

# TRAINING MANUAL: SUBJECT REGISTRY

## GETTING STARTED WITH SUBJECT REGISTRY

### Training Prerequisites:

- *Brain-CODE Portal Overview* Training Module
- *Subject Naming Convention* Training Module

### What is the Subject Registry?

The Brain-CODE Subject Registry tracks all subject IDs across all projects, subjects and subsystems throughout Brain-CODE. The existence of clinical, molecular or imaging data records for each subject is noted in this centralized Registry, along with a complete record of all known subject identifiers. The Registry stores secure, encrypted Health Card Numbers (eHCNs) for each subject and has features to enable multiple subject IDs representing a single subject to be identified, either through manual matching or eHCN matching.

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## SUBJECT REGISTRY OVERVIEW

### What is the purpose of using Subject Registry?

The Subject Registry allows for the collection of encrypted Health Card numbers. No raw health card information is ever stored on Brain-CODE. This enables researchers to connect and integrate the data they have collected with external databases such as, hospital administrative data collected by Institute of Clinical and Evaluative Sciences via eHCN.

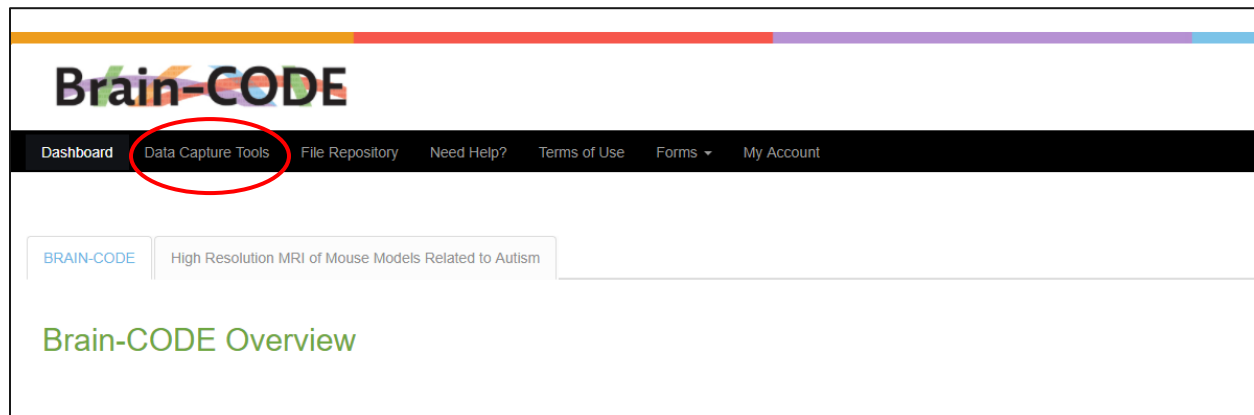
### How are participants added to the Brain-CODE Subject Registry?

New participants are added to the Subject Registry either through direct entry to Subject Registry or via reporter from each of the Brain-CODE sub-platforms.

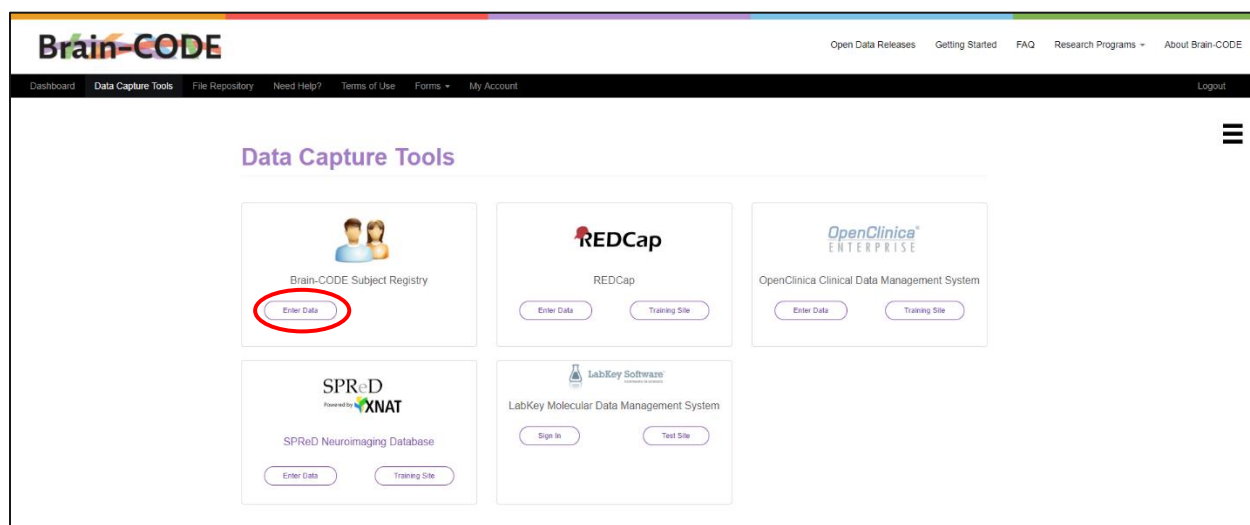
### How should I access the Brain-CODE Subject Registry?

You may access Subject Registry via the Brain-CODE Portal ([www.braincode.ca](http://www.braincode.ca))

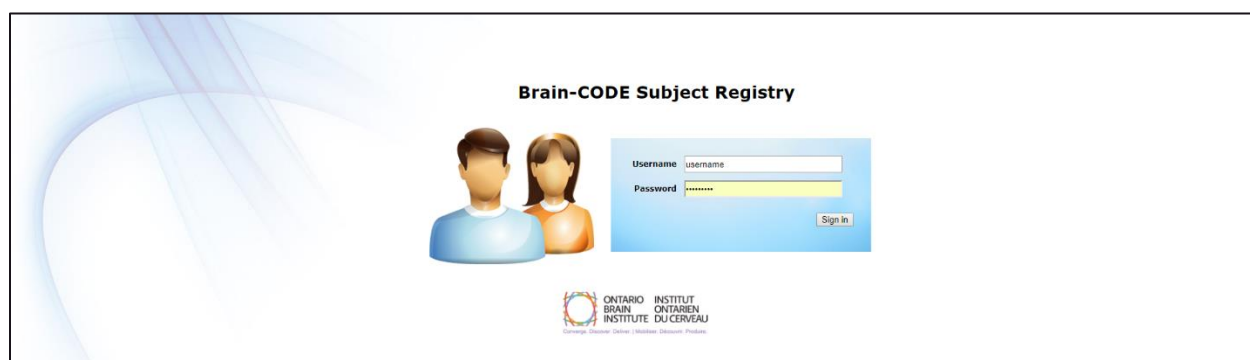
1. Visit the Brain-CODE Portal and use your credentials to log in ([www.braincode.ca](http://www.braincode.ca))
2. Navigate to Data Capture Tools at top of your homepage



3. Click “Enter Data” below the Subject Registry icon to be re-directed to ([www.registry.braincode.ca/sr](http://www.registry.braincode.ca/sr))



4. Login to Subject Registry with your credentials



## 5. Brain-CODE Subject Registry Default View

Projects

Project Name

Search All Projects

Showing Projects 1-2 / 2 (Filtered From 286 Projects)

Project Name	My Project Role	Subjects List	Subject Count	# of Non-Verified Subjects	Project Details	Add Subject	Upload Subjects	Lock
CAN-BIND CBN04 Test	Staff		0	0				
test	Staff		10	5				

Show 10 entries

First | Previous | 1 | Next | Last

- Default view is a list of project names for which you have been granted access
- You may search for a specific project by typing the project name in the search box at the top of the page, then click to initiate your search.

## VIEWING AN EXISTING PARTICIPANT WITHIN A PROJECT

1. Select the list icon from the Project of interest within the Subjects List column

Projects

Project Name

Search All Projects

Showing Projects 1-2 / 2 (Filtered From 286 Projects)

Project Name	My Project Role	Subjects List	Subject Count	# of Non-Verified Subjects	Project Details	Add Subject	Upload Subjects	Lock
CAN-BIND CBN04 Test	Staff		0	0				
test	Staff		10	5				

Show 10 entries

First | Previous | 1 | Next | Last

2. Navigate to the subject of interest, and select the cog icon within the “Subject Details” column to view details about the participant.

Project 'test' Subjects

Subject Reference

Project Details New Subject

Showing Subjects 1-10 / 10

Subject Reference	hGUID	mGUID	Subject Details	Verified	Remove	Created	Updated
TST09_TST_0001		MPMP8K731				18.7 h ago	18.7 h ago
TST02_TST_0099		M1LL4GQXD				Mar/06/2018 11:39	Mar/06/2018 11:39
TST01_TST_1234		M9DBVQF65				18.8 h ago	18.8 h ago

### 3. View the details for the existing subject within a project

**Subject 'TST01\_TST\_1234' Details**

[Project Details](#)
[Project's Subjects](#)

[Basic Details](#)
[Health Card Number Matching](#)
[Manual Matching](#)
[Informed Consent Forms](#)
[Change History](#)

\* Subject Reference:

Encrypted Health Card Number:

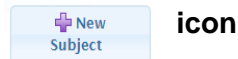
Subject is Verified:  yes  no

Notes:

\* Required Field

## ADDING A NEW SUBJECT TO A PROJECT

### 1. Within Project View select the “New Subject” plus sign icon



**Project 'test' Subjects**

Subject Reference

[Project Details](#)
[New Subject](#)


Showing Subjects 1-10 / 10

Subject Reference	hGUID	mGUID	Subject Details	Verified	Remove	Created	Updated
TST09_TST_0001		MPMP8K731				18.7 h ago	18.7 h ago
TST02_TST_0099		M1LL4GQXD				Mar/06/2018 11:39	Mar/06/2018 11:39
TST01_TST_1234		M9DBVQF65				18.8 h ago	18.8 h ago

### 2. Enter the Subject Reference number.

- Ensure that it meets Brain-CODE naming convention standards (See Brain-CODE Subject Naming Training Module)
- Ensure that the subject reference number is unique (You will receive a warning if it has already been entered within the system)
- This field must never contain identifying information, such as raw health card number, subject name or date of birth


**Add New Subject to Project 'test'**

* Subject Reference: ?	<input type="text" value="TST01_TST_4321"/>
Encrypted Health Card Number: ?	
Subject is Verified: ?	<input type="radio"/> yes <input checked="" type="radio"/> no
Notes:	<div style="border: 1px solid #ccc; height: 40px;"></div>

\* Required Field

3. Select the Key  icon to enter the Subject's Health Card Number

**Add New Subject to Project 'test'**

* Subject Reference: ?	<input type="text" value="TST01_TST_4321"/>
Encrypted Health Card Number: ?	
Subject is Verified: ?	<input type="radio"/> yes <input checked="" type="radio"/> no
Notes:	<div style="border: 1px solid #ccc; height: 40px;"></div>

\* Required Field

#### 4. Enter Subject's Health Card Number

- a. Health card numbers are entered twice to reduce **data entry error**. If you receive the message **The Health Card Numbers provided do not match**, then you must re-enter both health card numbers to ensure data entry is correct.
- b. **Encryption occurs in your browser, and therefore in your institution.** Health card numbers are **never** added to the Brain-CODE database. Once the Health Card Number has been entered, it is encrypted and only the first few digits of the encrypted version are displayed to prove that the number has been stored in the system.

\* Required Field

✓ Save Subject

Health Card Number

Enter the health card number:  
1212121212

Re-enter the health card number:  
1212121212

Encrypt Cancel

#### 5. Select Encrypt (Encryption occurs in browser and therefore within your institution)

\* Required Field



✓ Save Subject

Encrypting Health Card Number

Encryption in progress. Please wait.

Progress bar: 75% complete



## 6. Optional: Add notes to Notes Field

<b>* Subject Reference:</b> ?	TST01_TST_4321
<b>Encrypted Health Card Number:</b> ?	 1111872920... 
<b>Subject is Verified:</b> ?	<input type="radio"/> yes <input checked="" type="radio"/> no
<b>Notes:</b>	notes...

**\* Required Field**

Save Subject  Cancel

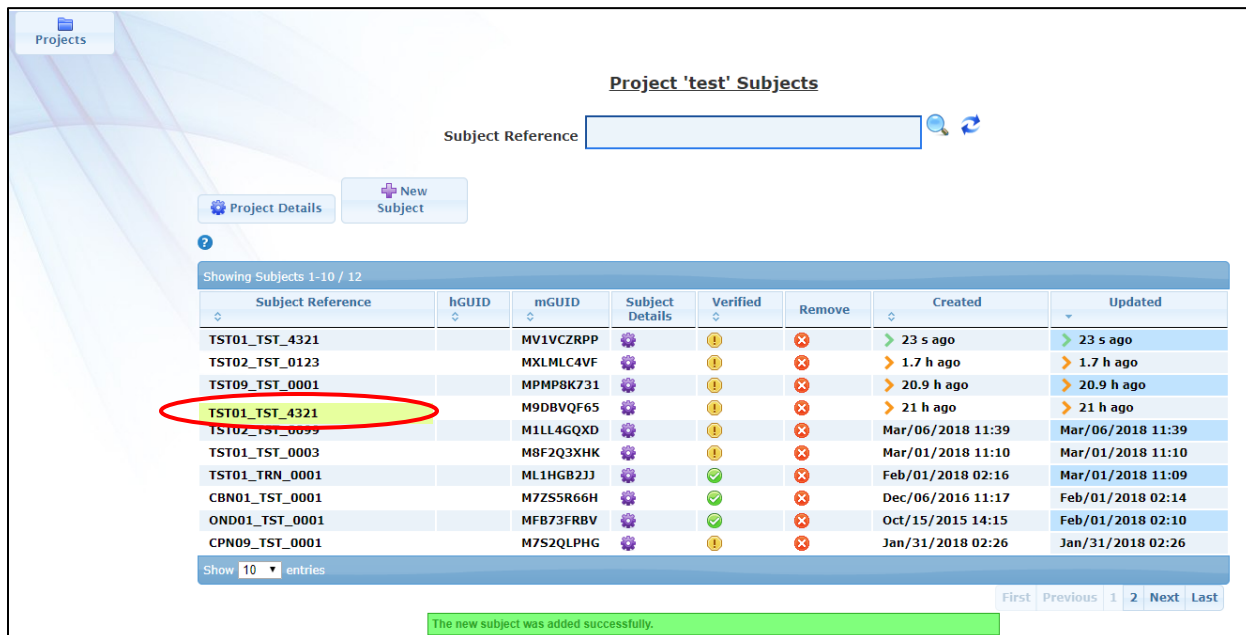
## 7. Select Save Subject

<b>* Subject Reference:</b> ?	TST01_TST_4321
<b>Encrypted Health Card Number:</b> ?	 1111872920... 
<b>Subject is Verified:</b> ?	<input type="radio"/> yes <input checked="" type="radio"/> no
<b>Notes:</b>	notes...

**\* Required Field**

Save Subject  Cancel

## 8. Confirm Subject is successfully added by viewing Subject Reference column within the Subjects list for the Project.



Project 'test' Subjects

Subject Reference

Project Details [New Subject](#)

Showing Subjects 1-10 / 12

Subject Reference	hGUID	mGUID	Subject Details	Verified	Remove	Created	Updated
TST01_TST_4321		MV1VCZRPP		!	✖	23 s ago	23 s ago
TST02_TST_0123		MXLMLC4VF		!	✖	1.7 h ago	1.7 h ago
TST09_TST_0001		MPMP8K731		!	✖	20.9 h ago	20.9 h ago
TST01_TST_4321		M9DBVQF65		!	✖	21 h ago	21 h ago
TST02_TST_0099		M1LL4GQXD		!	✖	Mar/06/2018 11:39	Mar/06/2018 11:39
TST01_TST_0003		M8F2Q3XHK		!	✖	Mar/01/2018 11:10	Mar/01/2018 11:10
TST01_TRN_0001		ML1HGB2JJ		✓	✖	Feb/01/2018 02:16	Mar/01/2018 11:09
CBN01_TST_0001		M7Z5SR66H		✓	✖	Dec/06/2016 11:17	Feb/01/2018 02:14
OND01_TST_0001		MFB73FRBV		✓	✖	Oct/15/2015 14:15	Feb/01/2018 02:10
CPN09_TST_0001		M7S2QLPHG		!	✖	Jan/31/2018 02:26	Jan/31/2018 02:26

Show 10 entries

First Previous 1 2 Next Last

The new subject was added successfully.

## HEALTH CARD NUMBER ENCRYPTION (ADDITIONAL INFORMATION)

**Encrypted Health Card Numbers (eHCN):** Health Card Numbers are stored in an encrypted format in the Subject Registry to prevent identifying information from leaving your institution, while still permitting matching of subjects based on the encrypted value.

### Where does Encryption Occur?

Health card numbers entered into the Subject Registry are encrypted within your browser, and therefore will never leave your institution.

### What is the purpose for entering the Health Card Number twice when adding a new subject?

This will reduce the risk of data entry error. If the two numbers do not match one another, you will be prompted to re-enter the health card numbers to ensure accuracy of the data.

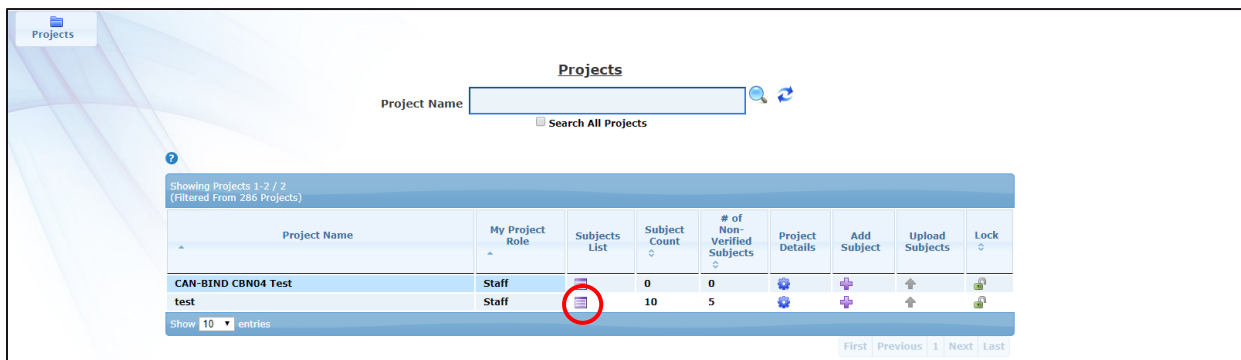
## HOW TO ADD INFORMED CONSENT FORMS TO A SUBJECT

### What is Informed Consent?


The dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.

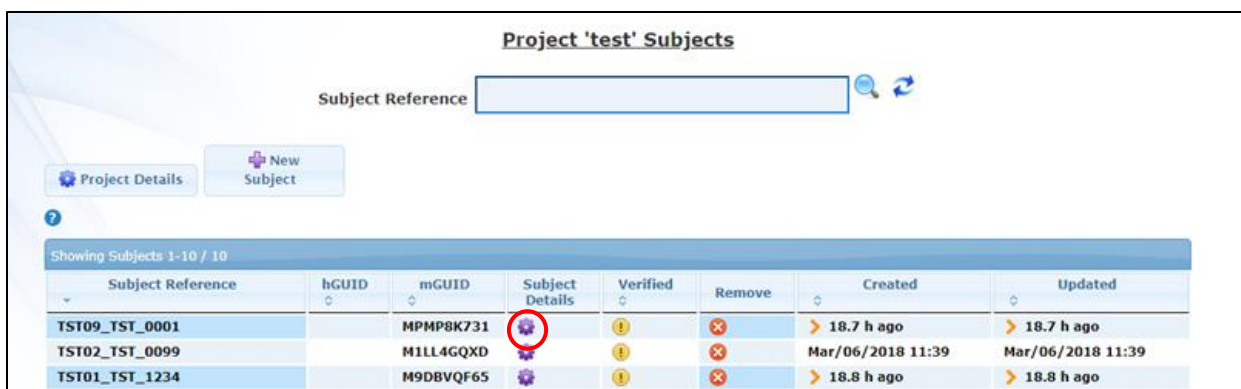


1. Select the list icon  from the Project of interest within the Subjects List column



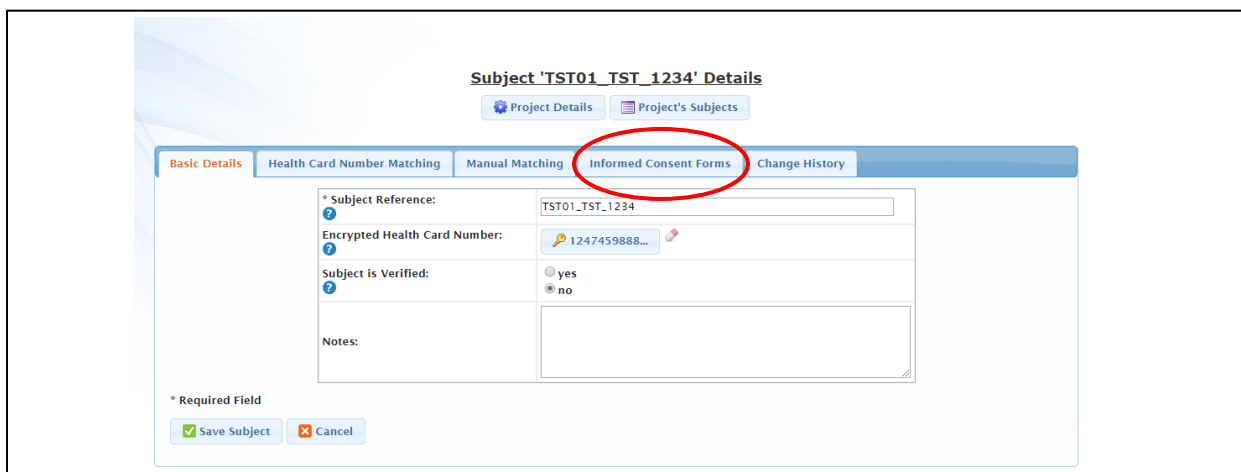
The screenshot shows the 'Projects' interface. At the top, there is a search bar for 'Project Name' and a 'Search All Projects' button. Below this is a table with the following columns: Project Name, My Project Role, Subjects List, Subject Count, # of Non-Verified Subjects, Project Details, Add Subject, Upload Subjects, and Lock. The table contains two rows: 'CAN-BIND CBN04 Test' and 'test'. The 'Subjects List' column for the 'test' row has a list icon circled in red. The table also shows 'Showing Projects 1-2 / 2 (Filtered From 286 Projects)' and 'Show 10 entries'.

2. Navigate to the subject of interest, and select the cog icon  within the "Subject Details" column to view details about the participant.




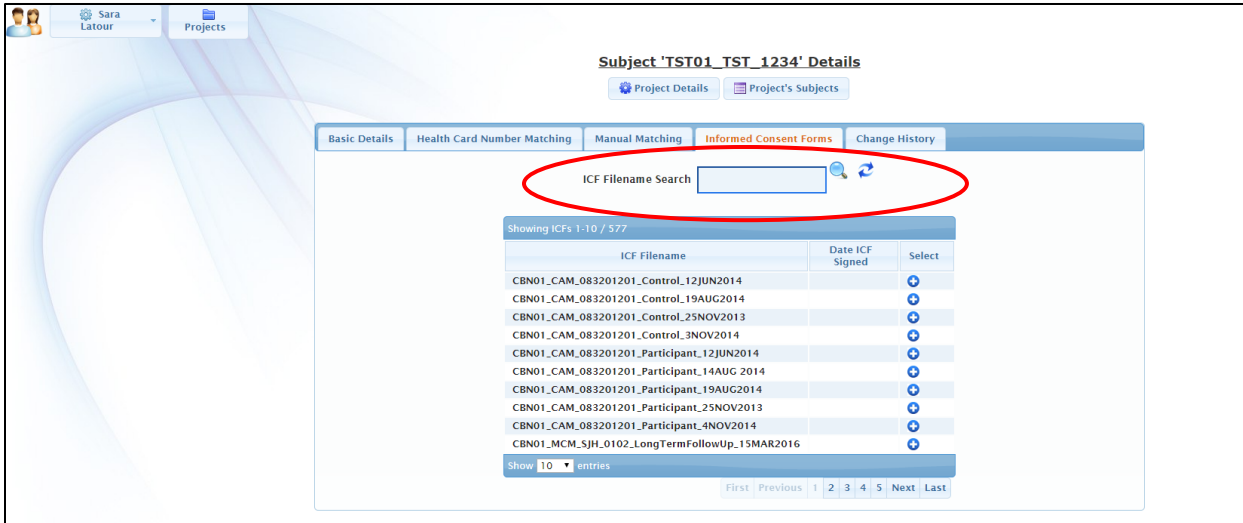
The screenshot shows the 'Project 'test' Subjects' interface. At the top, there is a search bar for 'Subject Reference' and a 'New Subject' button. Below this is a table with the following columns: Subject Reference, hGUID, mGUID, Subject Details, Verified, Remove, Created, and Updated. The table contains three rows: 'TST09\_TST\_0001', 'TST02\_TST\_0099', and 'TST01\_TST\_1234'. The 'Subject Details' column for the 'TST01\_TST\_1234' row has a cog icon circled in red. The table also shows 'Showing Subjects 1-10 / 10'.

3. Select the "Informed Consent Forms" tab from the Subject Details menu.



The screenshot shows the 'Subject 'TST01\_TST\_1234' Details' interface. At the top, there are two tabs: 'Project Details' and 'Project's Subjects'. Below this is a sub-menu with four tabs: 'Basic Details', 'Health Card Number Matching', 'Manual Matching', 'Informed Consent Forms', and 'Change History'. The 'Informed Consent Forms' tab is circled in red. The main content area shows a form with the following fields: Subject Reference (TST01\_TST\_1234), Encrypted Health Card Number (1247459888...), Subject is Verified (radio buttons for yes and no), and Notes. At the bottom, there are 'Save Subject' and 'Cancel' buttons.



4. Search for the correct Informed Consent form signed by the Subject using the search bar. Press  to initiate the search.













Subject 'TST01\_TST\_1234' Details

Project Details Project's Subjects

Basic Details Health Card Number Matching Manual Matching **Informed Consent Forms** Change History


ICF Filename Search   

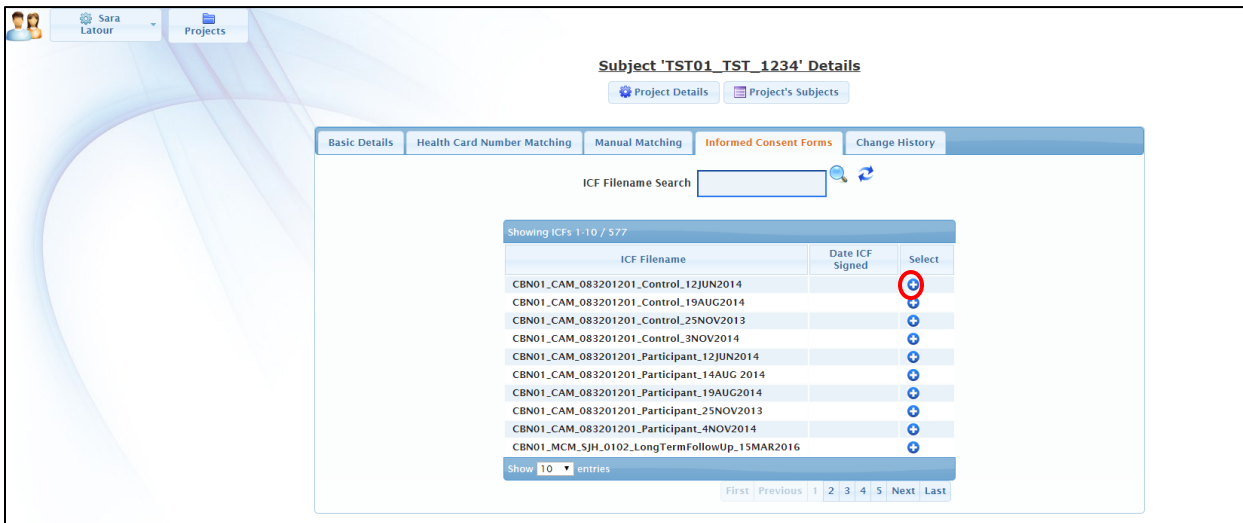
Showing ICFs 1-10 / 577

ICF Filename	Date ICF Signed	Select
CBN01_CAM_083201201_Control_12JUN2014		
CBN01_CAM_083201201_Control_19AUG2014		
CBN01_CAM_083201201_Control_25NOV2013		
CBN01_CAM_083201201_Control_3NOV2014		
CBN01_CAM_083201201_Participant_12JUN2014		
CBN01_CAM_083201201_Participant_14AUG 2014		
CBN01_CAM_083201201_Participant_19AUG2014		
CBN01_CAM_083201201_Participant_25NOV2013		
CBN01_CAM_083201201_Participant_4NOV2014		
CBN01_MCM_SJH_0102_LongTermFollowUp_15MAR2016		

Show 10 entries

First Previous 1 2 3 4 5 Next Last



5. To indicate that a particular Informed Consent Form has been signed by the subject, click on  in the Select column.













Subject 'TST01\_TST\_1234' Details

Project Details Project's Subjects

Basic Details Health Card Number Matching Manual Matching **Informed Consent Forms** Change History

ICF Filename Search   

Showing ICFs 1-10 / 577

ICF Filename	Date ICF Signed	Select
CBN01_CAM_083201201_Control_12JUN2014		
CBN01_CAM_083201201_Control_19AUG2014		
CBN01_CAM_083201201_Control_25NOV2013		
CBN01_CAM_083201201_Control_3NOV2014		
CBN01_CAM_083201201_Participant_12JUN2014		
CBN01_CAM_083201201_Participant_14AUG 2014		
CBN01_CAM_083201201_Participant_19AUG2014		
CBN01_CAM_083201201_Participant_25NOV2013		
CBN01_CAM_083201201_Participant_4NOV2014		
CBN01_MCM_SJH_0102_LongTermFollowUp_15MAR2016		

Show 10 entries




First Previous 1 2 3 4 5 Next Last

6. Enter the date that the subject signed the Informed Consent Form within the calendar window.











The screenshot shows the 'Subject 'TST01\_TST\_1234' Details' page with the 'Informed Consent Forms' tab selected. A table lists ICF files with columns for 'ICF Filename', 'Date ICF Signed', and 'Select'. A calendar window is overlaid on the table, showing the month of March 2018. The date 27 is highlighted in yellow, indicating it has been selected.

ICF Filename	Date ICF Signed	Select
CBN01_CAM_083201201_Control_12JUN2014		
CBN01_CAM_083201201_Control_19AUG2014		
CBN01_CAM_083201201_Control_25NOV2013		
CBN01_CAM_083201201_Control_3NOV2014		
CBN01_CAM_083201201_Participant_12JUN2014		
CBN01_CAM_083201201_Participant_14AUG_2014		
CBN01_CAM_083201201_Participant_19AUG2014		
CBN01_CAM_083201201_Participant_25NOV2013		
CBN01_CAM_083201201_Participant_4NOV2014		

7. Confirm the form was added by checking that the blue icon  changed to a green checkmark icon 

- If the date selected is too early for that particular ICF you will get an error message.
- If you need to remove your selection, click on the  in the Select column. The icon will change to  Confirm your deletion by clicking on 
- If you do not want to delete, simply leave the screen at this point (the deletion will be disregarded)

The screenshot shows the same 'Subject 'TST01\_TST\_1234' Details' page. The date 'Mar 22, 2018' has been entered in the 'Date ICF Signed' column for the first row. The 'Select' column for that row now displays a green checkmark icon, indicating the form has been successfully added.

ICF Filename	Date ICF Signed	Select
CBN01_CAM_083201201_Control_12JUN2014	Mar 22, 2018	
CBN01_CAM_083201201_Control_19AUG2014		
CBN01_CAM_083201201_Control_25NOV2013		
CBN01_CAM_083201201_Control_3NOV2014		
CBN01_CAM_083201201_Participant_12JUN2014		
CBN01_CAM_083201201_Participant_14AUG_2014		
CBN01_CAM_083201201_Participant_19AUG2014		
CBN01_CAM_083201201_Participant_25NOV2013		
CBN01_CAM_083201201_Participant_4NOV2014		
CBN01_MCM_SJH_0102_LongTermFollowUp_15MAR2016		

## CONTACT INFORMATION

**Subject Registry Administrator:** [registry@braincode.ca](mailto:registry@braincode.ca)

**General Help:** [help@braincode.ca](mailto:help@braincode.ca)

## RESOURCES

**Brain-CODE Portal:**

<https://www.braincode.ca>

**Informed Consent and Governance Policies:**

<https://www.braincode.ca/content/governance>

<https://www.braincode.ca/sites/default/files/about/OBI-Governance-v2-2016-02-03.pdf>

**Subject Registry Training Video:**

<https://www.youtube.com/watch?v=2OKFOkL37aw>