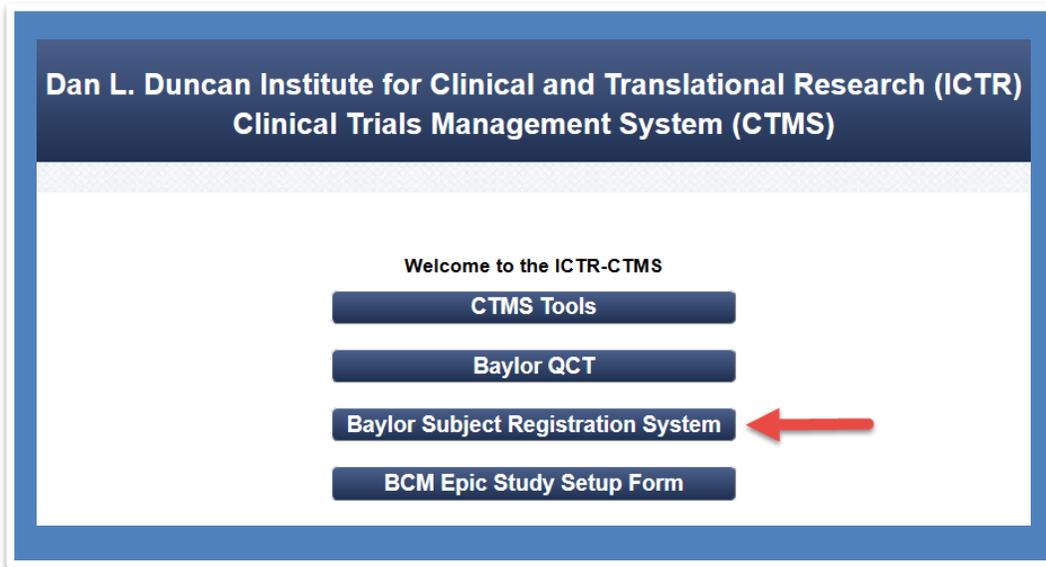


Baylor Subject Registration System

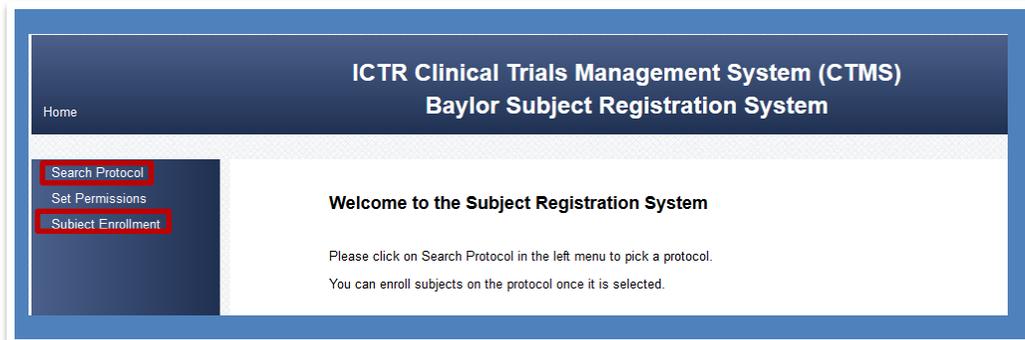
CTMS Module

Patient registration in the Baylor *Subject Registration System* (SRS) is required for all subjects enrolled by BCM faculty. New subjects must be registered in the SRS within 48 hours of enrollment. Registration in the Baylor SRS will integrate with BCM Epic.

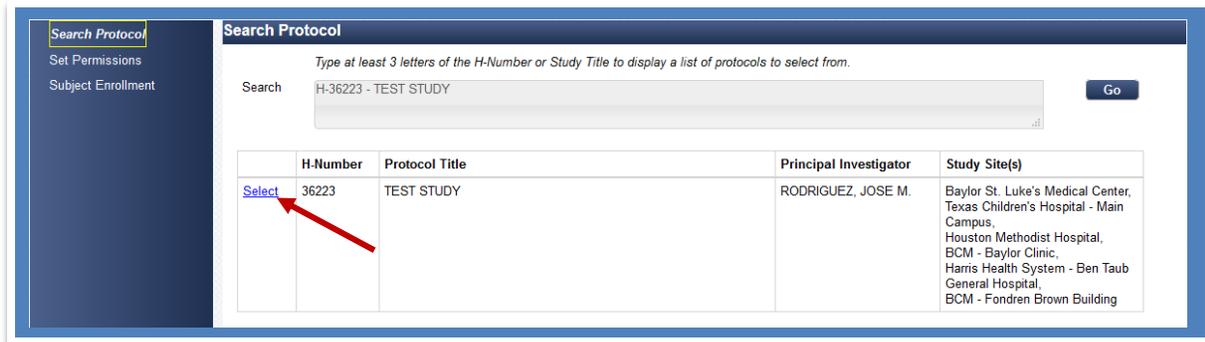
Step 1. Select “Baylor Subject Registration System” button after logging into the CTMS system to initiate the process.



Step 2. Select “Subject Enrollment” or “Search Protocol” on the left hand menu to select the protocol in which the subject is enrolled.



Step 3. Search for the protocol, select it from the list and click **“Go”**. Click on the **“Select”** link to begin the subject registration process.



The screenshot shows a web interface for searching protocols. On the left is a navigation menu with 'Search Protocol' highlighted. The main area has a search bar containing 'H-36223 - TEST STUDY' and a 'Go' button. Below the search bar is a table with the following data:

	H-Number	Protocol Title	Principal Investigator	Study Site(s)
Select	36223	TEST STUDY	RODRIGUEZ, JOSE M.	Baylor St. Luke's Medical Center, Texas Children's Hospital - Main Campus, Houston Methodist Hospital, BCM - Baylor Clinic, Harris Health System - Ben Taub General Hospital, BCM - Fondren Brown Building

If you do not see the protocol listed, search for it by entering the H number or the study title in the search bar. In the event you still do not see the protocol it may be for one of the following reasons:

1. The study is not be in the QCT system.
2. The study is not in the CTMS system.
3. A BCM Epic Study Setup Form for the study has not been completed.

Step 4. Enter required subject-specific information. Fields marked with a red asterisk (*) is required and the others, if applicable, are optional. Click “Save” when finished.

- **Name:** Last, First, Middle
- **Gender:** Male , Female
- **Date of birth:** use calendar button to select date
- **MRN:** enter medical record number
- **Ethnicity:** Hispanic, non-Hispanic, declined
- **Race:** American Indian, Hawaiian or Pacific Islander, Asian, Black or African American, White or Caucasian, More than one race, other, Declined; specify race if “other” is selected
- **Trial specific subject ID:** Number assigned by sponsor
- **Site:** Sites selected in Protocol Information section where subject accrual will occur
- **Initial consent date:** use calendar button to select date
- **Subject Status:** On study, off study
 - If subject status is “Off Study”, the off study date, off study reason are subsequently required.
 - Off Study Reason—withdrawn, complete, lost to follow up, screen/randomization failure; enter withdrawn reason

The screenshot shows a web application interface for entering subject information. On the left is a dark blue sidebar with navigation links: 'Search Protocol', 'Set Permissions', and 'Subject Enrollment' (highlighted with a yellow box). The main content area is titled 'Study Subject Information' and contains the following sections:

- Protocol Information:** A box containing 'BCM Protocol #' (H - 36223), 'Study Title' (TEST STUDY), and 'Principal Investigator' (RODRIGUEZ, JOSE M.). Below this is a 'Back to Subject Enrollment page' button.
- Demographics:** Fields for 'Last name', 'First name', and 'Middle name' (text inputs); 'Gender' (dropdown menu), 'Birth date' (calendar icon), 'Ethnicity' (dropdown menu), 'Race' (dropdown menu), and 'Please specify race' (text input).
- Subject MRNs:** A box with 'Site' (dropdown menu) and 'MRN' (text input).
- Study Subject Information:** Fields for 'Study specific subject ID' (text input), 'Enrolling site' (dropdown menu), 'Initial consent date' (calendar icon), 'Subject status' (dropdown menu), 'Off study date' (text input), 'Off study reason' (dropdown menu), and 'Withdrawn reason' (text input).

At the bottom of the form are two buttons: 'Save' (highlighted with a red box) and 'Cancel'.

Appendix A: Setting Permissions

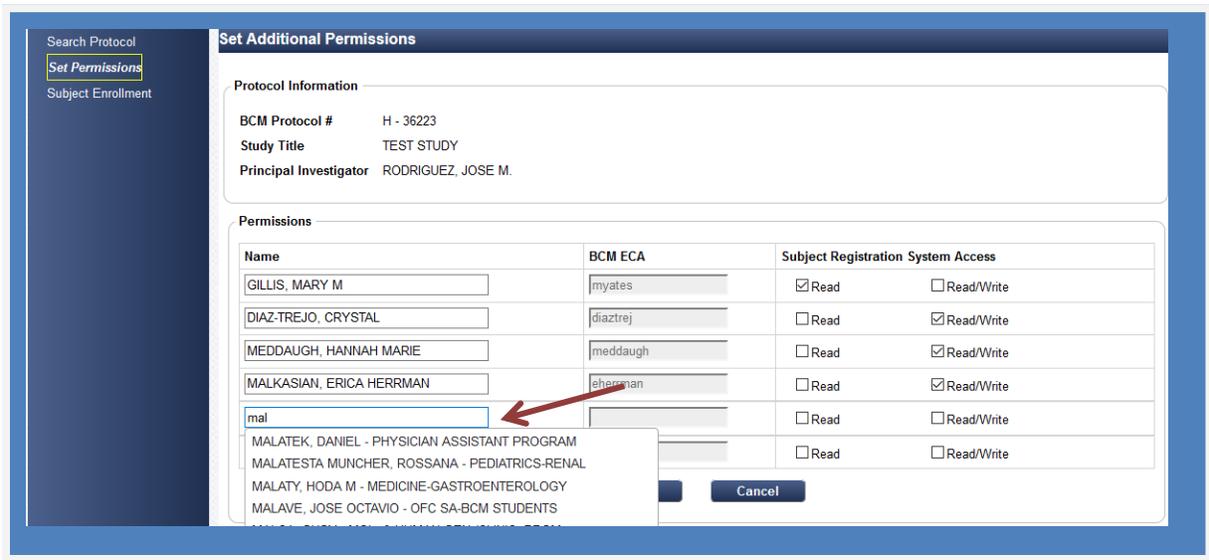
Setting permission allows the addition of study personnel who may have access the Subject Registration System for a particular trial. Initial permission is granted to the PI and Administrative contact, please request permission from these individuals.

Step 1. To begin, select “Set Permissions” on the left hand menu. To provide access to additional personnel, select the “Add Users” button. You may add as many additional users as needed.



The screenshot shows the 'Set Additional Permissions' interface. On the left is a navigation menu with 'Set Permissions' highlighted. The main area is titled 'Set Additional Permissions' and contains two sections: 'Protocol Information' and 'Permissions'. The 'Protocol Information' section displays: BCM Protocol # H - 36223, Study Title TEST STUDY, and Principal Investigator RODRIGUEZ, JOSE M. The 'Permissions' section is currently empty, and a red arrow points to the 'Add Users' button located at the bottom right of this section.

Step 2. Under the Name column, begin by typing the last name of the contact to whom you are granting access to the system. Once three (3) letters are entered, you will be able to select from a drop down list, continue typing to narrow down the list.



The screenshot shows the 'Set Additional Permissions' interface with the 'Permissions' section populated. A search filter 'mal' is entered in the 'Name' column, and a dropdown list of suggestions is visible. A red arrow points to the dropdown list. The table below shows the current state of the permissions list.

Name	BCM ECA	Subject Registration System Access	
GILLIS, MARY M	myates	<input checked="" type="checkbox"/> Read	<input type="checkbox"/> Read/Write
DIAZ-TREJO, CRYSTAL	diaztrej	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
MEDDAUGH, HANNAH MARIE	meddaugh	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
MALKASIAN, ERICA HERRMAN	eherrman	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
mal		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write
MALATEK, DANIEL - PHYSICIAN ASSISTANT PROGRAM		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write
MALATESTA MUNCHER, ROSSANA - PEDIATRICS-RENAL		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write
MALATY, HODA M - MEDICINE-GASTROENTEROLOGY		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write
MALAVE, JOSE OCTAVIO - OFC SA-BCM STUDENTS		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write

Step 3. Select the desired contact from the list. The BCM ECA is automatically populated. Select the system access type you will be granting to the new user. You can choose read (only able to view the form, no editing functions) or read/write (can view and edit the form) access to the subject registration system. Once you have completed setting the permission, click **“Save”**.

Set Additional Permissions

Protocol Information

BCM Protocol # H - 36223
 Study Title TEST STUDY
 Principal Investigator RODRIGUEZ, JOSE M.

Permissions

Name	BCM ECA	Subject Registration System Access	
GILLIS, MARY M	jmyates	<input checked="" type="checkbox"/> Read	<input type="checkbox"/> Read/Write
DIAZ-TREJO, CRYSTAL	ldiaztrej	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
MEDDAUGH, HANNAH MARIE	jmeddaugh	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
MALKASIAN, ERICA HERRMAN	jherrman	<input type="checkbox"/> Read	<input checked="" type="checkbox"/> Read/Write
		<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write

Save **Cancel**