Version: 2 11-Jun-09

Functional Dyspepsia Treatment Trial (FDTT) U01 DK 065713

Adverse Event Log

Subject ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ Page _____ of _____

Adverse Event

AE #	Event	Serious AE (1)	Severity (2)	Relationship to Study Drug (3)	Start Date Month Day Year	Stop Date Month Day Year	Action (4)	Body System (5)	Outcome (6)

Investigator signature:_____ Date signed (month/day/year):_____

1: Serious AE
- 0 = No
- 1 = Yes
- **If Serious = 1, complete SAE form.**

2: Severity
- 1 = Mild
- 2 = Moderate
- 3 = Severe

3: Relationship to Study Drug
- 0 = Not Suspected
- 1 = Suspected

4: Action (List all that apply)
- 0= No Action Taken
- 1= Study drug temporarily interrupted
- 2= Study drug permanently discontinued due to this adverse event
- 3= Concomitant medication taken (report on Concomitant med page)
- 4= Non-drug therapy given
- 5= Hospitalization/prolonged hospitalization
- 6= Other (write in)

5: Body System
- 1 = NS
- 2 = Cardiac
- 3 = GI
- 4 = Pulmonary
- 5 = Renal
- 6 = Hematologic
- 7 = Skin
- 8 = Endocrine
- 9 = Musculoskeletal
- 10 = Other

6:Outcome
- 1 = Resolved
- 2 = Recovered with minor sequelae
- 3 = Recovered with major sequelae
- 4 = Condition still present and under treatment
- 5 = Condition continues to worsen
- 6 = Patient died

NOTE: Fax this form to the DCC at 507-538-7202, per the SOP.

If participant has no AE's during the trial, this form is not needed.

If any AE's are noted above, the Site PI is to sign and date this form upon participants completion of the study.

Fax the final signed form to the DCC at the fax number above.