

## Call For Self-Nominations:

### TrialNet Biomarkers & Mechanisms Panel

#### 1. Background

We are seeking talented and experienced investigators with an interest in type 1 diabetes biomarkers and disease mechanisms to join the Type 1 Diabetes TrialNet clinical trial network. Selected investigators will be active participants in the design, implementation and analysis of clinical research in type 1 diabetes.

The Diabetes Prevention Trial-Type 1 (DPT-1, initiated in 1993) tested whether two separate interventions involving insulin administration could prevent progression from autoimmunity to type 1 diabetes (T1D): (1) parenteral insulin in subjects with projected 5-year T1D risk of greater than 50%, and (2) oral insulin in subjects with projected 5-year T1D risk of 25-50%. Although protective effects of insulin were not demonstrated, DPT-1 did show, in a very large cohort, that: (1) the diabetes risk (over 5-10 years) of relatives of people with T1D could be accurately predicted based on genetic evaluation, tests of autoantibodies in blood, and metabolic status; and (2) trials requiring massive screening efforts to identify eligible subjects and involving intensive treatment regimens could be efficiently accomplished.

TrialNet, which evolved from DPT-1, was established in 2001 to provide a large, highly collaborative clinical trials network. The network is currently engaged in the performance of three trials for T1D prevention, and is preparing to launch two additional prevention trials in the screened TrialNet subject population. More information about TrialNet is available here: <http://www.diabetestrialnet.org/>

The TrialNet partnership currently includes 14 North American Clinical Centers (infrastructure funded by NIDDK U01 grants), four international Clinical Centers (infrastructure funded by JDRF), and a Data Coordinating Center (TNCC) (funded by a NIDDK contract and grants). Each TrialNet Clinical Center grant currently funds a Principal Investigator Clinical Endocrinologist and a Co-Investigator Immunologist. Each of these Clinical Center leaders is a voting member of the Steering Committee and participates in other subcommittees that review new protocols, develop and review processes, and participate in data analysis and publication of findings.

A competition is currently underway for the TrialNet North American Clinical Centers. U01 grants will be awarded to the Clinical Centers that successfully compete in mid-2014. The new grants will no longer include Co-Investigator Immunologists. Instead, immunologists will be independently solicited to participate in TrialNet as members of a newly formed TrialNet Biomarkers & Mechanisms Panel (BMP).

TrialNet has the following specific needs which are expected to be fulfilled through the BMP:

- Development of a strategic plan for mechanistic and biomarkers research within TrialNet, updated yearly. BMP members will participate in conference calls as needed to develop the plan and 1-2 meetings in person, per year. In person meetings will usually be held in the Washington D.C. area. Chair will be selected by TrialNet's executive committee for 3 year term.
- BMP members will also participate in one or more of TrialNet's activities:
  - Ancillary Studies: Approval of mechanistic ancillary studies using TrialNet subjects and samples, participation in sample selection for ancillary studies. Monthly teleconferences.
  - Scientific Review: Review of new clinical research proposals and protocols for scientific merit. A few times per year by telephone, as needed (required).
  - Mechanistic Outcomes: Development of specific plans for biomarkers and mechanisms research within TrialNet's subject populations. Quarterly teleconferences (required).
  - Laboratory Monitoring: review of performance of TrialNet's core laboratories and policies. Monthly teleconferences.
  - Individual study chair committees: Development of mechanistic analysis plans for specific TrialNet studies. 2-3 teleconferences.
  - Rotating participation on the TrialNet Steering Committee and other oversight committees. Yearly in person meetings (required).

## **2. The Solicitation**

Interested and qualified persons may nominate themselves for membership on TrialNet's BMP.

Applicants can be new to TrialNet but must be technically qualified experts in their field (e.g., clinical endocrinology of type 1 diabetes with a mechanistic focus, clinical immunologist with clinical trial experience, basic immunologist with interest and experience in human disease, biostatistics). Applicants should hold an R01 or its equivalent as a Principal Investigator. Former TrialNet Immunology Co-Investigators funded via Clinical Center grants, or former or current Clinical Center Principal Investigators or applicants who are interested in being actively involved as described above, should apply for membership on the Panel.

## **3. Proposal Details and Deadlines**

All proposals must include the following:

- a. Complete curriculum vitae for each nominee.
- b. Current business and/or home address, telephone number, and e-mail address.
- c. Describe how you will contribute to TrialNet's mission to prevent type 1 diabetes.
- d. Indicate how much time you would be willing to commit to TrialNet activities. Indicate whether you would like to be considered for the Chair. Depending on your level of commitment, you will be compensated either as a consultant or as a

- subcontractor. Indicate any preferences for compensation mechanism. If you are selected you will need to provide additional information relevant to subcontract or consulting agreements.
- e. Provide information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Applications should be e-mailed from the institution's business official to Sarah Muller ([sarah.muller@epi.usf.edu](mailto:sarah.muller@epi.usf.edu)) with "TrialNet B&M Panel Application" in the subject line. Applications should be received by 5:00 PM, MAY 9, 2014. Pre-award documentation will include disclosures of other support and potential conflicts of interest, and will be updated yearly. Notification of intent to award is by June 1, 2014.

#### **4. Criteria for Evaluation and Selection**

Proposals will be evaluated by the TrialNet Executive Committee (with ad hoc reviewers as needed) primarily on the basis of scientific expertise, experience in T1D mechanistic research, and innovation and vision demonstrated in the proposal. Consideration will be given to assemble a Panel that is representative of the TrialNet scientific community and covers the breadth and depth of scientific areas of interests.

For more information contact:

Lisa M. Spain, Ph. D.

Project Scientist, Type 1 Diabetes TrialNet

Division of Diabetes, Endocrinology, and Metabolism

National Institute of Diabetes & Digestive & Kidney Diseases

National Institutes of Health

301-451-9871

[spainl@niddk.nih.gov](mailto:spainl@niddk.nih.gov)