Appendix G. Definitions

Abbreviation	Item	Definition
AE	Adverse Event	Defined for this protocol as “any occurrence or worsening of an undesirable or unintended sign, symptom or disease whether or not associated with the treatment and study procedures.”
AEDAMS	Adverse Events Data Management System	System for reporting Adverse Events in TrialNet
	Assessment Tools	Documents in which data collected for a clinical trial is first recorded. These data are usually later entered in the electronic case report form.
	Certificate of Confidentiality	A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.
CTCAE	Common Terminology Criteria for Adverse Events	The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.
	Concomitant Medications	Used to collect all medications that the participant is taking before and during the study. After screening visit, only changes in con meds need to be captured on source documents and the e-CRF.
	Continuing IRB/ERB Review	The IRB/ERB determines the period of approval and frequency of review for all studies involving human subjects research. A continuing review must be performed by the IRB/ERB of an investigator intends to continue the study beyond the period for which it was approved.
DSMB	Data and Safety Monitoring Board	An impartial group that oversees a clinical trial and reviews the results to see if they are acceptable. This group determines if the trial should be changed or closed.
DOC	Date of Collection	Date on which a laboratory specimen was physically collected.
DUI/DoA	Duality of Interest/Duality Disclosure form	Form through which dualities will be reduced, eliminated or managed as necessary for all participants in TrialNet. Includes but not limited to personal associations or professional collaborations that could affect scientific objectivity or commitment to a research endeavor.
eCRF	Electronic Case Report Form	Tool used to collect data for each participant on a particular study. All eCRFs will be located online on the members website.
	FDA 1572 Statement of Investigator Form	A form that must be filed by an investigator running a clinical trial to study a new drug or agent. The investigator agrees to follow the U.S. Food and Drug Administration (FDA) Code of Federal Regulations for the clinical trial. The investigator verifies that he or she

		has the experience and background needed to conduct the trial and that it will be done in a way that is ethical and scientifically sound.
FTL	[*formerly "*First Three Letters"]	A three-letter code assigned by the clinical site to identify a participant. FTL format is at the site's discretion.
GCP	Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that they rights, integrity and confidentiality of the subjects are protected.
IRB/ERB	Institutional/Ethical Review Board	A committee formed to ensure the protection of human subjects in research.
	Institutional/Ethical Review Board Approval	Appropriate IRB approval consists of correspondence from the IRB of record for the study site indicating that the TrialNet Protocol (and related materials) was approved.
	Interim Medical History	Review the participant's health during the study and document any changes to their medical history
ICH	International Conference on Harmonisation	Regulatory authority that creates guidelines for clinical research through international scientific consensus.
IND	Investigational New Drug	A drug that has not been approved for general use by the Food and Drug Administration but is under investigation in clinical trials regarding its safety and efficacy first by clinical investigators and then by practicing physicians using subjects who have given informed consent to participate
	Laboratory CRA	A TNCC Clinical Research Administrator dedicated to management of TN laboratory operations. The Laboratory CRA is the primary liaison between the sites and core laboratories. TNCC laboratory operations include all aspects of specimen handling, result reporting, inventory management, and facilitation of laboratory-related subcommittees.
LID	Local Identification Number	ID assigned to a participant by the clinical site. For subjects enrolled prior to the transition to the USF TNCC, the Local ID is the former participant ID under the previous Data Coordinating Center. For subjects enrolled after the transition, the Local ID is created by the site; format is unspecified.
MOO	Manual of Operations	A manual in which study specific standard operating procedures can be found.
	Members' Directory	Document located in the member's website that lists contact information for all TrialNet sites.
MMTT	Mixed Meal Tolerance Test	Commonly used in the U.S. and involves the ingestion of a liquid meal in the fasting state. The MMTT assesses an individual's insulin production capability by measuring the participant's plasma glucose and c-peptide levels before and at defined intervals for 2 to 4 hours following the ingestion of Boost® High Protein, the liquid meal used in TrialNet.
CU/NU/RU	New User/Remove User Contact Correction form	Form to be completed by site if contact information has changed or if a new user needs to gain access to the member's website. Forms should be completed and

		faxed or emailed to the TNCC.
	Participant Details Screen	Provides, by participant, a list of all events generally required to be completed once the participant is registered on the study. The forms present at each visit follow the Schedule of Events/Assessments from the protocol. In order to navigate to the participant details follow the instruction provided in section 9.1.2.
PID	Patient Identification Number	Six-digit ID assigned to a participant by the TrialNet online data capture system. Subjects who participate in more than one study must retain the same PID throughout all protocols.
PE	Physical Exam	The process by which a health care provider investigates the body of a patient for signs of disease.
	Portlet	Located on the member's website, these are the organized sections of specific pages.
PI	Principal Investigator	Person responsible for all study conduct at the participating site.
PRN	Pro Re Nata Forms	Study visit forms that should be completed on an as needed visit. Visit completed out of window should use PRN forms for data entry.
	Protocol Chair Committee	Committee responsible for making decisions on each protocol. Each protocol has a committee that will meet throughout the course of the study.
	Protocol CRA	Member of the TNCC that coordinates the administrative processes and is the main TNCC contact for that protocol.
PIC	Protocol Implementation Checklist	Checklist provided to sites documenting requirements for site activation on a protocol.
PPD	Purified Protein Derivative Test	The PPD is a special skin test for tuberculosis (TB). It is a test used to determine if someone has developed an immune response to the bacterium that causes tuberculosis (TB).
QC Program	Quality Control Program	A process of ensuring the maintenance of TN standards in the collection, shipping, processing, and analysis of laboratory specimens.
QC Specimen	Quality Control Specimen Collections	Duplicate specimen collected in order to conduct a quality control assessment.
	Randomization	Randomization is a method based on chance alone by which study participants are assigned to a treatment group.
	Reimbursement Schedule	Details the reimbursement rates for clinical centers, and affiliate sites that are activated on a protocol.
	Reportable Adverse Event	For this protocol, only AE's determined to be CTCAE v3.0 Grade 2 or greater and related to study procedures are reportable.
	Screening Medical History	Medical History is defined as an account of a patient's past and present state of health obtained from the patient or relatives.
SAE	Serious Adverse Event	An adverse event associated with the treatment or study procedures that suggest a significant hazard, contraindication, side effect or precaution (as described below) is to be reported as a serious adverse event (SAE).
	Site Activation	Site specific process that must be completed prior to start of enrollment. Steps to site activation are as

		follows: 1. The site must submit to the TNCC an appropriate IRB approval for the study to be activated 2. The site must submit to the TNCC an up-to-date site delegation log reflecting the current study and detailing the responsibilities of each staff member as designated by the site PI 3. The site must submit to the TNCC the appropriate Duality of Interest form(s) for each individual listed on the site delegation log 4. At least one person at the site must be trained on the online data capture system (protocol manager) and be certified for all required study procedures and tests
SDL	Site Delegation Log	A comprehensive list, current and maintained at each study site, detailing the name, credentials, time began service on a protocol, time ended service on a protocol, explicit description of protocol responsibilities for each site staff member directly involved in the conduct of the research (e.g., study coordinator, sub-Investigator) or staff associated with, but not directly involved in, the research trial (e.g., pharmacist, laboratory staff).
	Split Duplicate Specimen	Alternate term for QC Specimen; terms are interchangeable
SOP	Standard Operating Procedures	Established procedures to be followed in carrying out a given operation or within a given situation.
	Specimen Collection Visit	Collection of specimens ONLY (No physical exam, no assessment of adverse events, no assessment of concomitant medications)
SMS	Specimen Management System	Component of the TN online data capture system used to record and manage the collection, shipment, tracking, result reporting, and analysis of laboratory specimens.
	Study Coordinator	The Study Coordinator is a specialized research professional working with and under the direction of the clinical Principal Investigator (PI). While the Principal Investigator is primarily responsible for the overall design, conduct, and management of the clinical trial, the Study Coordinator supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.
	Study Drug Administration	The injection will be a standard subcutaneous injection. Do not administer in the area that the subject used for insulin injection. No pre-med required.
	Study Group Committee	All participating sites on a protocol will participate in the study group call. This is where information from the chair committee will be disseminated to all sites.
	Study Visit	All procedures associated with a particular visit which includes but is not limited to: specimen collection, physical examination, adverse event assessment, concomitant medication
SIP	Subject Information Portal (TN01 only)	Provides a single location for coordinators to access all participant results and demographic information for the Pathway to Prevention study.
SOS	Supply Ordering System	A secure, web-based portal managed by Fisher BioServices and the TNCC to facilitate procurement of

		supplies to the clinical sites, including clinical supplies, specimen collection and processing supplies, specimen shipping supplies, diabetes management supplies, recruitment and retention materials, and participant questionnaires. Sites place orders online, which are then approved by the TNCC and fulfilled by the appropriate provider.
TNCC	TrialNet Coordinating Center	Supports the overall coordination, data management and analysis of research data for the TrialNet network.
UI	User Interface	A general term for the component of the TN member's website and online data capture system with which individuals interact.
FDA	U.S. Food and Drug Administration	FDA is an agency within the Department of Health and Human Services. The FDA's organization consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.
	Volunteer Survey	As part of the screening consent process, the participant will also be required to complete a short, written Volunteer Survey that is designed to ensure that the participant understands the study, as well as what is being asked of him/her. The purpose of the Volunteer Survey is to enhance the consenting process.
	W8 BEN	Certificate of foreign status of beneficial owner for United States tax withholding.
	W9	An IRS form, also known as "Request for Taxpayer Identification Number and Certification", which is used by an individual defined as a "U.S. person" or a resident alien to verify his or her taxpayer identification number (TIN).