

Diabetes Prevention Trial - Type 1 ELIGIBILITY CHECKLIST

Complete this form immediately prior to randomization. Eligibility criterion should be verified at this time even though specific items may have been assessed previously.

Subject ID #: Subject Initials: Date: / /
F M L M M D D Y Y

Name of person completing form (please print): _____

Inclusion Criteria	YES	(STOP) NO*
1. a. Complete ONLY for subjects to be randomized on Oral Antigen:		
Subject is 3-45 years of age and is a sibling, offspring or parent of an individual with IDDM. or Subject is 3-20 years of age, is not a sibling, offspring or parent of an individual with IDDM, but is another type of relative of an individual with IDDM.	<input type="checkbox"/>	<input type="checkbox"/>
b. Complete ONLY for subjects to be randomized on Parenteral Antigen:		
Subject is 4-45 years of age and is a sibling, offspring or parent of an individual with IDDM. or Subject is 4-20 years of age, is not a sibling, offspring or parent of an individual with IDDM, but is another type of relative of an individual with IDDM.	<input type="checkbox"/>	<input type="checkbox"/>
2. Subject is willing to accept assignment to any treatment group and stay in that group for the length of the study.	<input type="checkbox"/>	<input type="checkbox"/>
3. Subject has completed pre-randomization tasks, interviews and informed consent for randomization.	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion Criteria	(STOP) YES*	NO
1. Subject has diabetes.	<input type="checkbox"/>	<input type="checkbox"/>
2. Subject has been treated with insulin or oral diabetes medications.	<input type="checkbox"/>	<input type="checkbox"/>
3. Subject has been previously enrolled in another clinical study for the prevention of IDDM.	<input type="checkbox"/>	<input type="checkbox"/>
4. Subject has:		
Chronic active hepatitis	<input type="checkbox"/>	<input type="checkbox"/>
Severe cardiac disease	<input type="checkbox"/>	<input type="checkbox"/>
Renal insufficiency	<input type="checkbox"/>	<input type="checkbox"/>
Immunodeficiency	<input type="checkbox"/>	<input type="checkbox"/>
Hepatic disease	<input type="checkbox"/>	<input type="checkbox"/>
Other disease which could limit life expectancy or lead to immunosuppressive therapy	<input type="checkbox"/>	<input type="checkbox"/>
5. Subject has been treated with immunosuppressive drugs or glucocorticoids within past two years for a period of more than three months.	<input type="checkbox"/>	<input type="checkbox"/>
6. Ongoing use of any of the following:		
Potassium depleting diuretics	<input type="checkbox"/>	<input type="checkbox"/>
Beta-adrenergic blockers	<input type="checkbox"/>	<input type="checkbox"/>
Niacin	<input type="checkbox"/>	<input type="checkbox"/>
Anticonvulsant therapy	<input type="checkbox"/>	<input type="checkbox"/>
Growth hormone	<input type="checkbox"/>	<input type="checkbox"/>
7. Subject is currently pregnant or planning pregnancy during the next five years.	<input type="checkbox"/>	<input type="checkbox"/>

***Any entry in this column makes the subject ineligible. Do not proceed with randomization.**

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DMU Use Only
Date rcvd: _____