

Manual for the Completion of caBIG[®] Case Report Form (CRF) Modules

Introduction

In 2006, members of the Cancer Biomedical Informatics Grid or caBIG[®] in conjunction with the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into three categories:

- Mandatory – must be included when this data is collected for reporting
- Conditional – there are business rules to indicate situations under which this element should be used on a CRF
- Optional – no requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data, this is the element to include on the CRF

A template form with modules that contain questions or variables representing data to be collected was developed. The companion eCRF instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc.

Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

NCI Standard Demography Module Template Instructions

Field Descriptions and Instructions

<i>Field Name/Status</i>	<i>Description/Instructions</i>	<i>Conditionality Rules</i>	<i>Format</i>	<i>CDE Public ID</i>
Race (m)	Enter the patient/participant's OMB race category. When the subject is multi-racial, choose all the categories that apply.		Use choice list	2192199v1.0
Ethnicity (m)	Enter one of the identified OMB ethnicity categories listed.		Use choice list	2192217v2.0
Gender (m)	Enter the patient/participant's gender.		Use choice list	2200604v2.0
Patient's Date of Birth (m)	Enter the patient's full date of birth.		Use prescribed date entry format.	793v5.1
Country of Residence (c)	Enter the name of the country in which the patient/participant resides.	Requirement for collection is imposed by the trial sponsor.	Enter the full name of country of residence.	315v4.0
Zip Code (c)	Enter the string of characters used to identify the five-digit Zone Improvement Plan (ZIP) and four-digit extension code of a location for mail delivery.	Requirement for collection is imposed by the trial sponsor.	Enter the five digit ZIP code plus four digit extension if known	2179606v2.0
Payment Method (c)	Enter the code to identify the Primary Payer/insurance carrier information for a patient/participant on a protocol.	Requirement for collection is imposed by the trial sponsor. Sponsor now stipulates the use of codes with the values.	Use choice list	2865130v1.0
Date Completed (c)	Enter the date the Case Report Form (CRF) was completed Note: This question may be unnecessary for electronic data capture system.	Data Collection is done using paper Case Report Forms (CRFs) instead of an Electronic Data Capture system.	Use prescribed date entry format.	2003745v5.0

<p>CDC Race Code (c)</p>	<p>Enter the code for reporting race as determined by the Center for Disease Control and Prevention (CDC). Note: Use of this question is dependent on the study design, and contains more detail than the mandatory item 'Race'. The detail in the CDC Race Code question is intended to capture data that can be summarized for the 'Race' question. Both questions are NOT needed in the same module.</p>	<p>In the event the sponsor requires the data be collected using the CDC codes, use this CDE instead of 2192199. Do NOT collect both items.</p>	<p>Use choice list</p>	<p>2200286v1.0</p>
<p>CDC Ethnicity Code (c)</p>	<p>Enter the code for reporting ethnicity as determined by the Center for Disease Control and Prevention (CDC). Note: Use of this question is dependent on study design, and contains more detail than the mandatory item 'Ethnicity'. The detail in the CDC Ethnicity Code question is intended to capture data that can be summarized for the 'Ethnicity' question. Both questions are NOT needed in the same module.</p>	<p>In the event the sponsor requires the data be collected using the CDC codes, use this CDE instead of 2192217. Do NOT collect both items.</p>	<p>Use choice list</p>	<p>2200284v2.0</p>
<p>Person Census Tract Code at Enrollment (o)</p> <p>Note: Partition was changed from Mandatory to Optional on March 9, 2009 based on the decision of CTROC.</p>	<p>Enter the Census Tract code for a location defined by boundaries identified in the year 2000. Note: This question is an extension of the prior item, which covers through 1990.</p>		<p>Six digit number between 000100 and 999998</p>	<p>2943243v1.0</p>
<p>Education Level (o)</p>	<p>Enter the subdivision that describes the highest level of education completed by a person. Note: This question collects detailed level information, as compared to the question 'Educational Attainment'. Both questions are NOT needed in the same module.</p>		<p>Use choice list</p>	<p>2674076v2.0</p>

Educational Attainment (o)	Enter the subdivision that summarizes the highest level of education completed by a person. Note: This question collects summary level information, as compared to the question 'Educational Level'. Both questions are NOT needed in the same module.		Use choice list	2681552v1.0
Marital Status (o)	Enter the self-reported term to describe a patient/participant's current conjugal status.		Use choice list	2188083v2.0
Country of Birth (o)	Enter the geographic location where a patient/participant was born.		Enter full geographic location name	2001708v5.0

NCI Standard Demography Module Template

Mandatory Questions

Race

American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
Not Reported
Unknown
White

[CDE Public ID and Version 2192199v1.0: The text for reporting information about race based on the Office of Management and Budget (OMB) categories.]

Ethnicity

Hispanic or Latino
Not Hispanic or Latino
Not reported
Unknown

[CDE Public ID and Version 2192217v2.0: The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories.]

Gender

Female Gender
Male Gender
Unknown
Unspecified

[CDE Public ID and Version 2200604v2.0: Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles. [Explanatory Comment 1: Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.]]

Patient's Date of Birth

Exchange Format: YYYYMMDD

[CDE Public ID and Version 793v5.1: The month, day and year on which the person was born.]

Conditional Questions

Country of Residence

Text field – Maximum length = 75

[CDE Public ID and Version 315v4.0: The name of a country from which a person or their biological family had previous residence or past ancestors.]

ZIP Code

Text Field – Maximum length = 15

[CDE Public ID and Version 2179606v2.0: The string of characters used to identify the five-digit Zone Improvement Plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the U.S., where the mail is delivered.]

Payment Method

Managed Care/Medicare
Medicaid
Medicaid and Medicare
Medicare
Medicare and Private Insurance
Military or Veterans Sponsored, NOS
Military Sponsored (Including CHAMPUS & TriCare)
No Means of Payment (No Insurance)
Other
Private Insurance
Self-Pay (No Insurance)
State Supplemental Health Insurance
Unknown
Veterans Sponsored

[CDE Public ID and Version 2865130v1.0: Text term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service.]

Date Completed

Exchange Format: YYYYMMDD

[CDE Public ID and Version 2003745v5.0: The date on which a data capture form (CRF or case report form) was completed.]

CDC Race Code

Text field – maximum length = 6

[CDE Public ID and Version 2200286v1.0: The unique identifier code for reporting information about race based on the Center for Disease Control and Prevention (CDC) categories. Code set is available as a .pdf file or an Excel spreadsheet. URL: <http://www.cdc.gov/nedss/DataModels/>]

CDC Ethnicity Code

Text field – maximum length = 6

[CDE Public ID and Version 2200284v2.0: The unique identifier for reporting information about ethnicity based on the Centers for Disease Control and Prevention (CDC) categories. Code set is available as a .pdf file or an Excel spreadsheet. URL: <http://www.cdc.gov/nedss/DataModels/>]

Optional Questions

Person Census Tract Code at Enrollment

Text field for six digit number between 000100 and 999998

[CDE Public ID and Version 2943243v1.0: The 2000 United States Census Bureau's Area Classifications code that describes the census tract of a person's residence at time of enrollment into a clinical trial.]

Education Level

Preschool
Kindergarten
1st Grade
2nd Grade
3rd Grade
4th Grade
5th Grade
6th Grade
7th Grade
8th Grade
9th Grade
10th Grade
11th Grade
12th Grade No Diploma
High School Graduate
General Equivalency Diploma
Bachelor Degree
Associate Degree
Academic Doctorate Degree
Master's Degree
Professional Doctorate Degree
VoTech Program
No Formal Schooling
Refused
Some College, No Degree
Don't Know

[CDE Public ID and Version 2674076v2.0: A subdivision of the demographic parameter indicating the highest level of education attained by a human being.]

Educational Attainment

Not high school graduate
High school graduate (including equivalency)
Some college or associate degree
Bachelor's degree
Graduate or professional degree
Master's degree
Doctoral degree or professional degree

[CDE Public ID and Version 2681552v1.0: The subdivisions that summarize the highest level of education attained by a person.]

Marital Status

Divorced
Domestic Partnership
Married
Never Married
Separated
Widowed

[CDE Public ID and Version 2188083v2.0: Text term to describe a self-reported demographic parameter indicating a person's current conjugal status.]

Country of Birth

- Other country
- Other country, specify
- USA
- USA, specify the 2 letter State code, eg NY

[CDE Public ID and Version 2001708v5.0: The type or name of the country in which a person was born.]

End of Demography Module