

Site Number: _____ Screening ID: _____ - ____ Participant Letters: _____

Complete this form during the Infant Enrollment Visit for infants who entered through Entry A.

A. VISIT INFORMATION


1. Date of visit (e.g. 05/Sep/2006): _____ / _____ / _____
DAY MONTH YEAR

B. INCLUSION CRITERIA

1. Does the infant have: (check all that apply)
- a. A higher risk HLA genotype
 - b. Another first or second degree relative with type 1 diabetes and a lower risk HLA genotype.
2. Was one of the above checked? Y N

C. EXCLUSION CRITERIA

1. Was the infant less than 36 weeks of gestational age at birth? Y N
2. Is the infant required to take a pre-term infant formula? Y N
3. Do you believe the infant or mother have any conditions that will put her or infant at an unacceptable medical risk for participation in this study? Y N
- a. If YES, list any condition(s) for her or infant: _____



STOP AND DOUBLE CHECK ELIGIBILITY

Double-check **Sections B** and **C**. To allow the infant to continue in this study you must have:

Answered **YES** to *every* **inclusion** criteria.

AND Answered **NO** to *every* **exclusion** criteria.

D. ELIGIBILITY VERIFICATION

1. Is the infant eligible to continue in the study? Y N

If not eligible, **STOP HERE.**

- **Complete the Participant Status Form (NPP18), Study Substance Compliance Form (NPP16) and Study Substance Dispensation and Return Form (NPP15).**
- **Continue to monitor mother and infant for one month for adverse events.**

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

Date form completed: _____ / _____ / _____
DAY MONTH YEAR

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.).*