SOP 304-CPC Accrual Data Merge and Analysis

Approval signature: _____
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Purpose:
To document and standardize the methods for merging and analyzing accrual data from research projects involving human subjects that are not directly managed by the Clinical Research Shared Services, Clinical Trials Office.

References:
- Data Structure for Research Projects Involving Human Subjects (SOP 302-CPC).
- Submission of Required Accrual Data (SOP 303-CPC).
- Reporting Accrual Data to AZCC Clinical Trials Shared Service, Clinical Trials Office (SOP 305-CPC).

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
- OnCore Data Coordinator

Definition of Terms:
- **OnCore Data Coordinator**: The individual responsible for the collection, merge, validation, analysis, management, and distribution of this data for the Clinical Trials Office.
- **Accrual Common Database**: This database will hold the data elements defined in SOP 302-CPC entitled *Data Structure for Research Projects Involving Human Subjects* for all research studies involving human subjects that are not directly managed by the Clinical Trials Office.
- **Original Submitter**: The research individuals that submitted the primary data for their specific trial.
- **Erroneous Data**: Any data that does not contain the expected value. It could be incomplete or blank or may contain values out of the expected ranges.
- **Trial-Specific Data File**: The data set submitted to the Oncore Data Coordinator by the Original Submitter.
- **Protocol Number**: The University of Arizona Human Subjects Committee/IRB Number.
- **Gender**: Biologically born male or female.
- **Consent Date**: The date the study subject signed the Human Subjects Committee approved study informed consent form.

- **Unique Participant Identification Code**: A series of alphanumeric characters that uniquely identifies a study subject. This identification code cannot contain any identifiers such as the following: initials, name, social security number, treatment arm.
- **Ethnic Category**: Designated by research subject self-identification, and is based on social and cultural characteristics as well as ancestry. Ethnic categories include:
  - Hispanic or Latino;
  - Not Hispanic or Latino.
- **Primary Racial Category**: Designated by research subject self-identification, and is based on social and cultural characteristics as well as ancestry:
  - American Indian or Alaskan Native;
  - Asian;
  - Black or African American;
  - Native Hawaiian or Other Pacific Islander;
  - White;
  - Other.
- **Date of Birth (DOB)**: The month, day and year the participant was born.
- **ZIP Code**: The United States Postal Service's Zone Improvement Program (ZIP) Code that corresponds to the participant's primary residence address.

Safety Issues:
De-identification of data and standard data security methods as required by the University of Arizona Institutional Review Board will ensure human subject confidentiality.

Process Steps:
1) Accrual Common database Data Fields to be captured for each research subject:
   - HSC, BIO or other protocol number
   - Unique Participant Identification Code
   - Consent Date
   - Gender
   - Ethnic Category
   - Primary Racial Category
   - Date of Birth
   - ZIP code
2) Initializing the Accrual Common database for each reporting phase.
   - All data merged from previous submissions will be archived.
   - The database will be emptied and repopulated with the new data submissions from each research trial.
3) Data will be received from each human research trial as described in SOP 303-CPC entitled Submission of Required Accrual Data.
   - Data received in compressed and encrypted electronic form.
   - Decompressing the data file successfully will confirm an accurate transmission of data.

4) Verification of each Trial-Specific Data File.
   - Various queries will be used to analyze the imported data
   - Complete: all data entered no incomplete data or blank fields.
   - Accurate: only appropriate values for each field allowed.
   - Verification: Study's Participant Identification Codes within the trial specific data file are unique (no duplicate records).
   - Any erroneous or incomplete data will be listed and returned to the original submitter.
   - If the trial specific data file is successfully received and no corrections are required, a confirmation message will be sent to the original submitter.
5) Merge Trial Specific Data Files into the Accrual Common Database.
   - Standardized routines will merge the exported data into the database.
   - The two variables, Study Participant Identification Code and HSC, BIO or other protocol number will be verified to assure that no duplicate records exist in the Accrual Common Database.
6) Analysis
   - Monitoring systems will be used to ensure data has been collected from all sources.
   - Reference all ongoing studies' protocol numbers and compare to submitted data to discover who has and has not submitted trial data.
   - The Research Administrator and all Program Directors will be responsible for ensuring compliance with the required data submission deadlines (refer to SOP 303-CPC entitled *Submission of Required Accrual Data*).
7) Reporting to Clinical Trials Office
   - The procedures are specified in SOP 305-CPC entitled *Reporting Accrual Data to AZCC Clinical Research Shared Service, Clinical Trials Office*.