1. Is the participant/subject on any GI therapies?

Yes  No (leave rest of form blank)

1. Are the feedings given:

Orally only (skip to Q5)  Tube Feeding only  Combination oral and tube feeding

1. Tube Type:

Nasogastric  Nasojejunal  Gastrostomy  Gastrojejunal  Jejunal  Other, specify:

1. Date Feeding Tube First Placed (m m/dd/yyyy):
2. 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)

1. Is the participant/subject taking nutritional supplements? Yes No

If yes, specify supplements:

Turmeric Fiber  Creatine  CoQ10 Other, specify:

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 Table

| Type of Feeding | Method | # of Feeds per Day | Duration\* (hh:mm) | Amount of Formula per Feed (include unit: mL, fl oz, etc.) | Formula Name (Trade or Generic) | Caloric Density of Formula (Calories / unit: mL, fl oz, etc.) | Amount of water flush\* (include unit: mL, fl oz, etc.) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Tube  Oral liquid supplement intake | Bolus  Continuous | Data to be filled in by site | (hh:mm) | Unit | Data to be filled in by site | unit | N/A – no flush |
| Tube  Oral liquid supplement intake | Bolus  Continuous | Data to be filled in by site | (hh:mm) | unit | Data to be filled in by site | unit | N/A – no flush |
| Cf. questions 2 & 3 | Some tubes can use either | Can be used to calculate rate if necessary. Continuous = 1 feed/day, over duration | Table 2 Continuous’ start/end time would yield this | Can be used to calculate rate if necessary | N/A | Can be used to calculate caloric intake w/ # feeds or duration, and amount/feed | N/A |

\*Tube only

Other Oral Intake Table

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

## 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 Nissen 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.
* 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.