Measuring Opioid Tolerance Induced by Fentanyl (or Other Opioids) (MOTIF) Study
Overview of Public Use Datasets

This document overviews the general principles used in creating the public use datasets for the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development Collaborative Pediatric Critical Care Research Network (CPCCRN) MOTIF study. Please see the attached Research Data Use Agreement (RDUA) for a description of intended use and disclaimer.

Within the included .ZIP file, there are a total of 16 datasets available as both CSV (.CSV) and SAS® (.SAS7BDAT) files (with formats and labels). Accompanying documentation and resources provided include the study protocol, the annotated eCRF, and, for each dataset, an Adobe PDF document summarizing variables in that dataset (i.e., frequency distributions or descriptive statistics). For SAS software users, an example script to set up the SAS library and apply SAS formats is also provided. The annotated eCRF should be referenced frequently during analysis as this is the most complete reference of all variables included in each dataset.

GENERAL PRINCIPLES FOR CREATION OF DATASET

1. The population for the public use dataset is all enrolled patients. Screening information is not included. See the protocol for a detailed list of inclusion/exclusion criteria and for additional details of study conduct including data collection schedule and variable definitions.

2. The datasets are primarily based on raw data as collected by the clinical sites and outlined in the study protocol. All variables are described in the annotated eCRF.

3. Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed. Dates were recoded to reflect number of days from study entry (date of first opioid infusion). For daily data, there is also a "study day" defined as Day 1 - Day 14. Study Day 1 is the day of study entry, so corresponds to day 0 for any recoded dates.

4. Many of the available datasets include only one record per patient (unique identifier *subjectID*). Other datasets are relational, that is, may have more than one record per patient. The annotated eCRF provides information as to the structure of each dataset and the unique identifier for each record.

LIST OF PUBLIC USE DATASETS AVAILABLE

- Demographics (DEMOGRAPHICS)
- Study Entry (STUDYENTRY)
- Study Entry - Secondary Diagnoses (SECONDARYDX)
- Study Entry - Chronic Diagonses (CHRONICDX)

- Study Day 1 (STUDYDAY1)
- Daily Data (Study Days 2-14) (DAILYDATA)
- Study Day 1/Daily Data - Continuous IV Infusions of Morphine (DCIVMORPH)
- Study Day 1/Daily Data - Boluses of Morphine (DBMORPH)
- Study Day 1/Daily Data - Continuous IV Infusions of Fentanyl (DCIVFENT)
- Study Day 1/Daily Data - Boluses of Fentanyl (DBFENT)
- Study Day 1/Daily Data - Continuous IV Infusions of Midazolam (DCIVMIDAZ)
- Study Day 1/Daily Data - Boluses of Midazolam (DBMIDAZ)
- Study Day 1/Daily Data - Boluses of Lorazepam (DBLORAZ)
- Study Day 1/Daily Data - Other Sedative Drugs (DSEDATIVES)
- Study Day 1/Daily Data - Other Analgesic Drugs (DANALGESICS)
- Study Exit (STUDYEXIT)