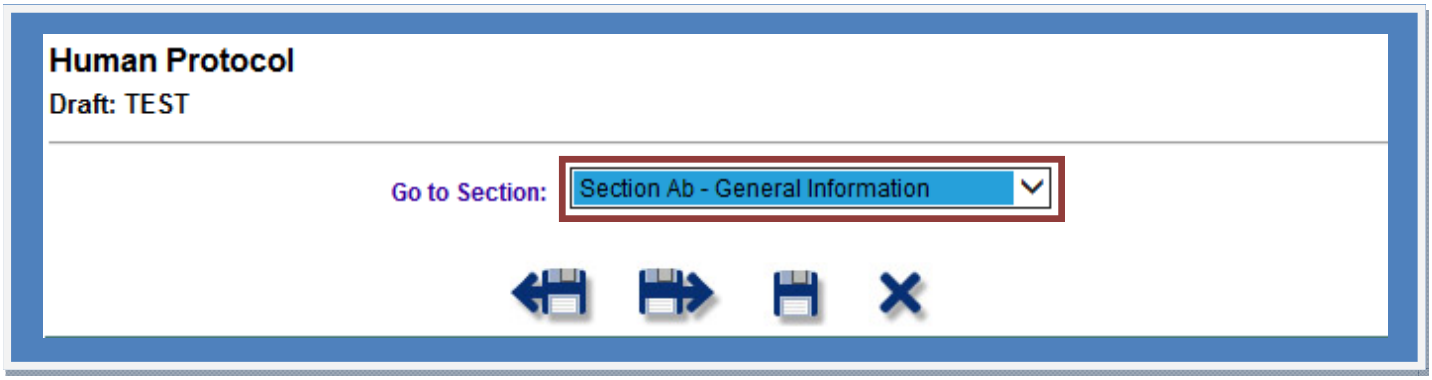
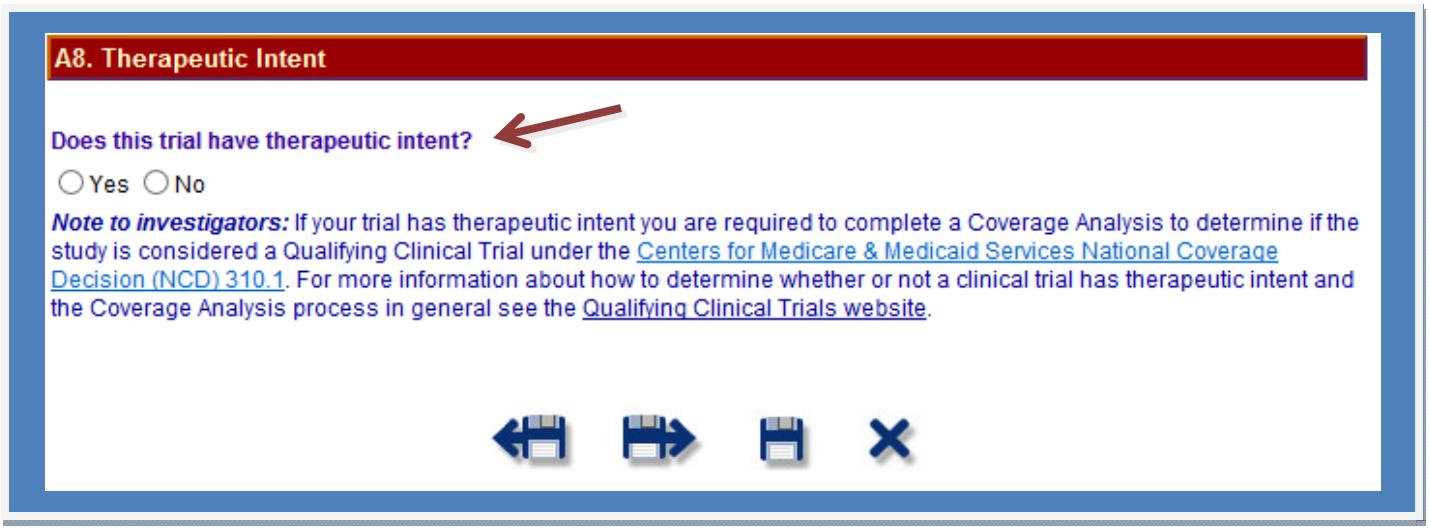
Qualifying Clinical Trials Module Instructions

Accessing QCT Module through BRAIN ESP1

To initiate the Qualifying Clinical Trial (QCT) process in BRAIN ESP1, the answer to question A8, which is in Section Ab, must be provided.

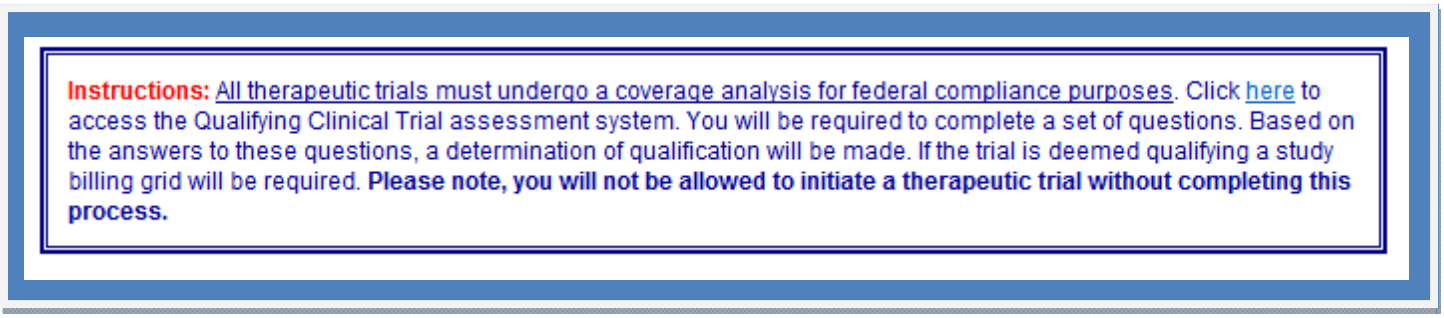


Section A8 asks whether the trial has therapeutic intent. For purposes of the QCT process, a trial with therapeutic intent is one with an objective or aim that assesses the effects of the intervention on patient outcomes (i.e., prolongation of life, shrinkage of tumor, or improvement in quality of life). A trial is not considered therapeutic if it is exclusively designed to test toxicity or disease pathophysiology. Links to the Center for Medicare & Medicaid Services site are available for further information about this policy.

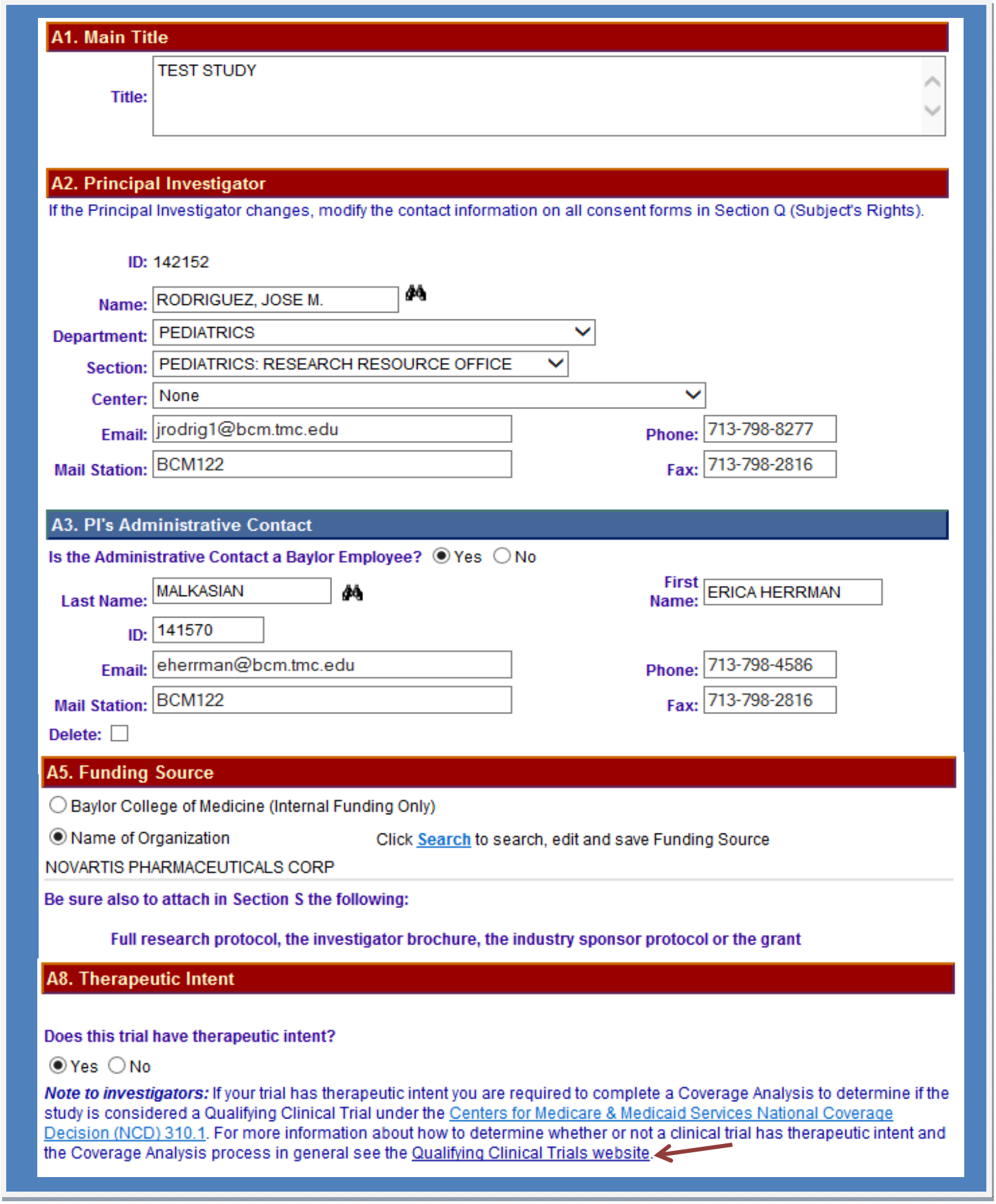


If the trial does not have therapeutic intent, i.e. "No" is selected for question A8, then the trial is not a qualifying clinical trial and the process is complete. No additional requirements or sign offs are needed.

If the trial has therapeutic intent, i.e. "Yes" is selected for question A8, then the trial may be a qualifying trial and completion of the QCT module is required. When yes is selected, pop up instructions in the box below appear. Included in the instructions is a hyperlink to the QCT module.



Completion of sections A1, A2, A3, A5 and A8 in the BRAIN application are required prior to initiating the QCT module (The information contained in these fields will transfer to the QCT module's protocol information page)



A1. Main Title

Title: TEST STUDY

A2. Principal Investigator

If the Principal Investigator changes, modify the contact information on all consent forms in Section Q (Subject's Rights).

ID: 142152

Name: RODRIGUEZ, JOSE M.

Department: PEDIATRICS

Section: PEDIATRICS: RESEARCH RESOURCE OFFICE

Center: None

Email: jrodrig1@bcm.tmc.edu Phone: 713-798-8277

Mail Station: BCM122 Fax: 713-798-2816

A3. PI's Administrative Contact

Is the Administrative Contact a Baylor Employee? (•) Yes ( ) No

Last Name: MALKASIAN First Name: ERICA HERRMAN

ID: 141570

Email: eherrman@bcm.tmc.edu Phone: 713-798-4586

Mail Station: BCM122 Fax: 713-798-2816

Delete: ☐

A5. Funding Source

( ) Baylor College of Medicine (Internal Funding Only)

(•) Name of Organization Click Search to search, edit and save Funding Source

NOVARTIS PHARMACEUTICALS CORP

Be sure also to attach in Section S the following:

Full research protocol, the investigator brochure, the industry sponsor protocol or the grant

A8. Therapeutic Intent

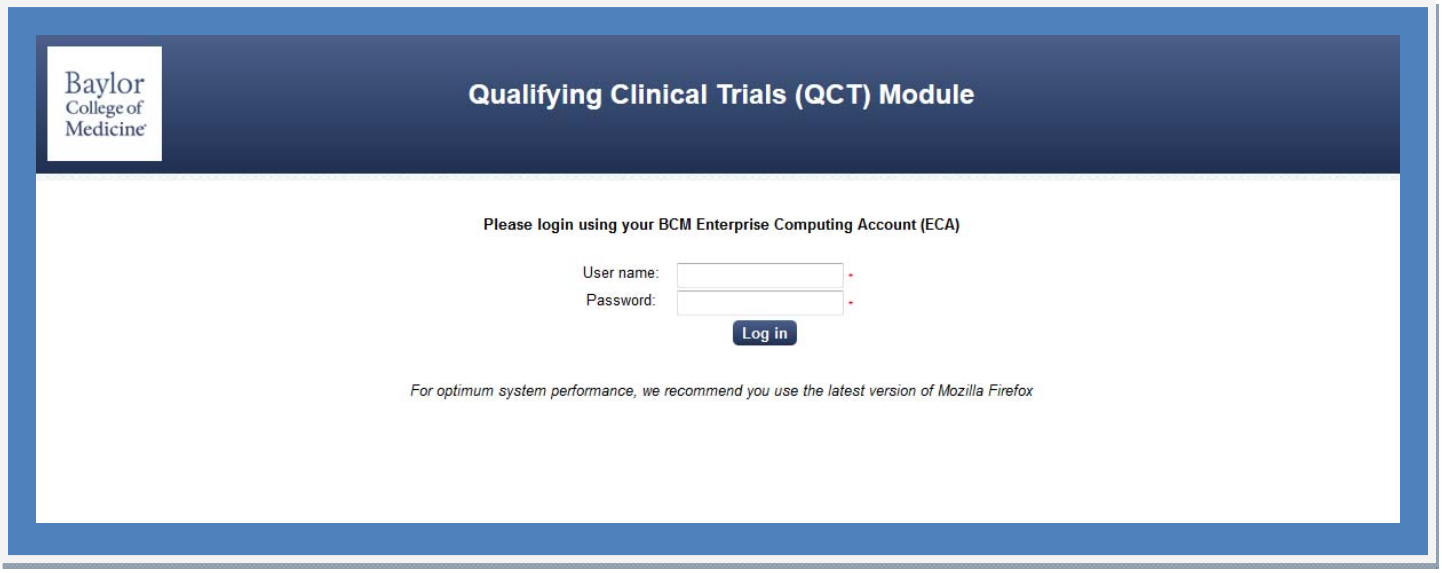
Does this trial have therapeutic intent?

(•) Yes ( ) No

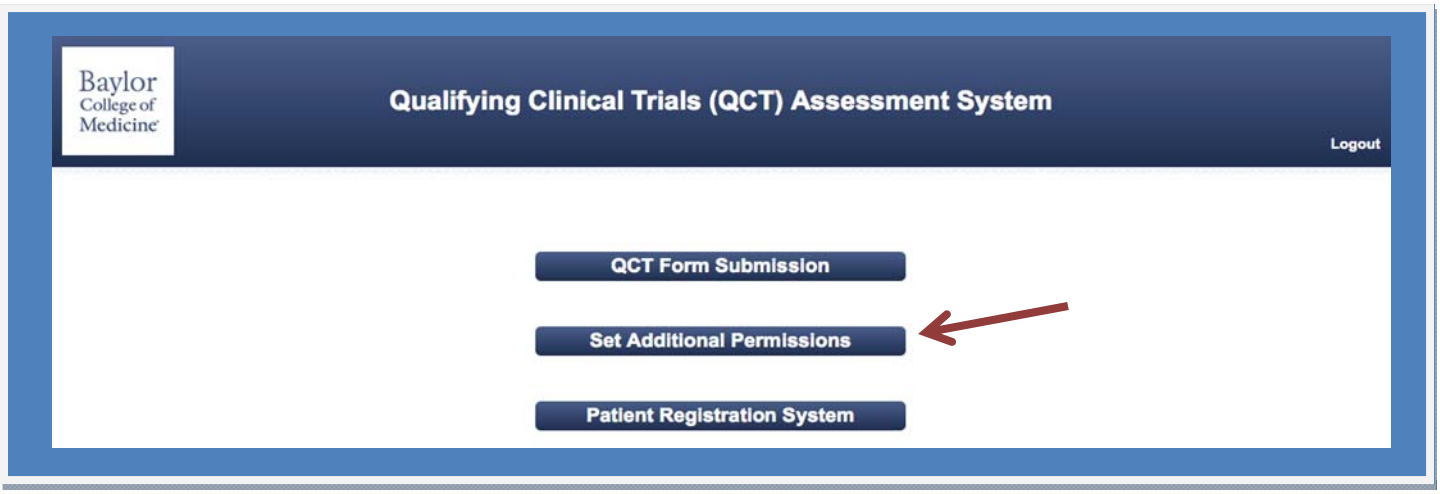
Note to investigators: If your trial has therapeutic intent you are required to complete a Coverage Analysis to determine if the study is considered a Qualifying Clinical Trial under the Centers for Medicare & Medicaid Services National Coverage Decision (NCD) 310.1. For more information about how to determine whether or not a clinical trial has therapeutic intent and the Coverage Analysis process in general see the Qualifying Clinical Trials website.

Link to the Qualiying Clinical Trial website by clicking on the hyperlink in BRAIN at the arrow above or go directly to this link: https://ictr.research.bcm.edu/BaylorQCT/Login.aspx

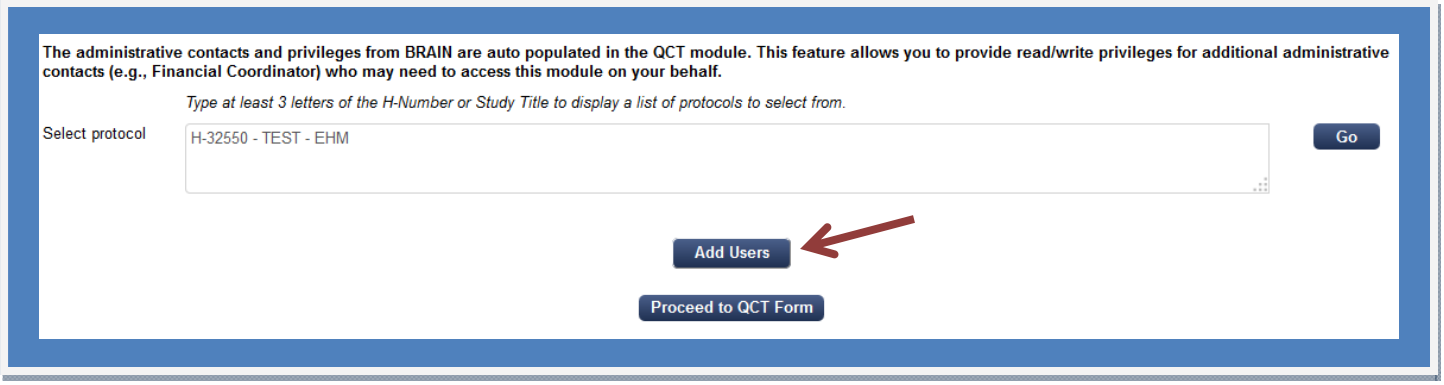
If prompted, enter your Enterprise Computing Account (ECA) user name and password to log into the system. (Same user name and password used to access your desktop and BCM email)



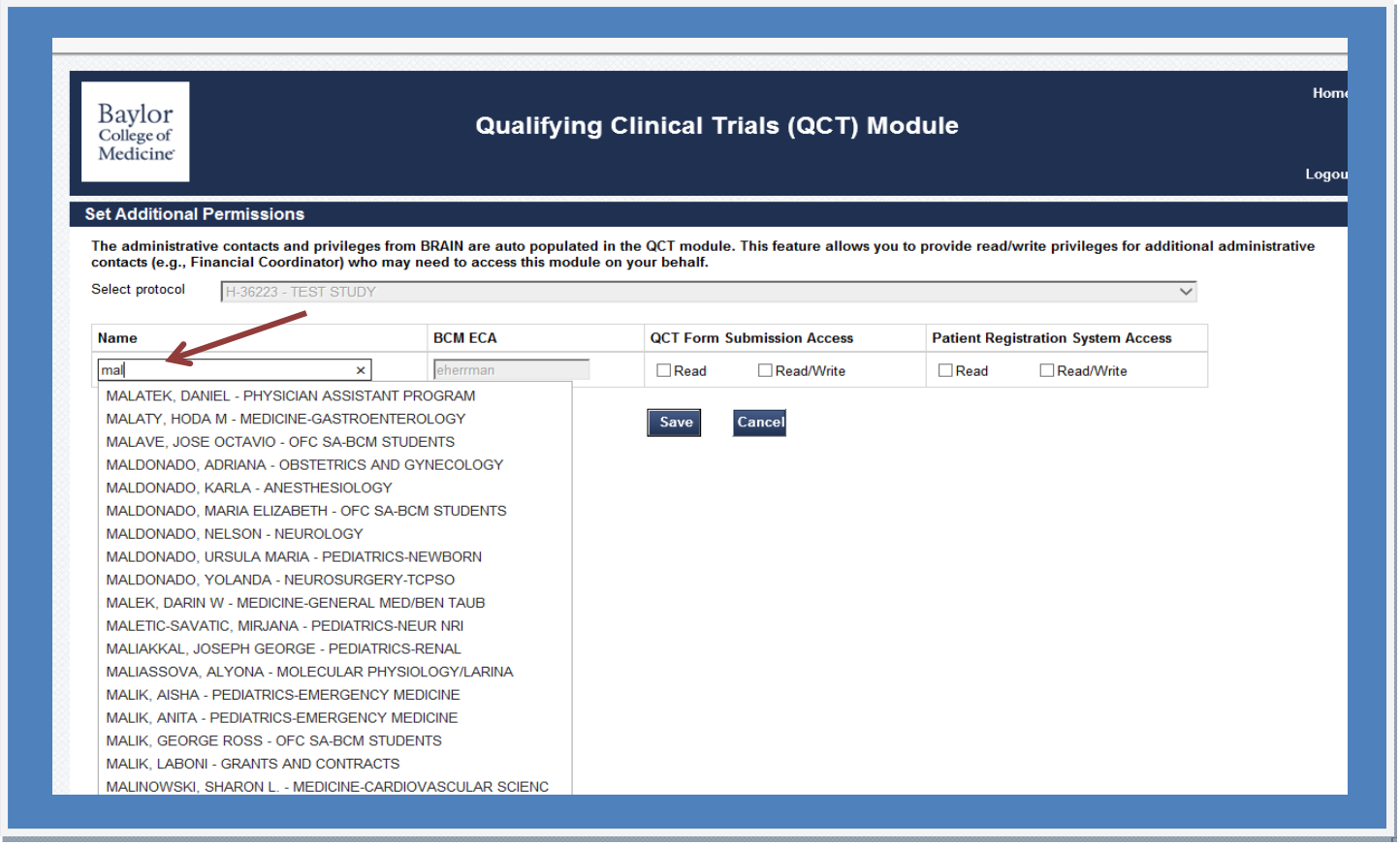
*Once in the QCT module, a landing page provides access to the QCT assessment form (**QCT Form Submission**) as well as the ability to provide additional users access to the QCT module for your trial (**Set Additional Permissions**).*



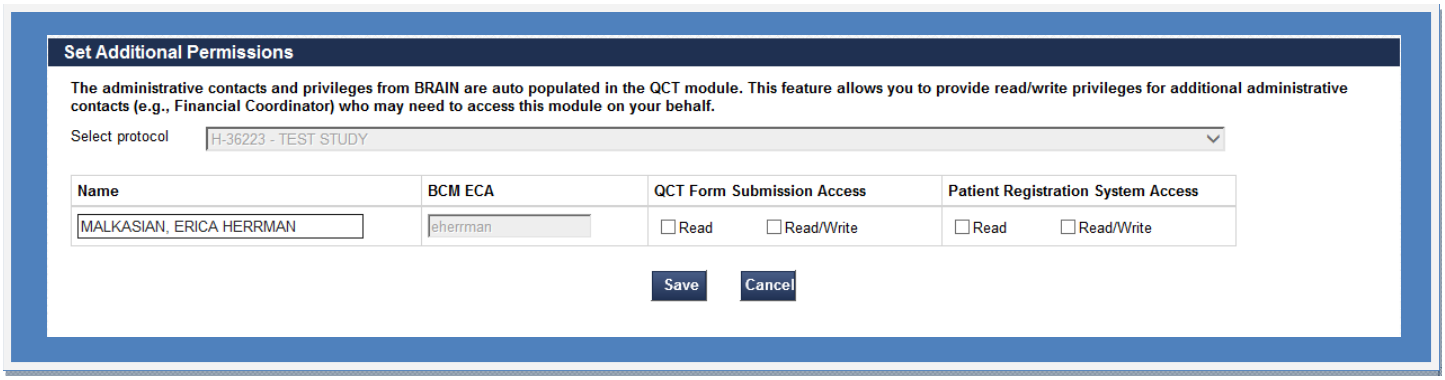
*Setting permission allows the addition of personnel who may have access the QCT form for a particular trial. Initial permission is granted based on BRAIN ESP1 access. To provide access to additional personnel, select the "**Add Users**" button. You may add as many additional users as needed.*



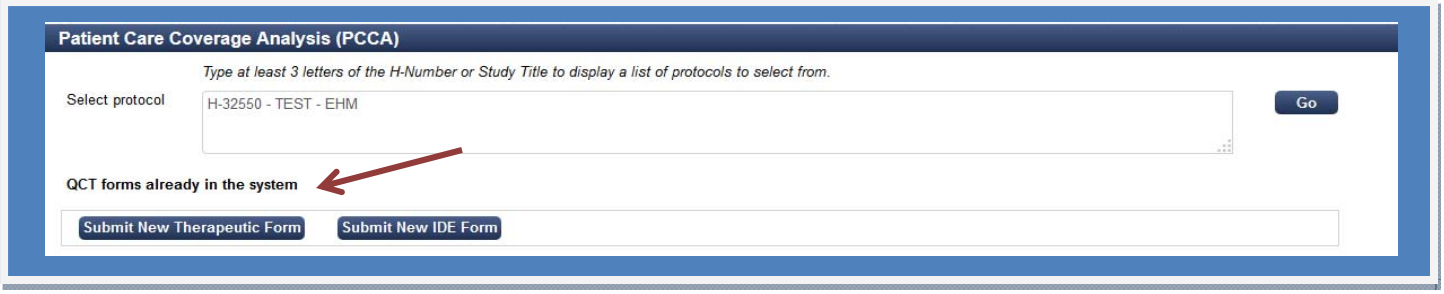
Under the Name column, begin by typing the last name of the contact to whom you are granting access to the system. Once three (3) letters are entered, you will be able to select from a drop down list, continue typing to narrow down the list.



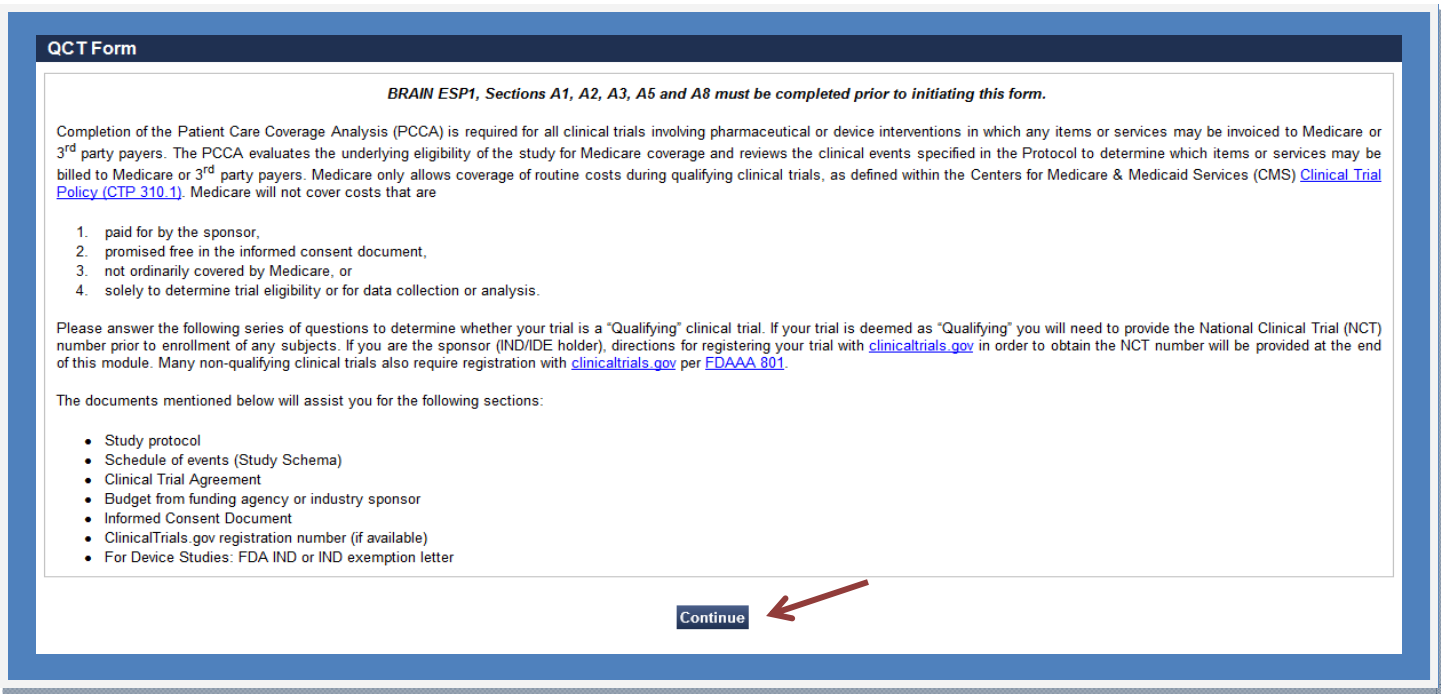
*Select the desired contact from the list. The BCM ECA is automatically populated. Select the system access and type you will be granting to the new user. You can choose read (only able to view the form, no editing functions) or read/write (can view and edit the form) access to the QCT form or patient registration system. Once you have completed setting the permission, click "**Save**". Access may be granted to only one system, if applicable.*



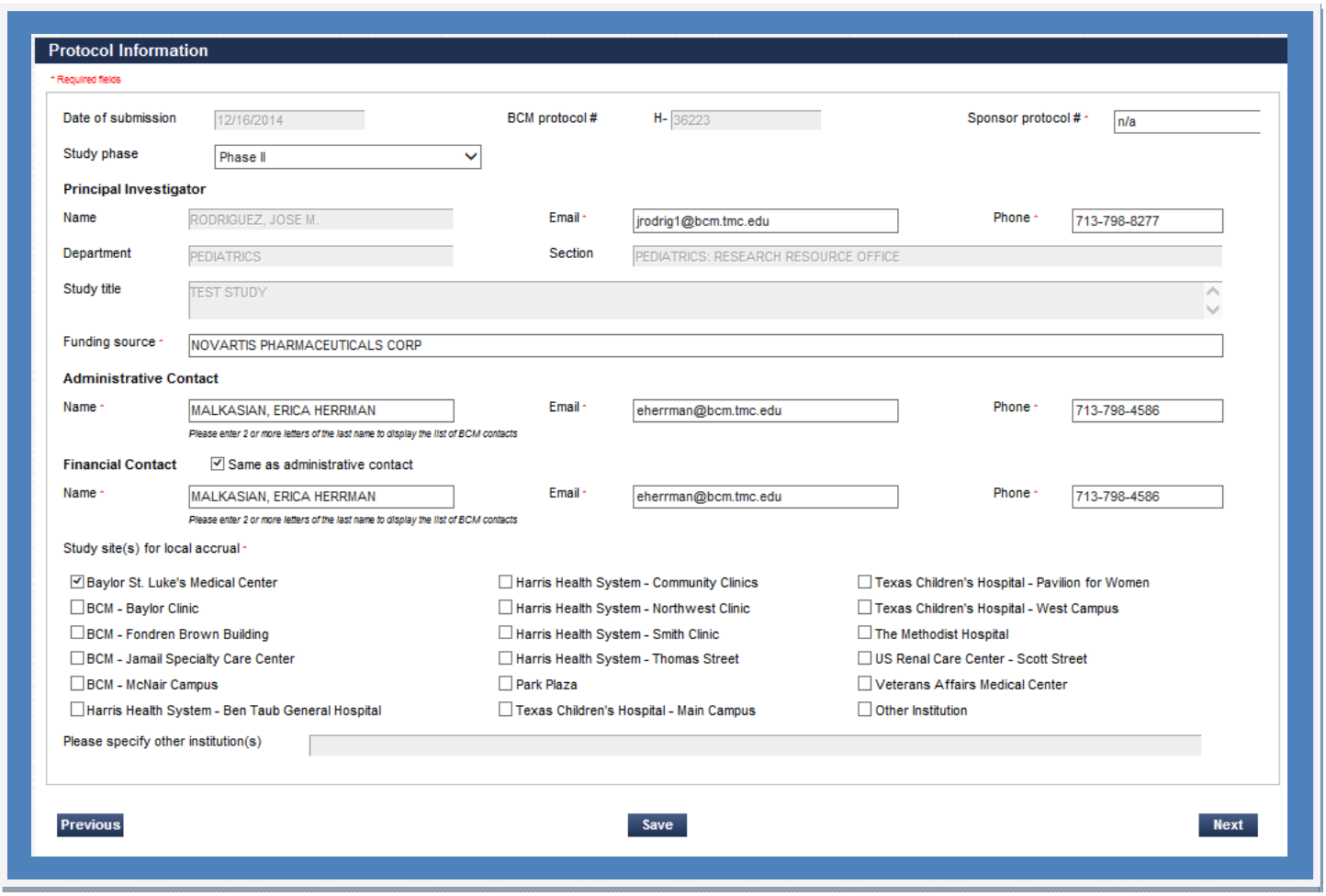
*Select "**Proceed to QCT Form**" to complete the QCT process. In the next page select the type of clinical trial QCT form being completed. There are two choices: "**Submit New Therapeutic Form**" or "**Submit New IDE Form**". For clinical trials involving drugs and biologics select the therapeutic form. For clinical trials involving devices, select the IDE form. For those studies that involve **both** drugs/biologics and devices, contact QCT@bcm.edu.*



*The landing page contains additional information and links that will help during the QCT process. This page also highlights the section in BRAIN that need to be completed and documents to have on hand. Select "**Continue**" to proceed to the QCT form.*



The next page, protocol information section, includes prepopulated fields (gray background; these fields are populated by data entered in BRAIN ESP 1) that are non-editable as well as several blank fields. Those blank fields with a red asterisk (*) are required in order to continue to the next section.



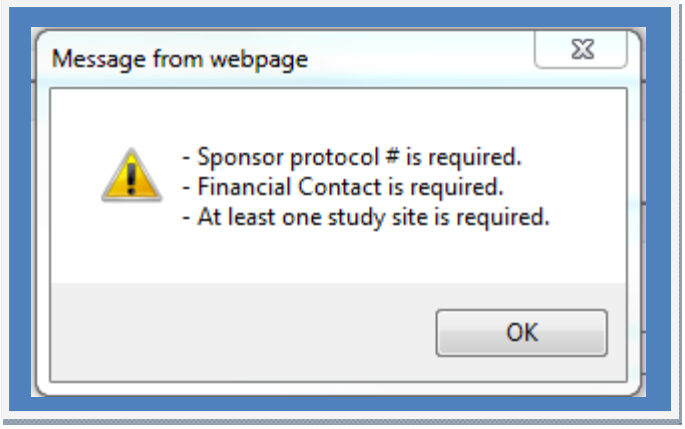
Required items:

1. *Sponsor protocol number - enter the sponsor's protocol number, if none exists enter n/a.*
2. *Financial Contact - include financial contact for the selected study. Start typing person's last name for drop down list. Contact may be the same as administrative contact.*
3. *Study site for patient accrual - select the study site(s) where patients will be consented and seen. You may select more than one site. If site is not in list, select other and type in the site.*

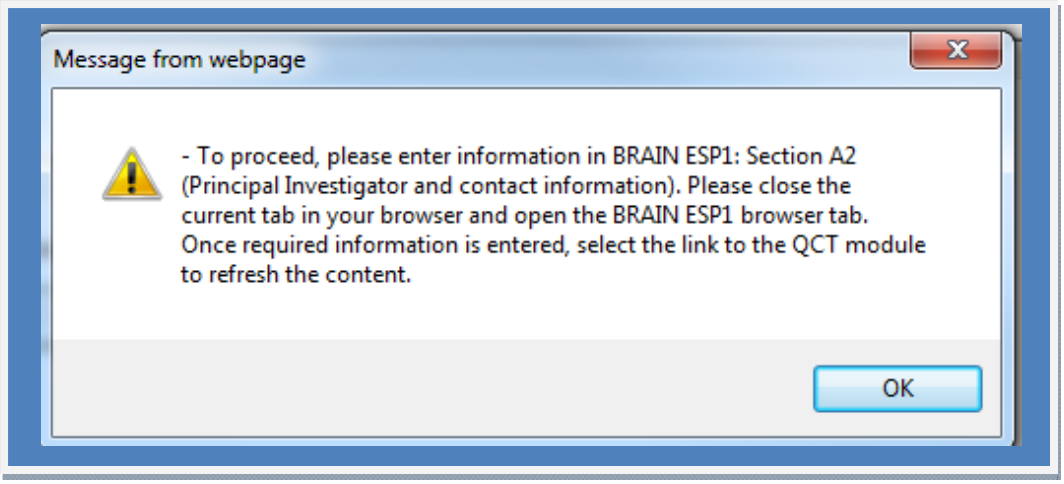
If required fields are missing, a message will prompt users to enter missing fields and will not allow users to proceed to next page.

Non-required item:

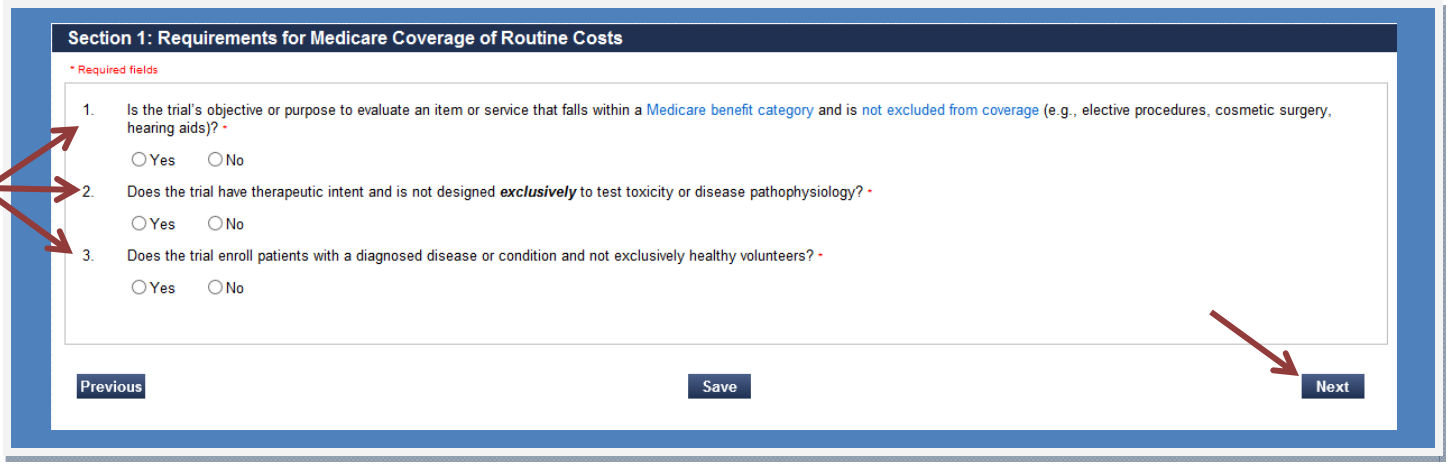
- *Study phase - enter if study has an associated phase*



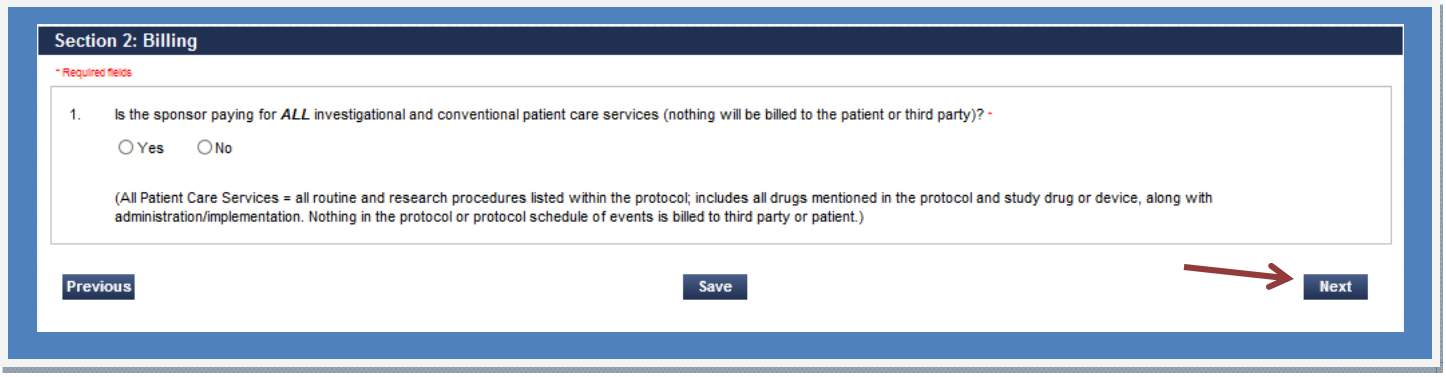
If required sections (A1, A2, A3, A5 and A8) in BRAIN ESP1 are not completed prior to entering the QCT module a message will prompt user to return to BRAIN ESP1, update the section and refresh the information by selecting the QCT module link in BRAIN.



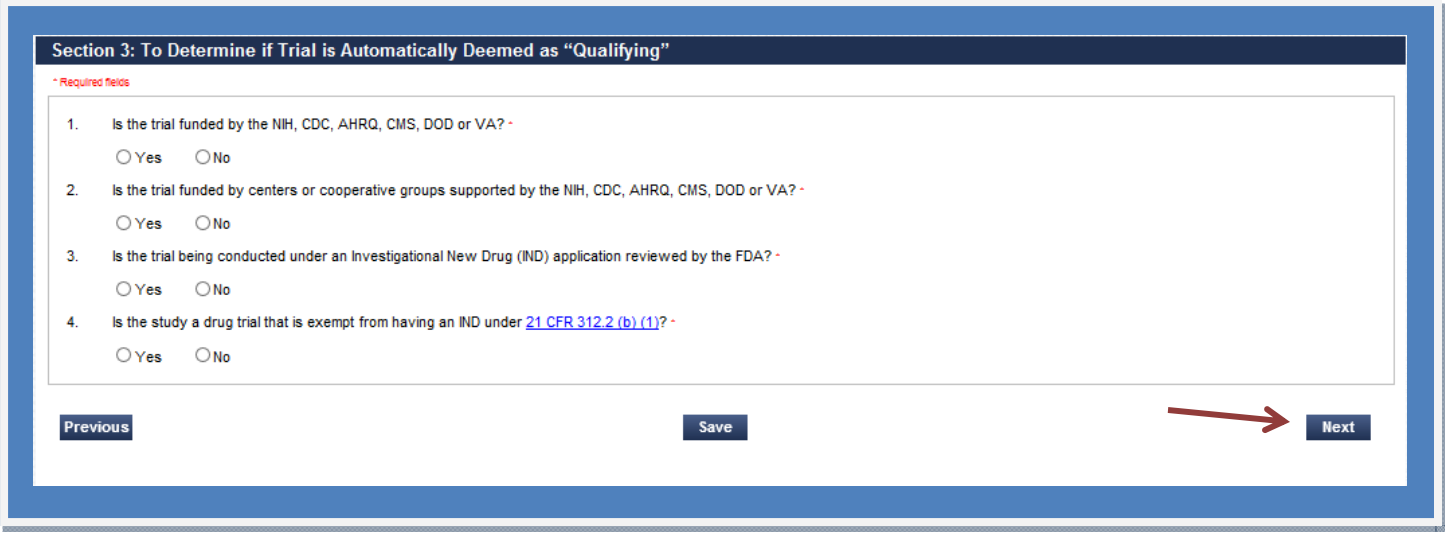
*Once the protocol information section is complete, section one (1) of the module is available. Answers to the three (3) mandatory criteria found in the CMS clinical trial policy (links to the policy are embedded in the question) must be provided. Once all three questions are answered, proceed by clicking the "**Next**" button.*



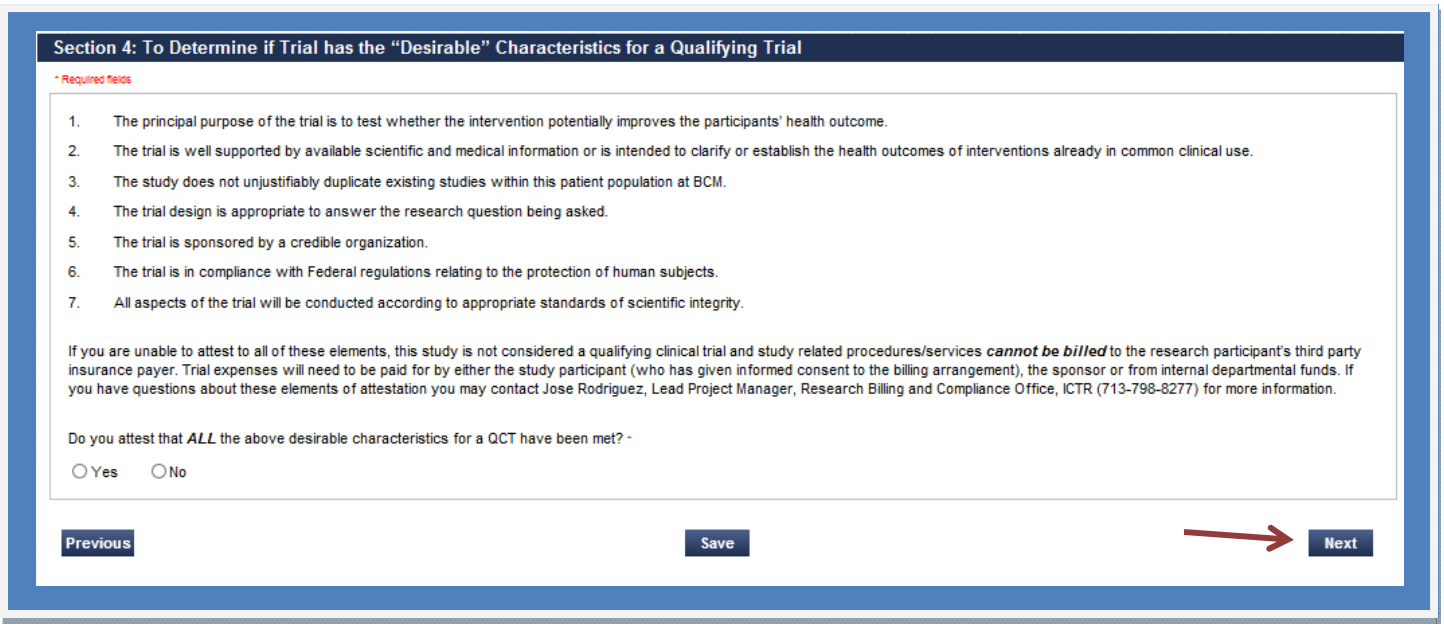
*Section two (2) pertains to billing of patient care items. If the study sponsor has agreed to pay all patient care items related to the protocol and nothing will be billed to the patient, select "Yes". If this is not know or if the routine costs are being billed to patient/ insurance/Medicare, select "No" and click **Next** to proceed.*



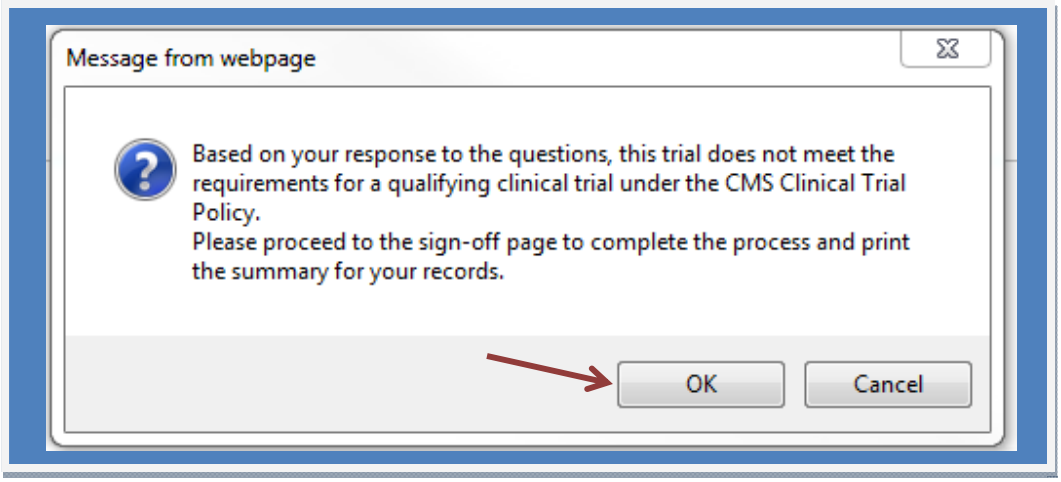
*For section three (3), questions are related to the seven (7) desirable characterizes outlines in the CMS clinical trial policy and those that automatically qualify for those characteristics. Select appropriate answer to all four (4) questions, click **Next** to proceed.*



*Section four (4) outlines the seven (7) desirable characteristics and asks investigator to attest that all seven (7) desirable characteristics are found in the clinical trial. Select appropriate answer and click **Next** to proceed.*



*If the study is a non qualifying clinical trial, the following message appears in a pop up window. Click **OK** to proceed.*



For non-qualifying clinical trials, the signature page contains a summary of the protocol information, how the QCT questions were answered and the determination. There are no additional requirements besides sign off and completion of the process.

Signature

Preview QCT Form Summary

BRAIN number:	H-36223	**Initial submit date:**	12/04/2014
Protocol title:	TEST STUDY		
Funding source:			
Principal Investigator:			
Name:	RODRIGUEZ, JOSE M.	BCM ID:	142152
Department/Section:	PEDIATRICS: RESEARCH RESOURCE OFFICE	Phone:	713-798-8277
Center:		Email:	jrodrig1@bcm.tmc.edu
Administrative Contact:			
Name:	MALKASIAN, ERICA HERRMAN	BCM ID:	141570
Department/Section:		Phone:	713-798-4586
Center:		Email:	eherrman@bcm.tmc.edu
Financial Contact:			
Name:	MALKASIAN, ERICA HERRMAN	BCM ID:	141570
Department/Section:		Phone:	713-798-4586
Center:		Email:	eherrman@bcm.tmc.edu

Yes	No	Requirements for Coverage of Routine Costs
	✔	1. Is the trial's objective or purpose to evaluate an item or service that falls within a Medicare benefit category and is not excluded from coverage (e.g., elective procedures, cosmetic surgery, hearing aids)?
✔		2. Does the trial have therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology?
✔		3. Does the trial enroll patients with a diagnosed disease or condition and not exclusively healthy volunteers?

Based on the response to the questions above, this trial is NOT deemed a Qualifying Clinical Trial under the CMS Clinical Trial Policy.

* Required fields

NCT #

Finalized Billing Grid Browse...

1

PI signoff * ☐ I sign-off on this Patient Care Coverage Analysis form.

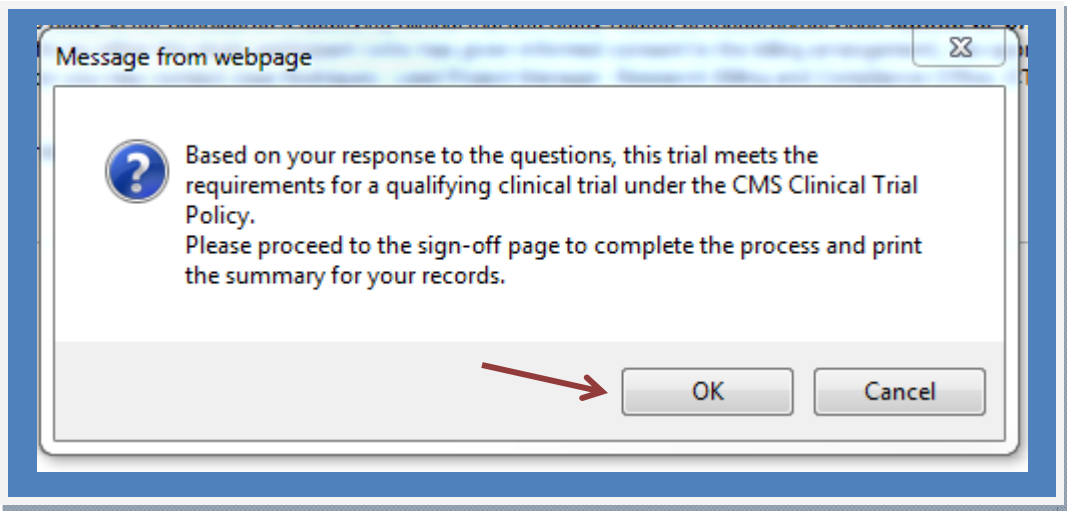
Signoff date *

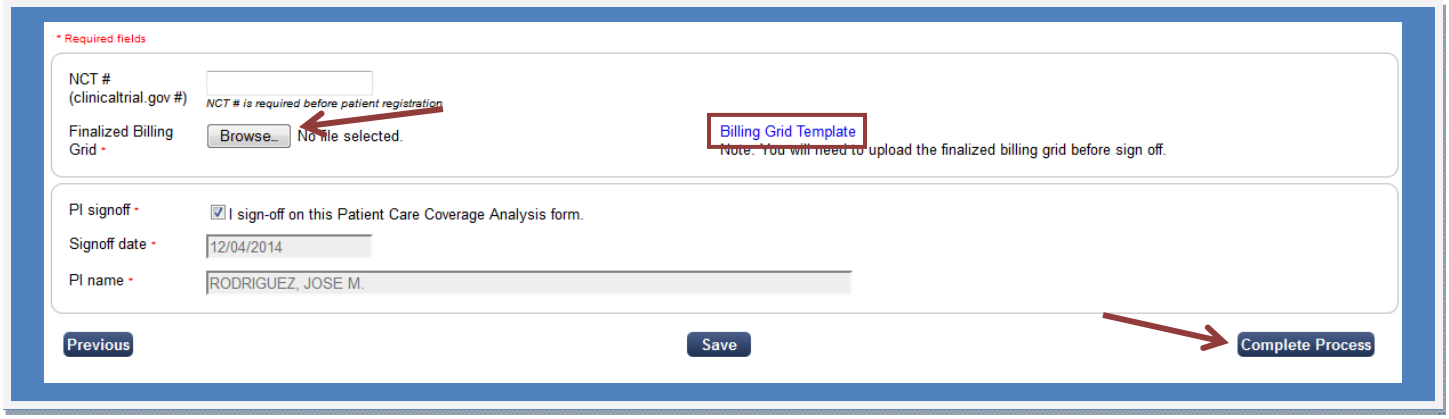
PI name *

2

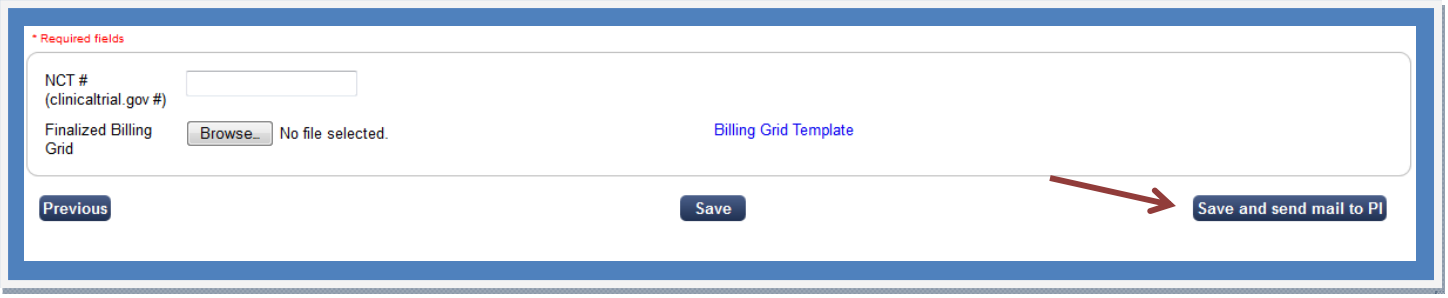
Previous Save Complete Process

*If the study is a qualifying clinical trial, the following message appears in a pop up window. Click **OK** to proceed. The signature page is displayed. It also contains a summary of the protocol information, how the QCT questions were answered and the determination. For those studies that are qualifying clinical trials, a billing grid will be an additional requirement prior to completing the process. A link to the Billing Grid Template is available in this page. A finalized billing gird will need to be uploaded (using the "**Browse…**" button and selecting the correct file on your computer) into the module for all new qualifying clinical trials. Once the finalized billing grid is uploaded, PI sign off is available and the QCT form can be submitted for institutional review. The NCT (clinicaltrials.gov) number can be entered in the designated field at this time but it is not a requirement to proceed (it will be required at the point of patient registration in the QCT module).*



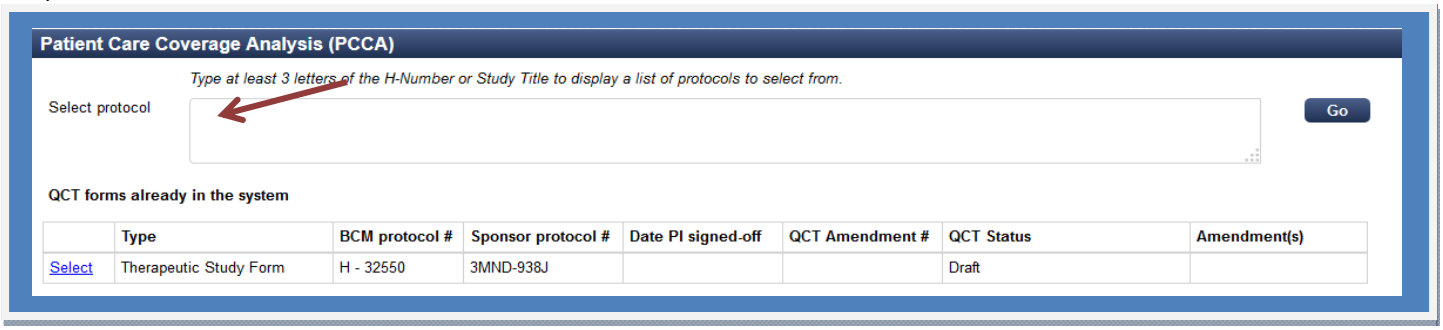


*If the investigator is completing the form, he or she will see a PI signoff check box, signoff date and PI name as well as complete process button at the lower right-hand corner. Clicking on the Complete Process button finalized the QCT assessment form and sends it for institutional review and sign-off. If an administrator or financial contact is completing the form, they will not see the signature section but instead have a button to "**Save and Send to PI**" for review. Clicking this button will generate an email to the PI with a direct link to the signature page in the QCT module. Entering from the emailed link will allow the PI direct access to review, request/ make changes to any of the sections in the QCT module and complete the process of the particular study.*



Accessing QCT Module with Direct Link

The Qualifying Clinical Trial module can be accessed directly to initiate without having to go through BRAIN by using the direct link (https://ictr.research.bcm.edu/BaylorQCT/Login.aspx). In order to initiate the QCT module for a study, user will require Read/Write access in BRAIN (if you do not have Read/Write access in BRAIN, please contact PI or administrator of the study for the privilege). Without Read/Write access the system will return a "XYZ didn't match any items" prompt. If you have recently set up the protocol in BRAIN or received Read/Write access, 15 minutes may be needed in order for the system to refresh, update and be able to find the protocol.



*To search for a protocol to initiate the QCT assessment, start typing in the H number or the study title in the **Select protocol** bar. As soon as three characters are entered, the search feature will begin to display items that match, continue typing to narrow down the list. Once the protocol for QCT review is selected, click on the Go button.*

The landing page for a QCT assessment initiated through the QCT module includes the question "Does this trial have therapeutic intent?", if the question is answered "yes", proceed to the QCT form as outlined for studies initiated through BRAIN (page 5 of these instructions). If the question is answered "no", the process is complete.