

## NCI CTRP Registration 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 clicks “Login”

Step 3: User enters “Email Address” and “Password” – see screenshot, page 3

Step 4: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 4

Step 5: System displays “Search Submitted Clinical Trials” page – see screenshot, page 15

Step 6: Alternative workflows, a – c, a user may perform any of these actions upon entering the system:

- a. User selects to perform “Initial Trial Registration” and completes initial registration – see screenshots, pages 5 - 9, OR**
- b. User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 10 - 14, OR**
- c. User selects to “Search Submitted Clinical Trials” and searches for an existing trial – see screenshot, page 15**

**CTRP Home page**

NCI Registry - Mozilla Firefox

File Edit View History Bookmarks Tools Help

# CTRP Login Screen

National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

## NCI CTRP Registration Site

Log In

**NCI CTRP**

- Home
- Create Account
- Register Trial
- Search Trials
- Log In**
- Help

**QUICK LINKS**

- Clinical Trials Reporting Program (CTRP)
- Useful Templates and Documentation
- National Cancer Institute (NCI)
- NCI Center for Bioinformatics (NCICB)
- caBIG™ - Cancer Biomedical Informatics Grid™

### Login

Help

Please log in to search, view and register clinical trial details. If you do not have an account, you may [create an account](#).

Email Address:

Password:

[\(Forgot Your Password?\)](#)  
[\(Create an Account\)](#)

Log In

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# CTRP Burden Statement

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Welcome to NCI's Clinical Trials Reporting Program

Help



OMB#: 0925-XXXX EXP. DATE: XX/XX/XXXX

### NCI CLINICAL TRIALS REPORTING PROGRAM NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average one (1) to two (2) hours 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-XXXX). Do not return the completed form to this address.

Continue to CTRP



Register Trial - Mozilla Firefox

# Initial Trial Registration

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https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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## NCI CTRP Registration Site

Welcome, nshimko@scenpro

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### Register Trial

Register trial with NCI's Clinical Trials Reporting Program. Required fields are marked by asterisks(\*).

#### Trial Details

**Lead Organization Trial Identifier:**\*

**NCT Number:**

**Title:**\*  Max 4000 characters

**Phase:**\* --Select--

**Phase Comment:**  Required if Phase equals 'Other'

**Trial Type:**\*  Interventional  Observational

**Purpose:**\* --Select--

**Purpose Comment:**  Required if Purpose equals 'Other'


#### Lead Organization/Principal Investigator

Lead Organization/Principal Investigator

Lead Organization:\*  

Principal Investigator:\*  

Sponsor/Responsible Party

Sponsor:\*  


Responsible Party:\*  PI  Sponsor

Responsible Party Email Address:\*  (work information)

Responsible Party Phone Number:\*  (work information)

Summary 4 Information (for trials at NCI-designated cancer centers)

Summary 4 Funding Sponsor Type:  

Summary 4 Funding Sponsor:  

NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Register Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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### NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code
--Select--	--Select--		--Select--

Add Grant

### Status/Dates

Current Trial Status:\* --Select--

Why Study Stopped?:  Required for Administratively Complete and Temporarily Closed statuses only

Current Trial Status Date:\*  (mm/dd/yyyy)

Trial Start Date:\*  (mm/dd/yyyy)  Actual  Anticipated

Primary Completion Date:\*  (mm/dd/yyyy)  Actual  Anticipated

### FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

Done trials-qa.nci.nih.gov

Register Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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### FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

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)	
<input type="radio"/> IND <input type="radio"/> IDE	<input type="text"/>	-Select- ▾	-Select- ▾	-Select- ▾	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select- ▾	Add IND/IDE

### Trial Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, please submit them separately using the fields below.

**Protocol Document:**

**IRB Approval:**

**List of Participating Sites:**

**Informed Consent Document:**

**Other:**

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



Register Trial - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/submitTrial.action

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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)	
<input type="radio"/> IND <input type="radio"/> IDE	<input type="text"/>	-Select- ▾	-Select- ▾	-Select- ▾	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select- ▾	Add IND/IDE

### Trial Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, please submit them separately using the fields below.

**Protocol Document: \***

**IRB Approval: \***

**List of Participating Sites:**

**Informed Consent Document:**

**Other:**

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

Amend Trial - Mozilla Firefox

# Submit Trial Amendment

File Edit View History Bookmarks Tools Help

https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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## NCI CTRP Registration Site

Welcome, nshimko@scenpro

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### QUICK LINKS

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- caBIG™ - Cancer Biomedical Informatics Grid™

### Amendment Trial

Register trial with NCI's Clinical Trials Reporting Program. Required fields are marked by asterisks(\*).

#### Amendment Details

**Amendment Number:**

**Amendment Date:** \*  (mm/dd/yyyy)

#### Trial Details

**NCI Trial Identifier:** NCI-2009-00753

**Lead Organization Trial Identifier:**\*

**NCT Number:**

**Title:**\*  Max 4000 characters

**Phase:**\*

**Phase Comment:**  Required if Phase equals 'Other'

**Trial Type:**\*  Interventional  Observational

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**Trial Type:**  Interventional  Observational

**Purpose:** Treatment

**Purpose Comment:**  Required if Purpose equals 'Other'

**Lead Organization/Principal Investigator**

**Lead Organization:** Mercy Hospital

**Principal Investigator:** Kraft, Andrew

**Sponsor/Responsible Party**

**Sponsor:** National Cancer Institute Medicine

**Responsible Party:**  PI  Sponsor

**Responsible Party Email Address:**  (work information)

**Responsible Party Phone Number:**  (work information)

**Summary 4 Information (for trials at NCI-designated cancer centers)**

**Summary 4 Funding Sponsor Type:** --Select--

**Summary 4 Funding Sponsor:**

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Amend Trial - Mozilla Firefox

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https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318

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### Summary 4 Information (for trials at NCI-designated cancer centers)

Summary 4 Funding Sponsor Type: --Select--

Summary 4 Funding Sponsor:

### NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
B09	AA	123456	N/A	<input type="button" value="Add Grant"/>

### Status/Dates

Current Trial Status: Temporarily Closed to Accrual and

Why Study Stopped?:  Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

Current Trial Status Date: 04/02/2009  (mm/dd/yyyy)

Trial Start Date: 03/31/2009  (mm/dd/yyyy)  Actual  Anticipated

Primary Completion Date: 03/31/2011  (mm/dd/yyyy)  Actual  Anticipated

Done  trials-qa.nci.nih.gov

Amend Trial - Mozilla Firefox

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### FDA IND/IDE Information for applicable trials

Assign values to all editable IND/IDE elements and click 'Add IND/IDE' button for adding this IND/IDE to the trial. Note that the button becomes active when all required IND/IDE attributes are assigned.

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)	
<input checked="" type="radio"/> IND <input type="radio"/> IDE	123	CDER	Organizat	-Select-	<input type="radio"/> Yes <input checked="" type="radio"/> No	-Select-	Add IND/IDE

### Exiting Trial Related Documents

Document Types	File Name
Protocol Document	<a href="#">PD.doc</a>
IRB Approval Document	<a href="#">PD.doc</a>
Change Memo Document	<a href="#">PD.doc</a>

### Amendment Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, please submit them separately using the fields below.

Amendment Protocol Document: \*

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Protocol Document	<a href="#">PD.doc</a>
IRB Approval Document	<a href="#">PD.doc</a>
Change Memo Document	<a href="#">PD.doc</a>

### Amendment Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, please submit them separately using the fields below.

**Amendment Protocol Document:**

**Change Memo Document:**

**Protocol Highlighted Document:**

**IRB Approval:**

**List of Participating Sites:**

**Informed Consent Document:**

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Search Submitted Clinical Trials - Mozilla Firefox

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https://trials- **Search Submitted Clinical Trials** Google

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Search Submitted Clinical Trials

Title:

Phase:

Identifier Type:

Organization Type:

Purpose:



Identifier:

(e.g. NCI-2008-00015; ECOG-1234, etc)

Organization:

*Search My Trials: Search the trials I have submitted.*  
*Search All Trials: Search all trials I have submitted as well as those registered by others.*

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