Procedures for D2d Registry for future contact

Objective: To establish a Registry of participants from the Vitamin D and Type 2 Diabetes (D2d) study who are interested in learning about future research opportunities related to the D2d study.

Background: Participant involvement in the NIDDK-funded D2d study will be coming to an end in 2018. The D2d study cohort is unique for a number of reasons, including: (1) largest modern day U.S.-based cohort of people diagnosed with prediabetes using the current American Diabetes Association criteria; (2) collection of valuable data beyond the primary outcome of diabetes (e.g., cancer and cardiovascular disease); (3) outstanding participant dedication (e.g., only 53 out of 2423 participants have withdrawn consent after a mean follow-up of 3 years). Continuing the collection of key data after D2d ends would lead to even greater understanding of the natural history of prediabetes and diabetes. Therefore, engaging the D2d participants in a follow-up study would be enormously valuable.

Description of Registry: To provide D2d participants with the opportunity to participate in a follow-up study, Tufts Medical Center (where the D2d Coordinating Center is located) is establishing a registry of D2d participants who wish to be contacted in the future by Tufts Medical Center researchers about a potential follow-up study to collect longer-term data on diabetes, cancer, cardiovascular disease and safety (e.g., kidney stones). Once the follow-up study becomes active, individuals in the Registry will be contacted and invited to participate. Research staff at Tufts Medical Center led by Dr. Pittas (the principal investigator of the D2d study) will manage the registry, which will be securely managed in a HIPAA-compliant database. The staff managing the Registry will *not* have access to the electronic data capture system that stores participant data collected during the D2d study. Prior to the Tufts Medical Center researchers reaching out to any participants in the Registry, a protocol will need to be approved by the Tufts Medical Center IRB.

Important Note: because any follow-up study to D2d will be observational, D2d participants may take part in any other study (trial or observational) they wish to.

Implementation: During the close-out period of D2d, all participants who have not withdrawn consent will be informed about the possibility of a follow-up study, which will be observational with remote collection of data, i.e., no study pills to take and no visits required.

At the last D2d study visit, site staff will inform participants about the D2d Registry and the potential opportunity to participate in a future follow-up study. Participants will be provided with an invitation letter (Attachment A) and a response card (Attachment B). Site staff will complete the top part of the card (Site Name and D2d Study ID) prior to giving it to the participant. Participants who wish to be included in the Registry will complete the rest of the card and mail it using the provided self-addressed stamped envelope. Participants may also sign up on-line at www.d2dos.org (If a participant wishes to sign up during the last D2d visit, site staff can assist the participant with the response card or website).

For participants who complete the last D2d study encounter over the phone (e.g., they have moved to another state and are unable to come for a visit), site staff will communicate the Registry opportunity during the phone call and the invitation letter and response card will be mailed to them.

In addition, sites will mail to participants a copy of the invitation letter and response card at two time-points: (1) when communicating results of the last D2d visit and (2) a few months later when informing participants of their D2d study pill assignment.