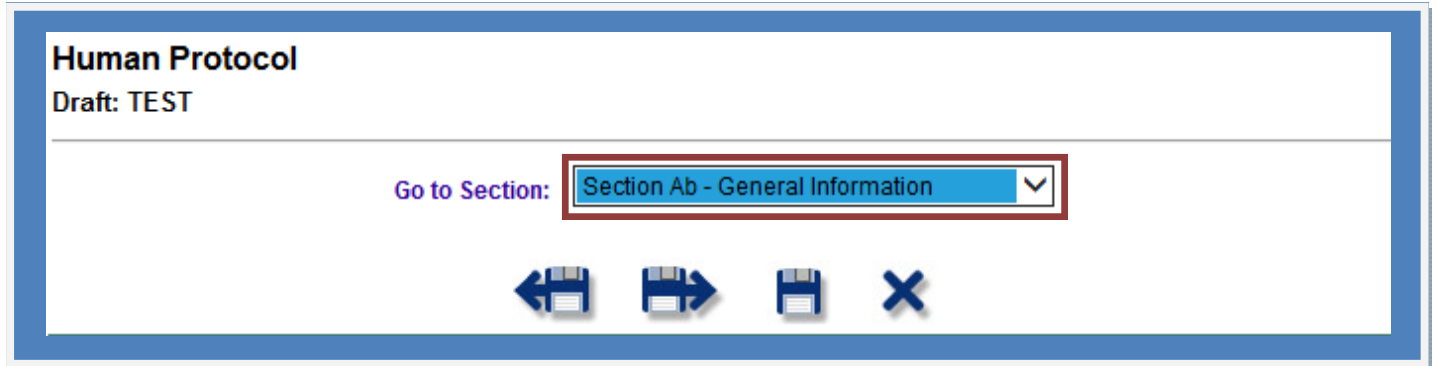


# Qualifying Clinical Trials Module Instructions

## 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.

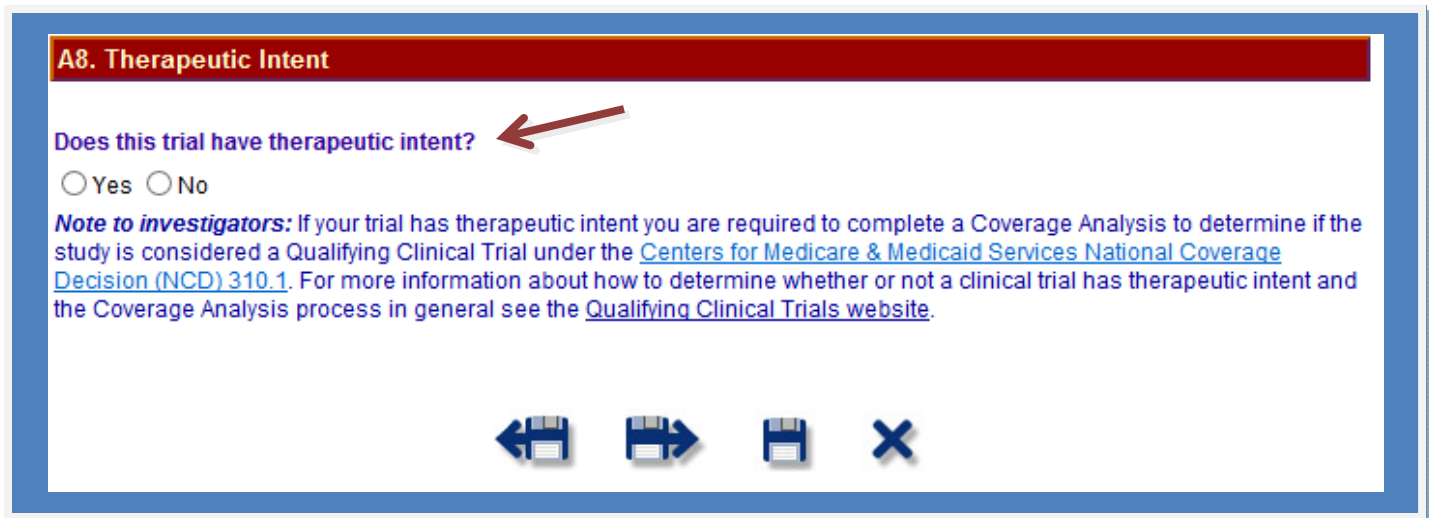


**Human Protocol**  
Draft: TEST

Go to Section: Section Ab - General Information ▼

⏪ ⏩ 💾 ✕

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.



**A8. Therapeutic Intent**

Does this trial have therapeutic intent? ↖

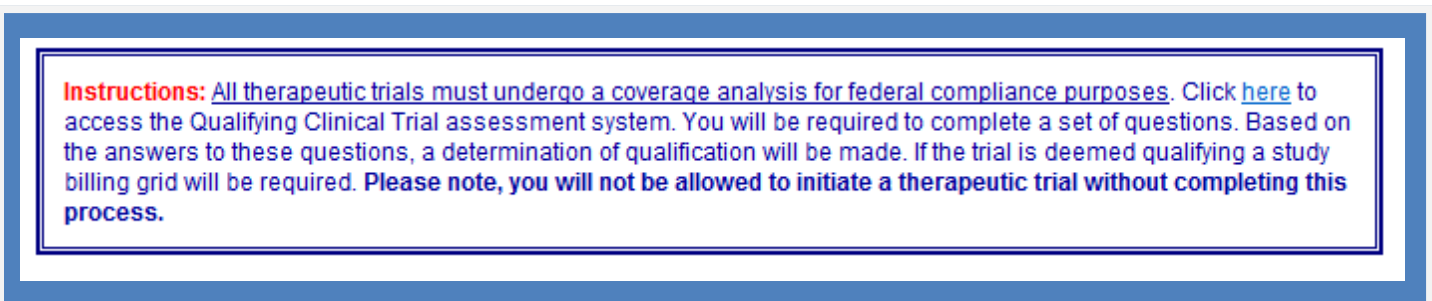
Yes  No

**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](#).

⏪ ⏩ 💾 ✕

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.



**Instructions:** All therapeutic trials must undergo a coverage analysis for federal compliance purposes. Click [here](#) to access the Qualifying Clinical Trial assessment system. You will be required to complete a set of questions. Based on the answers to these questions, a determination of qualification will be made. If the trial is deemed qualifying a study billing grid will be required. Please note, you will not be allowed to initiate a therapeutic trial without completing this process.

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 Qualifying 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)

The screenshot shows the login page for the Qualifying Clinical Trials (QCT) Module. At the top left is the Baylor College of Medicine logo. The main heading is "Qualifying Clinical Trials (QCT) Module". Below this, it says "Please login using your BCM Enterprise Computing Account (ECA)". There are two input fields: "User name:" and "Password:". Below the password field is a "Log in" button. At the bottom, there is a note: "For optimum system performance, we recommend you use the latest version of Mozilla Firefox".

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**).

The screenshot shows the landing page for the Qualifying Clinical Trials (QCT) Assessment System. At the top left is the Baylor College of Medicine logo. The main heading is "Qualifying Clinical Trials (QCT) Assessment System". In the top right corner, there is a "Logout" link. In the center, there are three buttons: "QCT Form Submission", "Set Additional Permissions", and "Patient Registration System". A red arrow points to the "Set Additional Permissions" button.

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.

The screenshot shows the interface for adding users. At the top, there is a text box with the following text: "The administrative contacts and privileges from BRAIN are auto populated in the QCT module. This feature allows you to provide read/write privileges for additional administrative contacts (e.g., Financial Coordinator) who may need to access this module on your behalf." Below this, there is a text box with the instruction: "Type at least 3 letters of the H-Number or Study Title to display a list of protocols to select from." Below the instruction, there is a search box labeled "Select protocol" containing the text "H-32550 - TEST - EHM". To the right of the search box is a "Go" button. Below the search box, there are two buttons: "Add Users" and "Proceed to QCT Form". A red arrow points to the "Add Users" button.

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.

**Qualifying Clinical Trials (QCT) Module**

**Set Additional Permissions**

The administrative contacts and privileges from BRAIN are auto populated in the QCT module. This feature allows you to provide read/write privileges for additional administrative contacts (e.g., Financial Coordinator) who may need to access this module on your behalf.

Select protocol: H-36223 - TEST STUDY

Name	BCM ECA	QCT Form Submission Access		Patient Registration System Access	
mal	eherrman	<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write	<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write

Save Cancel

MALATEK, DANIEL - PHYSICIAN ASSISTANT PROGRAM  
 MALATY, HODA M - MEDICINE-GASTROENTEROLOGY  
 MALAVE, JOSE OCTAVIO - OFC SA-BCM STUDENTS  
 MALDONADO, ADRIANA - OBSTETRICS AND GYNECOLOGY  
 MALDONADO, KARLA - ANESTHESIOLOGY  
 MALDONADO, MARIA ELIZABETH - OFC SA-BCM STUDENTS  
 MALDONADO, NELSON - NEUROLOGY  
 MALDONADO, URSULA MARIA - PEDIATRICS-NEWBORN  
 MALDONADO, YOLANDA - NEUROSURGERY-TCP SO  
 MALEK, DARIN W - MEDICINE-GENERAL MED/BEN TAUB  
 MALETIC-SAVATIC, MIRJANA - PEDIATRICS-NEUR NRI  
 MALIAKKAL, JOSEPH GEORGE - PEDIATRICS-RENAL  
 MALIASSOVA, ALYONA - MOLECULAR PHYSIOLOGY/LARINA  
 MALIK, AISHA - PEDIATRICS-EMERGENCY MEDICINE  
 MALIK, ANITA - PEDIATRICS-EMERGENCY MEDICINE  
 MALIK, GEORGE ROSS - OFC SA-BCM STUDENTS  
 MALIK, LABONI - GRANTS AND CONTRACTS  
 MALINOWSKI, SHARON L. - MEDICINE-CARDIOVASCULAR SCIENC

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.

**Set Additional Permissions**

The administrative contacts and privileges from BRAIN are auto populated in the QCT module. This feature allows you to provide read/write privileges for additional administrative contacts (e.g., Financial Coordinator) who may need to access this module on your behalf.

Select protocol: H-36223 - TEST STUDY

Name	BCM ECA	QCT Form Submission Access		Patient Registration System Access	
MALKASIAN, ERICA HERRMAN	eherrman	<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write	<input type="checkbox"/> Read	<input type="checkbox"/> Read/Write

Save Cancel

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.

**Patient Care Coverage Analysis (PCCA)**

Type at least 3 letters of the H-Number or Study Title to display a list of protocols to select from.

Select protocol: H-32550 - TEST - EHM

Go

QCT forms already in the system

Submit New Therapeutic Form Submit New IDE Form

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.

### QCT Form

BRAIN ESP1, Sections A1, A2, A3, A5 and A8 must be completed prior to initiating this form.

Completion of the Patient Care Coverage Analysis (PCCA) is required for all clinical trials involving pharmaceutical or device interventions in which any items or services may be invoiced to Medicare or 3<sup>rd</sup> party payers. The PCCA evaluates the underlying eligibility of the study for Medicare coverage and reviews the clinical events specified in the Protocol to determine which items or services may be billed to Medicare or 3<sup>rd</sup> party payers. Medicare only allows coverage of routine costs during qualifying clinical trials, as defined within the Centers for Medicare & Medicaid Services (CMS) [Clinical Trial Policy \(CTP 310.1\)](#). Medicare will not cover costs that are

1. paid for by the sponsor,
2. promised free in the informed consent document,
3. not ordinarily covered by Medicare, or
4. solely to determine trial eligibility or for data collection or analysis.

Please answer the following series of questions to determine whether your trial is a “Qualifying” clinical trial. If your trial is deemed as “Qualifying” you will need to provide the National Clinical Trial (NCT) number prior to enrollment of any subjects. If you are the sponsor (IND/IDE holder), directions for registering your trial with [clinicaltrials.gov](#) in order to obtain the NCT number will be provided at the end of this module. Many non-qualifying clinical trials also require registration with [clinicaltrials.gov](#) per [FDAAA 801](#).

The documents mentioned below will assist you for the following sections:

- Study protocol
- Schedule of events (Study Schema)
- Clinical Trial Agreement
- Budget from funding agency or industry sponsor
- Informed Consent Document
- ClinicalTrials.gov registration number (if available)
- For Device Studies: FDA IND or IND exemption letter

Continue

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.

### Protocol Information

\* Required fields

Date of submission	<input type="text" value="12/16/2014"/>	BCM protocol #	<input type="text" value="H-36223"/>	Sponsor protocol # *	<input type="text" value="n/a"/>
Study phase	<input type="text" value="Phase II"/>				

**Principal Investigator**

Name	<input type="text" value="RODRIGUEZ, JOSE M."/>	Email *	<input type="text" value="jrodrig1@bcm.tmc.edu"/>	Phone *	<input type="text" value="713-798-8277"/>
Department	<input type="text" value="PEDIATRICS"/>	Section	<input type="text" value="PEDIATRICS: RESEARCH RESOURCE OFFICE"/>		
Study title	<input type="text" value="TEST STUDY"/>				
Funding source *	<input type="text" value="NOVARTIS PHARMACEUTICALS CORP"/>				

**Administrative Contact**

Name *	<input type="text" value="MALKASIAN, ERICA HERRMAN"/>	Email *	<input type="text" value="eherrman@bcm.tmc.edu"/>	Phone *	<input type="text" value="713-798-4586"/>
Please enter 2 or more letters of the last name to display the list of BCM contacts					

**Financial Contact**  Same as administrative contact

Name *	<input type="text" value="MALKASIAN, ERICA HERRMAN"/>	Email *	<input type="text" value="eherrman@bcm.tmc.edu"/>	Phone *	<input type="text" value="713-798-4586"/>
Please enter 2 or more letters of the last name to display the list of BCM contacts					

Study site(s) for local accrual \*

<input checked="" type="checkbox"/> Baylor St. Luke's Medical Center	<input type="checkbox"/> Harris Health System - Community Clinics	<input type="checkbox"/> Texas Children's Hospital - Pavilion for Women
<input type="checkbox"/> BCM - Baylor Clinic	<input type="checkbox"/> Harris Health System - Northwest Clinic	<input type="checkbox"/> Texas Children's Hospital - West Campus
<input type="checkbox"/> BCM - Fondren Brown Building	<input type="checkbox"/> Harris Health System - Smith Clinic	<input type="checkbox"/> The Methodist Hospital
<input type="checkbox"/> BCM - Jamail Specialty Care Center	<input type="checkbox"/> Harris Health System - Thomas Street	<input type="checkbox"/> US Renal Care Center - Scott Street
<input type="checkbox"/> BCM - McNair Campus	<input type="checkbox"/> Park Plaza	<input type="checkbox"/> Veterans Affairs Medical Center
<input type="checkbox"/> Harris Health System - Ben Taub General Hospital	<input type="checkbox"/> Texas Children's Hospital - Main Campus	<input type="checkbox"/> Other Institution

Please specify other institution(s)

Previous
Save
Next

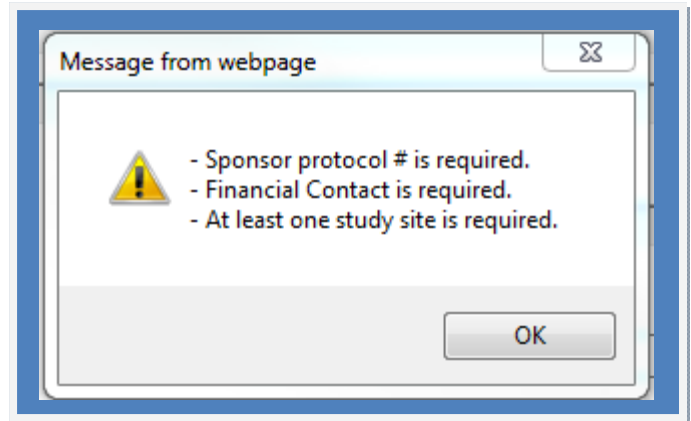
**Required items:**

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.

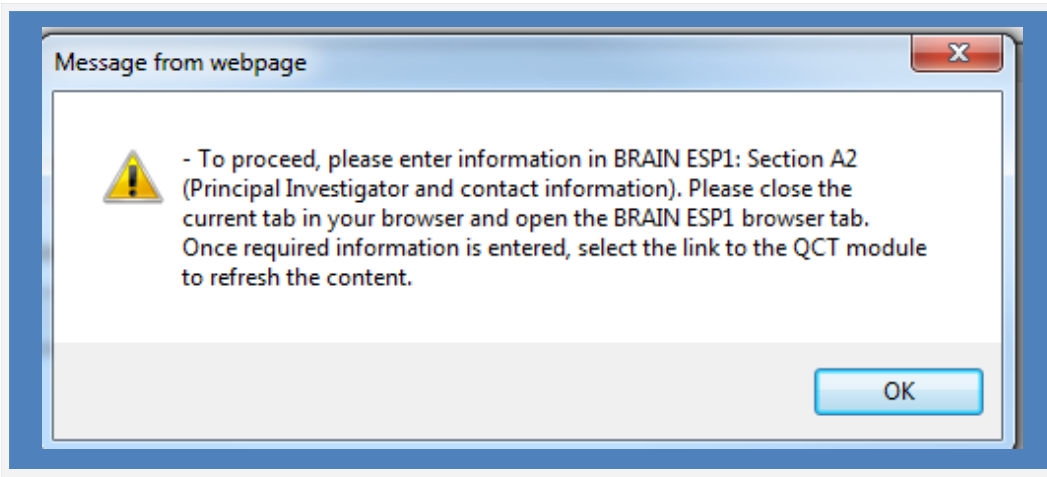
If required fields are missing, a message will prompt users to enter missing fields and will not allow users to proceed to next page.

**Non-required item:**

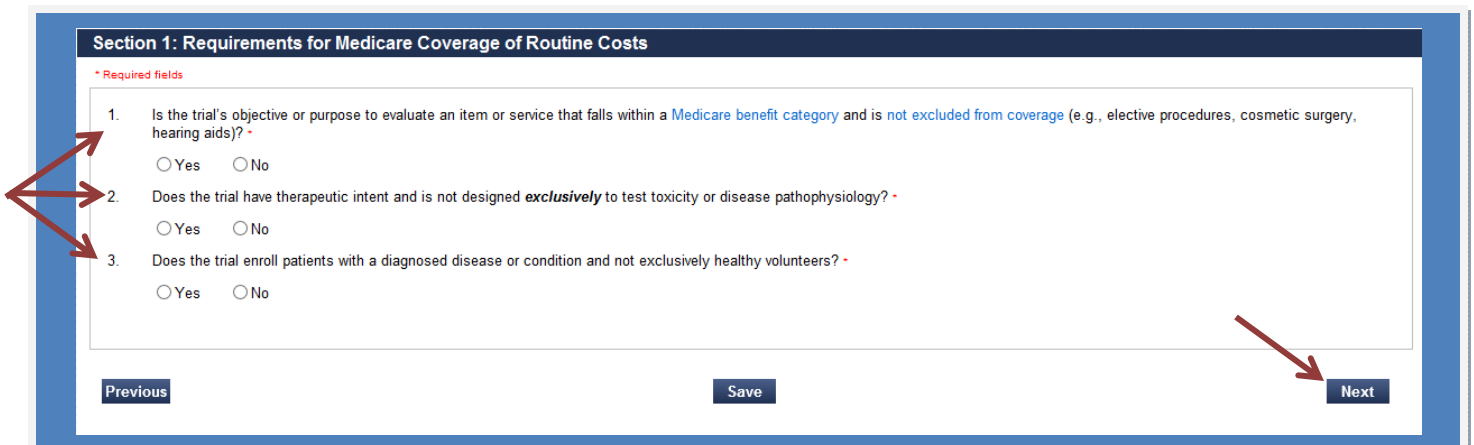
- *Study phase* - enter if study has an associated phase



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.

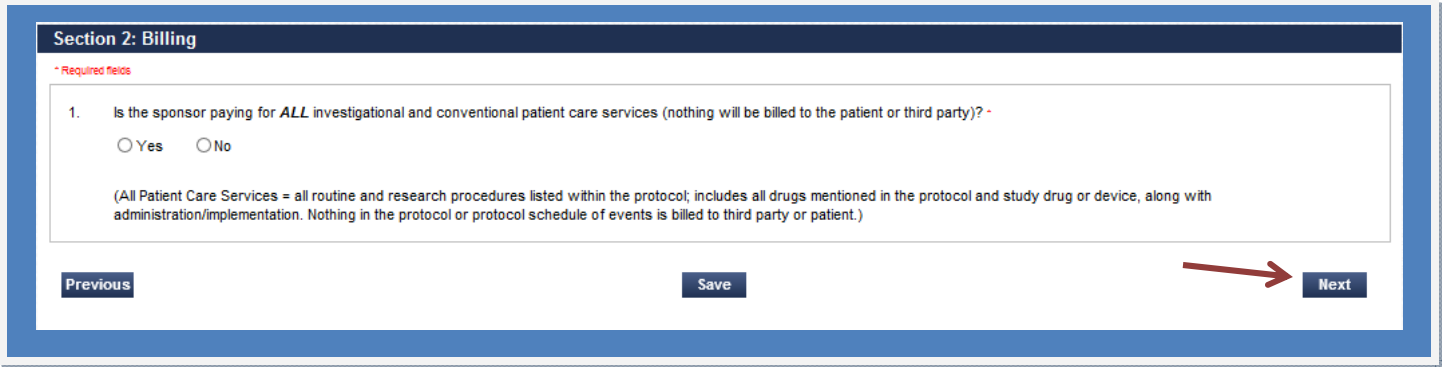


Once the protocol information section is complete, section one (1) of the module is available. Answers to the three (3) mandatory criteria found in the CMS clinical trial policy (links to the policy are embedded in the question) must be provided. Once all three questions are answered, proceed by clicking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



**Section 2: Billing**

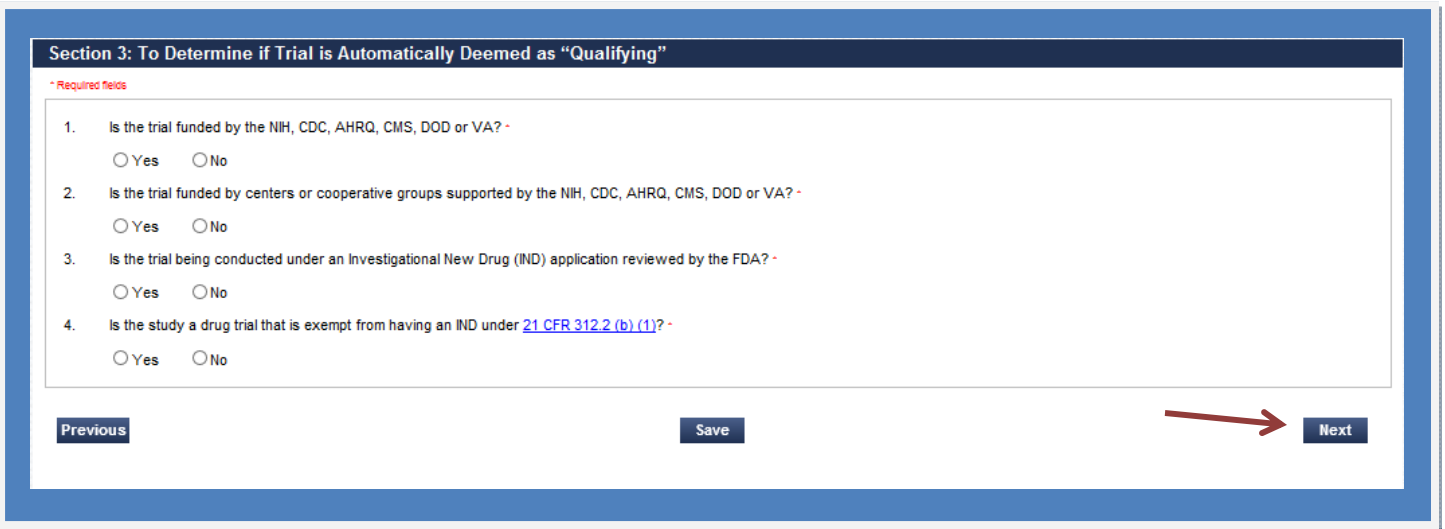
\* Required fields

1. Is the sponsor paying for **ALL** investigational and conventional patient care services (nothing will be billed to the patient or third party)? -

Yes  No

(All Patient Care Services = all routine and research procedures listed within the protocol; includes all drugs mentioned in the protocol and study drug or device, along with administration/implementation. Nothing in the protocol or protocol schedule of events is billed to third party or patient.)

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 3: To Determine if Trial is Automatically Deemed as "Qualifying"**

\* Required fields

1. Is the trial funded by the NIH, CDC, AHRQ, CMS, DOD or VA? -

Yes  No

2. Is the trial funded by centers or cooperative groups supported by the NIH, CDC, AHRQ, CMS, DOD or VA? -

Yes  No

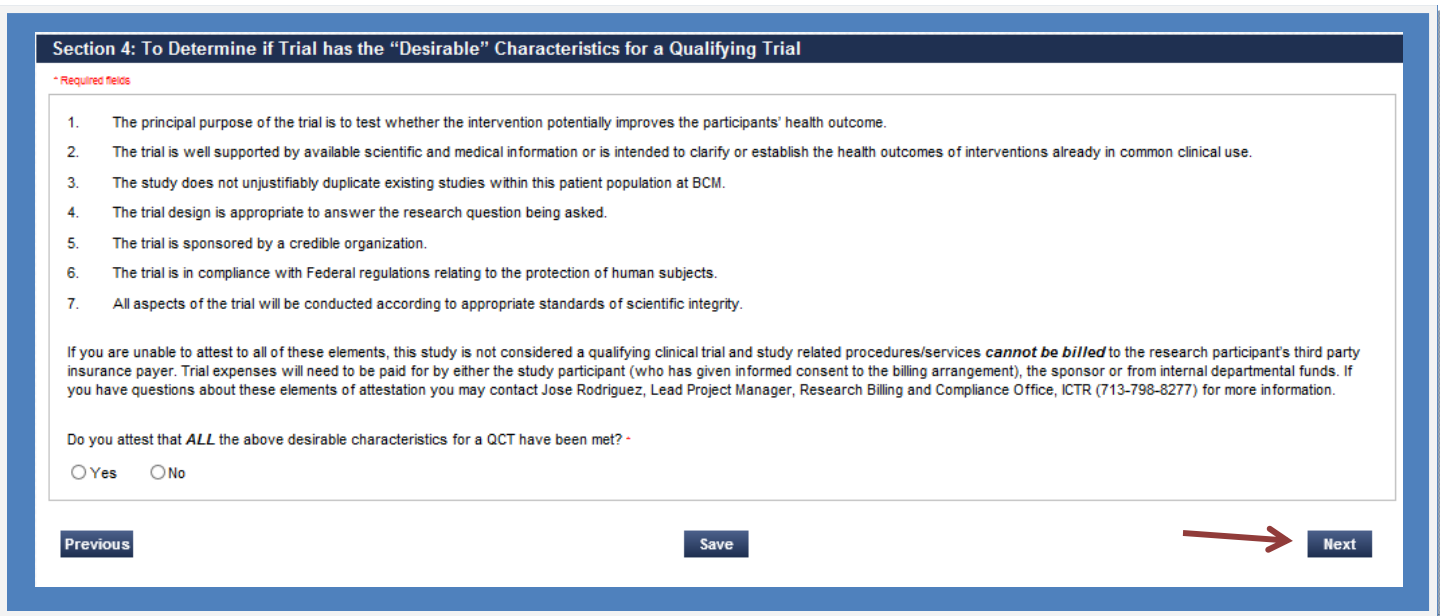
3. Is the trial being conducted under an Investigational New Drug (IND) application reviewed by the FDA? -

Yes  No

4. Is the study a drug trial that is exempt from having an IND under [21 CFR 312.2 \(b\) \(1\)](#)? -

Yes  No

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.



**Section 4: To Determine if Trial has the "Desirable" Characteristics for a Qualifying Trial**

\* Required fields

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcome.

2. The trial is well supported by available scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use.

3. The study does not unjustifiably duplicate existing studies within this patient population at BCM.

4. The trial design is appropriate to answer the research question being asked.

5. The trial is sponsored by a credible organization.

6. The trial is in compliance with Federal regulations relating to the protection of human subjects.

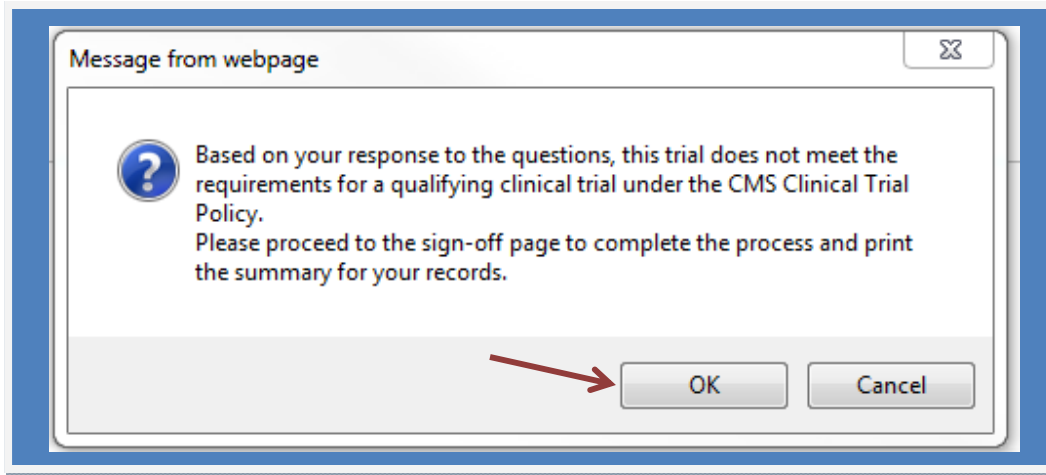
7. All aspects of the trial will be conducted according to appropriate standards of scientific integrity.

If you are unable to attest to all of these elements, this study is not considered a qualifying clinical trial and study related procedures/services **cannot be billed** to the research participant's third party insurance payer. Trial expenses will need to be paid for by either the study participant (who has given informed consent to the billing arrangement), the sponsor or from internal departmental funds. If you have questions about these elements of attestation you may contact Jose Rodriguez, Lead Project Manager, Research Billing and Compliance Office, ICTR (713-798-8277) for more information.

Do you attest that **ALL** the above desirable characteristics for a QCT have been met? -

Yes  No

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](#)

<b>BRAIN number:</b>	H-36223	<b>Initial submit date:</b>	12/04/2014
<b>Protocol title:</b>	TEST STUDY		
<b>Funding source:</b>			
<b>Principal Investigator:</b>			
<b>Name:</b>	RODRIGUEZ, JOSE M.	<b>BCM ID:</b>	142152
<b>Department/Section:</b>	PEDIATRICS: RESEARCH RESOURCE OFFICE	<b>Phone:</b>	713-798-8277
<b>Center:</b>		<b>Email:</b>	jrodrig1@bcm.tmc.edu
<b>Administrative Contact:</b>			
<b>Name:</b>	MALKASIAN, ERICA HERRMAN	<b>BCM ID:</b>	141570
<b>Department/Section:</b>		<b>Phone:</b>	713-798-4586
<b>Center:</b>		<b>Email:</b>	eherrman@bcm.tmc.edu
<b>Financial Contact:</b>			
<b>Name:</b>	MALKASIAN, ERICA HERRMAN	<b>BCM ID:</b>	141570
<b>Department/Section:</b>		<b>Phone:</b>	713-798-4586
<b>Center:</b>		<b>Email:</b>	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 <a href="#">Medicare benefit category</a> and is <a href="#">not excluded from coverage</a> (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

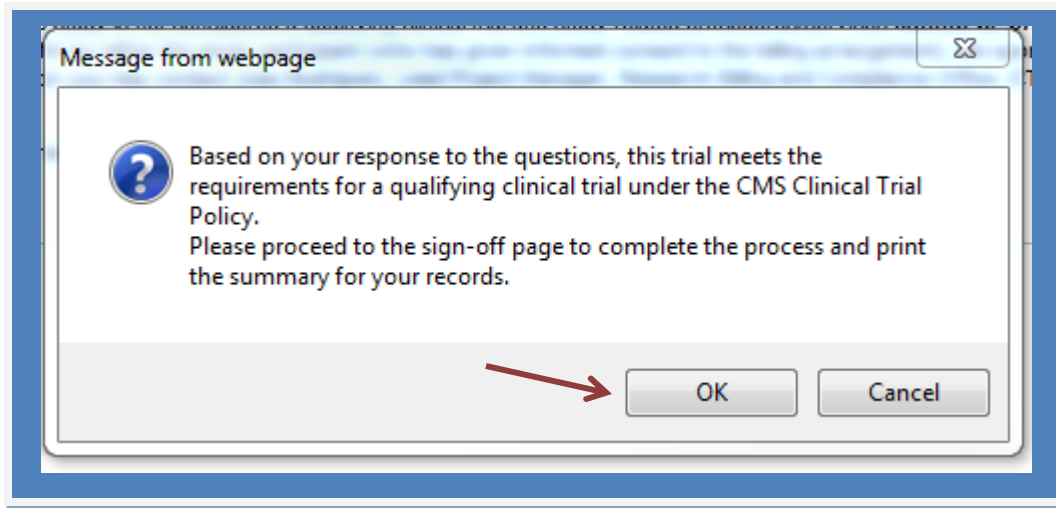
PI signoff -  I sign-off on this Patient Care Coverage Analysis form. **1**

Signoff date -

PI name -  **2**



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 grid 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).



\* Required fields

NCT # (clinicaltrials.gov #)  NCT # is required before patient registration

Finalized Billing Grid  No file selected. [Billing Grid Template](#) Note: You will need to upload the finalized billing grid before sign off.

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

Signoff date

PI name

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.

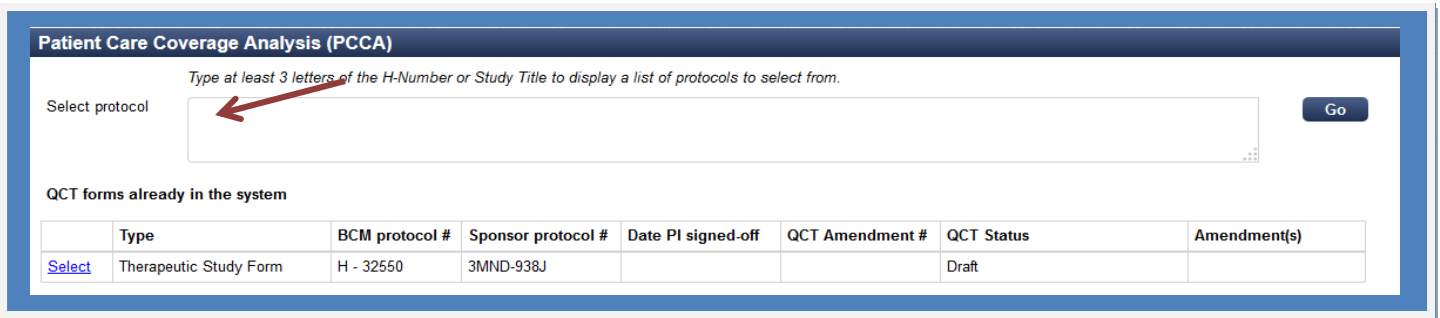
\* Required fields

NCT # (clinicaltrials.gov #)

Finalized Billing Grid  No file selected. [Billing Grid Template](#)

## 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.



Patient Care Coverage Analysis (PCCA)

Type at least 3 letters of the H-Number or Study Title to display a list of protocols to select from.

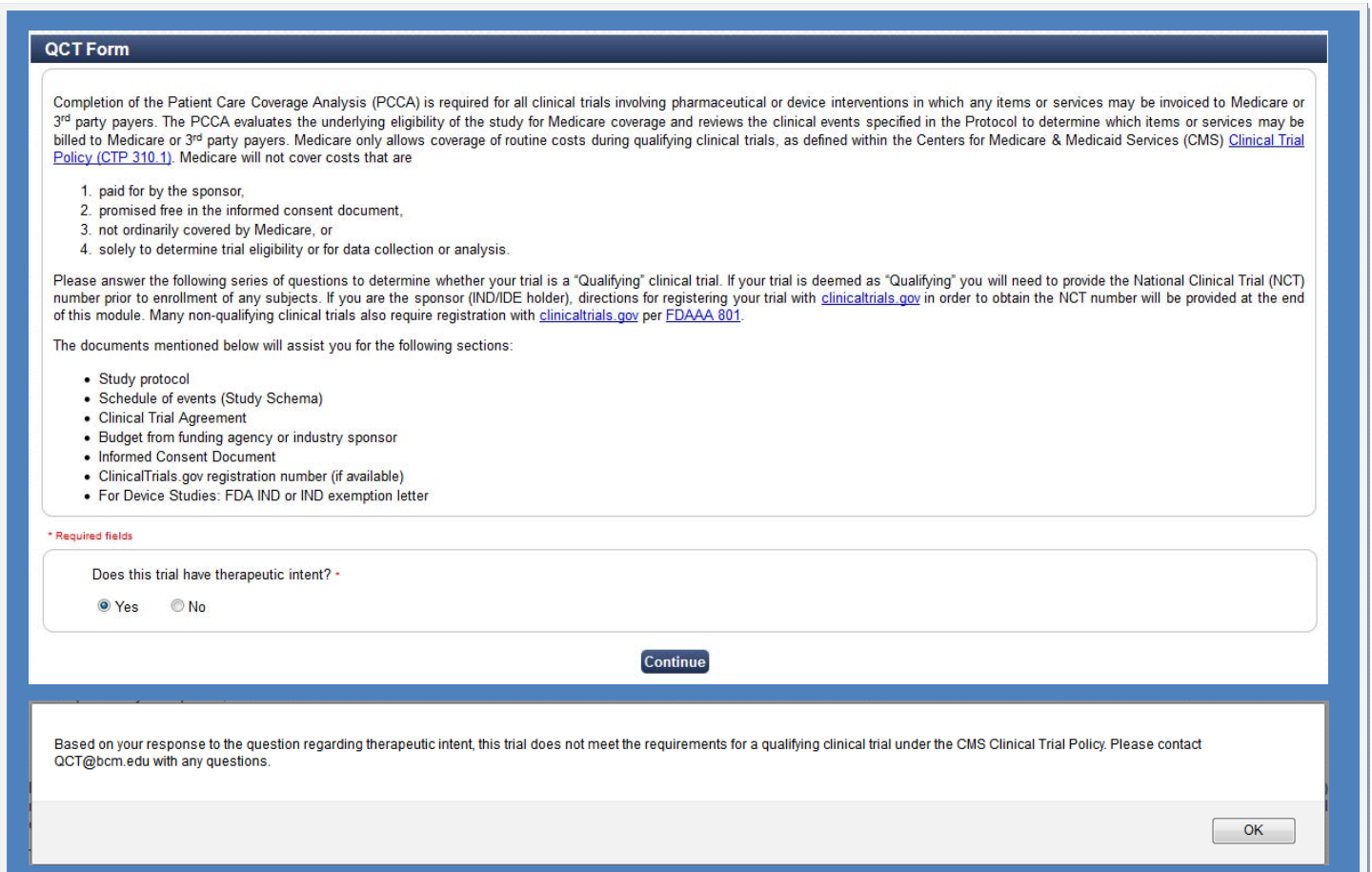
Select protocol

QCT forms already in the system

Type	BCM protocol #	Sponsor protocol #	Date PI signed-off	QCT Amendment #	QCT Status	Amendment(s)
<a href="#">Select</a> Therapeutic Study Form	H - 32550	3MND-938J			Draft	

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.



QCT Form

Completion of the Patient Care Coverage Analysis (PCCA) is required for all clinical trials involving pharmaceutical or device interventions in which any items or services may be invoiced to Medicare or 3<sup>rd</sup> party payers. The PCCA evaluates the underlying eligibility of the study for Medicare coverage and reviews the clinical events specified in the Protocol to determine which items or services may be billed to Medicare or 3<sup>rd</sup> party payers. Medicare only allows coverage of routine costs during qualifying clinical trials, as defined within the Centers for Medicare & Medicaid Services (CMS) [Clinical Trial Policy \(CTP 310.1\)](#). Medicare will not cover costs that are

1. paid for by the sponsor,
2. promised free in the informed consent document,
3. not ordinarily covered by Medicare, or
4. solely to determine trial eligibility or for data collection or analysis.

Please answer the following series of questions to determine whether your trial is a "Qualifying" clinical trial. If your trial is deemed as "Qualifying" you will need to provide the National Clinical Trial (NCT) number prior to enrollment of any subjects. If you are the sponsor (IND/IDE holder), directions for registering your trial with [clinicaltrials.gov](http://clinicaltrials.gov) in order to obtain the NCT number will be provided at the end of this module. Many non-qualifying clinical trials also require registration with [clinicaltrials.gov](http://clinicaltrials.gov) per [FDAAA 801](#).

The documents mentioned below will assist you for the following sections:

- Study protocol
- Schedule of events (Study Schema)
- Clinical Trial Agreement
- Budget from funding agency or industry sponsor
- Informed Consent Document
- ClinicalTrials.gov registration number (if available)
- For Device Studies: FDA IND or IND exemption letter

\* Required fields

Does this trial have therapeutic intent? \*

Yes  No

Based on your response to the question regarding therapeutic intent, this trial does not meet the requirements for a qualifying clinical trial under the CMS Clinical Trial Policy. Please contact [QCT@bcm.edu](mailto:QCT@bcm.edu) with any questions.