Clinical Research Shared Service Standard Operating Procedure

SOP 303-CPC  Submission of Required Accrual Data

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Purpose:
To standardize the procedures to submit accrual data from the research trial to the Clinical Trial Data Manager (CTDM) as required by the Clinical Research Shared Service for NCI summary reporting.

References:
- Data Structure for Research Projects Involving Human Subjects (SOP 302-CPC).
- Accrual Data Merge and Analysis (SOP 304-CPC).
- NIH Requirements for Comprehensive Cancer Centers-Standard Cancer Center Information Summaries (NCI Summary 4 Guidelines 06/06):-

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
Data managers and/or research staff involved in research involving human subjects whose enrollment is not directly managed by the Clinical Research Shared Service, Clinical Trials Office.

Tools:
- Software for computerized collection of data.
- OnCore®

Definition of Terms:
- **Clinical Trial Data Manager (CTDM):** The individual responsible for the collection, merge, validation, analysis, management, and distribution of this data for the Clinical Trials Office.
- **Consented Participant:** A human subject who agrees to participate in an Institutional Review Board (IRB)-approved research study according to the consenting procedures that have been approved by the IRB (e.g., signed consent form, signed authorization, verbal authorization).
- **Protocol Number:** The University of Arizona Human Subjects Committee/IRB approval number.
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.

Consent Date: The date the study subject signed the IRB approved study consent form or agreed to participate in a research study according to the IRB-approved consent process.

Gender: Biologically born male or female.

Ethnic Categories: Designated by research subject self-identification, and is based on social and cultural characteristics as well as ancestry. Ethnic categories include: 1) Hispanic or Latino; 2) Not Hispanic or Latino.

Racial Categories: Designated by research subject self-identification, and is based on social and cultural characteristics as well as ancestry. Racial categories include, at a minimum:
1) American Indian or Alaskan Native;
2) Asian;
3) Black or African American;
4) Native Hawaiian or Other Pacific Islander;
5) White;
6) 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 standardized procedures for data submission are necessary for the protection of human subjects and for the submission of accurate and valid data for institutional reporting purposes.

Process Steps:
1) Collect and enter the data as per SOP 302-CPC Data Structure Research Projects Involving Human Subjects.
2) Develop a computer procedure to export all above-listed fields to an unformatted comma-delimited text file.
3) The comma-delimited file is to be created according to the following specifications:
   - Exported data will include ALL data records. This will be a compilation of accumulated data from the time of initial IRB approval.
   - Place the fields in this specific order:
     - Protocol number without spaces or periods, ie 10-0227-04
     - Participant ID
     - Consent Date
     - Gender
     - Ethnic Category
     - Primary Racial Category
4) Name the export file using the following specification:
   - Each separate human research study is to be exported to its own filename.
   - Start the filename with the Protocol Number. Do not use spaces.
   - Use an underscore (_) to separate the Protocol number from the next part of the filename.
   - Use the submission date for the remainder of the filename in the form of YYYYMM.
   - Use the extension of TXT.
   Examples of valid filenames for exported data:
   
   10-0027-04_200106.txt
   10-0225-02_200311.txt

5) Send the comma-delimited file to the CTDM using the web portal as described in SOP-306 entitled Web-Based Accrual Data Submission Procedures.

6) The CTDM will process the data as according to the specifications in the SOP 304-CPC entitled Accrual Data Merge and Analysis.

7) A report will be returned via e-mail to confirm the receipt of data. If problems occur or if data are incorrectly structured, a resubmission is required after corrections are made to the original data.

8) Comma-delimited files, containing all consented subjects to date, must be submitted to the CTDM via the web portal quarterly, on or before the following dates:
   - April 1
   - July 1
   - October 1
   - January 1

9) If no consenting or accrual has taken place within a quarter, resubmit the same data from the previous quarter and simply rename the file to the current quarter data.
10) If no consenting or accrual has yet begun on an IRB-approved research project, please submit a blank data file.

11) If all consenting has been completed and all data have been submitted according to University of Arizona Cancer Center Standard Operating Procedures, no further submissions are necessary. Please notify the CTDM that all accrual is complete.

12) Notify the OnCore Coordinator when the protocol has changed statuses, i.e., "closed to accrual", "on-hold", or "IRB Study Closure" (concluded) via email to oncore@azcc.arizona.edu or by phone 520-626-8018. Include status date. You may be requested to send follow-up paperwork such as the IRB approval letter.

13) You may choose to use MS Excel. Follow the above (but no quotation marks).