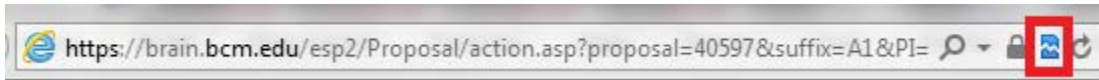
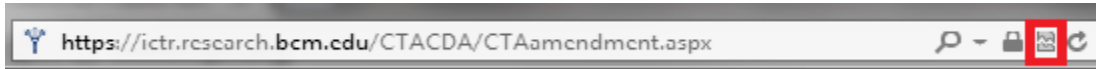


Browser Compatibility – PCs Only

For optimum system performance, we recommend you use Google Chrome. If you are unable to download Chrome due to administrative restrictions on your computer and are using Internet Explorer (IE) 9 or 10 you will need to be in *compatibility mode* while in BRAIN and switch out of *compatibility mode* when in the CTA system. Compatibility mode is denoted in the address bar – when the icon is highlighted you are in compatibility mode (blue icon).



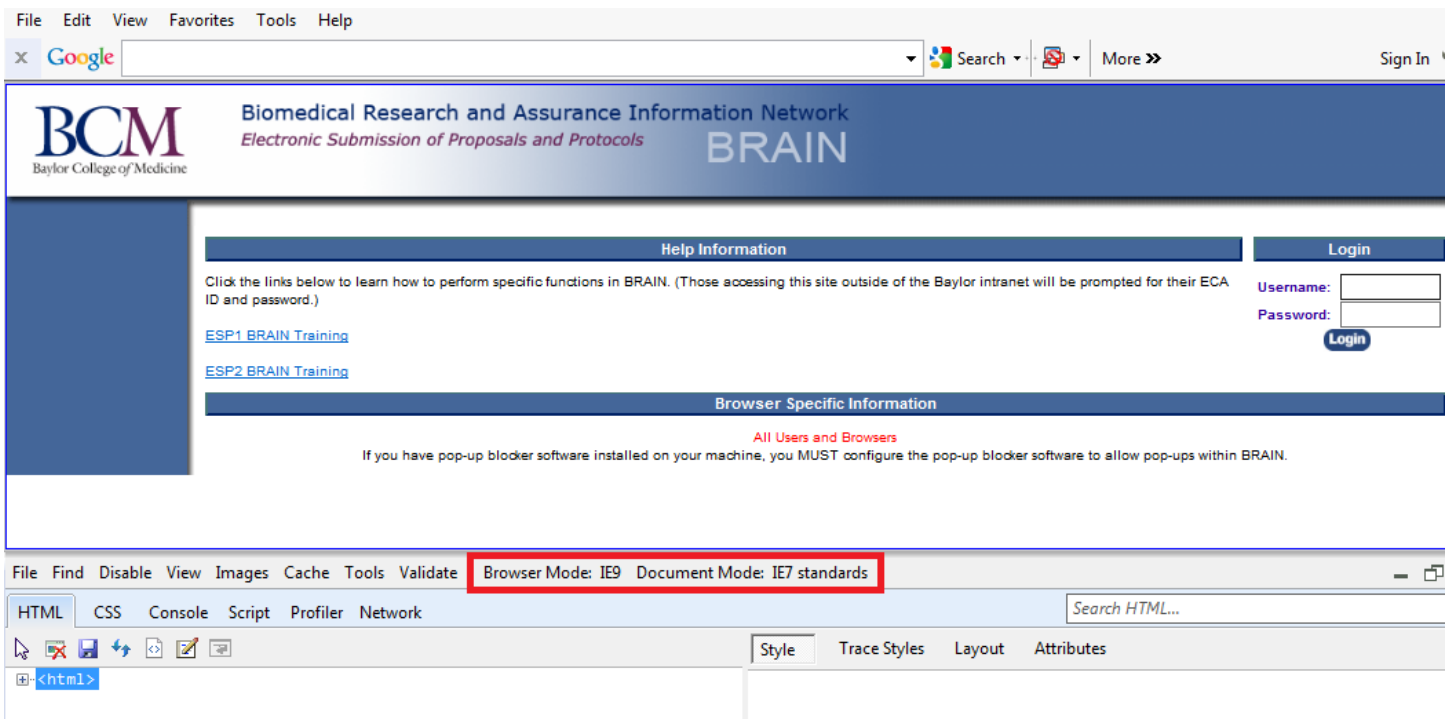
To turn off compatibility mode you will need to click on the icon (note the compatibility icon *turns grey*).



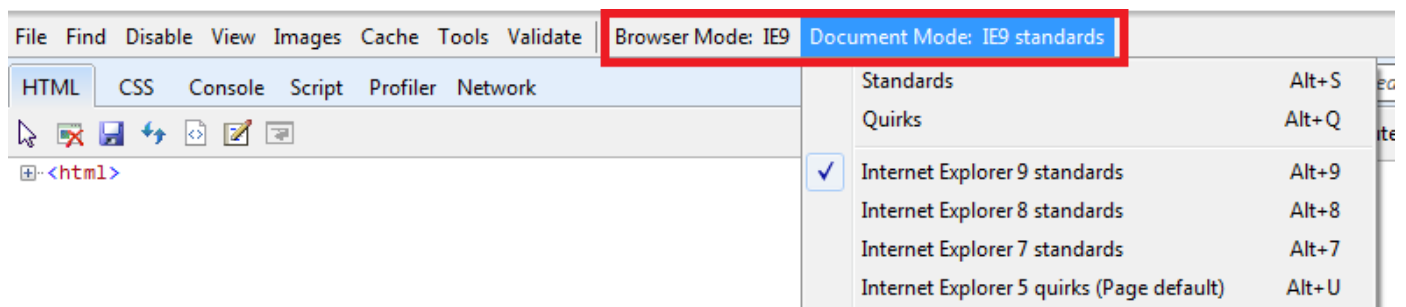
If you are using IE7 you will need to upgrade. If you have IE9 or 10 installed but it is set in IE7 mode, you will need to set your *Browser Mode* and *Document Mode* to IE9.

How do you find out what browser you are in?

Open your browser and press the F12 button on your keyboard. A small window opens in the bottom half of your screen that lists *Browser Mode* and *Document Mode*.



Both *Modes* should be set to IE9. If they are not, click on them to update.



CTA Pre-Review Form Instructions

1. Clinical Trial Agreements funded by for-profit, industry sponsors should be submitted via the Clinical Trial Agreement link in BRAIN esp2.

Steps:

1. Create a new proposal in BRAIN esp2 – from the left hand menu bar of the home screen in esp2, choose ‘**Create Proposal**’. For Industry Sponsored Clinical Trials you should choose **New** or **Resubmission / Amendment**. Click on the disk forward icon.

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ESP2 Electronic Submission of Proposals
BRAIN

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Please select the type of proposal and click the continue icon, below:

Create a Proposal

- New**
Use for the first time a project is entered in BRAIN.
- Resubmission / Amendment**
Use for applications being resubmitted for a second review, or for other amendments to a proposal such as changing the BCM PI or changing the primary institution of a subcontract, or for contract amendments.
- Non-Competing Renewal**
Use for progress reports or non-competing applications to get the next year of expected funding, for annual amendments to subcontracts and for No Cost Extensions.
- Competing Continuation**
Use for renewal applications that must undergo review before the project can be extended.
- Transfer**
Use for transferring an already funded grant from another institution to BCM.
- Supplement**
Use for additional funding requests on an already funded project such as for equipment or students who qualify for diversity funding.

[Who can access your proposal](#)

Continue

- a. If you are creating a **New** proposal, you will need to select **Edit Proposal** from the ‘What would you like to do?’ drop down menu. To initiate the CTA Pre-Review Form you will need to enter the PI Name (Section 1) and Proposal Title (Section 2).

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Proposal - [44151-I]

Title: TEST CTA SUBMISSION
Principal Investigator: MALKASIAN, ERICA HERRMAN
Status: Draft
Primary Institution: not available
Consortium: not available
Appointment Info: not available

What would you like to do? Edit Proposal Go

- Edit Proposal
- Edit Awards
- Set OOR Pre-Reviewer
- Delete Proposal
- Set Privileges
- Add/View Comments
- View/Print Award Routing Sheet
- View/Print Proposal
- Industry Clinical Trial Agreement

- b. If you are creating an **Amendment** proposal and the PI and Proposal Title will remain the same as the initial proposal, you can select **Industry Clinical Trial Agreement** from the ‘What would you like to do?’ drop down menu and hit “GO”.

- ▼ INVESTIGATOR
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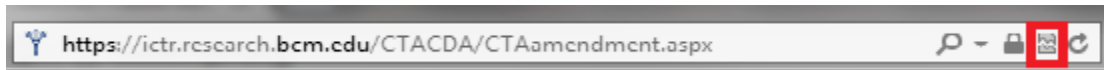
Proposal - [44151-I]

Title: TEST CTA SUBMISSION
Principal Investigator: MALKASIAN, ERICA HERRMAN
Status: Draft

What would you like to do? Go

- Edit/Submit Proposal
- Delete Proposal
- Set Privileges
- View/Print Proposal
- View Awards
- Industry Clinical Trial Agreement

Clicking on the Industry CTA link will take you to the new Clinical Trial Agreement System in a different browser window. If you are using IE9 or 10, you will need to turn off compatibility mode for the CTA system landing page to load correctly (the icon turns grey and the CTA page will reload).



2. To submit the new CTA Pre-Review Form, the answer to the first question must be **YES**. *If the answer is NO*, the agreement should be submitted to through BRAIN esp2 and will be reviewed by the Sponsored Programs Office or Baylor Licensing.
 - a. Are you submitting an industry (for-profit) sponsored Clinical Trial Agreement (or amendment) for research involving human subjects? Select **Yes** and click on the **Submit** button.

Clinical Trial Agreement (CTA) System

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Please answer the following question to submit a CTA pre-review form

Are you submitting an industry (for-profit) sponsored Clinical Trial Agreement (or amendment) for research involving human subjects? Yes No


Submit

RESPONSIBLE PARTY	AGREEMENT TYPE
Institute for Clinical and Translational Research	Clinical Trial Agreement (CTA) – industry sponsored
	Clinical Services Agreement (CSA) – industry sponsored, clinical
	Confidentiality Disclosure Agreement (CDA) - industry sponsored, clinical
	Non-Disclosure Agreement (NDA) – industry sponsored, clinical
Sponsored Programs Office	Clinical Trial Agreement (CTA) – federal, foundation funding
	Clinical Services Agreement (CSA) – federal, foundation funding
	Grant sub-awards and sub-contracts
Baylor Licensing Group	Confidentiality Disclosure Agreement (CDA) - industry sponsored, non clinical
	Non-Disclosure Agreement (NDA) – industry sponsored, non-clinical
	Data Use Agreement (DUA)
	Data Transfer Agreement (DTA)
	Exclusive or Non-Exclusive License Agreements
	Material Transfer Agreements (MTA)
	Research Collaboration Agreement
	Sponsored Research Agreement (SRA) – basic science
Other Agreements	Consulting Agreements – Faculty member and outside legal counsel
	Fee-for-service Agreement – General Counsel
	Testing Agreement – General Counsel
	Software In-Licenses – Supply Chain Management
	Equipment Loan Agreements – Supply Chain Management

You are required to complete each page of the CTA Pre-Review Form. **Required fields**, which are marked with a **red asterisk***, need to be completed before you can proceed to the **NEXT** page. You can **SAVE** the form at any time. Access to the system is available through the esp2 proposal (choose Industry Clinical Trial Agreement from the 'What would you like to do?' drop down menu) or directly (<https://ictr.research.bcm.edu/CTACDA>). Once you are in the CTA system, you can access any of the forms in Draft or Submitted status by clicking the appropriate link on the left menu bar.

- b. The Proposal Number, PI Name and Proposal Title auto-populate on the CTA Pre-Review Form based on what was entered in BRAIN.

CTA Pre-Review Form – Page 1



Clinical Trial Agreement (CTA) System

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CTA
CTA Pre-Review Form - Page 1

Draft Pre-Review Forms
Submitted Pre-Review Forms

*** Required Fields**

Investigator: Last name * First name *

Required

Department *

Study Title *

Study Title-Short *

Proposal Number H-Number

Sponsor *

Study Location(s) *

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

Do you plan to use the Western IRB (WIRE) for protocol approval? *

Upload CTA provided by sponsor (only MS Word document) *

Upload additional documents

Document name	Upload document
<input type="text"/>	<input type="text" value="Browse..."/>

Sponsor contact information

Last name *	<input type="text"/>	First name *	<input type="text"/>
Telephone *	<input type="text"/>	Email *	<input type="text"/>
Street	<input type="text"/>		
City	State	<input type="text" value="Please Select"/>	ZIP <input type="text"/>

Save

Cancel

Next

- CTA
- Draft Pre-Review Forms
- Submitted Pre-Review Forms

CTA Pre-Review Form - Page 2

* Required Fields

Primary administrative contact

The primary administrative contact is the contract analyst's main administrative point of contact throughout the contract negotiations, and will be copied on all email correspondence relating to the negotiation process.

Last name * First name *
Telephone * Email *

If you would like to add a secondary administrative contact, click here

If the budget will be negotiated by someone other than the primary administrative contact, click here

Administrator to whom study payments should be mailed

If same as primary administrative contact, click here


Last name * First name *
Telephone * Email *
Street *
City * State * ZIP *

Baylor contact information for study related PI notifications

If same as above, check here

Last name * First name *
Telephone * Email *
Street *
City * State * ZIP *

Previous Save Cancel Next



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CTA

Draft Pre-Review Forms

Submitted Pre-Review Forms

CTA Pre-Review Form - Page 3

*** Required Fields**

Type of clinical trial agreement:

Study type:

Although contracts are negotiated on behalf of the Institution, some investigator concerns may be addressed in the language.

Please let us know if there are any issues or concerns that you feel need to be addressed in the contract (e.g. "I would like to publish, teach or present study results one year after study is completed," or "I would like to use the drug/device/product for a new use or novel therapy").

If you have any contracting concerns, please check below:

I would like to publish, teach or present study results one year after study is completed

I would like to use the drug/device/product for a new use or novel therapy

I would like to subcontract to other institutions for a multi-center research study/project or consortium

I would like to subcontract to one other institution and/or company for a study service

Other

Budget

Effective November 1, 2014, Baylor College of Medicine's indirect cost rate for clinical trials sponsored by for-profit entities will be 35%. The rate is applied to all budgeted items (e.g., patient care costs, personnel and any invoiceable items, excluding IRB fees). Departments may still charge an additional overhead rate to cover departmental expenses. Please reference the Office of Research website for more information on Indirect rates:

[Intranet site](#)

[External site](#)


ICTR must approve any rate below 35% before the budget can be finalized. A complete budget is not mandatory for contract negotiations to begin.

Does the budget include at least a 35% indirect cost (overhead) rate? Yes No

Previous
Save
Submit
Cancel

Upon submission of the completed Pre-Review Form an automated email acknowledgement will be sent to the PI and Administrative Contact listed on Page 2 of the form. Once the contract has been assigned to a contract associate, you will receive a second email noting the assignment.

You can check the status of a submitted agreement at any time by going back through BRAIN and selecting the Clinical Trial Agreement from the 'What would you like to do?' drop down menu for each proposal.



Biomedical Research and Assurance Information Network

ESP2 Electronic Submission of Proposals

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Proposal - [44151-I]

Title: TEST CTA SUBMISSION

Principal Investigator: MALKASIAN, ERICA HERRMAN

Status: Draft

What would you like to do?

Edit/Submit Proposal

Delete Proposal

Set Privileges

View/Print Proposal

View Awards

Industry Clinical Trial Agreement

Go

Alternatively you can access the system directly (<https://ictr.research.bcm.edu/CTACDA>) to see status of forms that have been initiated and not yet submitted (draft) and those that have been submitted.

Statuses in the CTA system include:

1. In Review with ICTR
2. In Review with Sponsor
3. CTA & IRB finalized – waiting for IRB approval
4. CTA & IRB finalized – waiting for budget
5. CTA finalized – waiting on IRB approval and budget
6. All final – waiting for PI to complete COI task
7. All final – waiting for PI to submit Proposal / sign agreement
8. Partially-executed with Sponsor
9. Approved
10. Funded

The left hand menu-bar allows you to access Forms in **Draft** and **Submitted** statuses.

The screenshot shows the Baylor College of Medicine Clinical Trial Agreement (CTA) System interface. The top navigation bar is dark blue with the Baylor College of Medicine logo on the left, the title "Clinical Trial Agreement (CTA) System" in the center, and "Help", "Home", and "Logout" links on the right. A left-hand menu is open, showing "CTA" with a sub-menu containing "Draft Pre-Review Forms" and "Submitted Pre-Review Forms". The main content area displays the text: "To view submitted CTA Pre-review Forms, click the link below." followed by a blue hyperlink: "Go to submitted CTA pre-review forms".

Once the Agreement has been finalized, retrieval of the final document for PI signature will be via this system. Upon PI signature, the signed agreement will need to be uploaded and submitted back to the ICTR for institutional signature and final processing. You will also need to go back into BRAIN and complete the esp2 Proposal. For Department review and approval, you will need to attach a *final internal budget* to the BRAIN esp2 proposal. The assigned Contract Associate will approve and fund the Proposal, attach the final fully-executed agreement and route to Grants & Contracts Accounting for account setup.