



Vitamin **D** and
type **2** diabetes

diabetes prevention research matters

News and Information for Collaborating Clinical Sites

Save the Date for the D2d Annual Meeting: November 16th and 17th, 2014 at the Renaissance Capital View in Arlington, Virginia, beginning with dinner on November 16th and ending mid-afternoon on the 17th.

Study Progress [5/31/14]

Screenings 1177
Baselines 563
Randomizations 288

May 65

Retention Tools

Watch for insulated lunch bags. They should be given to participants at the month 6 visit. If you would like a few extra to give to support staff (e.g. phlebotomy), please let the CC know.



Supply Inventory

Please evaluate your stock of the following items and contact the CC or Central Lab for re-supply:

Coordinating Center

- Food Frequency Questionnaires (specify English or Spanish)
- NDEP Small Steps, Big Rewards packet
- Gulick measuring tapes

Central Laboratory

- Visit kits (specify which visit kit type is low)
- Insulated shipping boxes
- DNA tubes
- Extra supply

Meet the D2d study team | D2d individuals, sites, components that make a difference

D2d Site | Nebraska: Omaha Department of Veterans Affairs and University of Nebraska Medical Center

The Omaha, NE D2d study team is extremely excited to be part of this landmark study! There are two clinic sites in Omaha, separated by three blocks. The Omaha Department of Veterans Affairs (VA) and University of Nebraska Medical Center (UNMC) have been working hard to enroll as many participants as possible. Surprising to most, the Omaha metropolitan area is roughly 900,000 people strong and there **are** more people than cows!

With Dr. Desouza as the driving force behind the Omaha D2d Research Team, a great wealth of knowledge is brought to the table. Dr. Desouza is Professor and Chief of the Division of Diabetes, Endocrinology and Metabolism, at the University of Nebraska Medical Center. He is also the Director of the Diabetes and Obesity Program for the VA Nebraska-Western Iowa Healthcare System (NWIHCS). Jeffery Newcomb, the lead coordinator for D2d, joined us in January 2014 and has never looked back. He is enthusiastic and always wants to be the “top” recruiting site each month. Jeff and Robert Heineman, the recruitment coordinator, are favorites with the veterans who commit to D2d as participants.

The Omaha team is happy with its success and looks forward to contributing to the knowledge to help people with pre-diabetes!



Questions? Please contact D2d Coordinating Center at d2d@tuftsmedicalcenter.org or 617-636-D2d2 (3232)



Regulatory Reminders

Send to CC:

- Protocol version 1.6 signature page
- Protocol version 1.6 IRB approval letter and stamped Informed Consent Forms
- Continuing review approval letter

If additional information is needed by IRB for continuing review application, please contact the CC

Protocol Version 1.6

Protocol version 1.6 was released in early May and is under review at most sites. The major changes are:

- Inclusion criteria age range was expanded to allow 25 year olds to participate if of American-Indian, Alaska Native, Native Hawaiian or Other Pacific Islander race
- Individuals who report taking > 1000 but ≤ 2000 IU of supplemental vitamin D per day must reduce intake to ≤ 1000 IU for **8** weeks prior to baseline. Those taking > 2000 IU must still decrease intake to ≤ 1000 IU per day for 12 weeks prior to baseline.

New MOP sections

Modifications have been made to the Manual of Procedures. Additionally, sections have been updated with additional information to help sites. Sections to re-review include:

- Section 5 – Recruitment and appendices
- Section 6 – Screening
- Section 9 – new schematics in appendix to assist in visit specimen collection and processing
- Section 13 – Source Documents (Screening and Screening-Baseline Combined source documents)
- Section 17 – Retention and appendices
- Section 18 – Outcomes (appendix 1, exclusionary medications)
- Section 19 – Frequently Asked Questions

Randomizations By Site

