Clinical Research Shared Service Standard Operating Procedure

SOP 302-CPC Data Structure for Research Projects Involving Human Subjects

Approval signature: ____________________________
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Purpose:
To standardize the structure of data that is required for accrual reports.

References:
- National Institute of Health (NIH) Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research.
- NIH Requirements for Comprehensive Cancer Centers-Standard Cancer Center Information Summaries (NCI Summary 4 Guidelines 06/06):
- 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
  http://www.whitehouse.gov/omb/fedreg/ombdir15.html

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
University of Arizona Cancer Center staff, faculty, program members, collaborators and/or employees responsible for data collected in research projects involving human subjects whose enrollment is not directly managed by the Clinical Research Shared Service, Clinical Trials Office.

Definition of Terms:
- **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).
- **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 Alaska Native;
  2) Asian;
  3) Black or African American;
  4) Native Hawaiian or Other Pacific Islander;
  5) White;
  6) Other.

• **American Indian or Alaska 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 other region not mentioned above.

• **Gender:** Biologically born male or female.

• **Protocol Number:** The University of Arizona Human Subjects Committee/IRB approval number.

• **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.

• **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: date of birth, initials, name, social security number, treatment arm.

• **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:
The Federal Government requires that each of the above data elements (listed in Definition of Terms) be reported for all research protocols involving the consent of human subjects. The University of Arizona Cancer Center is required to comply with this mandate for all research studies conducted by its members and employees. Data requested for reporting purposes will be de-identified to protect the privacy of human subjects.

Process Steps for Data Structure:
1) For all research protocols involving human subjects, data entered must capture each of the following items for each consented participant: a) IRB approval number; b) unique participant identification code; c) consent date; d) gender; e) the two ethnic categories; f) the five racial categories; g) date of birth; and h) ZIP code.
2) To standardize data fields and to minimize future recoding of data, the following data structure should be used in all research trials.
3) Please select either character OR numeric values for all variables to be reported. Do not submit data mixed coding schemes for the same variable.

<table>
<thead>
<tr>
<th>4) Use the coding scheme from the following table: Variable</th>
<th>Value (character)</th>
<th>Value (numeric)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB approval number</td>
<td>(HSC or BSC prefix, followed by numeric approval number)</td>
<td></td>
</tr>
<tr>
<td>Participant ID</td>
<td>(flexible)</td>
<td></td>
</tr>
<tr>
<td>Consent Date</td>
<td>MM/DD/YYYY</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>M</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>F</td>
<td>2</td>
</tr>
<tr>
<td>Unknown</td>
<td>UN</td>
<td>9</td>
</tr>
<tr>
<td>Ethnic Categories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>HS</td>
<td>1</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>NH</td>
<td>2</td>
</tr>
<tr>
<td>Unknown</td>
<td>UN</td>
<td>9</td>
</tr>
<tr>
<td>Racial Categories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>AI</td>
<td>1</td>
</tr>
<tr>
<td>Asian</td>
<td>AS</td>
<td>2</td>
</tr>
<tr>
<td>Black or African American</td>
<td>AA</td>
<td>3</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>PI</td>
<td>4</td>
</tr>
<tr>
<td>White</td>
<td>WI</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>OT</td>
<td>6</td>
</tr>
<tr>
<td>Unknown</td>
<td>UN</td>
<td>9</td>
</tr>
</tbody>
</table>
5) A consented participant may select multiple racial categories; however, when a list of
races is provided to respondents, the list should not contain a “multi-racial” category.
When given the option of selecting more than one category, respondents should be
asked to indicate their primary racial affiliation in order to facilitate the tabulation of
responses. Do not identify or designate certain racial or ethnic groups as “minority
groups.”

6) Refer to SOP 301-CPC, Flow Chart for Accrual Data Reporting and SOP 303-CPC,
Submission of Required Accrual Data.