Participant ID:	Date of Registration:	
Local ID:	Letters:	
Status:		
Site:		

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	OT02 - Eligibility				
	* These fields are required in order to				
	* These fields are required in order to COM	PLETE the for			
Date of Visit: *					
interviewer User ID: * []				
3. Eligibility					
L. Inclusion Criteria					
a.) Is the participant between 3 and 45 years of age and a sibling, offspring or parent of an individual with T1D OR participant between 3 and 20 years of age with another relative with T1D?					
b.) Is the participant willing to accept random assignments?					
c.) Does the participant hav	e confirmed positive mIAA with in the past 6 months?	\bigcirc Yes \bigcirc No			
d.) Does the participant have at least one other antibody present on two separate samples, One of which was drawn with in the past six months?					
e.) Does the participant have a normal glucose tolerance test within the past 7 weeks and, if more than one glucose tolerance test has been performed, are the two most recent tests normal?					
2. Exclusion Criteria					
a.) Does the participant have T1D?					
b.) Has the participant previously been enrolled in another clinical trial for T1D prevention?					
c.) Is the participant immunodeficient?					
d.) Does the participant have a disease which would limit his/her ability to participate in the study?					
e.) Has the participant been treated with immunosuppressive drugs or glucocorticoids within the past 2 years for a period of more than 3 months?					
f.) Does the participant have the HLA DQA1*0102, DQB1*0602 Haplotype?					
g.) is the participant taking any medications that affect glucose homeostasis?					
h.) Does the participant have a history of treatment with insulin or any oral hypoglycemic agents?					
.) Has the participant ever had an abnormal OGTT?					
2.) If yes, has the participant had two consecutive normal OGTTs since the abnormal OGTT?					
3. Eligibility Committee R	eview				
	ion ONLY if the participant has not met eligibility requirements an ittee review; otherwise, leave blank.	d has			
Subject is eligible per eligib	\bigcirc Yes \bigcirc No				
C. HOUSEHOLD PARTICIP	ATION IN ORAL INSULIN STUDY				
 Is there anyone in your in currently randomized in the 	mmediate family or living in your household who is Oral Insulin Trial?	○ No			
a. If Yes, specify how many	r individuals				

Add
Participant is ELIGIBLE for the study according to the Inclusion/Exclusion criteria. Prior to randomization, ensure the site PI has reviewed all central laboratory test results and has confirmed eligibility.
Please contact the TN07 Oral Insulin CRA at the Coordinating Center for any questions regarding the Inclusion/Exclusion Criteria.