

# 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

Field Name/Status	Description/Instructions	Format
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
Ethnicity (m)	Enter one of the identified OMB ethnicity categories listed.	Use choice list
Gender (m)	Enter the patient/participant's gender.	Use choice list
Patient's Date of Birth (m)	Enter the patient's full date of birth.	Use prescribed date entry format.
2000 Census Tract Code (m)	Enter the Census Tract code for a location defined by boundaries identified in the year 2000. <b>Note:</b> This question is an extension of the prior item, which covers through 1990.	Six digit number between 000100 and 999998
Country of Residence (c)	Enter the name of the country in which the patient/participant resides.	Enter the full name of country of residence.
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.	Enter the five digit ZIP code plus four digit extension if known
Method of Payment (c)	Enter the code to identify the Primary Payer/insurance carrier information for a patient/participant on a protocol.	Use choice list
Date Completed (c)	Enter the date the Case Report Form (CRF) was completed <b>Note:</b> This question may be unnecessary for electronic data capture system.	Use prescribed date entry format.

CDC Race Code (o)	Enter the code for reporting race as determined by the Center for Disease Control and Prevention (CDC). <b>Note:</b> 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.	Use choice list
CDC Ethnicity Code (o)	Enter the code for reporting ethnicity as determined by the Center for Disease Control and Prevention (CDC). <b>Note:</b> 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.	Use choice list
Education Level (o)	Enter the subdivision that describes the highest level of education completed by a person. <b>Note:</b> This question collects detailed level information, as compared to the question 'Educational Attainment'. Both questions are NOT needed in the same module.	Use choice list
Educational Attainment (o)	Enter the subdivision that summarizes the highest level of education completed by a person. <b>Note:</b> 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
Marital Status (o)	Enter the self-reported term to describe a patient/participant's current conjugal status.	Use choice list
Place of Birth (o)	Enter the geographic location where a patient/participant was born.	Enter full geographic location name

# NCI Standard Demography Module Template

## Mandatory Questions

### Race

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

[CDE Public ID and Version 106v5.1: The patient's self declared racial origination, independent of ethnic origination, using OMB approved categories.]

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### Ethnicity

Hispanic or Latino  
Not Hispanic or Latino  
Not reported  
Unknown

[CDE Public ID and Version 2002440v4.2: The patient's/participant's self declared ethnic origination, independent of racial origination, based on OMB approved categories.]

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### Gender

Female  
Male  
Unknown

[CDE Public ID and Version 62v6.0: The classification of the sex or gender role of the patient.]

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### Patient's Date of Birth

Exchange Format: YYYYMMDD

[CDE Public ID and Version 793v4.0: The month, day and year on which the patient/participant was born.]

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### 2000 Census Tract Code

Text field for six digit number between 000100 and 999998

[CDE Public ID and Version 2681528v1.0: The number that represents the Census Tract for a location as defined by boundaries identified in the year 2000.]

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## Conditional Questions

### Country of Residence

Text field – Maximum length = 75

[CDE Public ID and Version 315v3.0: The name of the country in which the patient resides.]

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## 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.]

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## Method of Payment

- 1 Private Insurance
- 2 Medicare
- 3 Medicare and Private Insurance
- 4 Medicaid
- 5 Medicaid and Medicare
- 6 Military or Veterans Sponsored NOS
- 6a Military Sponsored (Including CHAMPUS & TRICARE)
- 6b Veterans Sponsored
- 7 Self Pay (No Insurance)
- 8 No Means of Payment (No Insurance)
- 98 Other
- 99 Unknown

[CDE Public ID and Version 2003309v3.0: Primary Payer/insurance carrier information at the time of treatment on a protocol.]

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## 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.]

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## Optional Questions

### 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/>]

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### 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/>]

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### 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.]

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### **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.]

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### **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.]

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### **Place of Birth**

Text Field – Maximum length = 50

[CDE Public ID and Version 2188083v2.0: The words that describe the geographic location where a person was born.]

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End of Demography Module