NCI CTRP Attachment 3c

NCI CTRP Trial 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 views trial information and selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 5 – 12

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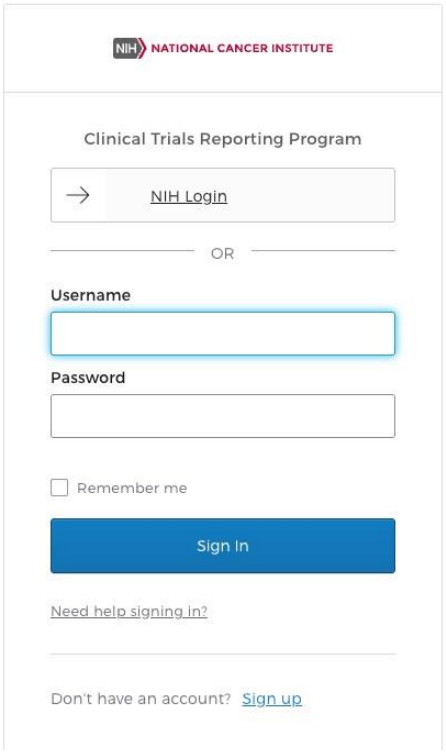
CTRP Login & Home page

Clinical Trials Reporting Program Login



You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following:

You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system.

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

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CTRP Burden Statement

Clinical Trials Reporting Program Registration

NCI CLINICAL TRIALS REPORTING PROGRAM (CTRP) SYSTEM

Warning Notice

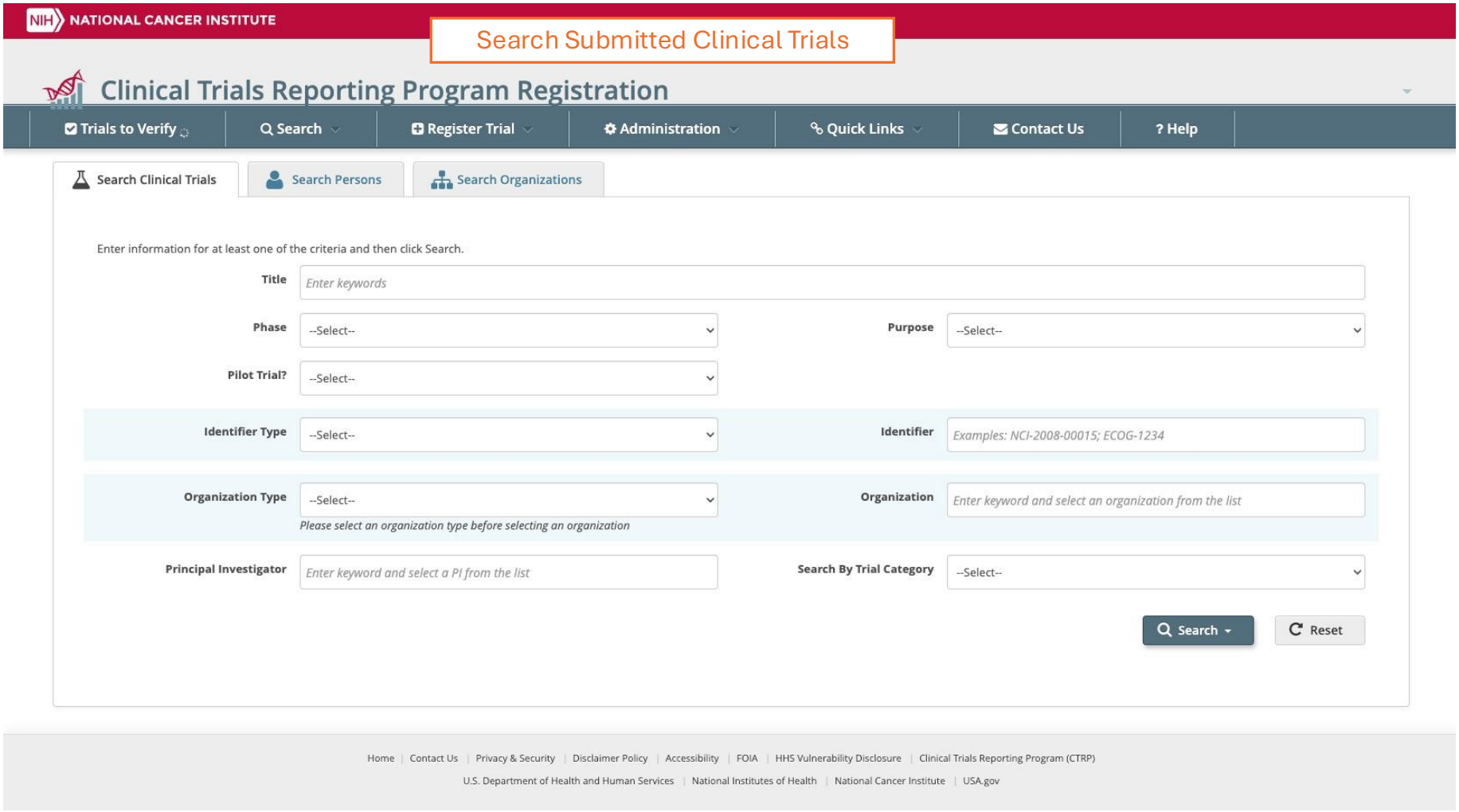
- This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media 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.

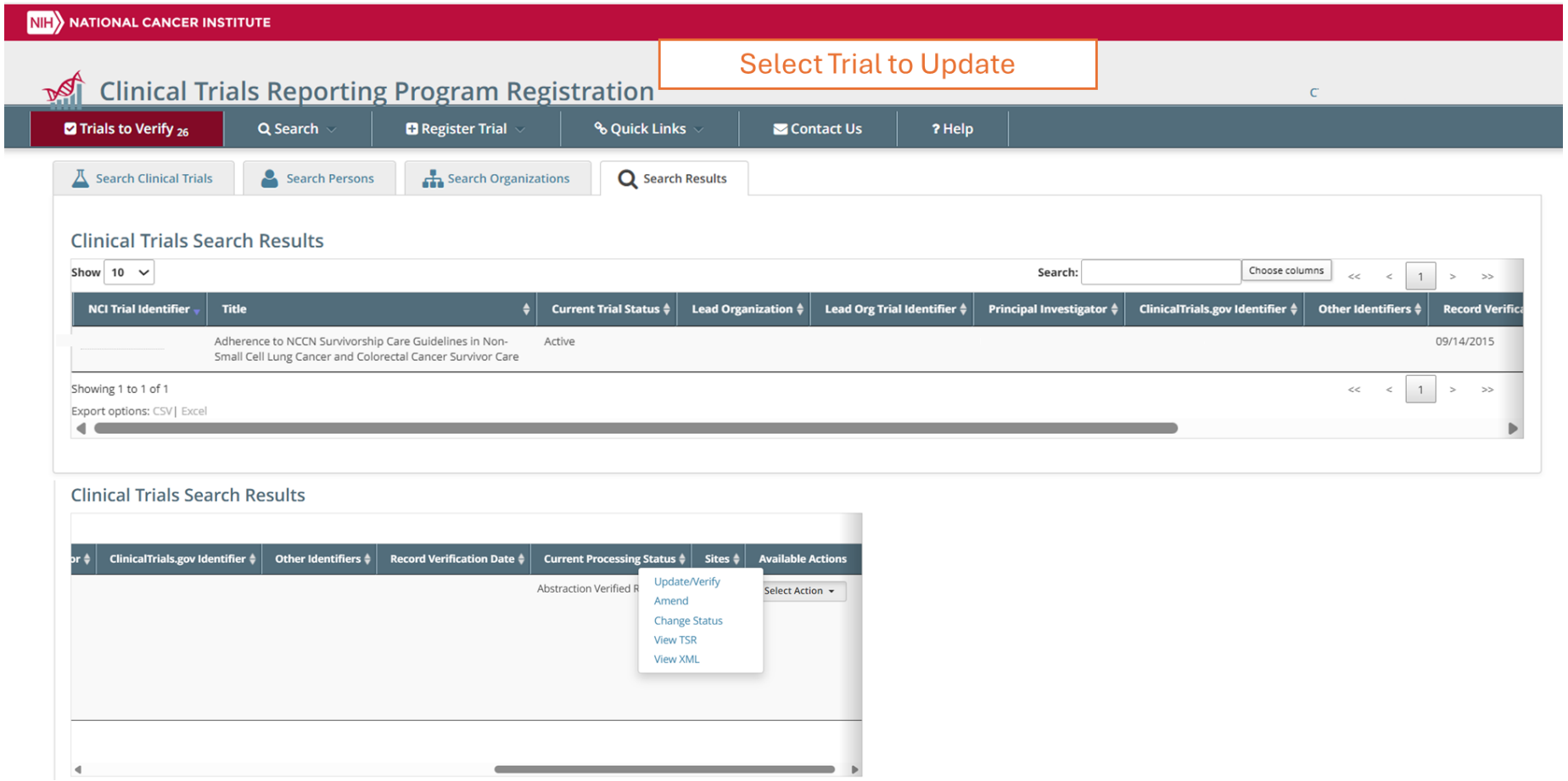
NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

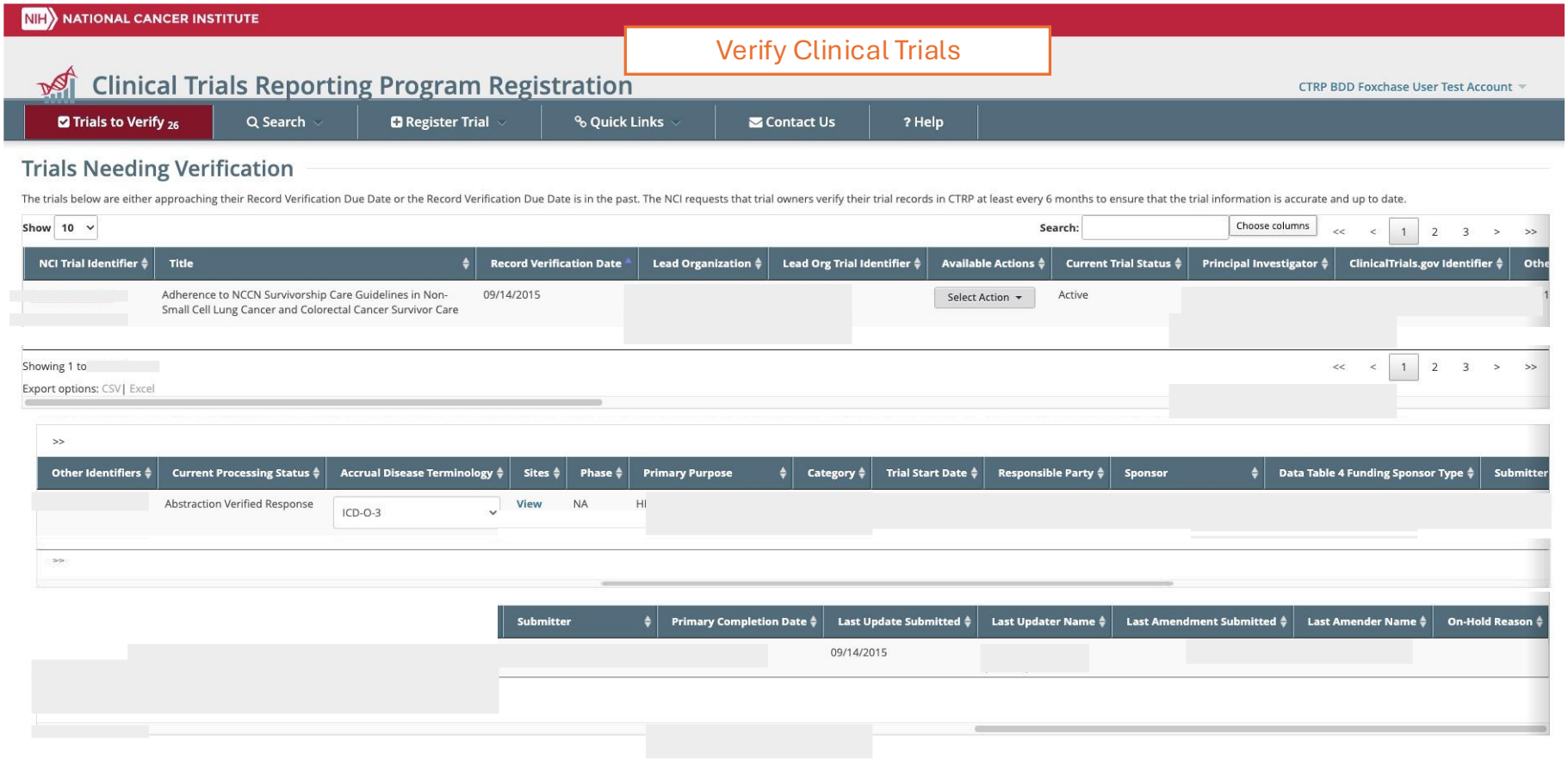
OMB#: 0925-0600 EXP. DATE: 2/28/26

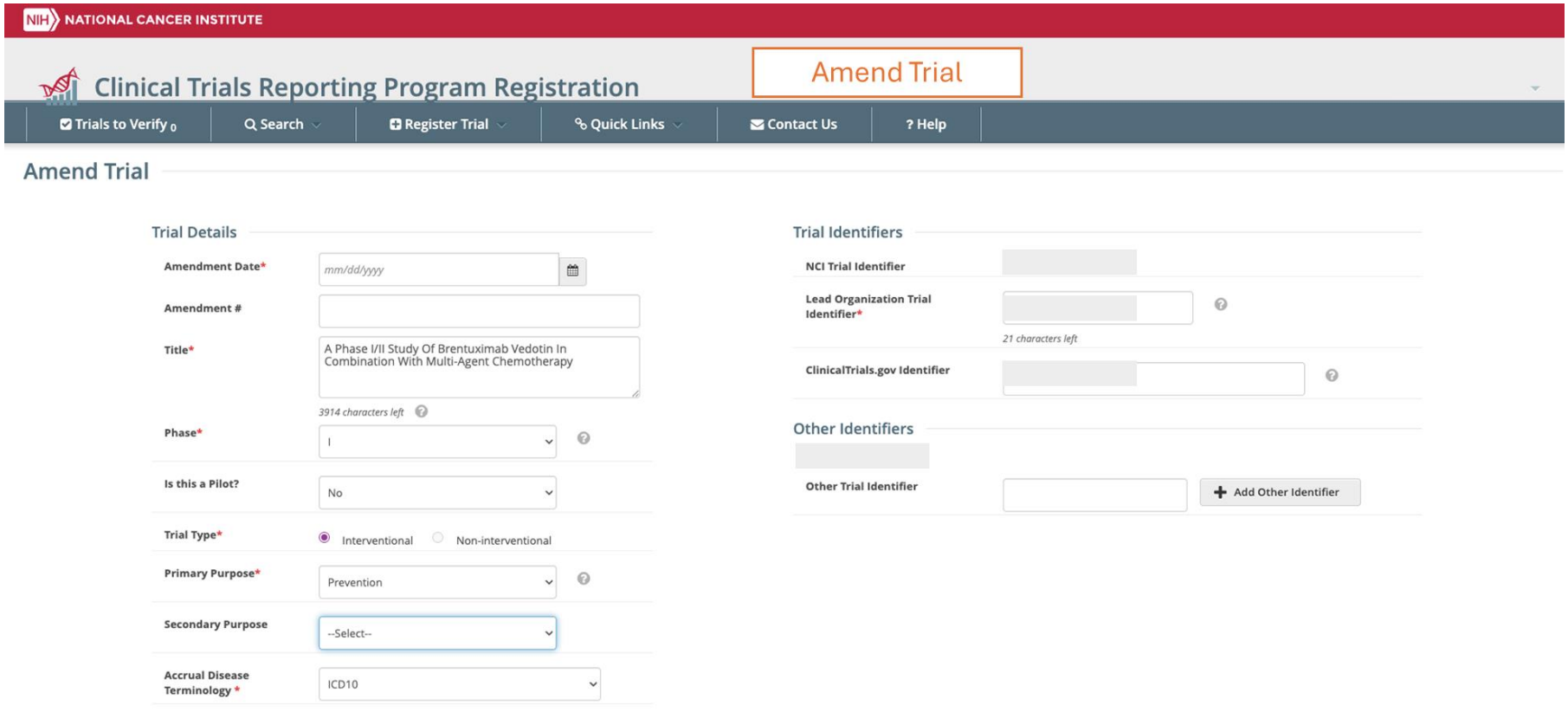
Public reporting burden for this collection of information is estimated to average sixty (60) minutes for this questionnaire, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. An agency 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.

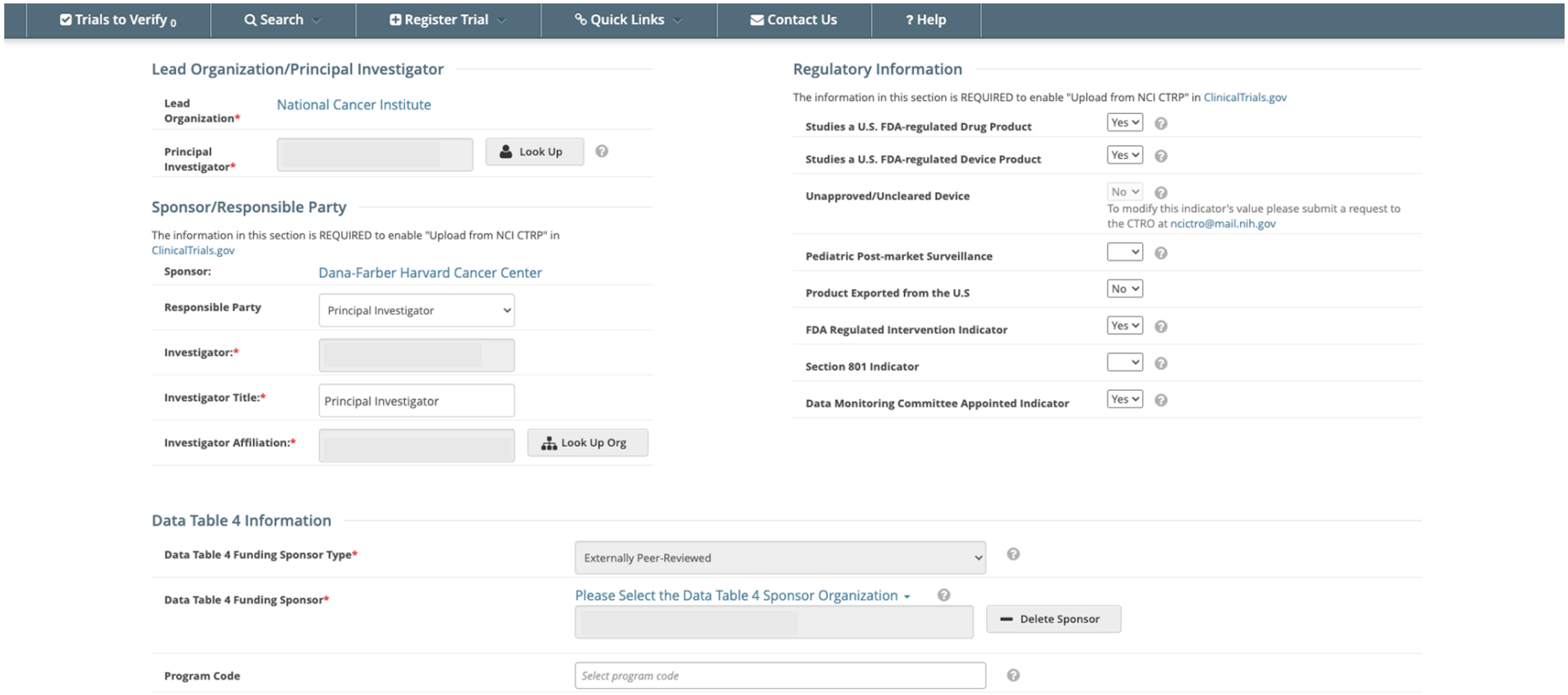
Accept Reject

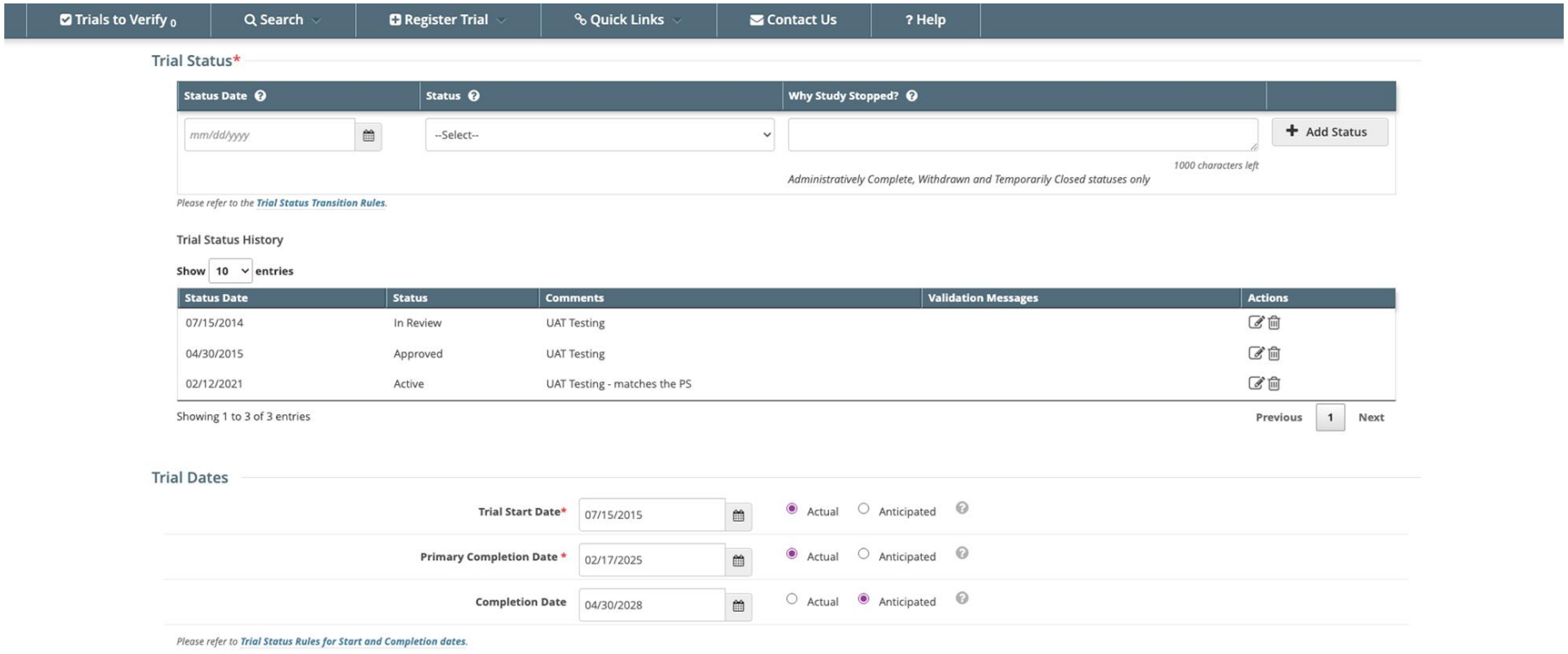

NIH NATIONAL CANCER INSTITUTE
Search Submitted Clinical Trials
Clinical Trials Reporting Program Registration
Trials to Verify
Search
Register Trial
Administration
Quick Links
Contact Us
? Help
Search Clinical Trials
Search Persons
Search Organizations
Enter information for at least one of the criteria and then click Search.
Title
Enter keywords
Phase
--Select--
Purpose
--Select--
Pilot Trial?
--Select--
Identifier Type
--Select--
Identifier
Examples: NCI-2008-00015; ECOG-1234
Organization Type
--Select--
Please select an organization type before selecting an organization
Organization
Enter keyword and select an organization from the list
Principal Investigator
Enter keyword and select a PI from the list
Search By Trial Category
--Select--
Search
Reset
Home | Contact Us | Privacy & Security | Disclaimer Policy | Accessibility | FOIA | HHS Vulnerability Disclosure | Clinical Trials Reporting Program (CTRP)
U.S. Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov

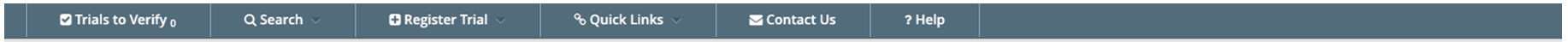

NATIONAL CANCER INSTITUTE
Select Trial to Update
Clinical Trials Reporting Program Registration
Trials to Verify 26
Search
Register Trial
Quick Links
Contact Us
Help
Search Clinical Trials
Search Persons
Search Organizations
Search Results
Clinical Trials Search Results
Show 10
Search:
Choose columns
NCI Trial Identifier
Title
Current Trial Status
Lead Organization
Lead Org Trial Identifier
Principal Investigator
ClinicalTrials.gov Identifier
Other Identifiers
Adherence to NCCN Survivorship Care Guidelines in Non-Small Cell Lung Cancer and Colorectal Cancer Survivor Care
Active
09/14/2015
Showing 1 to 1 of 1
Export options: CSV | Excel
Clinical Trials Search Results
ClinicalTrials.gov Identifier
Other Identifiers
Record Verification Date
Current Processing Status
Sites
Available Actions
Abstraction Verified R
Select Action
Update/Verify
Amend
Change Status
View TSR
View XML


NIH NATIONAL CANCER INSTITUTE
Verify Clinical Trials
Clinical Trials Reporting Program Registration
CTRP BDD Foxchase User Test Account
Trials to Verify 26
Search
Register Trial
Quick Links
Contact Us
? Help
Trials Needing Verification
The trials below are either approaching their Record Verification Due Date or the Record Verification Due Date is in the past. The NCI requests that trial owners verify their trial records in CTRP at least every 6 months to ensure that the trial information is accurate and up to date.
Show 10
Search:
Choose columns
NCI Trial Identifier
Title
Record Verification Date
Lead Organization
Lead Org Trial Identifier
Available Actions
Current Trial Status
Principal Investigator
ClinicalTrials.gov Identifier
Adherence to NCCN Survivorship Care Guidelines in Non-Small Cell Lung Cancer and Colorectal Cancer Survivor Care
09/14/2015
Select Action
Active
Showing 1 to
Export options: CSV| Excel
Other Identifiers
Current Processing Status
Accrual Disease Terminology
Sites
Phase
Primary Purpose
Category
Trial Start Date
Responsible Party
Sponsor
Data Table 4 Funding Sponsor Type
Submitter
Abstraction Verified Response
ICD-O-3
View
NA
Submitter
Primary Completion Date
Last Update Submitted
Last Updater Name
Last Amendment Submitted
Last Amender Name
On-Hold Reason
09/14/2015


NIH NATIONAL CANCER INSTITUTE
Clinical Trials Reporting Program Registration
Amend Trial
Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Amend Trial
Trial Details
Amendment Date*
mm/dd/yyyy
Amendment #
Title*
A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy
3914 characters left
Phase*
I
Is this a Pilot?
No
Trial Type*
Interventional
Non-interventional
Primary Purpose*
Prevention
Secondary Purpose
--Select--
Accrual Disease Terminology *
ICD10
Trial Identifiers
NCI Trial Identifier
Lead Organization Trial Identifier*
21 characters left
ClinicalTrials.gov Identifier
Other Identifiers
Other Trial Identifier
Add Other Identifier


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Lead Organization/Principal Investigator
Lead Organization*
National Cancer Institute
Principal Investigator*
Look Up
Sponsor/Responsible Party
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Sponsor:
Dana-Farber Harvard Cancer Center
Responsible Party
Principal Investigator
Investigator:*
Investigator Title:*
Principal Investigator
Investigator Affiliation:*
Look Up Org
Regulatory Information
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Studies a U.S. FDA-regulated Drug Product
Yes
Studies a U.S. FDA-regulated Device Product
Yes
Unapproved/Uncleared Device
No
To modify this indicator's value please submit a request to the CTRO at ncictro@mail.nih.gov
Pediatric Post-market Surveillance
Product Exported from the U.S
No
FDA Regulated Intervention Indicator
Yes
Section 801 Indicator
Data Monitoring Committee Appointed Indicator
Yes
Data Table 4 Information
Data Table 4 Funding Sponsor Type*
Externally Peer-Reviewed
Data Table 4 Funding Sponsor*
Please Select the Data Table 4 Sponsor Organization
Delete Sponsor
Program Code
Select program code


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Trial Status*
Status Date
Status
Why Study Stopped?
mm/dd/yyyy
--Select--
Add Status
1000 characters left
Administratively Complete, Withdrawn and Temporarily Closed statuses only
Please refer to the Trial Status Transition Rules.
Trial Status History
Show 10 entries
Status Date
Status
Comments
Validation Messages
Actions
07/15/2014
In Review
UAT Testing
04/30/2015
Approved
UAT Testing
02/12/2021
Active
UAT Testing - matches the PS
Showing 1 to 3 of 3 entries
Previous
1
Next
Trial Dates
Trial Start Date*
07/15/2015
Actual
Anticipated
Primary Completion Date *
02/17/2025
Actual
Anticipated
Completion Date
04/30/2028
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)	Availability of Expanded Access	Expanded Access Record (if applicable)	
-Select-		-Select-	-Select-	-Select-	Unknown		+ Add IND/IDE

IND/IDE Type	Number	Grantor	Holder	Program Code	Availability of Expanded Access	Expanded Access Record	Action
IND	111111	CDER	NIH	NEI-National Eye Institute	Yes		
IDE	222222	CDRH	NCI	CCR	Yes		

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 NCI funded? * ○ Direct ◉ Indirect ○ No

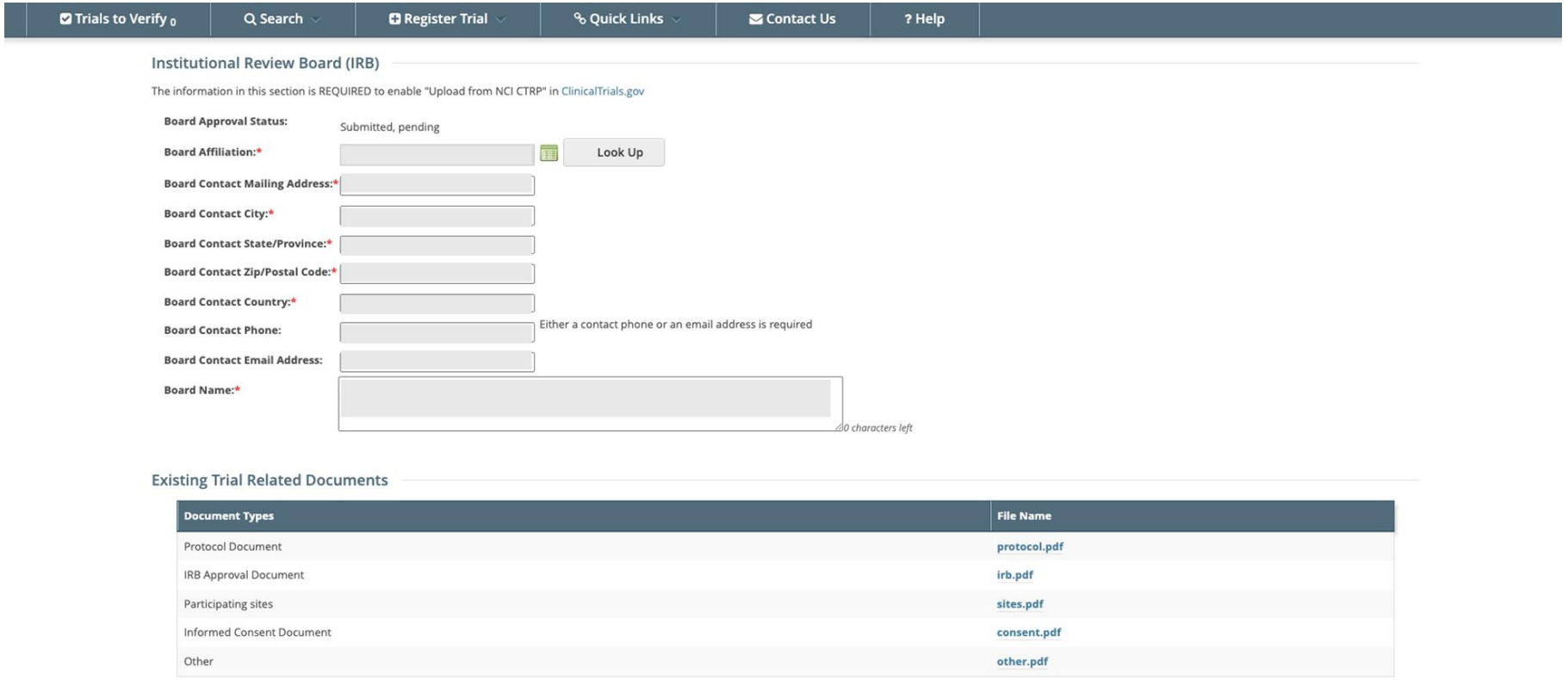
Funding Mechanism	Institute Code	Serial Number	NCI Division/Program	
--Select--	--Select--		--Select--	+ Add Grant

Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program	Action
B09	AA	111111	CCR	

*Please refer to **Recording NIH Grants**.*

Collaborators

Collaborator	Functional Role
	Laboratory


Trials to Verify 0
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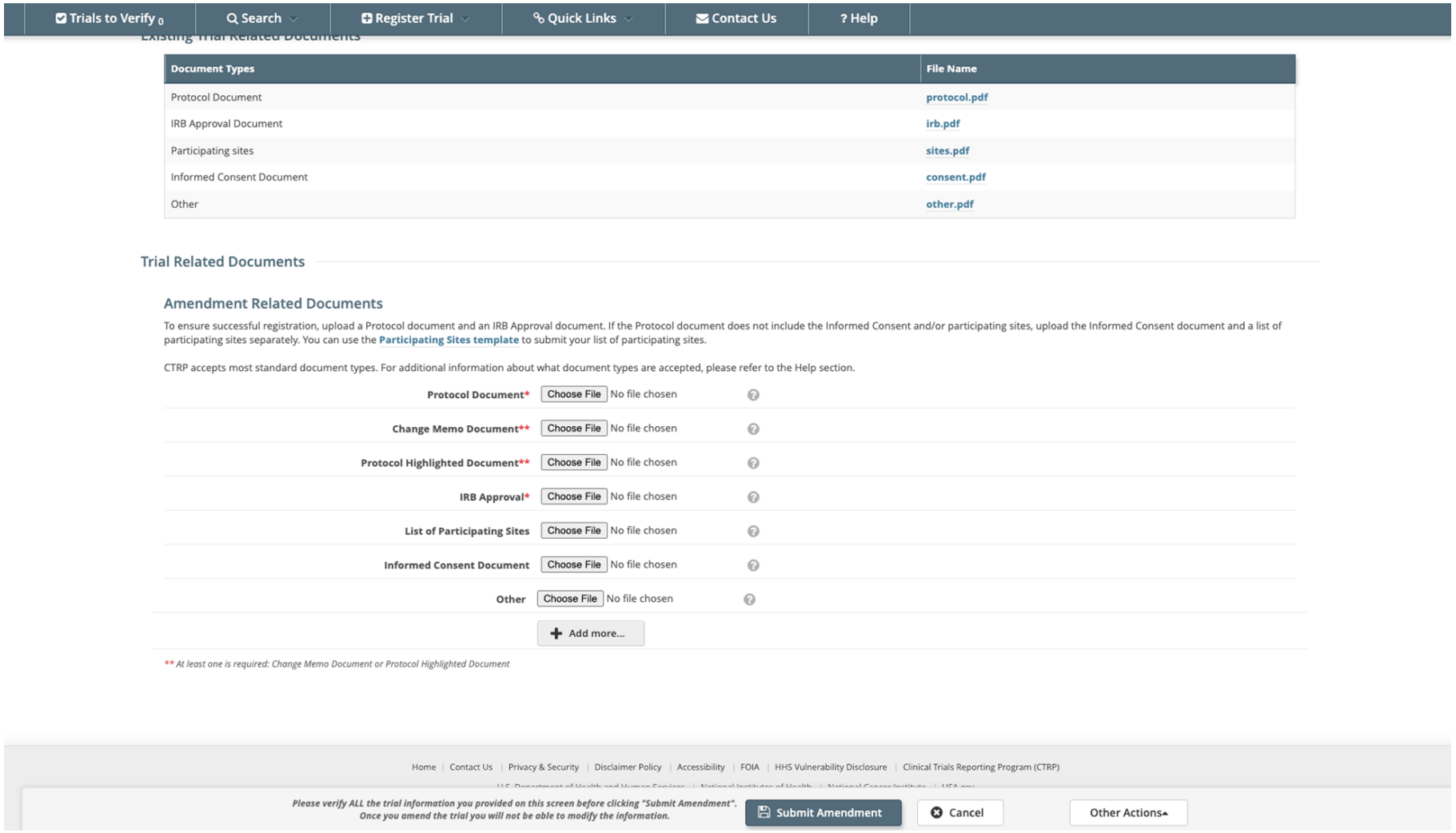
Institutional Review Board (IRB)
The information in this section is REQUIRED to enable "Upload from NCI CTRP" in ClinicalTrials.gov
Board Approval Status:
Submitted, pending
Board Affiliation:*
Look Up
Board Contact Mailing Address:*
Board Contact City:*
Board Contact State/Province:*
Board Contact Zip/Postal Code:*
Board Contact Country:*
Board Contact Phone:
Either a contact phone or an email address is required
Board Contact Email Address:
Board Name:*
0 characters left
Existing Trial Related Documents
Document Types
File Name
Protocol Document
protocol.pdf
IRB Approval Document
irb.pdf
Participating sites
sites.pdf
Informed Consent Document
consent.pdf
Other
other.pdf


Trials to Verify 0
Search
Register Trial
Quick Links
Contact Us
? Help
Existing Trial Related Documents
Document Types
File Name
Protocol Document
protocol.pdf
IRB Approval Document
irb.pdf
Participating sites
sites.pdf
Informed Consent Document
consent.pdf
Other
other.pdf
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*
Change Memo Document**
Protocol Highlighted Document**
IRB Approval*
List of Participating Sites
Informed Consent Document
Other
Choose File
No file chosen
Add more...
** At least one is required: Change Memo Document or Protocol Highlighted Document
Home | Contact Us | Privacy & Security | Disclaimer Policy | Accessibility | FOIA | HHS Vulnerability Disclosure | Clinical Trials Reporting Program (CTRP)
Please verify ALL the trial information you provided on this screen before clicking "Submit Amendment".
Once you amend the trial you will not be able to modify the information.
Submit Amendment
Cancel
Other Actions