

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*)

☐ ₁ 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?
2. Is the infant required to take a pre-term infant formula?
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

	Y	N
1. The company has a clear vision and mission statement.		
2. The company has a strong leadership team.		
3. The company has a clear understanding of its target market.		
4. The company has a strong financial foundation.		
5. The company has a clear understanding of its competitive advantage.		
6. The company has a strong customer base.		
7. The company has a clear understanding of its industry trends.		
8. The company has a strong brand identity.		
9. The company has a clear understanding of its core values.		
10. The company has a strong commitment to social responsibility.		

	Y	N
1. The company should be required to disclose the names of its directors and officers.	90	10
2. The company should be required to disclose the names of its shareholders.	85	15
3. The company should be required to disclose the names of its employees.	75	25
4. The company should be required to disclose the names of its customers.	65	35
5. The company should be required to disclose the names of its suppliers.	55	45
6. The company should be required to disclose the names of its competitors.	45	55
7. The company should be required to disclose the names of its vendors.	35	65
8. The company should be required to disclose the names of its distributors.	25	75
9. The company should be required to disclose the names of its franchisees.	15	85
10. The company should be required to disclose the names of its licensees.	10	90

- 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.).*