Site Number:	___ ___ ___ ___	Participant ID:	___ ___ ___ ___ ___ ___	Participant Letters:	___ ___ ___

A. VISIT INFORMATION

1. Visit Date:* __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

B. ELIGIBILITY

1. Inclusion Criteria*

a. Is the participant in TrialNet Natural History/Pathway to Prevention Study (TN01) and thus, a relative of a proband with T1D and between the ages of 1-45 at the time of enrollment in TN01?	Y	N
b. If most recent OGTT demonstrates Normal Glucose Tolerance, is the participant ≥3 years? **OR** If most recent OGTT demonstrates Abnormal Glucose Tolerance, is the participant age 3-7 at time of randomization in this trial?	Y	N
c. Does the participant have a confirmed positive mIAA result within the past 6 months?	Y	N
d. Does the participant have at least one other diabetes-associated autoantibody present on two separate samples, one of which was drawn within the past six months?	Y	N
e. Does the participant weigh ≥ 12kg at the time of screening?	Y	N
f. Is the participant willing to provide informed consent or, if the subject is <18 years of age, have a legal guardian provide informed consent?	Y	N

2. Exclusion Criteria*

a. Has the participant been diagnosed with type 1 diabetes, or has their most recent OGTT shown a fasting glucose ≥126 mg/dl or a 2 hour glucose ≥ 200 mg/dl?	Y	N
b. Has the participant had prior participation in a clinical research study for secondary prevention of type 1 diabetes?	Y	N
c. Does the participant have a history of treatment with insulin or any oral hypoglycemic agent?	Y	N
d. Does the participant have current chronic use of medications altering stomach acid (such as H2 blockers, proton pump inhibitors, and antacids)?	Y	N
e. Does the participant have a history of gastric ulcer or gastric surgery?	Y	N
f. Has the participant been treated with immunosuppressive drugs or glucocorticoids within the past 2 years for a period of more than 3 months?	Y	N
g. Does the participant have a disease which would limit his/her ability to participate in the study?	Y	N
h. Does the participant have ongoing use of medications known to influence glucose tolerance, e.g. sulfonylureas, growth hormone, metformin, anticonvulsants, thiazide or potassium depleting diuretics, beta adrenergic blockers, niacin. Participants on such medications should be changed to a suitable alternative, if available, and will become eligible one month after medication is discontinued?	Y	N
i. Is the participant pregnant, intending to become pregnant while on study, or lactating?	Y	N

j. Is the participant deemed unlikely or unable to comply with the protocol, or does the participant have any complicating medical issues or abnormal clinical laboratory values that interfere with study conduct or cause increased risk? Y N

C. HOUSEHOLD PARTICIPATION IN TN20 ORAL INSULIN STUDY

1. Is there anyone in the immediate family or living in the household who is currently randomized in the TN20 Immune Effects of Oral Insulin Trial?* Y N

   a. If YES**,** how many individuals? ____

   Record the Participant ID(s) and relationship(s) below.

Participant ID:		**Relationship:**	
1) Participant ID:	___ ___ ___ ___ ___ ___	a)	___ ___
2) Participant ID:	___ ___ ___ ___ ___ ___	b)	___ ___
3) Participant ID:	___ ___ ___ ___ ___ ___	c)	___ ___

P=Parent	**IT**=Identical Twin	**FS**=Brother/Sister	**AU**=Aunt/Uncle	**C**=Cousin
GP=Grandparent	**NT**=Non-identical Twin	**HS**=Half Brother/Sister	**N**=Niece/Nephew	**CH**=Child