

Site Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_ Participant Letters: \_\_\_\_\_

**For this study, only events Grade 2 and above will be reported to the Coordinating Center.**

**The Study Coordinator should complete this form to report:**

- A new adverse event, or
- A change in intensity, frequency, or duration of a previously reported adverse event.

**If updating a previously reported adverse event, make the necessary changes to your site copy of the original report and send a copy of the updated pages to the Coordinating Center. Include a copy of the first page for updates so that changes can be linked to the original Adverse Event ID Number.**

An *adverse event* is described as any unfavorable or unintended clinical event, sign, symptom, or disease, or any event that has *changed* adversely in nature, intensity, or frequency. Refer to the Manual of Operations for reportable events.

**This form should be completed with as much information as is currently known regarding the adverse event. A question should be answered with a “?” if the information is currently unavailable, but will be known in future updates. Write “\*” if the information is permanently unknown, and the question will be unknown in all future updates. No questions should be left blank.**

**A. REPORT INFORMATION**

Adverse Event ID Number:

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

2. Report is for (check one):  1 Pregnant woman  2 Nursing mother  3 Infant/Child (participant)

3. Was the participant currently taking the study substance at the time of the event?

4. Last attended study visit (check one):

<input type="checkbox"/> 91 Pregnant Woman Screening/ Enrollment	<input type="checkbox"/> 94 Infant Enroll/6 mo	<input type="checkbox"/> 15 15 Months old	<input type="checkbox"/> 36 36 Months old
<input type="checkbox"/> 1 Infant Screening	<input type="checkbox"/> 95 Entry A Screening/ Infant Enroll	<input type="checkbox"/> 18 18 Months old	<input type="checkbox"/> 40 40 Months old
<input type="checkbox"/> 2 Infant Enrollment	<input type="checkbox"/> 6 6 Months old	<input type="checkbox"/> 21 21 Months old	<input type="checkbox"/> 48 48 Months old
<input type="checkbox"/> 3 3 Months old	<input type="checkbox"/> 9 9 Months old	<input type="checkbox"/> 24 24 Months old	<input type="checkbox"/> 99 Other, a. Specify date:
<input type="checkbox"/> 93 Infant Enroll/ 3 mo	<input type="checkbox"/> 12 12 Months old	<input type="checkbox"/> 30 30 Months old	<input style="width: 80px;" type="text" value="___/___/___"/>
			<small>DAY MONTH YEAR</small>

5. The adverse event was first reported during (check one):

1 Interim Follow-up Visit (*unplanned*)  3 Unattended Visit (*phone-call, etc.*)

2 Routine Follow-up Visit (*planned*)

6. How many separate adverse events are being reported at this time?

**IF MORE THAN 1, each adverse event requires the completion of a separate Adverse Event Report form.**

**B. EVENT DESCRIPTION**

1. Date of onset of adverse event:   
DAY MONTH YEAR

2. Describe the event:

*(Include information leading up to the event, procedures or tests completed, date stopped study substance, etc.):*

3. Intensity of reported event (check one):  2 Grade 2  3 Grade 3  4 Grade 4  5 Grade 5

NOTE: Refer to NCI Common Toxicity Criteria (CTC) to grade intensity

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**B. EVENT DESCRIPTION (CONTINUED)**

4. Has the adverse event resolved? Y N  
 a. If YES, date resolved: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DAY MONTH YEAR

5. Event Type (*check one*):

**Pregnancy – Related Events**

- |  |   |
|--|---|
| <input type="checkbox"/> 1 Miscarriage | <input type="checkbox"/> 3 Pre-term delivery (< 36 weeks) |
| <input type="checkbox"/> 2 Stillbirth  | <input type="checkbox"/> 4 Post-partum depression         |

**Clinically Significant Abnormality (*Mother or Infant*)**

5 Laboratory Abnormality  
 a. If Laboratory Abnormality, specify: \_\_\_\_\_

**Maternal Diabetes – Related Events During Pregnancy**

- 6 Ketoacidosis w/ ER visit, but no hospital admission
- 7 Ketoacidosis requiring admission to hospital
- 8 Hypoglycemia requiring medical or non-medical assistance but not necessitating IV glucose or IV glucagon
- 9 Hypoglycemia resulting in seizure and/or coma
- 10 Hypoglycemia necessitating IV Glucagons or IV glucose

**Other**

99 Other, a. Specify: \_\_\_\_\_

**If the adverse event was Grade 2, skip to section C.**

6. If the adverse event was **Grade 3 or above**,

- a. Was the serious adverse experience:
- |                        |     |  |     |
|------------------------|-----|--|-----|
| 1) Congenital anomaly? | Y N | 4) Due to overdose of study substance?   | Y N |
| 2) Cancer?             | Y N | 5) Condition that could have resulted in one of the previous outcomes if left untreated? | Y N |
| 3) Life-threatening?   | Y N |  |     |
- b. Did the adverse event result in any of the following?
- |                                       |     |                                   |     |
|---------------------------------------|-----|-----------------------------------|-----|
| 1) Require or prolong hospitalization | Y N | 2) Permanent or severe disability | Y N |
|---------------------------------------|-----|-----------------------------------|-----|
- c. Was this an **unexpected adverse event**? Y N

An **unexpected adverse event** is defined as one for which the specificity or severity is not consistent with known events. For a list of expected adverse events for DHA or infant formula see the Manual of Operations.

**C. RELATIONSHIP AND ACTIONS TAKEN**

1. Relationship to study substance (*check one*):

- 1 Not related     2 Unlikely     3 Possible     4 Probable     5 Definite

2. Actions taken for the adverse event:

- |   |     |                        |     |
|---|-----|------------------------|-----|
| a. Discontinued study substance?  | Y N | d. Non-drug treatment? | Y N |
| b. Concomitant medication prescribed?<br>( <i>Complete the Concomitant Medication Worksheet (NWK02)</i> ) | Y N | e. None?               | Y N |
| c. Outpatient procedure?  | Y N | f. Other?              | Y N |
|   |     | 1) Specify _____       |     |

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**C. RELATIONSHIP AND ACTIONS TAKEN (CONTINUED)**

3. Did treatment require any of the following?

- |                            |   |  |   |
|----------------------------|---|--|---|
| a. Visit to study site     | <input type="checkbox"/> Y <input type="checkbox"/> N | d. Admission to hospital                 | <input type="checkbox"/> Y <input type="checkbox"/> N |
| b. Visit to emergency room | <input type="checkbox"/> Y <input type="checkbox"/> N | e. Admission to skilled nursing facility | <input type="checkbox"/> Y <input type="checkbox"/> N |
| c. Clinic visit            | <input type="checkbox"/> Y <input type="checkbox"/> N |  |   |

If treatment involved admission to hospital or skilled nursing facility,

1) Record length of stay: \_\_\_\_\_ Days

4. Did treatment of the adverse event require unmasking of the participant's treatment group assignment?  Y  N

If YES, a. Describe the circumstances:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**D. EVENT OUTCOME**

1. What was the outcome of the adverse event? (*check one*)

- |   |  |
|---|--|
| <input type="checkbox"/> 1 Recovered, no residual effect  | <input type="checkbox"/> 6 Death,                  |
| <input type="checkbox"/> 2 Residual effect, no treatment  | a. Date of death: ____/____/____<br>DAY MONTH YEAR |
| <input type="checkbox"/> 3 Residual effect, being treated | b. Probable cause of death: _____                  |
| <input type="checkbox"/> 4 Persistent, no treatment       | <input type="checkbox"/> 99 Other,                 |
| <input type="checkbox"/> 5 Persistent, being treated      | c. Specify: _____                                  |

Reported all **Serious Adverse Events** to the TrialNet Coordinating Center **within 24 hours**.  
Faxed a **TrialNet MedWatch Form** to the TrialNet Coordinating Center at **(866) 804-6058** or **(301) 468-1676** within **24 hours** of clinic notification.

**E. MEDWATCH** (*Complete only for serious adverse events.*)

1. Date the TrialNet MedWatch Form was faxed to the TrialNet Coordinating Center: \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

a. Time the TrialNet MedWatch Form was faxed (*24-hour clock*): \_\_\_\_:\_\_\_\_  
Hour Min

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

**Date form completed:** \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

**Signature of Principal Investigator:** \_\_\_\_\_ **Signed?**  Y  N

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