

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
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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
---	---

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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?	
	Y	N		Y	N
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*)

<input type="checkbox"/> ₁ Pre-elementary school	<input type="checkbox"/> ₄ College/Trade School
<input type="checkbox"/> ₂ Elementary school	<input type="checkbox"/> ₅ Graduate/Professional School
<input type="checkbox"/> ₃ Secondary school (<i>includes high school</i>)	

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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)

- ₁ Agriculture or fishing
- ₂ Craftsman, foreman, or similar worker
- ₃ Homemaker
- ₄ Laborer
- ₅ Manager, official, or proprietor
- ₆ Operator, assembler, or similar worker
- ₇ Professional, technical, or similar worker
- ₈ Sales worker
- ₉ Service worker
- ₁₀ Student
- ₉₉ Other/Unknown

b. Parent/guardian 2 (if participant less than 18)

- ₁ Agriculture or fishing
- ₂ Craftsman, foreman, or similar worker
- ₃ Homemaker
- ₄ Laborer
- ₅ Manager, official, or proprietor
- ₆ Operator, assembler, or similar worker
- ₇ Professional, technical, or similar worker
- ₈ Sales worker
- ₉ Service worker
- ₁₀ Student
- ₉₉ Other/Unknown

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

- ₁ Live with parent/guardian
- ₂ Live with family/friend (not parent/guardian or spouse)
- ₃ Live alone

- ₄ Live with spouse/partner
- ₅ Live with roommate(s) (not related to patient)

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 <i>before</i> meals (including snacks): | | _ _ |
| 2. How many occur <i>after</i> 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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G. GENERAL PHYSICAL EXAMINATION

1. Collect the following physical assessments:

Note: Have the participant rest for 5 minutes before doing these assessments.

- a. Temperature: _____ °C or _____ °F
- b. Seated arm blood pressure: _____ mmHg / _____ mmHg
Systolic 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 (<i>Head, eyes, ears, neck, throat</i>)	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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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 Y N	12. Breakfast a. Before Y N b. After Y N	13. Lunch a. Before Y N b. After Y N	14. Dinner a. Before Y N b. After Y N	15. Before Bed Y N
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J. CONCOMITANT MEDICATION

- Are you currently taking any prescription medications other than insulin? Y N
 - Are you currently taking vitamin supplements that contain Niacin or Vitamin E? Y N
 - 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
 - Are you currently taking any antidepressant or anti-anxiety medications? Y N
 - Are you currently taking any medications for the treatment of high blood pressure? Y N
 - 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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**MMF-DZB Study
BASELINE FORM**

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October 01, 2005
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