

## **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 – 10

# CTRP Home and Login page

NCI CTRP Registration



## Welcome to NCI's Clinical Trials Reporting Program

### Warning Notice

- ✓ This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.
- ✓ This system is provided for Government-authorized use only.
- ✓ Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.
- ✓ Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.
- ✓ By using this system, you understand and consent to the following:
  - ✓ The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system.
  - ✓ Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

➔ Sign In
✍ Sign Up
🔍 Reset Password

**Username**

**Password**

[Sign In ➔](#)

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

- Register clinical trials
- 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. If you have questions or want to report any issues, send an email to [ctrp\\_support@nih.gov](mailto:ctrp_support@nih.gov)



# CTRP Burden Statement



## NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

### Warning Notice

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  - Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

## NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

OMB#: 0925-0600 EXP. DATE: 8/31/19

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.

# Search Submitted Clinical Trials

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:

Please select an organization type before selecting an organization

Organization:

Principal Investigator:

Search By Trial Category:

Search

Reset

# NCI CTRP Registration

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[Search Clinical Trials](#) | 
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 [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
<a href="#">NCI-2016-00006</a>	test0003	3.5.1 CTEP/CTRP Test Org	test0003	Test, Test			Active	Accepted

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## 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	Abstract	Update Amend Change Status View TSR View XML Verify Data	SDC	View	I,II	TREATMENT	Complete

Search

Register Trial

Quick Links

Contact Us

### Amendment Trial

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


Collapse All

#### Amendment Details

Amendment Number:

Amendment Date:\*   

#### Trial Identifiers\*

Lead Organization Trial Identifier:\*  

22 characters left

ClinicalTrials.gov Identifier:  

NCI Trial Identifier: NCI-2017-00782

DCP Identifier:  

#### Other Identifiers\*

Other Trial Identifier:

Other Trial Identifier:

Trial Details\*

Title:\* test test test test test ?

3976 characters left

Phase:\* I/II ?

Is this a Pilot? --Select-- ?

Trial Type:\*  Interventional  Non-interventional

Primary Purpose:\* Prevention ?

Secondary Purpose: --Select-- ?

Accrual Disease Terminology: ICD10 ?

Lead Organization/Principal Investigator\*

Lead Organization:\* Dana-Farber Cancer Institute

Principal Investigator:\* Izbicki, Michael Look Up Person ?

Sponsor/Responsible Party

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov

Sponsor: Dana-Farber Cancer Institute

Responsible Party: Sponsor ?

Data Table 4 Information\*

Data Table 4 Funding Sponsor Type:\* National ?

Data Table 4 Funding Sponsor:\* Please Select the Data Table 4 Sponsor Organization - ?  
Dana-Farber Cancer Institute Delete Sponsor

Program Code: ZZZ296 ?

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	
--Select--	--Select--		--Select--	<b>+ Add Grant</b>
Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program	Action
P30	CA	89017	CTEP	

Trial Status\*

Status Date	Status	Why Study Stopped?	
mm/dd/yyyy	--Select--		<b>+ Add Status</b>
		<i>Administratively Complete, Withdrawn and Temporarily Closed statuses only</i>	1000 characters left

Please refer to the Trial Status Transition Rules.

Trial Status History

Show 10 entries

Status Date	Status	Comments	Validation Messages	Actions
04/05/2017	In Review			 

Showing 1 to 1 of 1 entries

Previous **1** Next

Trial Dates\*

Trial Start Date:	<input type="text" value="07/04/2017"/>	<input checked="" type="radio"/> Actual <input type="radio"/> Anticipated
Primary Completion Date:	<input type="text" value="mm/dd/yyyy"/>	<input type="radio"/> Actual <input checked="" type="radio"/> Anticipated <input type="radio"/> N/A
Completion Date:	<input type="text" value="07/28/2018"/>	<input type="radio"/> Actual <input checked="" type="radio"/> 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)	Availability of Expanded Access	Expanded Access Record (if applicable)	
-Select-		-Select-	-Select-	-Select-	Unknown		<b>+ Add IND/IDE</b>

IND/IDE Type	Number	Grantor	Holder	Program Code	Availability of Expanded Access	Expanded Access Record	Action
IND	132024	CDER	NCI	DEA	Yes	NCT12345678	
IDE	48176	CDRH	Investigator		Unknown		
IND	153116	CDER	Investigator				

< Scroll left/right to view full table >

Regulatory Information

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in [ClinicalTrials.gov](https://ClinicalTrials.gov)

Studies a U.S. FDA-regulated Drug Product:  Yes  No ?

Studies a U.S. FDA-regulated Device Product:  Yes  No ?

Unapproved/Unleared Device:  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)

Pediatric Post-market Surveillance:  Yes  No ?

Product Exported from the U.S.:  Yes  No ?

FDA Regulated Intervention Indicator:  Yes  No ?

Section 801 Indicator:  Yes  No ?

Data Monitoring Committee Appointed Indicator:  Yes  No ?

Existing Trial Related Documents ▼

Document Types	File Name
IRB Approval Document	test - 2.docx
Change Memo Document	test - 3.docx
Protocol Document	test - 2.docx
TSR	TSR_NCI-2017-00782_2017-07-21-1245_A123.rtf

Trial Related Documents <sup>+</sup> ▼

#### 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:**<sup>+</sup>   ?

**Change Memo Document:**<sup>\*\*</sup>   ?

**Protocol Highlighted Document:**<sup>\*\*</sup>   ?

**IRB Approval:**<sup>+</sup>   ?

**List of Participating Sites:**   ?

**Informed Consent Document:**   ?

**Other:**   ?

<sup>\*\*</sup> 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.*

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NIH...Turning Discovery Into Health