

## **NCI CTRP Attachment 3c**

### **NCI CTRP Amendment Portal Workflow and Screen Shots**

Step 1: User accesses the NCI Clinical Trials Reporting Program website at <http://trials.nci.nih.gov> – see screenshot, page 2

Step 2: User enters “Username” and “Password” – see screenshot, page 2

Step 3: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 3

Step 4: System displays “Search Submitted Clinical Trials” page – see screenshot, page 4

Step 5: User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 5 - 8

# CTRP Home and Login page



## Welcome to NCI's Clinical Trials Reporting Program

This site enables you to register a trial with NCI's Clinical Trials Reporting Program. You can:

- ✓ Register clinical trials
- ✓ Register multiple trials at one time using a [batch upload template](#)
- ✓ Search registered trials by Title, Phase, Trial Identifiers and Organizations

Want to learn more about the Reporting Program? Visit the [NCI Clinical Trials Reporting Program](#) website. You can also email CBIIT Application Support at [ncicbiit@mail.nih.gov](mailto:ncicbiit@mail.nih.gov) if you have questions or need assistance.

Sign In

Sign Up

Forgot Your Password

**Username**

**Password**

Sign In

# CTRP Burden Statement



## NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

This is a U.S. Government computer system, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of this computer system may subject violators to criminal, civil, and/or administrative action.

All information on this computer system may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements. Access or use of this computer system by any person, whether authorized or unauthorized, constitutes consent to these terms. There is no right of privacy in this system.

## NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 5/31/16

Public reporting burden for this collection of information is estimated to average sixty (60) minutes for this questionnaire, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current, valid OMB control number.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0600).  
Do not return the completed form to this address.

Accept

Reject

# Search Submitted Clinical Trials

David Loose ▾

Search ▾

Register Trial ▾

Quick Links ▾

Contact Us

Help

 Search Clinical Trials

 Search Persons

 Search Organizations

Enter information for at least one of the criteria and then click Search.

**Title:**

**Phase:**

**Purpose:**

**Pilot Trial?:**

**Identifier Type:**

**Identifier:**

**Organization Type:**

**Organization:**

*Please select an organization type before selecting an organization*

**Principal Investigator:**

**Search By Trial Category:**

 Search ▾

 Reset

Search Register Trial Quick Links Contact Us Help

Search Clinical Trials Search Persons Search Organizations Search Results

Clinical Trials Search Results

Show 10 Search: Choose columns << < 1 2 > >>

NCI Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	Principal Investigator	ClinicalTrials.gov Identifier	Other Identifiers	Current Trial Status	Current Processing
NCI-2016-00006	test0003	3.5.1 CTEP/CTRP Test Org	test0003	Test, Test			Active	Accepted

Search Register Trial Quick Links Contact Us Help

Search Clinical Trials Search Persons Search Organizations Search Results

Clinical Trials Search Results

Search: Choose columns << < 1 2 > >>

Principal Investigator	ClinicalTrials.gov Identifier	Other Identifiers	Current Trial Status	Current Processing Status	Available Actions	Accrual Disease Terminology	Sites	Phase	Primary Purpose	Category
Test, Test			Active	Abstraction	Update Amend Change Status View TSR View XML Verify Data	SDC	View	I,II	TREATMENT	Complete

### Amendment Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (\*).

XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov?  Yes  No ?

#### Amendment Details

Amendment Number:

Amendment Date: \*  ?

#### Trial Identifiers\*

Lead Organization Trial Identifier: \*  ?  
22 characters left

ClinicalTrials.gov Identifier:  ?

NCI Trial Identifier: NCI-2016-00006

#### Other Identifiers\*

Other Trial Identifier:

#### Trial Details\*

Title: \*  ?  
3992 characters left

Phase: \*  ?

Trial Type: \*  Interventional  Non-interventional

Primary Purpose: \*  ?

Secondary Purpose:

Accrual Disease Terminology:

#### Lead Organization/Principal Investigator\*

Lead Organization: \* **3.5.1 CTEP/CTRP Test Org**

Principal Investigator: \*   ?

#### Sponsor/Responsible Party\*

Sponsor: \* **3.5.1 CTEP/CTRP Test Org**

Responsible Party: \*

Data Table 4 Information\*

Data Table 4 Funding Sponsor Type: National

Data Table 4 Funding Sponsor: Please Select the Data Table 4 Sponsor Organization -

3.5.1 CTEP/CTRP Test Org Delete Sponsor

Program code:

NIH Grant Information (for NIH funded Trials)\*

To record grant information, provide values for all fields, and then click the **Add Grant** button.

Is this trial funded by an NCI grant?  Yes  No

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
--Select--	--Select--		--Select--	<b>+ Add Grant</b>
Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program Code	Action
B08	AA	1234	CCR	
B08	AF	789456	CIP	
B01	AA	123456	CCR	

Trial Status\*

Status Date	Status	Why Study Stopped?	
mm/dd/yyyy	--Select--		<b>+ Add Status</b>

Administratively Complete, Withdrawn and Temporarily Closed statuses only 1000 characters left

Please refer to the [Trial Status Transition Rules](#).

Trial Status History

Show 10 entries

Status Date	Status	Comments	Validation Messages	Actions
01/01/2016	In Review			
01/02/2016	Approved			
01/03/2016	Active			

Showing 1 to 3 of 3 entries

Previous **1** Next

Trial Dates\*

Trial Start Date: 01/03/2016  Actual  Anticipated

Primary Completion Date: 02/03/2017  Actual  Anticipated

Completion Date: 02/03/2017  Actual  Anticipated

Please refer to [Trial Status Rules for Start and Completion dates](#).

FDA IND/IDE Information for applicable trials

To record IND/IDE information, provide values for all fields, and then click the **Add IND/IDE** button.

IND/IDE Types	IND/IDE Number	IND/IDE Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program Code (if applicable)	Expanded Access?	Expanded Access Type (if applicable)	Exempt? (if applicable)	
-Select-		-Select-	-Select-	-Select-	<input type="checkbox"/> Yes	-Select-	<input type="checkbox"/> Yes	<b>+ Add IND/IDE</b>

IND/IDE Type	Number	Grantor	Holder	Program Code	Expanded Access?	Expanded Access Type	Exempt?	Action
IND	123	CDER	Investigator		No		No	

< Scroll left/right to view full table >

Regulatory Information

**Trial Oversight Authority Country:** \* United States ?

**Trial Oversight Authority Organization Name:** \* Food and Drug Administration ?

**FDA Regulated Intervention Indicator:** \*  No  Yes ?

**Section 801 Indicator:** \*  No  Yes ?

**Delayed Posting Indicator:** \*  No  Yes ? To modify this indicator's value please submit a request to the CTRO at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov)

**Data Monitoring Committee Appointed Indicator:** \*  No  Yes ?

Existing Trial Related Documents

Document Types	File Name
Protocol Document	testtest.doc
IRB Approval Document	testtest.doc
TSR	TSR_NCI-2016-00006_2016-02-03-1550_O.rtf

Trial Related Documents

Amendment Related Documents

To ensure successful registration, upload a Protocol document and an IRB Approval document. If the Protocol document does not include the Informed Consent and/or participating sites, upload the informed Consent document and a list of participating sites separately. You can use the [Participating Sites template](#) to submit your list of participating sites.

CTRP accepts most standard document types. For additional information about what document types are accepted, please refer to the [Help](#) section.

**Protocol Document:** \*  No file selected. ?

**Change Memo Document:** \*\*  No file selected. ?

**Protocol Highlighted Document:** \*\*  No file selected. ?

**IRB Approval:** \*  No file selected. ?

**List of Participating Sites:**  No file selected. ?

**Informed Consent Document:**  No file selected. ?

**Other:**  No file selected. ?

**+ Add more...**

\*\* At least one is required: Change Memo Document or Protocol Highlighted Document

Please verify ALL the trial information you provided on this screen before clicking the "Review Trial" button below. Once you submit the trial you will not be able to modify the information.