1. Is the participant/subject on any GI therapies? [ ]  Yes [ ]  No (leave rest of form blank)
2. Are the feedings given: [ ]  Orally only (skip to Q5) [ ]  Tube Feeding only [ ]  Combination oral and tube feeding
3. Tube Type: [ ]  Nasogastric [ ]  Nasojejunal [ ]  Gastrostomy [ ]  Gastrojejunal [ ]  Jejunal [ ]  Other, specify:
4. Date Feeding Tube First Placed (m m/dd/yyyy):
5. Fundoplication? [ ] Yes [ ] No

If Yes,

1. Date (m m/dd/yyyy):
2. Age:
3. Method of placement:

[ ]  Microscopic Laparotomy [ ]  Interventional Radiology

[ ]  Percutaneous Endoscopic Gastrostomy

1. Medications: [ ]  PPI [ ]  H2 blocker [ ]  Gastric motility [ ]  Polyethylene glycol

(For each medication, complete a row on the ConMed form with detailed information about dosing and frequency)

Describe the subject’s/participant’s original feeding schedule and any changes to the feeding schedule over the course of the study.

Feeding Schedule Start Date (m m/dd/yyyy):

Feeding Schedule End Date (m m/dd/yyyy):

1. Feeding Schedule (Choose either table 1 or 2)

Table 1:

| Type of Feeding | Duration\* (hh:mm) | # of Times per Day | Amount of Formula per Feed (include units: e.g., 240ml) | Formula Name (Trade or Generic) | Estimated caloric intake | Amount of water flush |
| --- | --- | --- | --- | --- | --- | --- |
| [ ]  Bolus G tube[ ]  Continuous G tube[ ]  Oral liquid supplement intake | (hh:mm) | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  N/A: no: water flush |
| [ ]  Bolus G tube[ ]  Continuous G tube[ ]  Oral liquid supplement intake | (hh:mm) | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  N/A: no: water flush |
| [ ]  Bolus G tube[ ]  Continuous G tube[ ]  Oral liquid supplement intake | (hh:mm) | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  N/A: no: water flush |
| [ ]  Bolus G tube[ ]  Continuous G tube[ ]  Oral liquid supplement intake | (hh:mm) | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | Data to be entered by site. | [ ]  N/A: no: water flush |

Other Oral Intake Table

| Other Oral Intake | Estimated Calories |
| --- | --- |
| Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site |

Table 2:

| Type of Feeding | Frequency/Duration | Amount | Formula Type | Estimated caloric intake |
| --- | --- | --- | --- | --- |
| [ ]  Continuous Feeding | Start Time: hh: mm [ ] am [ ] pmEnd Time: hh: mm [ ] am [ ] pm | Rate (mL/hr) | Data to be entered by site. | Data to be entered by site. |
| [ ]  Bolus Feedings | Start Time: hh: mm [ ] am [ ] pmEnd Time: hh: mm [ ] am [ ] pm | Rate (mL/hr) | Data to be entered by site. | Data to be entered by site. |
| [ ]  Oral Feedings | Start Time: hh: mm [ ] am [ ] pmEnd Time: hh: mm [ ] am [ ] pm | Rate (mL/hr) | Data to be entered by site. | Data to be entered by site. |

| Other Oral Intake | Estimated Calories |
| --- | --- |
| Data to be filled in by site | Data to be filled in by site |
| Data to be filled in by site | Data to be filled in by site |

1. Start of Feeding Schedule: mm/ dd/ yyyy
2. End of Feeding Schedule: mm/ dd/ yyyy

## General Instructions

This CRF is used to capture data on GI therapies the participant/subject is undergoing during the course of the study. It also captures data on the feeding schedule of the participant/subject, as well as changes to it over the course of the study.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Is the participant/subject on any GI therapies? – If this question is answered No then leave the rest of the form blank
* Are the oral feedings given – If Orally Only is answered, then skip to question 5
* Date Feeding Tube First Placed – Record the date in the format MM/DD/YYYY. If the date is unknown, record as 99/99/999.
* Date Fundoplication – Only record the date if Yes is answered for Nissen fundoplication. Record the date in the format MM/DD/YYYY. If the date is unknown, record as 99/99/999.
* Medications – For each medication used for GI therapy, record on the ConMed form with detailed information about dosing and frequency.
* Feeding Schedule – Complete either Table 1 or Table 2, but nt both to capture data on the participant/subject’s feeding schedule and changes to the feeding schedule of the study.
* Start of Feeding Schedule – Record the date in the format MM/DD/YYYY. If the date is unknown, record as 99/99/999.
* End of Feeding Schedule– Record the date in the format MM/DD/YYYY. If the date is unknown, record as 99/99/999.