnaire that evaluates the key inclusion/exclusion criteria (see Appendix).

⇒ If the volunteer appears to qualify after the pre-screening questionnaire, a **diabetes risk score assessment** should be administered next as a second level of pre-screening. The American Diabetes Association Diabetes Risk Test is recommended, which has been adapted for D2d (see Appendix). In general, people who score higher than 5 should be scheduled for a screening visit.

Sites may also use a pre-screening questionnaire on its page on d2dstudy.org for interested volunteers to complete (e.g., see d2dstudy.org, d2dstudy.org/tufts and d2dstudy/stanford).

6.2.1.2 In Person

Pre-screening may also be conducted in person in a number of settings or events, as described below. In these settings or events, people will be provided information about the study (e.g. study brochures) and pre-screening activities may be completed. Regardless of where the in-person pre-screening takes place, ensuring privacy is essential.

Examples of settings for in-person screening include:

- Waiting rooms in outpatient clinics while patients wait for their appointments.
- Public events where a table can be set-up
    - Recreational events [farmers markets, sports, racing, festivals]
    - Health fairs
    - Community gathering places [bingo, flea markets]
- Medical center cafeterias

Sites may consider conducting a simple pre-screening visit (e.g. vital signs, point-of-care glucose testing, diabetes risk score assessment) to identify people at risk. These are also opportunities to gather information for people who are interested in participating in research to enter in a participant research database.

6.2.1.3 Database Review

Querying databases to identify potentially eligible volunteers is arguably the most efficient and potentially cost-effective recruitment strategy. Below are examples of databases that may be available at the sites. Please refer to MOP section 5 for additional details.

- Electronic Medical Record systems
- Research Participant Databases/Registries
- Medical Center Employee Database

6.2.2 Vitamin D and Calcium Supplementation

During prescreening, potential volunteers may report taking vitamin D or calcium supplementation in doses greater than what D2d allows (see below). People who are taking such doses on their own must be willing to reduce their dose to what the study allows to be eligible. The document titled "Talking Points about Vitamin D and Calcium supplementation," (see Appendix), provides an overview of current recommendations for vitamin D and calcium along with "talking points" that sites may consult when discussing use of supplements with potential participants.

6.2.2.1 Vitamin D

People who report taking >1000 units/day of supplemental Vitamin D (from all supplements combined) at pre-screening must agree to reduce their dose to ≤ 1000 units/day for the duration of the study.

- For potential volunteers who are taking > 1000 IU and ≤ 2000 units/day and are willing to reduce the dose to no greater than 1000 units/day for the duration of the study, the screening and baseline visits should be scheduled such that *at the baseline visit*, the person has been *taking ≤1000 IU/day for at least **8** weeks.*
- For potential volunteers who are taking > 2000 IU per day and are willing to reduce the dose to no greater than 1000 IU for the duration of the study, the screening and baseline visits should be scheduled such that *at the baseline visit the person has been taking ≤1000 IU/day for at least **12** weeks.*

6.2.2.2 Calcium

Participants who report taking > 600 mg/day of supplemental calcium (from all supplements) at pre-screening must agree to reduce their dose ≤ 600 mg/day for the duration of the study and the screening and baseline visits should be scheduled such that at the baseline visit, the person has been taking ≤ 600 mg/day for at least 1 week.

6.3 SCREENING VISIT

If the interested volunteer has met all inclusion and no exclusion criteria during pre-screening (preferably, also including meeting some indication of being at increased risk for diabetes), he will be invited in for a screening visit.

If the potential participant wants to read (or if it would be helpful for him to read) the informed consent forms prior to the screening visit, the forms can be sent to him. A site may also make consent forms available on its page on the study's website for interested volunteers to review.

⇒ ***It is important to inform the potential participant that he should come to the screening visit after fasting for 8 hours, to bring all medications and supplements with him, and to not participate in vigorous physical activity for 24 hours before the visit.***

⇒ If a participant ate the morning of the visit, the entire visit should be rescheduled.

⇒ If a participant consistently works during an evening or a night shift and typically sleeps into late morning or early afternoon, the visit may be scheduled in the early afternoon. *It is important that all subsequent visits follow this same pattern and be scheduled in the early afternoon.*

6.3.1 Informed Consent Process

At first contact with participants, prior to any study specific procedures, the informed consent process will be started. If the first contact is over the phone (see pre-screening above), a sample script (see Appendix) will be read to the potential participant providing a brief overview of the study, informing her that she will be asked questions to determine if she is potentially eligible, and, if she is potentially eligible, she will be invited to the research site for a screening visit.

At the first (screening) visit, written informed consent for the main study will be obtained prior to any study procedures.

Then, the informed consent process for the D2d Research Repository should be initiated. The informed consent process for the Specimen Repository should be conducted following the same guidelines as the consent for the study.

The informed consent process is ongoing and interactive. Participants will be given the opportunity to ask questions throughout their participation in the study.

6.3.1.1 Setting

The consent process should be conducted in a comfortable relaxed setting by the site PI or other qualified member of the site research team (e.g. co-investigator, research coordinator, research assistant or clinical research nurse) with in-depth knowledge of D2d, as delegated by the site PI.

6.3.1.2 Content

The full nature of the study (purpose, procedures, risks, potential benefits, etc.) is reviewed in detail.

⇒ *The importance of the study and the need to return for all scheduled visits and follow all study procedures even if the study pills have been stopped will be emphasized.*

Volunteers will be informed that they can cease participating in the study at any time for any reason.

6.3.1.3 Discussion

The person responsible for obtaining consent should encourage questions and a discussion. The process must not be rushed. Volunteers must be given ample time to review the ICFs.

6.3.1.4 Assessment of Comprehension

The volunteer should demonstrate an understanding of the study prior to being asked to sign the ICFs. For example, staff may ask the volunteer questions or the volunteer may verbalize what will happen or ask relevant detailed questions.

6.3.1.5 Documentation of Informed Consent

Once all questions have been answered and concerns addressed, the volunteer participant will be asked to sign the written informed consent form for the main study. The Informed Consent Form (ICF)

must be signed in the presence of the site PI (or designee). The original must be saved in the participant's folder and a copy of the signed form will be provided to the participant.

As documentation of the informed consent process, the following should be included in the source document: who led the discussion, who was present during the discussion, any issues (including any notable concerns or questions raised by the participant), and the date and time when written informed consent was obtained.

Documentation of informed consent is also recorded in the EDC system.

6.4 SCREENING ACTIVITIES

After written informed consent has been obtained, screening should proceed as follows:

Note: If at any point during the screening visit, it is determined that the participant meets an exclusion criterion, the remaining activities do not need to be completed.

6.4.1 Basic demographic information (if not done previously)

- ✓ Sex, date of birth, race and ethnicity, education level, and family history of diabetes

6.4.2 Physical Measurements (vital signs)

- ✓ Measure blood pressure and heart rate, following procedures in MOP section 11. Blood pressure and heart rate are done first, as other measures (e.g. weight) can be stressful and impact blood pressure and heart rate.
- ✓ Measure height and weight following procedures in MOP section 11.
- ✓ Calculate BMI.
    - o The calculation may be done by entering the height and weight in the vital signs e-CRF. After saving the form, the BMI is calculated (see MOP section 15)
    - o An online BMI calculator, such as the one provided by the NIH, can be used to calculate BMI (http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm). Choose the metric tab, and enter in the height and weight measured.

6.4.3 Medical history

- ✓ Obtain complete medical history. This task must be completed by staff trained to take medical history (e.g. physician investigator, nurse practitioner).
- ✓ The participant should be asked if she has or had any medical problems related to each system, with emphasis on conditions relevant to the inclusion/exclusion criteria (e.g. have you ever had a kidney stone?).

6.4.4 Review of concomitant medications and supplements

- ✓ If the participant came to the visit with her medications and supplements, go over all prescribed medications, over-the-counter medications, and supplements, recording the dosage, frequency, the reason for taking the medication, and start date (approximate is okay). If the participant did not

bring the actual medications but came with a list, review the list with the participant and collect as much detail as possible.

- ✓ If the participant reports taking a medication that is not for the treatment of any condition reported during the medical history, seek clarification from the participant.

- ✓ Staff, in consultation with the site PI, should review the participants' concomitant medication and supplement list to ensure that the participant is not taking any excluded medications (see MOP section 8).

- ✓ The research coordinator must add up the total dosage of non-dietary vitamin D a participant is taking, from all supplements combined, to make sure the total daily supplemental dose does not exceed 1000 IU/day. For example, 800 units/day in a multivitamin and 2800 IU/week [= 400 IU/day] from Fosamax Plus D = 1200 units/day, which excludes volunteer.

- ✓ The research coordinator must add up the total dosage of non-dietary calcium a participant is taking, from all supplements combined, to make sure the total daily supplemental dose does not exceed 600 mg/day.

⇒ ***Special attention should be made to ensure that the participant understands the calcium and vitamin D supplements restrictions and the rationale behind the restrictions.***

- ✓ Remind the participant to call the Research Coordinator or designee to discuss any changes in medications between study visits.

- ✓ Please note that although all medications and supplement use will be recorded in source documents, only certain medications and supplements will be entered in the EDC (see MOP section 8.5.2).

6.4.5 Laboratory Specimen Collection

- ✓ Blood and urine will be collected, while participant is fasting, and analyzed at the local site laboratory. Please see MOP section 9 for detailed collection instructions.

- ✓ Provide the participant with food and drink.

- ✓ Review assessment of eligibility based on safety laboratory criteria.

- ✓ Assessment of further eligibility based on glycemic criteria is shown in Figure 6.1 (same as Protocol Figure 6.1)

6.4.5.1 Use of Laboratory Tests done outside of D2d or by finger-stick

If a potential participant had the D2d screening laboratory tests done outside of D2d, the results may *be used in lieu of these labs done at the D2d screening visit, only if all the following criteria are met:*

- Blood samples were obtained via phlebotomy (i.e., not a finger-stick).

- The glucose (plasma or serum) drawn in clinical practice was done while fasting >8 hours overnight.
- The laboratory tests were run at the same local laboratory used for D2d.
- The laboratory tests were done within the time window allowed between screening and baseline visit (see MOP Table 4.2).

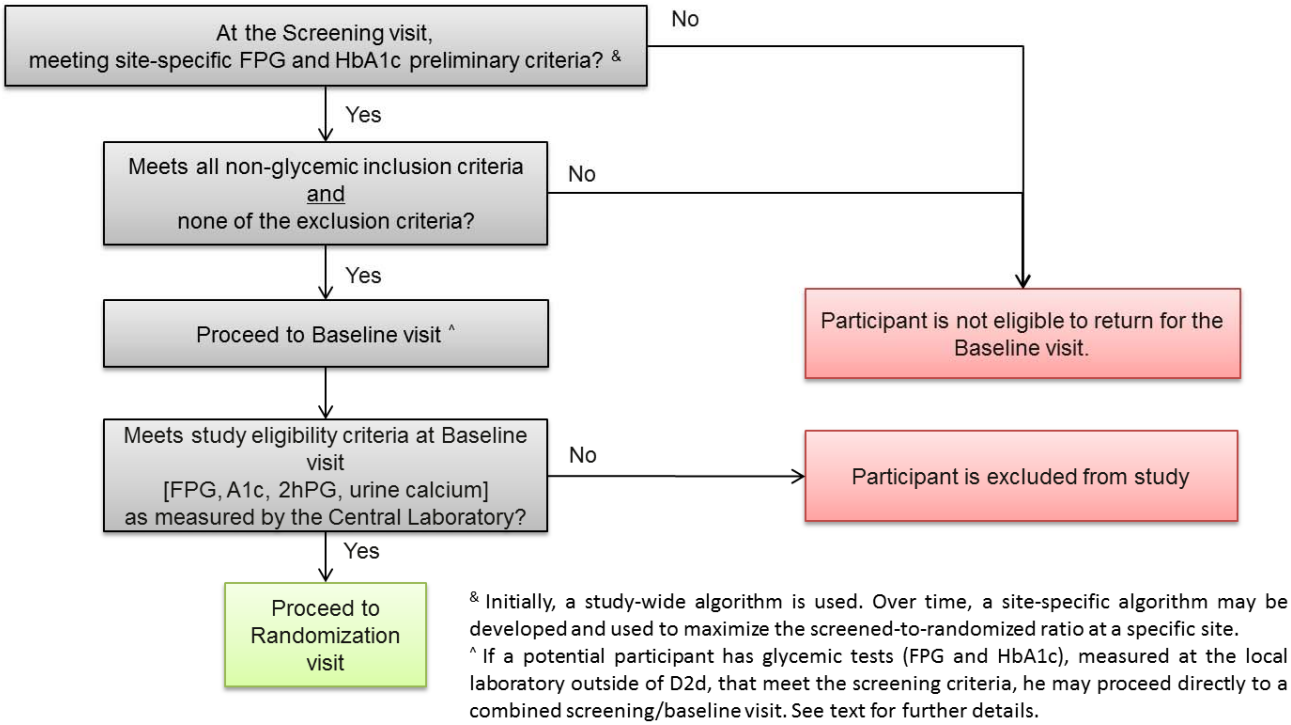
⇒ Sites may use a glucose and/or HbA1c result from a finger-stick as a pre-screening approach to see if the participant should proceed to a full screening visit. However, *before qualifying for the baseline visit, results of fasting glucose (from a sodium fluoride tube) and HbA1c (from an EDTA tube) by the local laboratory must be available.*

6.4.6 Eligibility to proceed to Baseline visit

Volunteers will be invited to the baseline visit if they meet the following criteria at the screening visit: (see Figure 6.1):

a) FPG and HbA1c results are within range, as defined by site-specific criteria. At the screening visit, sites use a site-specific Screening-to-Baseline glycemic algorithm to determine whether the FPG and HbA1c values fall within range to proceed to the baseline visit. A default algorithm has been developed for all sites to use initially (see below). As needed, the success of the default algorithm for that site is reviewed and, if appropriate, a site-specific algorithm can be developed to maximize the screened-to-randomized ratio.
b) All other non-glycemic inclusion criteria and meet none of the exclusion criteria

Figure 6.1: Flow diagram of assessment of eligibility at screening and baseline visits



6.4.6.1 Default (study-wide) Screening-to-Baseline glycemic algorithm

The following default study-wide Screening-to-Baseline glycemic algorithm is used by sites that have not developed their own algorithm yet.

FPG 100-125 mg/dL (inclusive) and HbA1c 5.1-6.4% (inclusive)
or
HbA1c 5.7-6.4% (inclusive) and FPG 91-99 mg/dL (inclusive)

6.4.6.2 Site-Specific Screening-to-Baseline glycemic algorithm

The success of the default Screening-to-Baseline algorithm for a specific site is reviewed periodically by the site and Coordinating Center, and, if appropriate, a site-specific algorithm is developed to maximize the screened-to-randomized ratio for that site, as follows:

- The CC provides to the sites a table with the glycemic data obtained at the Screening visit (by the local laboratory) and Baseline visit (by the Central Laboratory)
- The site reviews and compares the results of the FPG and HbA1c obtained at the Screening to the results obtained at the Baseline visit.
- The site proposes to the CC a Site Specific Screening-to-Baseline glycemic algorithm in writing, using the Site Specific Screening-to-Baseline Glycemic Algorithm Proposal form (see appendix). The proposal must include the specific algorithm to be followed and the rationale for it.
- The CC reviews and approves the algorithm prior to site's adopting the site-specific algorithm.
- Alternatively, the CC may propose an algorithm that the site must review and approve.

6.4.6.3 Repeating Screening Glycemic Labs

If a participant misses a screening glycemic criterion, as measured by the Local Laboratory, by a small margin (defined as margin of error for FPG ± 3 mg/dL or HbA1c ± 0.1%), the glycemic criterion that missed the margin (FPG or HbA1c) can be repeated once. The repeat test should be done within a short period to ensure that the time elapsed between the original screening date and the baseline visit remains within the allotted window (see schedule in Table 2, MOP section 4).

If a participant misses a screening glycemic criterion, and it is determined, after the visit, that there is a clear explanation for a larger margin than the one indicated above (e.g. participant donated whole blood or had an infection a few weeks before the visit), the glycemic criterion that missed the margin (FPG or HbA1c) may also be repeated; however, *such exceptions should be uncommon* and supported by an explanation that needs to be documented in the source documents.

The result of the repeat measure will be entered into the EDC screening local laboratory e-CRF and the new value will be used to determine if the participant meets the criteria to proceed to the baseline visit.

- ✓ Site staff should enter the result of the repeat measure by replacing the original value.
- ✓ Since the date of the repeat measure cannot be entered in the e-CRF, the site should send an email to the CC stating the participant's enrollment ID and the measure repeated. The CC will

open a query asking the site to enter the date of the repeat measurement in the query response box.

6.4.7 Screening Visit Administrative Activities

If it appears from the history and physical measures that the participant may be eligible to return for the baseline visit, obtain the following information if it was not obtained previously:

6.4.7.1 Contact Information

Participants will state their preferred method of communication (email, phone, text, etc.) with the research staff. If e-mail is agreed upon as the preferred method of communication, participants should be instructed to respond to emails, thereby letting the research staff sender know the message was received. It is best to obtain a few different ways to reach the participant. Please see source document titled Participant Contact Information in MOP section 13.

6.4.7.2 Medical Release

- ✓ Offer to share the participant's laboratory results with her primary care provider (PCP).
- ✓ Explain that D2d procedures require that the PCP provides results of laboratory tests done in the PCP's office to the researchers as needed.
- ✓ If the participant is amenable, have the participant sign a medical release authorizing you to share information with the PCP and authorizing the PCP to share information with the research staff.
- ✓ There is no template form provided by D2d. Please use a site-specific medical release form.

6.4.8 Establish a follow-up plan with the participant

The site can either:

a. Make a tentative baseline appointment for the participant and confirm the date once the glycemia and safety laboratory results have been reviewed.

b. Set up a time to call the participant and report the results and, if participant qualifies, schedule the baseline appointment.

6.4.9 Screening failures

If, during the screening visit, it is determined a participant meets an exclusion criterion, his participation will end and no other screening activities need to be completed. The participant should be provided with a snack and drink and thanked for his time and effort.

If, after reviewing the screening laboratory results, the participant does not qualify to return for the baseline visit, she should be notified by her preferred method of communication (e.g. phone, email).

- ✓ A personal thank you note signed by the staff that met with the participant should be sent a few days after the visit, thanking the person for her willingness to come to a screening visit. Personal thank you notes are often a pleasant surprise and an appreciated gesture, which may lead to

future willingness to participate in research, or may lead to referrals from friends or relatives who may also be at risk for diabetes.

6.4.9.1 Repeat screening

A repeat screening is defined as a full screening, i.e., all screening procedures are repeated.

PLEASE NOTE (see also section 6.4.6.3): If a participant misses a screening criterion (e.g. creatinine) by a small margin, he may return to have just that criterion re-measured, *within a short period to ensure that the time elapsed between the original screening date and the baseline visit remains within the allotted window*. If the participant cannot return within a short period to respect the screening-randomization window, the entire screening visit will need to be repeated (see below).

A repeat screening is encouraged ONLY if there is a high likelihood that a participant will meet the inclusion/exclusion criteria at the repeat screening because the exclusion criterion is modifiable and may improve (e.g. elevated blood pressure, recent initiation of oral contraceptives) or may evolve (e.g. the participant missed two out of three glycemic criteria by a small margin at the prior screening visit, but it is now a year later and has gained or lost some weight).

If there is a high likelihood that a participant will meet the inclusion/exclusion criteria at a repeat screening, the participant should be informed to contact the site in the future for re-screening. The site should also note the circumstances and plan on re-contacting the participant if appropriate.

- ✓ It is strongly recommended than participants do not return for a repeat (full) screening until 6 months have passed since the prior screening. This is recommended to ensure that a condition that previously disqualified a participant has changed sufficiently to increase the odds of the participant meeting the criteria on repeat screening.
- ✓ When a participant returns for a repeat screening visit, a new ID number is generated, as if the participant was a new participant.
- ✓ All data from the repeat screening (and all subsequent visits) are entered into EDC using the new ID number. Data from the prior screening are not replaced.
- ✓ The site should maintain a list of the original and repeat ID numbers that identify the same person and share the list with the CC.

⇒ A participant may be re-screened up to an additional 2 times (i.e. total of 3 D2d screenings).

6.4.9.2 Diabetes diagnosed at the Screening or Baseline visit

Given their high-risk profile, it is expected that some individuals will be found to have previously unrecognized hyperglycemia in the diabetes range at the screening (either HbA1c or FPG exceeds the site specific algorithm) or baseline (HbA1c ≥ 6.5%, FPG ≥ 126 mg/dL, or 2hPG ≥ 200 mg/dL) visits. These people are ineligible to participate in D2d and they will receive an informational letter (see Appendix) indicating the possibility that they may have diabetes and should be seen by their primary care provider to repeat testing for diabetes. Participants will be mailed copies of their laboratory results to share with their primary care provider, but study personnel will not participate in any further evaluation or treatment of participants who are found to have diabetes at baseline.

⇒ Because there is less than perfect correlation between glycemic tests done at the screening (by the local laboratory) and baseline (done by the Central Laboratory) visit, it is recommended that information on glycemic results is shared with participants and their physicians, as follows:

- ✓ If a participant does not qualify after the screening visit, the glycemic tests at the local laboratory are shared with participants and their providers.
- ✓ If the volunteer completes the baseline visit, only the glycemic tests done at the Central Laboratory are shared with volunteers and their providers.

6.5 COMBINED SCREENING/BASELINE VISIT

If a potential participant has glycemic tests (FPG and HbA1c), measured outside of D2d at the local laboratory, and the results meet the screening criteria, he may proceed directly to a combined screening/baseline visit, as long as all criteria outlined below are met.

- Blood samples were obtained via phlebotomy (i.e., not a finger-stick).
- The glucose (plasma or serum) drawn in clinical practice was done while fasting >8 hours overnight.
- The laboratory tests were run at the same local laboratory used for D2d.
- The laboratory tests were done within 6 weeks of the combined screening/baseline visit (to stay within the screening-baseline window described in MOP section 4).

During the combined visit:

- ✓ The informed consent process must be completed before any study procedures are started.
- ✓ Any screening blood tests that have not been done by the local laboratory in the past 6 weeks will be drawn and sent to the local laboratory for analysis.
- ✓ All baseline blood and urine will be collected (fasting and during the 2-hour OGTT) for baseline measurements and processed as described in MOP section 9. However, data relevant to the baseline visit will not be entered in EDC and samples will not be sent to the Central Laboratory until it is determined that the participant meets *all screening criteria, i.e., all screening local laboratory results have been received, reviewed, and entered into EDC. If the participant does not meet the screening eligibility criteria, the baseline specimens will not be sent to the Central Laboratory*.

See below for a list of the combined screening/baseline visit activities.

EXAMPLE: A potential volunteer has HbA1c, FPG, ALT, AST, and creatinine measured at the local laboratory as part of routine care (outside of D2d), within the time frame described above. If these tests meet the D2d criteria, then the volunteer can come in for a combined screening/baseline visit to complete the remaining screening procedures (e.g. signing of informed consent form, BMI, blood pressure, CBC, serum calcium) and the OGTT. Blood and urine collected for baseline measurements are processed locally and saved. All of the screening data are entered into EDC and then if the participant meets all screening criteria (including the missing laboratory tests done at the visit), data relevant to the BAS visit are entered in EDC, and the blood and urine are sent to the central laboratory.

NOTE: The combined screening/baseline visit should be done infrequently and only if the site has a quick turnaround of local laboratory results to ensure that the schedule for sending blood/urine to the Central Lab is not compromised.

Screening/Baseline Visit Activities

- ☐ Written informed consent
- ☐ Vital signs, including waist circumference: *Confirm that participant meets BMI and blood pressure eligibility criteria before proceeding*
- ☐ Medical history: *Confirm that participant meets eligibility criteria before proceeding*
- ☐ Medication and supplement review: *Confirm that participant is not taking any excluded medications (see MOP 8, section 8.4)*
- ☐ Physical Exam (may be done at the randomization visit, prior to randomization in SPIRS).
- ☐ Fasting laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)
    - o Urine pregnancy test (if female of reproductive potential)
    - o CBC without differential*
    - o LFTs (ALT, AST)*
    - o Serum calcium*
    - o Serum creatinine*
    - o Baseline fasting tubes for the Central Laboratory
- ☐ *Send specimens for local analysis to local laboratory and begin processing specimens for the Central Laboratory*
- ☐ Begin questionnaires (FFQ, IPAQ)
- ☐ 30 minute laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)
- ☐ 120 minute laboratory specimen collection (MOP 9, section 9.7.3 and appendix 7)
- ☐ Complete all screening e-CRFs
- ☐ If participant meets screening eligibility criteria complete baseline e-CRFs and send specimens to Central Laboratory. *Do not send specimens to Central laboratory until all Screening e-CRFs and baseline e-CRFs have been completed.*

** Do not need to be repeated, if completed within the past 6 weeks and meet the following criteria:*

- *Blood samples were obtained via phlebotomy (i.e., not a finger-stick).*
- *The laboratory tests were run at the same local laboratory used for D2d.*

6.6 APPENDICES

Appendix 1 ***Pre-screening Template Introductory Phone Script***

Appendix 2 ***Pre-screening Template Inclus*****ion Exclusion Criteria Questionnaire (includes BMI Table)**

Appendix 3 **Diabetes Risk Test**

Appendix 4 **Talking Points about Vitamin D and Calcium supplementation**

Appendix 5 **Site-specific Glycemic Algorithm Proposal Form**

Appendix 6 **Letter to Provider – Screening/Baseline Diabetes**