Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Complete this form during the first Screening visit for this study.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

B. INFORMED CONSENT

1. Date written informed consent obtained: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
2. Date HIV screening consent obtained: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
3. On the consent form, was permission given for blood to be examined for genetic factors in the development of type 1 diabetes (HLA testing)? Y N
4. On the consent form, was permission given for samples of the participant's blood to be stored for DNA testing and other tests, as indicated on the consent form? Y N

C. DEMOGRAPHIC INFORMATION

1. Date of birth: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)
2. Age (years): __ __ __
3. Sex: ☐ 1 Male ☐ 2 Female
4. Ethnicity *(check one):*
   ☐ 1 Hispanic or Latino ☐ 2 Not Hispanic or Latino
5. Race *(check all that apply):*
   a. ☐ 1 American Indian or Alaskan Native
   b. ☐ 1 Asian
   c. ☐ 1 Black or African American
   d. ☐ 1 Native Hawaiian or Other Pacific Islander
   e. ☐ 1 White
   f. ☐ 1 Other

   IF OTHER, 1. Specify: _____
6. How did you first hear about this study *(check one)*?
   ☐ 1 Physician ☐ 3 Family/Friend ☐ 5 Radio/TV
   ☐ 2 Meeting/Presentation ☐ 4 Poster ☐ 9 Other

   IF OTHER, a. Specify: _____

D. INCLUSION CRITERIA

1. Patient is within 3-months of diagnosis of type 1 diabetes based on ADA criteria (FPG ≥ 126mg/dl or NFPG ≥ 200 mg/dl)? Y N
2. Patient is between 12 and 35 years of age? Y N
3. Patient is willing to be randomized to treatment group? Y N
4. Patient is willing to attend all scheduled follow-up visits at the designated clinic (unforeseen events withstanding)? Y N
5. Patient is willing to comply with intensive diabetes management? Y N

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

E. EXCLUSION CRITERIA

1. Patient is sexually active and refuses to use an effective form of birth control?	Y N
2. Patient is a female with reproductive potential who refuses to undergo pregnancy testing during the course of the MMF/DZB study?	Y N
3. Patient is a female with reproductive potential who refuses to promptly report possible or confirmed pregnancies during the course of the MMF/DZB study?	Y N
4. Patient is a female who is currently pregnant or less than 3 months postpartum?	Y N
5. Patient is a female who is currently nursing or within 6 weeks of having completed nursing?	Y N
6. Patient anticipates becoming pregnant, or fathering a child, during the study?	Y N
7. Patient has complicating medical issues that would interfere with blood drawing or monitoring?	Y N
8. Patient has had any live vaccinations in the preceding 6 weeks?	Y N
9. Patient requires chronic use of steroids or other immunosuppressive agents for other conditions?	Y N

STOP AND DOUBLE CHECK ELIGIBILITY

Double check Sections D and E. To proceed, you must have:

Answered YES to *every* question in Section D

AND Answered NO to *every* question in Section E

If NOT eligible, **do not continue with any further assessments** and send the top copy of this form to the TrialNet Coordinating Center.

F. DIABETES HISTORY

1. Was your initial diagnosis based on *(check one):*

☐ 1	Random blood glucose check (incidental to other medical condition)	☐ 4	Symptoms of diabetes not requiring hospitalization
☐ 2	Routine screening for diabetes without presence of symptoms	☐ 5	Symptoms of diabetes requiring hospitalization
☐ 3	Formal testing for diabetes (OGTT)		

2. Date of diagnosis of type 1 diabetes: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

3. Which of the following symptoms or results did you have at the time of diagnosis? *(check all that apply)*

a.	☐ 1	Excessive thirst	e.	☐ 1	Frequent urination
b.	☐ 1	Unexplained weight loss	f.	☐ 1	Blood glucose ≥ 200 mg/dl at any time of day
c.	☐ 1	Fasting blood glucose ≥ 126 mg/dl	g.	☐ 1	Blood glucose ≥ 200 mg/dl during an oral glucose tolerance test
d.	☐ 1	Frequent infections	h.	☐ 1	No symptoms

4. Were you admitted to a hospital during the diagnosis period? Y N

IF YES,

a. Did you stay overnight in the hospital? Y N

b. Were you admitted to an Intensive Care Unit (ICU) while in the hospital? Y N

5. Did you have blood or urine ketones (trace or greater amounts) at the time of diagnosis? Y N

6. Most recent HbA1c *(if known)*: __ __. __ %

a. If known, indicate date HbA1c was measured: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

G. HYPOGLYCEMIA HISTORY

1. Can you usually recognize when your blood sugar level is low? Y N

IF YES,

a. Do you use a meter to check your blood sugar when you recognize it is getting low? Y N

2. Have you ever had an unconscious event or seizure caused by low blood sugar? Y N
3. Have you ever had low blood sugar requiring assistance from another person? Y N
4. Have you ever had low blood sugar while sleeping? Y N

H. AUTOIMMUNE DISEASE HISTORY

1. Have you ever been diagnosed with an autoimmune disease? Y N

IF YES,

Specify which autoimmune disease(s) you have been diagnosed with *(check all that apply):*

a.	☐ 1	Addison's Disease	d.	☐ 1	Alopecia	g.	☐ 1	Hypoparathyroidism
b.	☐ 1	Celiac Disease *(gluten allergy or Celiac sprue)*	e.	☐ 1	Grave's Disease (hyperthyroidism)	h.	☐ 1	Hashimoto's thyroiditis (goiter) or Hypothyroidism
c.	☐ 1	Hypogonadism	f.	☐ 1	Pernicious anemia	i.	☐ 1	Vitiligo
						j.	☐ 1	Other autoimmune disease

I. OTHER DISEASE HISTORY

1. Have you had any infections other than a cold or flu during the last year? Y N
2. Do you have a history of skin allergies or asthma? Y N

Question 2 is designed to ensure that the participant is not taking any steroid-based or other immunosuppressive medications chronically for treatment of these conditions.

3. Do you have any chronic (long-term) diseases *(other than autoimmune diseases)*? Y N

J. VACCINATION HISTORY

1. Have you had any vaccinations within the past six weeks? Y N

IF YES, have you had any of the following?

a. DTP vaccination?	Y	N	f. Hepatitis vaccination?	Y	N
b. Live flu vaccination?	Y	N	g. Live polio vaccination?	Y	N
c. MMR (second dose) vaccination?	Y	N	h. Meningococcal meningitis vaccination?	Y	N
d. Varicella (chickenpox) vaccination?	Y	N	i. Vaccinia (smallpox) vaccination?	Y	N
e. Yellow fever vaccination?	Y	N	j. Other	Y	N

K. CURRENT MEDICATIONS

1. Are you currently taking vitamin supplements that contain Niacin or Vitamin E? Y N
2. Are you currently taking steroids? *(Steroid use is an exclusion criterion for this study)* Y N
3. Are you currently taking antibiotics? Y N

IF YES,

a. For what? _____

4. Are you currently taking medication(s) for diabetes other than insulin? Y N
5. Are you currently taking other prescription medications? Y N

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

L. PREGNANCY MONITORING

1. Does the participant have reproductive potential? Y N

IF YES, continue (otherwise, proceed to **Section M**)

a. Do you currently use a form of birth control? *(Females and males of reproductive age are expected to use a form of birth control, or practice abstinence)* Y N

b. Do you plan on becoming pregnant, or fathering a child, in the next 3-months? Y N

IF FEMALE, continue with Questions c and d (otherwise, proceed to **Section M**)

c. Are you currently taking birth control medication? Y N

d. Was the pregnancy test completed at this study visit positive? Y N

STOP AND DOUBLE CHECK ELIGIBILITY

If **Question b** or **d** is answered YES, the participant should **not** be enrolled in this study.

M. PHYSICAL ASSESSMENTS

Collect the following physical assessments:
Note: *Have the participant rest for 5 minutes before doing these assessments.*

1. Temperature: __ __ . __ ºC or __ __ __ . __ ºF
2. Seated arm blood pressure: __ __ __ mmHg / __ __ __ mmHg (Systolic / Diastolic)
3. Seated heart rate: __ __ __ Beats/minute
4. Seated respiratory rate: __ __ __ Breaths/minute
5. Weight: __ __ __.__ kg or __ __ __. __ __ lbs
6. Height: __ __ __.__ cm or __ __. __ __ in
7. Was an ECG taken at this screening visit? Y N

IF YES,

a. Was the ECG classified as normal? Y N

N. LABORATORY ASSESSMENTS

Were the following blood samples taken or other assessments performed during this visit?

1. CBC with diff	Y N	4. HbA1c	Y N	7. EBV/CMV PCR	Y N
2. Chemistries	Y N	5. PPD Test	Y N	8. Viral Serology	Y N
3. Serum for autoantibodies	Y N	6. HIV, Hep B and C Screening	Y N	9. Urine pregnancy test	Y N

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*