

Joining the Type 1 Diabetes TrialNet Study Group

Information for Affiliate Sites

What is the role of an Affiliate Site?

For the Natural History Study your role will be to:

- Encourage subject participation and retention in study,
- Conduct informed consent,
- Perform phlebotomy,
- Perform IVGTTs and OGTTs,
- Submitting protocols for IRB approval.

What are the benefits of becoming an Affiliate Site?

Benefits to you include:

- Being able to actively recruit subjects into TrialNet Studies.
- Receiving information and potential opportunity to participate in intervention studies for prevention of type 1 diabetes, and preservation of insulin secretion in new onset type 1 diabetes.
- Participating in research with acknowledgement in TrialNet study publications.

What requirements does the Affiliate Site need to meet?

To be an Affiliate Site you must have/or obtain:

- An executed Letter of Agreement by signature of an authorized institutional official with the George Washington University. The Letter of Agreement outlines the details of participation in any TrialNet activity and reimbursement policies.
- IRB approval for participation in the study protocol(s).
- Appropriate assurance by the Office of Human Research Protections.
- HIPAA authorization.
- Assignment to one of 14 Clinical Centers in accordance with a regional distribution plan established by the TrialNet Steering Committee.
- A designated physician as Principal Investigator and nurse designated as Site Coordinator.
- Certification of staff for procedures in protocols they will be conducting.

How does reimbursement work?

Affiliate Sites do not receive core funding. Affiliates are reimbursed based on study visits and test performed per subject. Reimbursement rates are established by the TrialNet Steering Committee and approved by NIDDK for each protocol.

What does participating in the Natural History Study involve?

The TrialNet Natural History protocol is divided into three phases: Screening (Phase 1), Baseline Risk Assessment (Phase 2) and Follow-up Risk Assessments (Phase 3). Phase 1 involves drawing blood and shipping the specimen to a core laboratory for assessments of three autoantibodies that are predictive of the development of T1D. Positive subjects are eligible to enter Phase 2. Phase 2 includes additional blood tests to quantify the level of risk of developing T1D. In Phase 3 participants are followed-up every six months to see if their risk level for developing diabetes has changed. In the future, Phase 3 participants may be able to enroll in a prevention study. Participants who develop diabetes may be enrolled in an early treatment study aimed at preservation of islet cell function.

Affiliate Sites may choose to perform only Phase 1 (Screening) of the Natural History protocol. Affiliate Sites that conduct all three phases of the Natural History protocol and/or intend to conduct a TrialNet prevention or treatment protocol must have the capability to perform tolerance tests (intravenous glucose and oral glucose), maintain subject files, and carry out other various aspects of these protocols.

If you are unable to devote time or resources to screening or meeting the Affiliate requirements please consider supporting TrialNet activity by becoming a Participating Physician?

A Participating Physician performs phlebotomy services for participants in their community. The regional Clinical Centers for TrialNet conduct the consent process by phone. Screening kits are mailed to the participants to take to Participating Physicians for the blood draw and shipment of the specimen to the TrialNet Central Lab. Per the 18 June 2004 NIDDK approved Reimbursement Schedule, the Participating Physician receives \$50 per screening.

If you are interested in becoming a TrialNet Affiliate Site or a Participating Physician contact:

TrialNet Coordinating Center

6110 Executive Boulevard

Suite 750

Rockville, Maryland 20852

(800) 805-3705

(301) 816-8031

FAX: (301) 881-0179

TrialNet@biostat.bsc.gwu.edu

Public Web Site: www.diabetestrialnet.org

or

Call (800) HALT-DM1 and ask to be referred to a Study Team member at the Clinical Center over your geographic location.