

SUBJECT REGISTRATION CODEBOOK

You must follow this template exactly in order for accrual data to be accurately exported by the Masonic Cancer Center (MCC) for National Institute of Health (NIH) and National Cancer Institute (NCI) reporting purposes. Study staff not correctly using the template will be required to go back and fix incorrectly entered data.

Every field is required by the NIH and NCI unless notated as “optional for non-interventional studies”.

NCI definition of an interventional study:

Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

If your study is interventional, you must list the NIH and NCI under the following sentence in Section 4 of the HIPAA form to inform subjects that identifying information will be captured:

4. Parties Who May Receive or Use My Individual Health Information.

The individual health information disclosed by parties in item 3 and information disclosed by me during the course of the research may be received and used by Dr. XXXX and the researcher’s staff and:

- National Institutes of Health (NIH)
- National Cancer Institute (NCI)

In addition to using the updated template, **you must grant the MCC Data Analyst access to your study in REDCap** to extract data for NIH, NCI, and Cancer Protocol Review Committee (CPRC) reporting purposes. Once given access, MCC will have the ability to extract data without requesting further assistance from study personnel throughout the life cycle of the study. **Please grant access to Vidhya Ramesh, REDCap username: rames007**

This codebook will be reviewed on an annual basis and is subject to change. MCC will require incorporation of any additional fields to all existing MCC REDCap studies and those new fields must be utilized for all new patient enrollment going forward.

Required Form Name: CPRC # MCC Subject Registration Form

Example: 2014LS012 MCC Subject Registration Form

#	Field Label	Field Name	Field Attributes	Tips & Instructions
1	Subject ID	subj_id	text	

#	Field Label	Field Name	Field Attributes	Tips & Instructions																		
2	Zip Code	sr_zip_code	text	Enter 00000 if unknown <i>Optional for non-interventional studies.</i>																		
3	Born in the USA?	sr_born_in_usa	<table border="1"> <tr> <td>0</td> <td>No</td> </tr> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>88</td> <td>Unknown</td> </tr> </table>	0	No	1	Yes	88	Unknown	<i>Optional if zip code already provided.</i>												
0	No																					
1	Yes																					
88	Unknown																					
4	Year of Birth	sr_dob_yyyy	YYYY	Enter 1776 if unknown. <i>Optional for non-interventional studies.</i>																		
5	Month of Birth	sr_dob_mm	MM	Enter 07 for unknown <u>only</u> if 1776 is also listed as the year. <i>Optional for non-interventional studies.</i>																		
6	Gender	sr_gender	<table border="1"> <tr> <td>0</td> <td>Female</td> </tr> <tr> <td>1</td> <td>Male</td> </tr> <tr> <td>2</td> <td>Unspecified</td> </tr> <tr> <td>88</td> <td>Unknown</td> </tr> </table>	0	Female	1	Male	2	Unspecified	88	Unknown	For transgender subjects, please mark the self-reported gender. If left blank please use "2-Unsepcified".										
0	Female																					
1	Male																					
2	Unspecified																					
88	Unknown																					
7	Ethnicity	sr_ethnicity	<table border="1"> <tr> <td>0</td> <td>Hispanic or Latino</td> </tr> <tr> <td>1</td> <td>NOT Hispanic or Latino</td> </tr> <tr> <td>2</td> <td>Not Reported</td> </tr> <tr> <td>88</td> <td>Unknown</td> </tr> </table>	0	Hispanic or Latino	1	NOT Hispanic or Latino	2	Not Reported	88	Unknown	If patient refusal or institutional refusal, check '2 - Not Reported'.										
0	Hispanic or Latino																					
1	NOT Hispanic or Latino																					
2	Not Reported																					
88	Unknown																					
8	Race	sr_race	<table border="1"> <tr> <td>0</td> <td>American Indian or Alaska Native</td> </tr> <tr> <td>1</td> <td>Asian</td> </tr> <tr> <td>2</td> <td>Native Hawaiian or Other Pacific Islander</td> </tr> <tr> <td>3</td> <td>Black or African American</td> </tr> <tr> <td>4</td> <td>White</td> </tr> <tr> <td>5</td> <td>Not Reported</td> </tr> <tr> <td>6</td> <td>Patient Refusal</td> </tr> <tr> <td>7</td> <td>Institutional Refusal</td> </tr> <tr> <td>88</td> <td>Unknown</td> </tr> </table>	0	American Indian or Alaska Native	1	Asian	2	Native Hawaiian or Other Pacific Islander	3	Black or African American	4	White	5	Not Reported	6	Patient Refusal	7	Institutional Refusal	88	Unknown	Check all that apply. If more than one race, please select each race that applies. If subject writes in Other, please, select 'Unknown'.
0	American Indian or Alaska Native																					
1	Asian																					
2	Native Hawaiian or Other Pacific Islander																					
3	Black or African American																					
4	White																					
5	Not Reported																					
6	Patient Refusal																					
7	Institutional Refusal																					
88	Unknown																					
9	Subject Enrollment Date	sr_subject_key_date	MM-DD-YYYY	For studies that do not distinguish date of consent from date of enrollment, record date consent was obtained.																		

#	Field Label	Field Name	Field Attributes						
10	Site Identifier	sr_site_id	<table border="1"> <tr> <td>139049</td> <td>University of Minnesota, Masonic Cancer Center</td> </tr> </table>	139049	University of Minnesota, Masonic Cancer Center				
139049	University of Minnesota, Masonic Cancer Center								
11	Subject Disease Code	sr_subject_disease_code	Use correct ICD-9 Codes						
12	Subject Enrollment Complete	subject_registration_complete	<table border="1"> <tr> <td>0</td> <td>Incomplete</td> </tr> <tr> <td>1</td> <td>Unverified</td> </tr> <tr> <td>2</td> <td>Complete</td> </tr> </table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Tips & Instructions
<p>For other sites, please type in site name, you do not have to provide the number. This UMN number has been provided by the NCI's Clinical Trials Reporting Program (CTRP).</p>
<p>Healthy volunteer ICD-9: V99.</p> <p>V99 is how CTRP defines healthy volunteer even though it is defined in the ICD-9 codes as "Unspecified transport accident".</p>
<p>IMPORTANT: Only subject records that are marked "2 – Complete" will be counted as an accrued subject for NIH/NCI reporting purposes.</p> <p>0 – Incomplete = A subject who consented and never completed any protocol directed activity (surveys, tests, procedures, etc.)</p> <p>1 – Unverified = A subject who has consented, but has not yet completed any protocol directed activity (surveys, tests, procedures, etc.) The subject could have participated in screening activities.</p> <p>2 – Complete = A consented, eligible subject who has participated in ANY protocol directed activity (surveys, tests, procedures, etc.) This does not include activities for screening.</p>