ClinicalTrials.gov Document Upload

Cover Page

Study Title:
Study of Vitamin D and Omega-3 Supplementation for Preventing Diabetes

---

Sponsor:
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health

---

Study Identifier(s):

- ClinicalTrials.gov Identifier (NCT Number): NCT01633177
- Protocol ID: 0308112690000

Document:
Informed Consent Form

Date (Submission to NIH):
August 17, 2017

ID: 12-345-678

AUTHORIZATION TO OBTAIN MEDICAL RECORDS FOR RESEARCH

PRINCIPAL/OVERALL INVESTIGATOR: **Aruna D. Pradhan, MD, MPH; JoAnn E. Manson, MD DrPH**
IRB / HRC PROTOCOL NUMBER: **2010-P-002427/1**
PROTOCOL TITLE: **Diabetes Prevention in the VITAL Trial (*VIT*amin D and Omeg*A*-3 Tria*L*)**

Please read the following consent form and sign on the reverse side. Your signature will indicate that you have read and understood this document as well as provide permission for us to obtain medical records pertaining to your recently reported diagnosis/procedure: Diabetes

The VITAL trial (*VIT*amin D and Omeg*A*-3 Tria*L*) is a clinical trial conducted by Brigham and Women's Hospital, an affiliate of Harvard Medical School. The aim of VITAL is to investigate whether taking daily supplements of vitamin D_3 and omega-3 fatty acids (Omacor® fish oil, 1 gram) reduce the risks of cancer, heart disease, and stroke. By signing this form, you give permission to the healthcare providers and facilities listed on this form to release the medical records pertaining to your recently reported diagnosis/procedure. The information released will only be used for research purposes by VITAL and will be held in strict confidence. Examples of medical information to be requested include:

Discharge Summaries	Operative Reports	Radiology / Imaging Reports
History and Physical Reports	Procedure Reports	Consultations
ER Records	Pathology / Specimen Reports	MD / Progress Notes
Diagnostic / Procedure Codes	Laboratory Reports	Outpatient / Short Stay Records

By signing, you acknowledge that you have read and understood the following:

- Signing this authorization is voluntary. You have the right to choose not to sign this form, which will prevent us from obtaining and using information from your medical records related to the diagnosis you have reported. Choosing not to sign will not affect your present or future care at any healthcare facility and will not cause any penalty or loss of benefits to which you are otherwise entitled.
- Although not requested by VITAL, information released may include records related to behavior and/or mental health care, alcohol and drug abuse treatment, HIV/AIDS, and genetics.
- You have the right to withdraw or revoke your permission for the researchers and participating entities to use or share your protected health information. We will not be able to withdraw all of the information that already has been used or shared with others to carry out the research or any information that has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you want to withdraw or revoke your permission, you must do so in writing by contacting the researcher listed on the back page as the Study Contact.
- You have the right to request access to your protected health information that is used or shared during this research and that relates to your clinical treatment or billing status, but you may access this information only after the study is completed. To request this information, please contact the researcher listed under Study Contacts on the back page.
- We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may re-disclose it, so we share this information only if necessary, and we use all reasonable efforts to request that those who receive it take steps to protect your privacy.
- You have the right to receive a copy of this form.

(over)

PLEASE COMPLETE THE APPLICABLE INFORMATION AND SIGN BELOW:

Diagnosis: Diabetes Dates of diagnosis: _____

Name of physician who made the initial diagnosis: _____

Address of physician: _____

City: _____ State: _____ Zip: _____

Name of hospital where diagnostic testing or procedures were done: _____

Address of hospital: _____

City: _____ State: _____ Zip: _____

Name(s) of additional hospitals/physicians (if applicable): _____

Address of hospitals/physicians: _____

City: _____ State: _____ Zip: _____

Participant's full name: _____

Participant's date of birth: _____

By my signature below, I hereby grant permission to Drs. Aruna D. Pradhan and JoAnn Manson, Brigham and Women's Hospital, an affiliate of Harvard Medical School, 900 Commonwealth Avenue, 3rd Floor, Boston, MA 02215, to review a copy of the records of my hospitalization or treatment for the above specified diagnosis / procedure. (COPY VALID AS ORIGINAL; EXPIRES 12 MONTHS AFTER DATE OF SIGNATURE)

OR

_____
Participant's signature **Date**

_____
Print name

_____
Signature of authorized representative **Date**
(Please include any relevant paperwork)

_____
Print name

STUDY CONTACTS:

Aruna D. Pradhan, MD
Principal Investigator
1-800-388-3963 (toll-free)

Rosalyn Gray
BWH Human Research Compliance
(617) 424-4148 (call collect)