Clinical Research Shared Service Standard Operating Procedure

SOP 305-CPC Reporting Accrual Data to AZCC Clinical Research Shared Service, Clinical Trials Office

Approval signature: 
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Approval date: 220EC2011

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Purpose:
To provide accurate and current accrual data from all human subjects’ research associated with faculty/members/staff and/or collaborators of the University of Arizona Cancer Center to the Clinical Research Shared Service, Clinical Trials Office as required by the National Institutes of Health/National Cancer Institute.

References:
- NIH Standardized Racial and Ethnic Categories, as modified in order to comply with the new standards issued by the Office of Management and Budget (OMB) in Directive No. 15.

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.
- Clinical Trials Data Coordinator of the Clinical Research Shared Service

Definition of Terms:
- National Group Protocol: Research projects coordinated by a national cooperative group, such as the Southwest Oncology Group (SWOG), Gynecologic Oncology Group (GOG), Eastern Cooperative Oncology Group (ECOG), etc.
- Externally Peer-Reviewed Protocol: Research projects that have undergone external peer review prior to funding (e.g., P01 s, R01 s).
- Institutional Protocols: In-house, internally reviewed Cancer Center/University of Arizona research projects, including collaborative studies conducted with industry in which the center is a primary contributor to the design, implementation, and monitoring of the trial.
• **Industrial Protocols:** The design and implementation of the research is controlled by a pharmaceutical company.

• **Grant Number:** The full grant number (funding mechanism) that this trial is related to (does not apply for all research projects) (e.g., 1 R01 CA 11111-6).

• **Group/Sponsor:** The entity or organization providing funding to the University of Arizona, University of Arizona Cancer Center Investigator for the conduct of research. In the case at National Group Protocols, this is the cooperative group. For externally peer-reviewed, this is the funding agency or sponsor. For industrial trials, this is the pharmaceutical company that is sponsoring the trial.

• **Protocol ID:** This number uniquely identifies a research project. This is the University of Arizona Human Subjects/IRB approval number.

• **Principal Investigator:** The individual with primary responsibility for the implementation, conduct and reporting of the research project.

• **Program:** Each program within the Cancer Center is assigned a unique code. For example, this code is '4' for Cancer Prevention and Control.

• **Date Opened:** The date the research was IRB approved for accrual.

• **Date Closed:** The date the research was closed as officially reported to the Human Subjects Committee on a Periodic Review Form.

• **Phase:** The phase of the research as designated by the study design. Acceptable phases are I, II, III, IV, or pilot (may not apply to all research projects).

• **Trial Type:** This identifies what type of trial the study is related to. Per NIH guidelines, acceptable types are: Therapeutic, Chemoprevention, Ancillary or Companion, and Correlative (may not apply to observational research).

• **Title:** The name of the study as it appears on the IRB-approved research protocol.

• **Description:** A brief description of the research project (less than 200 words).

• **Target:** The number of patients needed to complete the study, i.e., the target accrual. This is not a targeted range, e.g., 10-100. In the case of a national trial, this is the number of patients the Cancer Center expects to accrue.

• **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.
  
  - **Hispanic or Latino:** a person of Cuban, Mexican, Puerto Rico, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."
  
  - **Not Hispanic or Latino:** a person who is not of Hispanic, Latino or Spanish culture or origin as defined above.

• **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.
   • American Indian or Alaskan Native: A person having origins in any of the original
     peoples of North, Central, or South America, and who maintains tribal affiliations or
     community attachment.
   • Asian: A person having origins in any of the original peoples of the Far East,
     Southeast Asia, or the Indian subcontinent including, for example, Cambodia,
     China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand,
     and Vietnam.
   • Black or African American: A person having origins in any of the black racial groups
     of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or
     African American."
   • Native Hawaiian or Other Pacific Islander: A person having origins in any of the
     original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
   • White: A person having origins in any of the original peoples of Europe, the Middle
     East, or North Africa.
   • Other: A person having origins in any location not mentioned above.
   • Gender: Biologically male or female.
   • Consent Date: The date the study subject signed the Human Subjects Committee
     approved study consent form.
   • Date of Birth (DOB): The month, day and year the participant was born.
   • 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.

Safety Issues:
De-identification of all individual subject data will be required to protect the privacy of human
subjects participating in University of Arizona Cancer Center clinical research studies.

Process Steps:
1) The Clinical Trials Data Coordinator will obtain information from each research project
   as it is initiated (Attachment 1, Table 1).
2) The Clinical Trials Data Manager will produce a data report including the required
   information for all research projects involving human subjects (Attachment 1, Table 2).
3) The Clinical Trials Data Coordinator and the Clinical Trials Data Manager will work
   together to provide a comprehensive report to the Clinical Trials Office (CTO) as
   required in the NIH Summary 4 instructions.
4) Data/Information from Process Steps above will be provided in two respective reports
   to the CTO.
a. The Data Manager's report will be submitted in an excel file consisting of the terms defined above and listed in Attachment 1. This report will be submitted on a quarterly basis (April 1, July 1, October 1, and January 1).

b. The Clinical Trials Data Manager reports will consist of the following: An ascii-delimited data file with Terms, provided per subject, for all subjects accrued to research protocols from the Date Opened to the Date Closed. (MS Excel is acceptable).

5) The accrual file will be submitted via the web-portal in SOP 306 or by e-mail (encrypted) to the OnCore Coordinator on or before the following dates:

   April 30 (Quarter I, January-March)
   July 31 (Quarter II, April-June)
   October 31 (Quarter III, July-September)
   January 31 (Quarter IV, October-December)
Attachment 1

NCI Summary 4 Report Required Information

Table 1. Research Administrator Report

<table>
<thead>
<tr>
<th>Group/ sponsor</th>
<th>Grant No.</th>
<th>Protocol ID</th>
<th>Principal Investigator</th>
<th>Program Code</th>
<th>Date Opened</th>
<th>Date Closed</th>
<th>Phase</th>
<th>Trial Type</th>
<th>Target Accrual</th>
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Table 2. Clinical Trial Office Data Manager Report, ascii-delimited data file per subject:

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Ethnic Category</th>
<th>Racial Category</th>
<th>Gender</th>
<th>Consent Date</th>
<th>Date of Birth</th>
<th>ZIP Code</th>
<th>Unique Participant Identification Code</th>
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