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

Complete this form at the Baseline study visit (Week 0).

A. VISIT INFORMATION

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

B. PREGNANCY MONITORING

1. Does the participant have reproductive potential? Y N

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

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 C**)

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

In order to be enrolled in this study,

The participant must answer YES to **Question a**

AND

The participant must answer NO to **Questions b** and **d**

If NOT eligible, **STOP** here and complete the first page of the Eligibility and Randomization Form (**MMF03)** to document this information.

C. VACCINATION AND SEROLOGY HISTORY

1. Have you had any vaccinations since your Screening visit? 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

2. Is the participant seropositive for Epstein-Barr Virus (EBV)? Y N

3. Is the participant seropositive for Cytomegalovirus (CMV)? 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: __ __ __

D. MEDICAL HISTORY

Has a physician ever told you that you have any of the following conditions?

Condition/Disease	Ever had?		IF YES, a. Within the last year?	
1. Asthma	Y	N	Y	N
2. High blood pressure	Y	N	Y	N
3. High cholesterol	Y	N	Y	N
4. Ulcer (stomach or duodenal)	Y	N	Y	N
5. Hepatitis/Liver disease	Y	N	Y	N
6. Cancer	Y	N	Y	N
7. Gallstones, gallbladder disease, or gallbladder surgery	Y	N	Y	N
8. Gout	Y	N	Y	N
9. Thyroid disease	Y	N	Y	N
10. Congenital heart disease or heart problems	Y	N	Y	N
11. Infectious mononucleosis	Y	N	Y	N
12. Epilepsy, convulsions, or seizures	Y	N	Y	N
13. Colitis or colon problems	Y	N	Y	N
14. Pernicious anemia	Y	N	Y	N
15. Leukopenia and/or Neutropenia	Y	N	Y	N
16. Psoriasis	Y	N	Y	N
17. Alopecia (Hair loss)	Y	N	Y	N
18. Rheumatologic disease (Lupus, Rheumatoid arthritis, etc.)	Y	N	Y	N
19. Allergies	Y	N	Y	N
20. Frequent urinary tract infections	Y	N	Y	N

E. PATIENT INFORMATION

1. Do you currently smoke or use tobacco products? Y N
2. During the last year, have you consumed an average of at least one alcoholic beverage per week? Y N
   IF YES, for an average week:
   a. How many 12-ounce bottles of beer do you usually consume *per week*? __ __ bottles
   b. How many 4-ounce glasses of wine do you usually consume *per week*? __ __ glasses
   c. How many 1.5-ounce shots of hard liquor or mixed drinks do you usually consume *per week*? __ __ shots
3. During the last year, have you ever consumed 7 or more alcoholic beverages (including mixed drinks, shots, beer, and/or wine) within a 24-hour period? Y N
4. Which is the highest level of school you have completed? *(check one)*

☐ 1 Pre-elementary school
☐ 2 Elementary school
☐ 3 Secondary school *(includes high school)*
☐ 4 College/Trade School
☐ 5 Graduate/Professional School

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

E. PATIENT INFORMATION (cont.)

5. What is your primary occupation (or **if less than 18,** indicate occupation of parent(s) or guardian(s)) *(Check one)*

a. Participant (**or** parent/guardian 1, if less than 18)		b. Parent/guardian 2 (if participant less than 18)	
☐ 1	Agriculture or fishing	☐ 1	Agriculture or fishing
☐ 2	Craftsman, foreman, or similar worker	☐ 2	Craftsman, foreman, or similar worker
☐ 3	Homemaker	☐ 3	Homemaker
☐ 4	Laborer	☐ 4	Laborer
☐ 5	Manager, official, or proprietor	☐ 5	Manager, official, or proprietor
☐ 6	Operator, assembler, or similar worker	☐ 6	Operator, assembler, or similar worker
☐ 7	Professional, technical, or similar worker	☐ 7	Professional, technical, or similar worker
☐ 8	Sales worker	☐ 8	Sales worker
☐ 9	Service worker	☐ 9	Service worker
☐ 10	Student	☐ 10	Student
☐ 99	Other/Unknown	☐ 99	Other/Unknown

6. What is your current living status? *(check one)*

☐ 1	Live with parent/guardian	☐ 4	Live with spouse/partner
☐ 2	Live with family/friend *(not parent/guardian or spouse)*	☐ 5	Live with roommate(s) *(not related to patient)*
☐ 3	Live alone		

F. BLOOD SUGAR MONITORING

1. Do you regularly monitor your blood sugar levels? Y N

   IF YES,

   a. How many times (on average) during the day? __ __

      OF THESE,

      1. How many occur *before* meals (including snacks): __ __

      2. How many occur *after* meals (including snacks): __ __

2. Do you check your blood sugar:

   a. When you wake up in the morning? Y N

   b. Before bedtime? Y N

   c. At any time during the night (e.g. 3:00 AM)? Y N

3. Do you regularly have a snack before bedtime? Y N

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

G. GENERAL PHYSICAL EXAMINATION

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

a. Temperature:	__ __ . __ ºC	or	__ __ __ . __ ºF
b. Seated arm blood pressure:	__ __ __ mmHg (Systolic) / __ __ __ mmHg (Diastolic)		
c. Seated heart rate:	__ __ __ Beats/minute		
d. Seated respiratory rate:	__ __ __ Breaths/minute		
e. Weight:	__ __ __.__ kg	or	__ __ __. __ __ lbs
f. Height:	__ __ __.__ cm	or	__ __. __ __ in

2. Record whether the following systems are normal or abnormal for the physical exam:

System	Normal?	System	Normal?
a. HEENT *(Head, eyes, ears, neck, throat)*	Y N	g. Abdomen	Y N
b. Neck	Y N	h. Musculoskeletal	Y N
c. Thyroid	Y N	i. Neurologic	Y N
d. Lungs	Y N	j. Genitourinary	Y N
e. Chest/Breasts	Y N	k. Skin/Nails	Y N
f. Heart/Circulatory	Y N	l. Lymph Nodes	Y N

3. Indicate the participant's sexual development using the Tanner Scale:

Tanner Stage	*Check one:*				
a. Breast/Genital	☐ 1 Stage 1	☐ 2 Stage 2	☐ 3 Stage 3	☐ 4 Stage 4	☐ 5 Stage 5
b. Pubic Hair	☐ 1 Stage 1	☐ 2 Stage 2	☐ 3 Stage 3	☐ 4 Stage 4	☐ 5 Stage 5

H. RECENT HYPOGLYCEMIC EVENTS

1. Have you had any low blood sugar events or periods since your Screening visit *(defined as any blood sugar level < 50 mg/dl and/or symptoms of low blood sugar)*? Y N

   IF YES,

   a. Number of events: __ __

   b. Of those, how many were major (loss of consciousness, seizure, or assistance required from another person)? __ __

IF *any major* hypoglycemic events have occurred since the Screening visit, complete Form **MMF04** to record the details of these events.

I. INSULIN REQUIREMENTS

1. Indicate your daily insulin routine *(check one)*:
   - ☐ 1 No insulin
   - ☐ 2 1-2 Injections per day
   - ☐ 3 3 + Injections per day (MDI)
   - ☐ 4 Insulin Pump (CSII)

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

I. INSULIN REQUIREMENTS (cont.)

Answer the following questions regarding your daily insulin requirements *(on an average day)*:

Type of Insulin	Use this type?	IF YES, a. Average daily dose
2. Humalog (H)	Y N	__ __ __.__ units
3. NovoLog	Y N	__ __ __.__ units
4. Regular (R)	Y N	__ __ __.__ units
5. NPH (N)	Y N	__ __ __.__ units
6. Lente	Y N	__ __ __.__ units
7. Ultralente	Y N	__ __ __.__ units
8. Lantus/Glargine	Y N	__ __ __.__ units
9. Detemir	Y N	__ __ __.__ units
10. Other	Y N	__ __ __.__ units

Indicate (by circling Yes or No) at which point(s) in the day these insulin injections (or bolus administrations for pump users) take place:

11. Wake Up	12. Breakfast		13. Lunch		14. Dinner		15. Before Bed
	a. Before	b. After	a. Before	b. After	a. Before	b. After	
Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N

J. CONCOMITANT MEDICATION

1. Are you currently taking any prescription medications other than insulin?	Y N
2. Are you currently taking vitamin supplements that contain Niacin or Vitamin E?	Y N
3. Are you currently taking steroid medications for the treatment of other conditions? *(Steroid use is an exclusion criterion for the MMF/DZB study)*	Y N
4. Are you currently taking any antidepressant or antianxiety medications?	Y N
5. Are you currently taking any medications for the treatment of high blood pressure?	Y N
6. Are you currently taking any antibiotics?	Y N

IF YES,
a. For what? _____

K. LABORATORY ASSESSMENTS

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

1. CBC with diff	Y N	8. Urine pregnancy test	Y N
2. Chemistries	Y N	9. RNA (stored)	Y N
3. Baseline C-peptide	Y N	10. T-cells (stored)	Y N
4. Immune Testing (CD4/CD25/apoptosis)	Y N	11. Serum (stored)	Y N
5. HLA Determination	Y N	12. DNA (stored)	Y N
6. Rubella titers	Y N	13. ELISPOT	Y N
7. Viral flu titers	Y N		

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

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

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

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