NCI CTRP Attachment 3

NCI CTRP Registration, Update, Amendment, Accrual 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 "Username" 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 19

Step 6: Alternative workflows, a – f, 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 - 8, OR

b. User selects to "Update Trial" and updates an existing trial record – see screenshots, pages 9 – 13, OR

c. User selects to "Submit Trial Amendment" and amends an existing trial record – see screenshots, pages 14 – 19, OR

d. User selects to "Search Submitted Clinical Trials" and searches for an existing trial – see screenshot, page 20

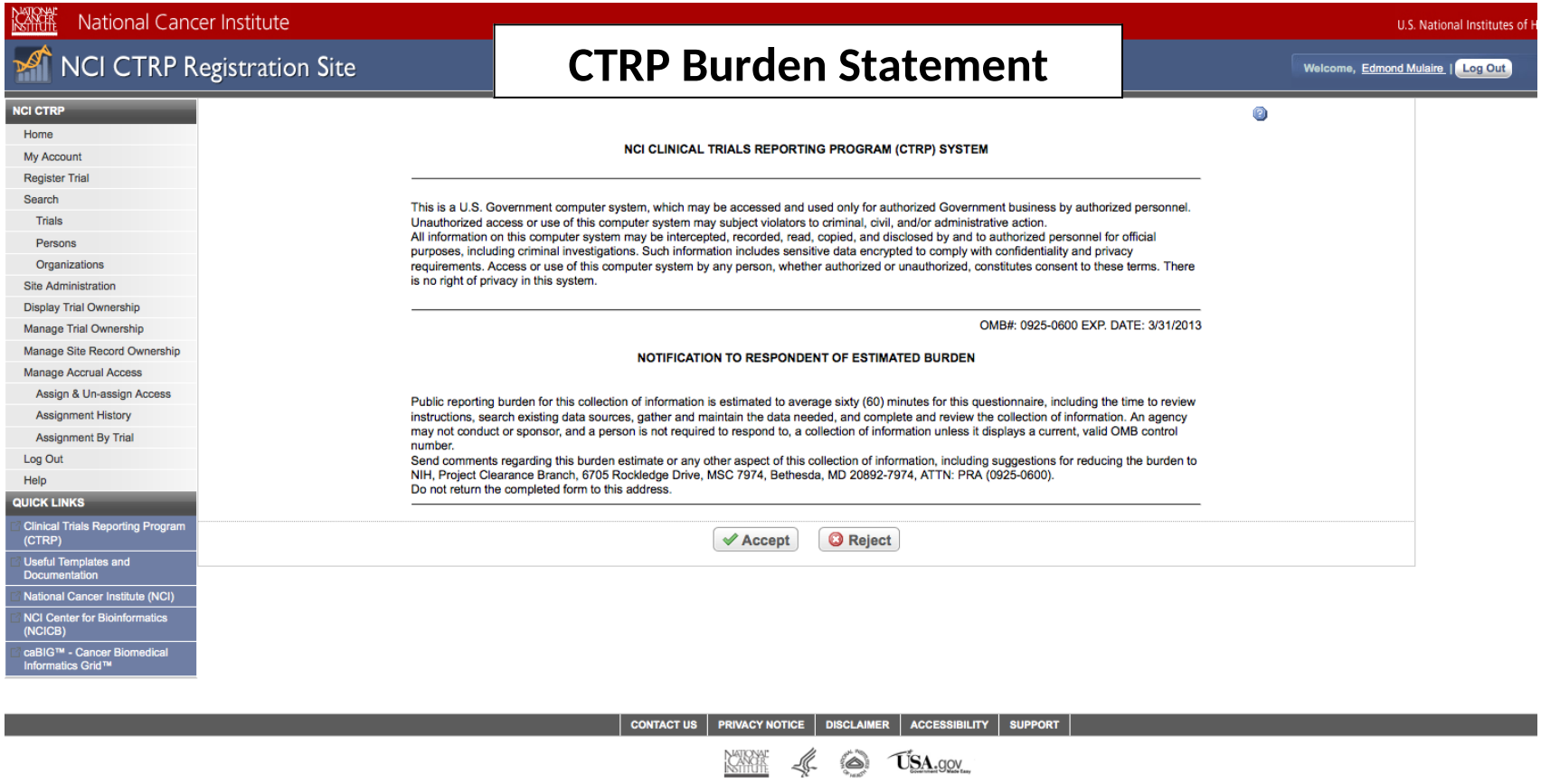
e. User selects to "Submit Study Subject Accrual Information" and submits subject level accrual information on a registered trial – see screenshots, pages 21 – 24

f. User selects to "Update Study Subject Accrual Information" and updates subject level accrual information on a registered trial – see screenshot, page 25

g. User selects to "Submit Aggregate Study Subject Accrual Information" and submits aggregate accrual information on a registered trial – see screenshot, page 26

CTRP Home page

CTRP Login Screen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CTRP Burden Statement
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NCI CTRP
Home
My Account
Register Trial
Search
Trials
Persons
Organizations
Site Administration
Display Trial Ownership
Manage Trial Ownership
Manage Site Record Ownership
Manage Accrual Access
Assign & Un-assign Access
Assignment History
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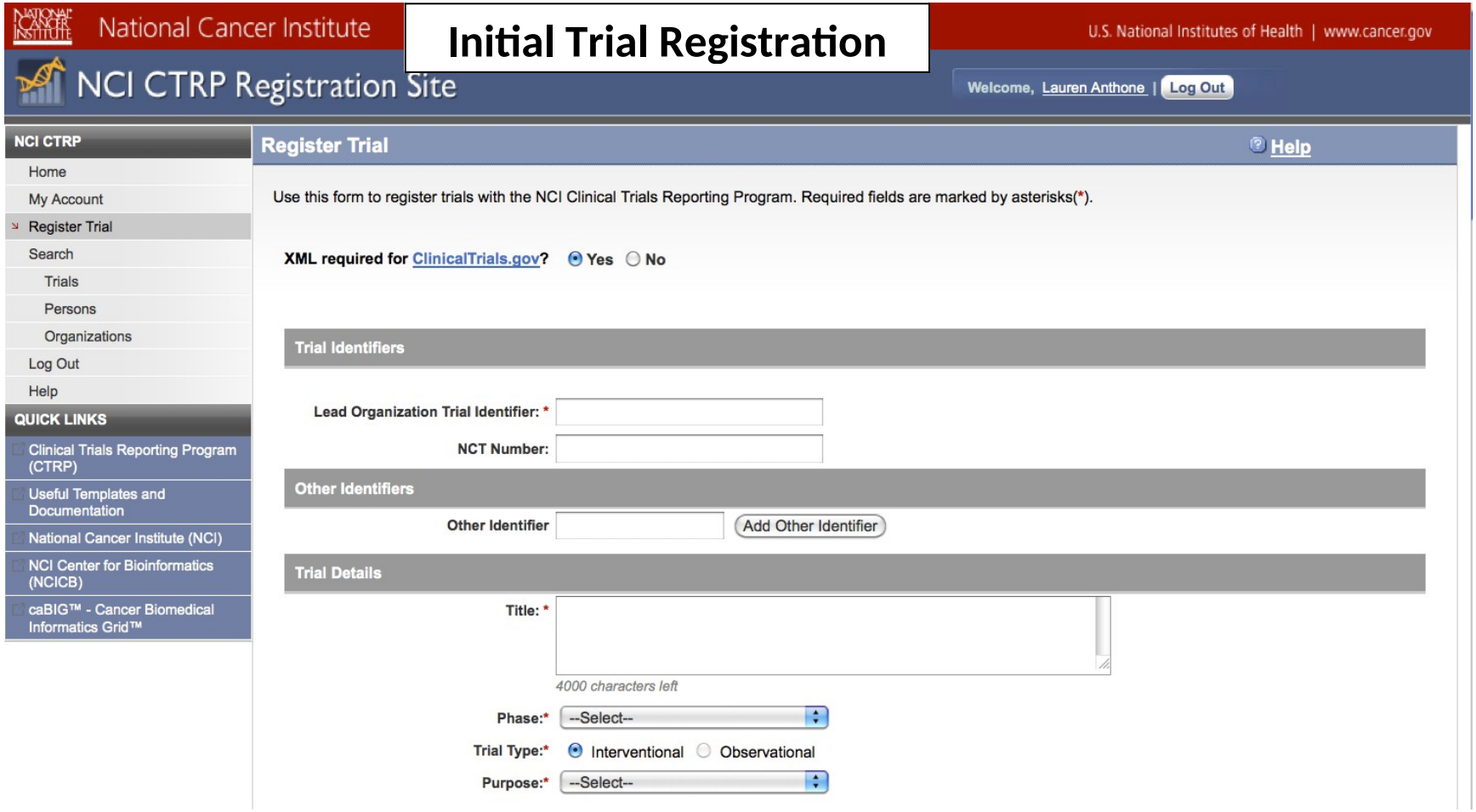
Initial Trial Registration



Lead Organization/Principal Investigator

Lead Organization: *

Look Up Org

Principal Investigator: *

Look Up Person

Sponsor/Responsible Party

Sponsor:*

Look Up Sponsor

Responsible Party:* PI Sponsor

Please provide professional contact information only.

Responsible Party Email Address:*

Responsible Party Phone Number:* Ext:

Contact information is required for internal administrative use only; it is not revealed to the public.

Summary 4 Information

Summary 4 Funding Sponsor Type: National

Summary 4 Funding Sponsor: *

Look Up 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.

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

Status/Dates

Current Trial Status: * --Select--

Why the Study Stopped:

160 characters left

Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

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

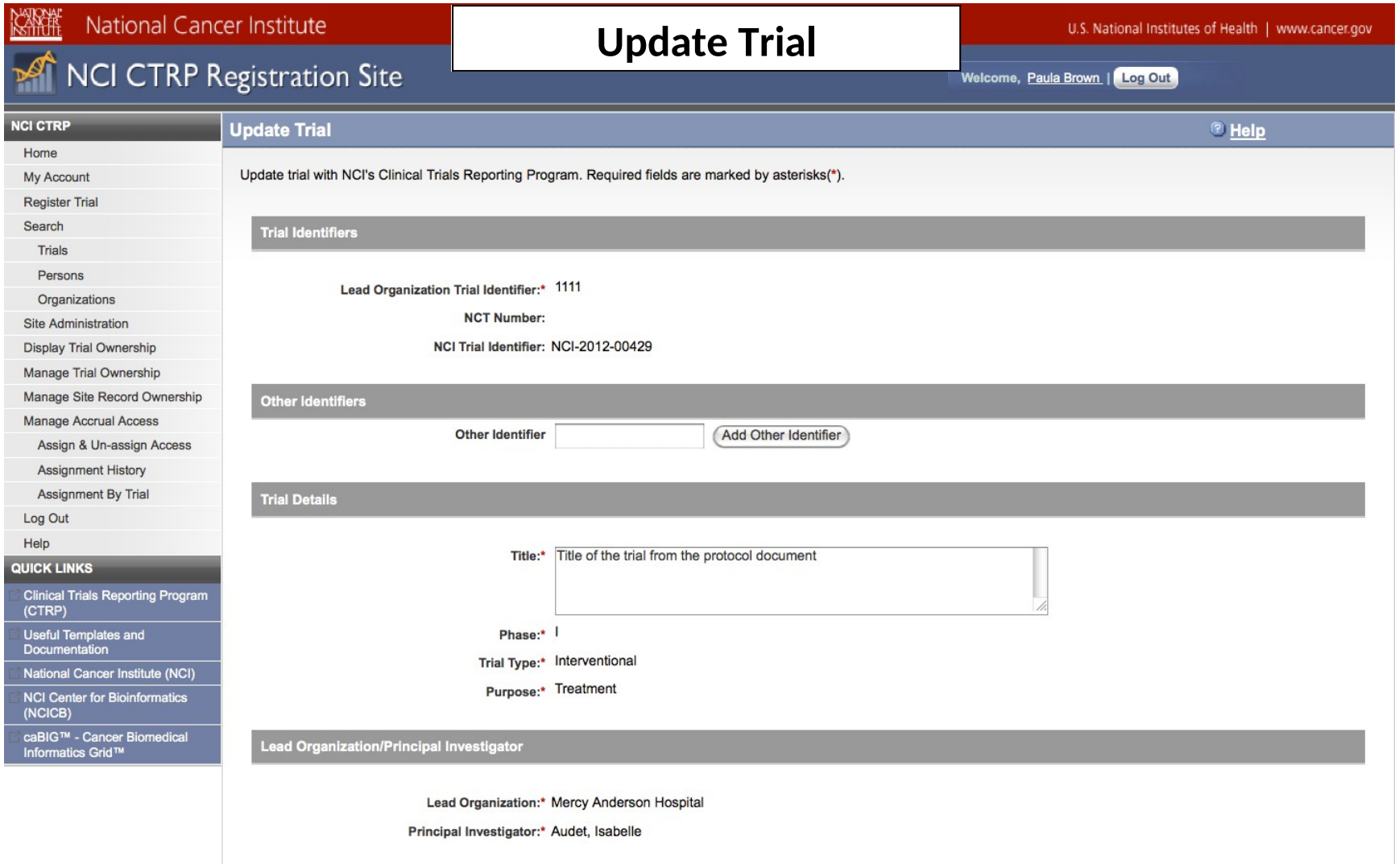
Trial Start Date: * (mm/dd/yyyy) **Actual** **Anticipated**

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

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

Please refer to the Trial Status Rules for Start and Completion dates.

Update Trial



Sponsor/Responsible Party

Sponsor:* American International Hospital

Responsible Party:* sponsor

Responsible Party Contact: Audet, Isabelle

Responsible Party Generic Contact:

Responsible Party Email Address:* iaudet@aih.org

Responsible Party Phone Number:* 123-123-1234

Summary 4 Information

Summary 4 Funding Sponsor Type:* National

Summary 4 Funding Sponsor: * National Cancer Institue

Program code:

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

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code
B09	AA	123456	N/A

Status/Dates

Current Trial Status: * Enrolling by Invitation

Participants are being (or will be) selected from a predetermined population.

Why the Study Stopped:

160 characters left
Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

Current Trial Status Date: * 10/31/2012 (mm/dd/yyyy)

Trial Start Date: * 10/01/2012 (mm/dd/yyyy) (•) **Actual** ( ) **Anticipated**

Primary Completion Date: * 10/01/2013 (mm/dd/yyyy) ( ) **Actual** (•) **Anticipated**

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

Please refer to the Trial Status Rules for Start and Completion dates.

FDA IND/IDE Information for applicable trials

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)
IND	123	CDER	Investigator		No		No

Regulatory Information

Trial Oversight Authority Country :* United States

Trial Oversight Authority Organization Name :* Food and Drug Administration

FDA Regulated Intervention Indicator :* Yes

Section 801 Indicator :* No

Delayed Posting Indicator :*

Data Monitoring Committee Appointed Indicator : Yes

Participating Sites

Site	Recruitment Status	Date	Program Code
Banner MD Anderson Cancer Center	Enrolling by Invitation	10/31/2012	

Collaborators

Collaborator	Functional Role
National Cancer Institute	Funding Source

Existing Trial Related Documents

Document Type	File Name
Protocol Document	protocol.doc
IRB Approval Document	irb_approval.doc
TSR	TSR_NCI-2012-00429_2012-10-31-1946_O.rtf

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, submit them separately.

Tips for creating CTRP compatible PDF documents

Protocol Document: Browse...

IRB Approval: Browse...

List of Participating Sites: Browse...

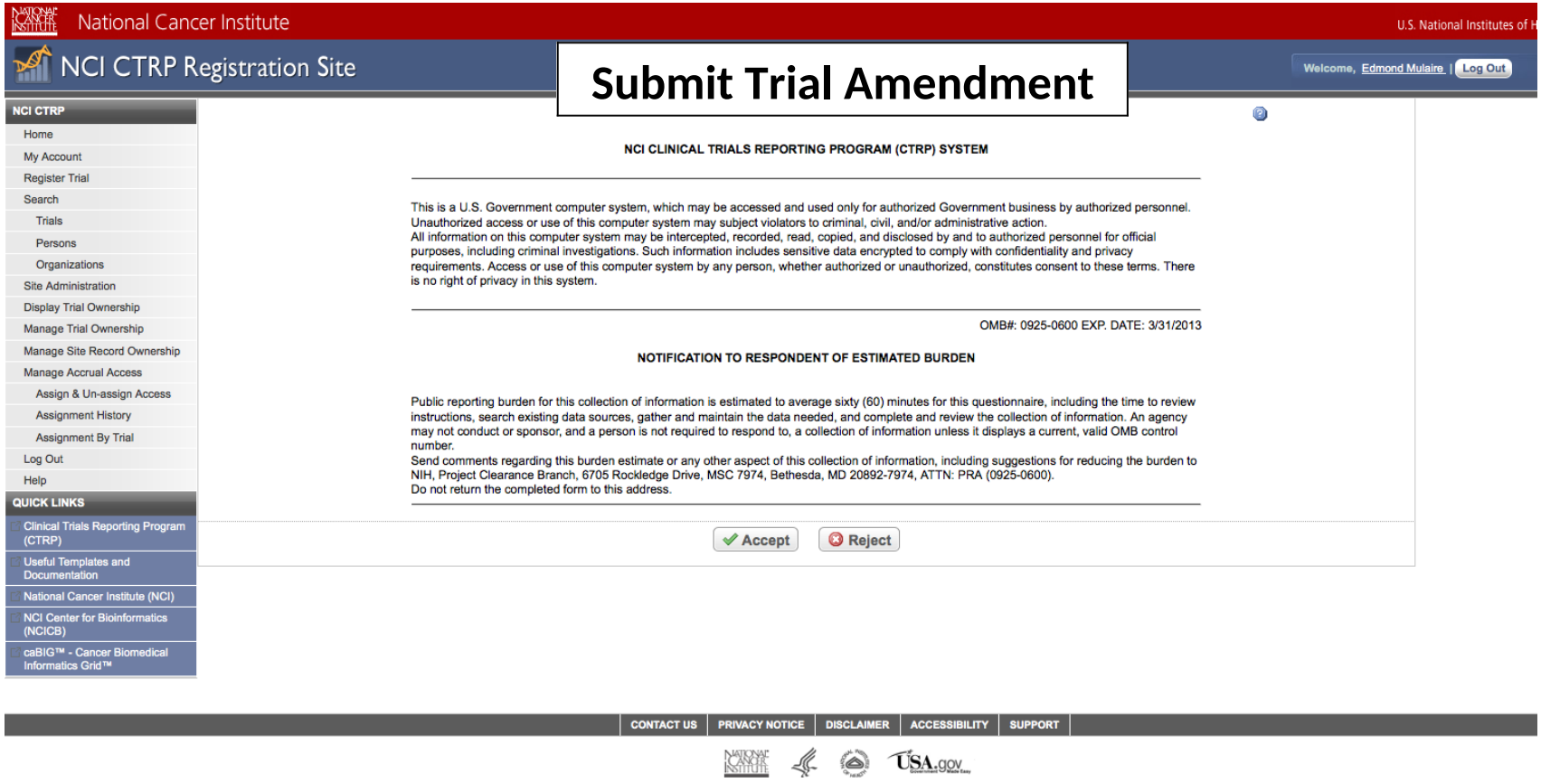
Informed Consent Document: Browse...

Other: Browse...

Add more...

Please verify ALL the trial information you provided on this screen before clicking the "Review Trial" button below.

Review Trial Cancel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Display Trial Ownership
Manage Trial Ownership
Manage Site Record Ownership
Manage Accrual Access
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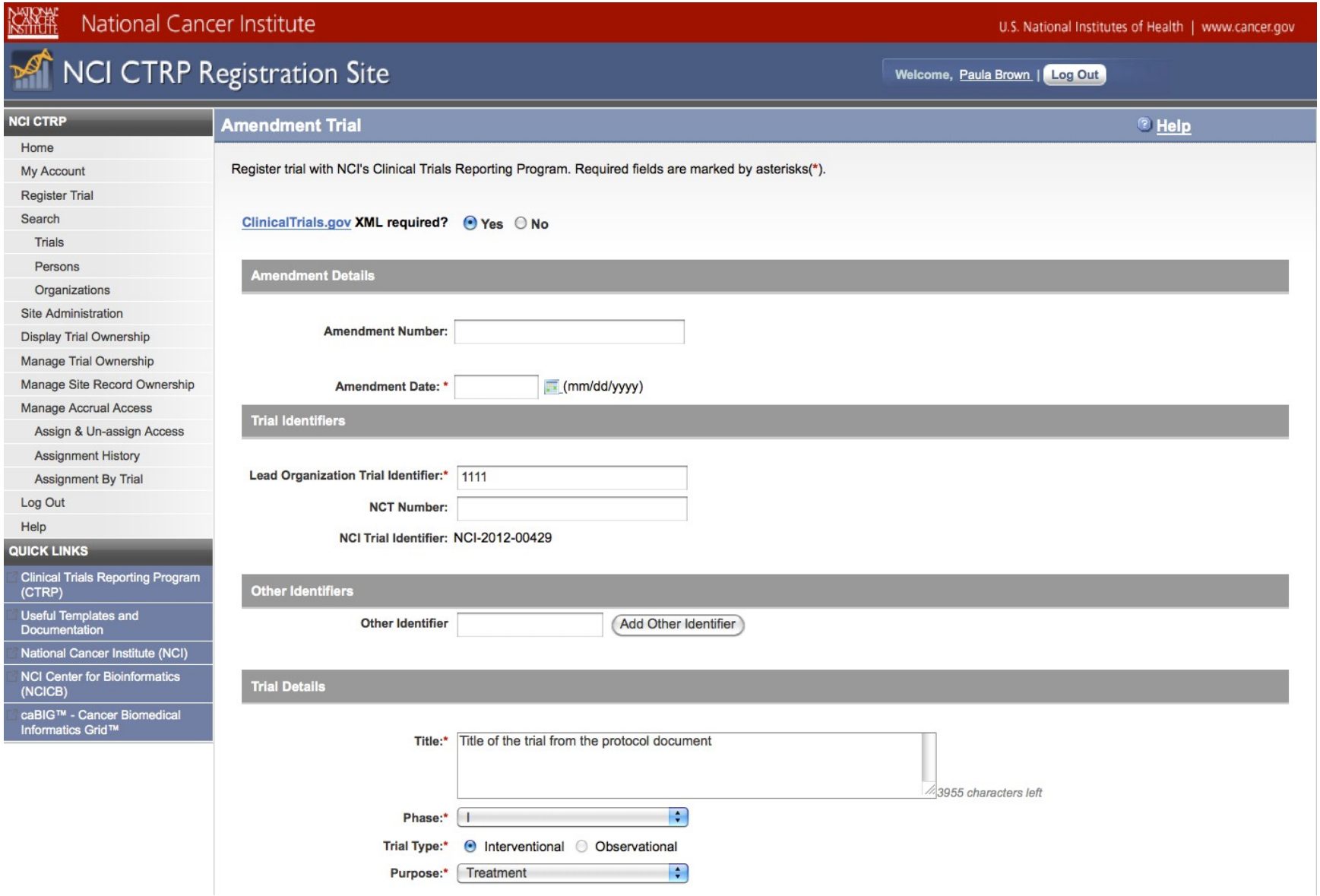
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Organizations
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Display Trial Ownership
Manage Trial Ownership
Manage Site Record Ownership
Manage Accrual Access
Assign & Un-assign Access
Assignment History
Assignment By Trial
Log Out
Help
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NCI Center for Bioinformatics (NCICB)
caBIG™ - Cancer Biomedical Informatics Grid™
Amendment Trial
Help
Register trial with NCI's Clinical Trials Reporting Program. Required fields are marked by asterisks(*).
ClinicalTrials.gov XML required? Yes No
Amendment Details
Amendment Number:
Amendment Date: * (mm/dd/yyyy)
Trial Identifiers
Lead Organization Trial Identifier:* 1111
NCT Number:
NCI Trial Identifier: NCI-2012-00429
Other Identifiers
Other Identifier
Add Other Identifier
Trial Details
Title:* Title of the trial from the protocol document
3955 characters left
Phase:* I
Trial Type:* Interventional Observational
Purpose:* Treatment

Lead Organization/Principal Investigator

Lead Organization:* Mercy Anderson Hospital — Look Up Org

Principal Investigator:* Audet, Isabelle — Look Up Person

Sponsor/Responsible Party

Sponsor:* American International Hospital — Look Up Sponsor

Responsible Party:* ○ PI ◉ Sponsor

Responsible Party Personal Contact: *Select Either Personal Contact or Generic Contact*
Audet, Isabelle — Look Up Person

Responsible Party Generic Contact: — Look Up Generic Contact

Please provide professional contact information only.

Responsible Party Email Address:* iaudet@aih.org

Responsible Party Phone Number:* 123-123-1234 Extn:

Contact information required for internal administrative use only; not revealed to public

Summary 4 Information

Summary 4 Funding Sponsor Type: * National

Summary 4 Funding Sponsor: * National Cancer Institue — Look Up 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.

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

Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program Code	Action
B09	AA	123456	N/A	

Status/Dates

Current Trial Status: * Enrolling by Invitation

Participants are being (or will be) selected from a predetermined population.

Why the Study Stopped:

160 characters left
Required for Administratively Complete, Withdrawn and Temporarily Closed statuses only

Current Trial Status Date: * 10/31/2012 (mm/dd/yyyy)

Trial Start Date: * 10/01/2012 (mm/dd/yyyy) ◉ **Actual** ○ **Anticipated**

Primary Completion Date: * 10/01/2013 (mm/dd/yyyy) ○ **Actual** ◉ **Anticipated**

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

Please refer to the 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-	☐ Yes	-Select-	☐ Yes

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

Regulatory Information

Trial Oversight Authority Country :* United States

Trial Oversight Authority Organization Name :* Food and Drug Administration

FDA Regulated Intervention Indicator :* Yes

Section 801 Indicator :* No

Delayed Posting Indicator :*

Data Monitoring Committee Appointed Indicator : Yes

Exiting Trial Related Documents

Document Types	File Name
Protocol Document	protocol.doc
IRB Approval Document	irb_approval.doc
TSR	TSR_NCI-2012-00429_2012-10-31-1946_O.rtf

Amendment Related Documents

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Tips for creating CTRP compatible PDF documents

Amendment Protocol Document: * Browse...

Change Memo Document: ** Browse...

Protocol Highlighted Document: ** Browse...

IRB Approval: * Browse...

List of Participating Sites: Browse...

Informed Consent Document: Browse...

Other: Browse...

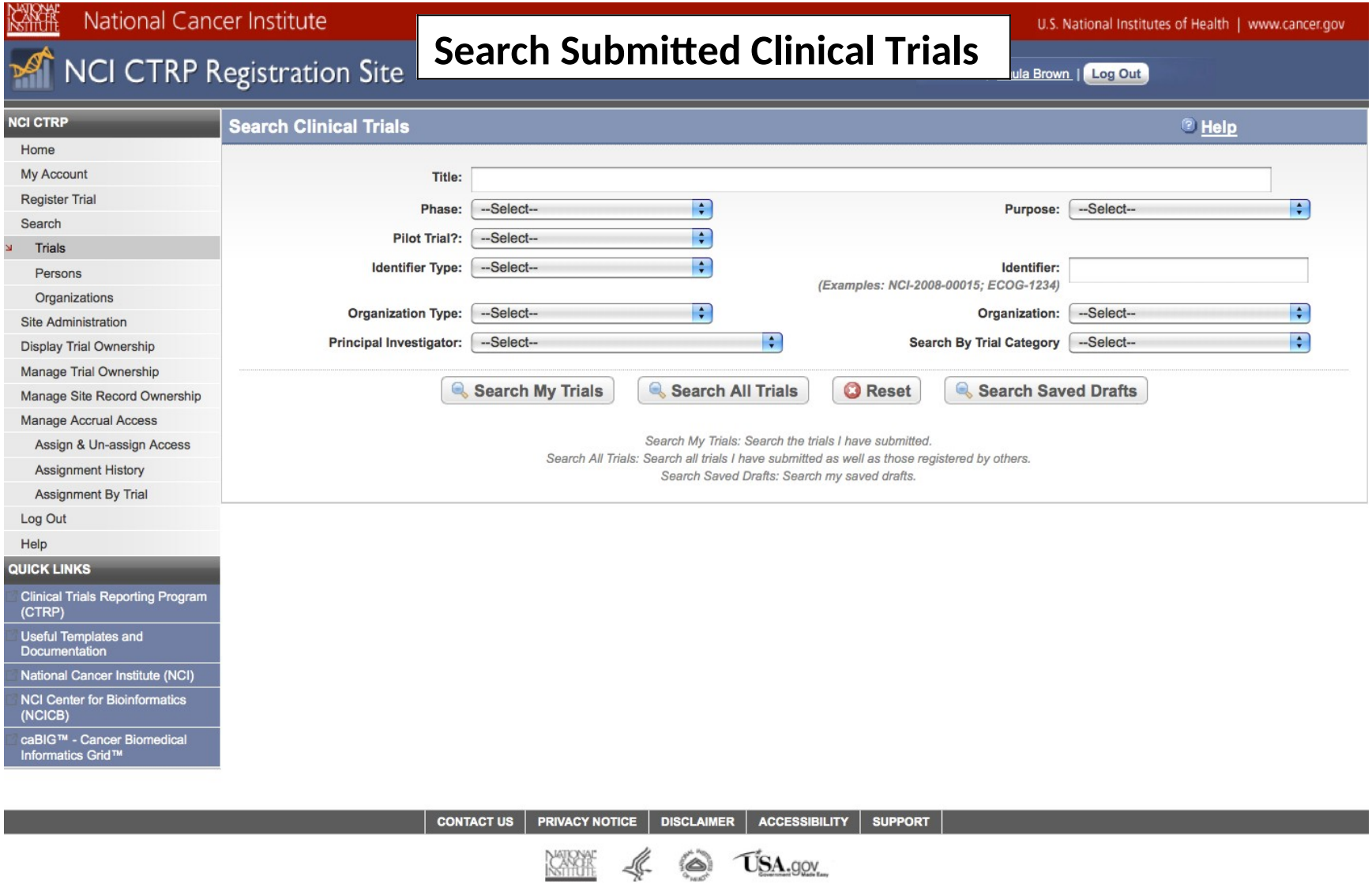
Add more...

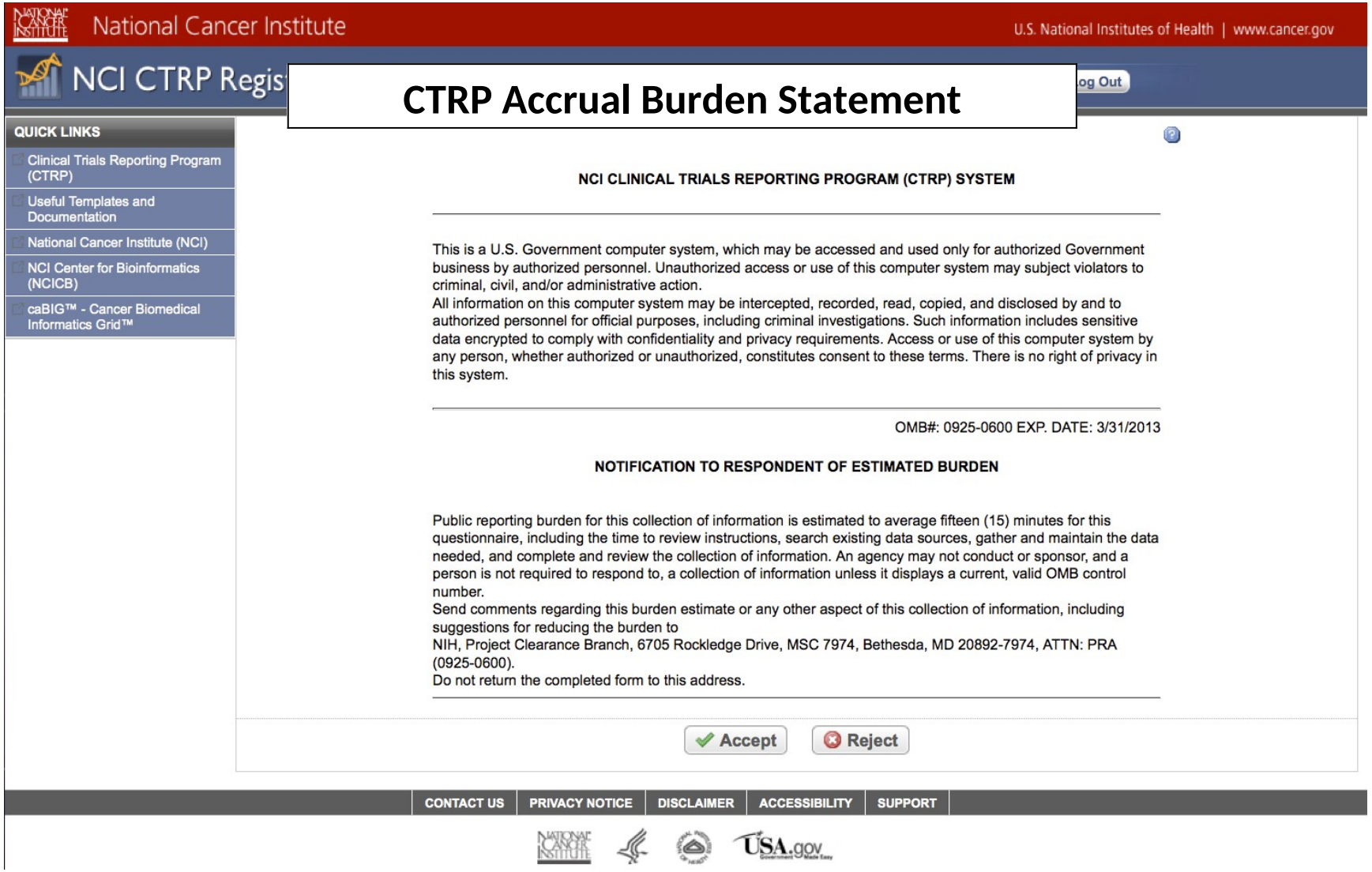
** At least one is required: Change Memo Document or Protocol Highlighted Document

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

Review Trial | Cancel

Search Submitted Clinical Trials

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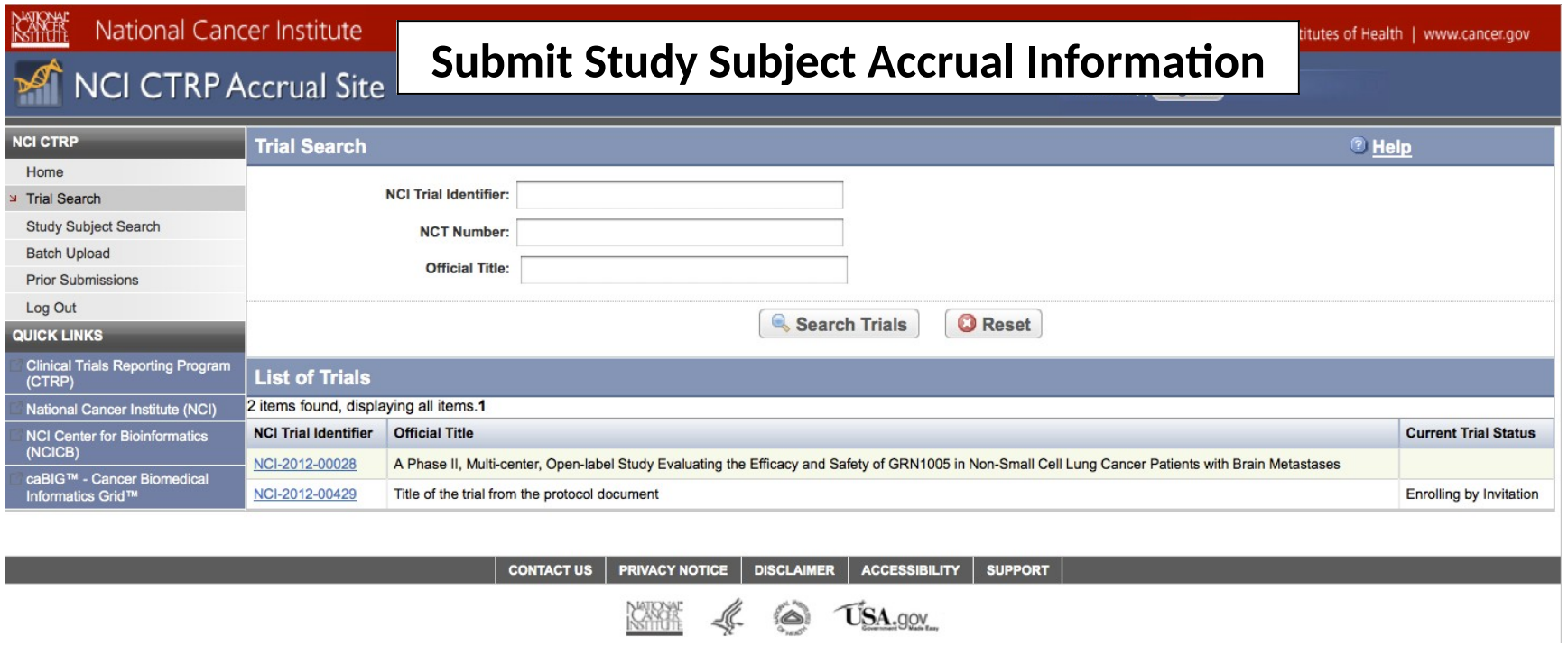
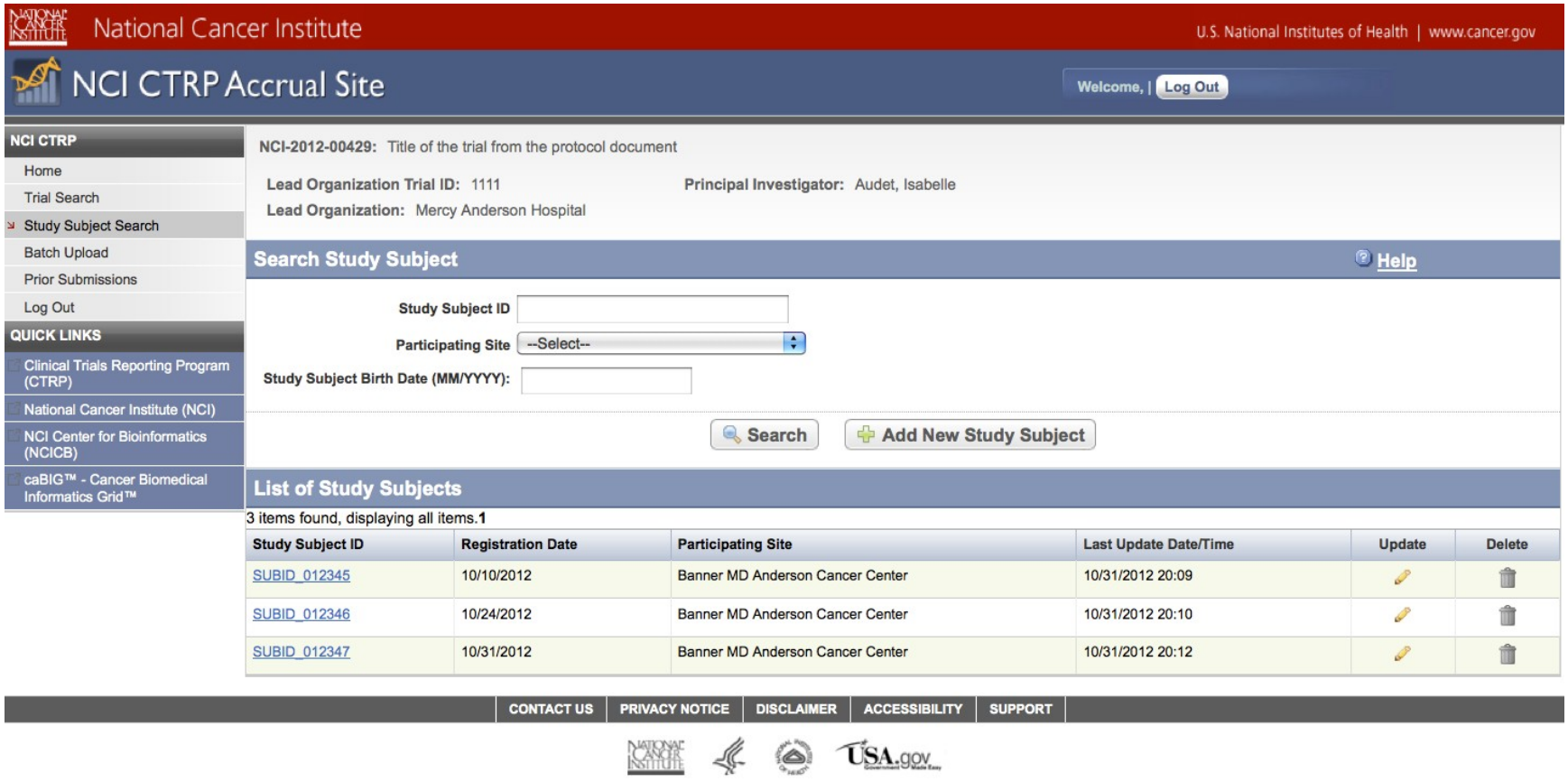
Submit Study Subject Accrual Information

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Study Subject Search
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NCI-2012-00429: Title of the trial from the protocol document
Lead Organization Trial ID: 1111
Principal Investigator: Audet, Isabelle
Lead Organization: Mercy Anderson Hospital
Search Study Subject
Help
Study Subject ID
Participating Site
--Select--
Study Subject Birth Date (MM/YYYY):
Search
Add New Study Subject
List of Study Subjects
3 items found, displaying all items.1
Study Subject ID
Registration Date
Participating Site
Last Update Date/Time
Update
Delete
SUBID_012345
10/10/2012
Banner MD Anderson Cancer Center
10/31/2012 20:09
SUBID_012346
10/24/2012
Banner MD Anderson Cancer Center
10/31/2012 20:10
SUBID_012347
10/31/2012
Banner MD Anderson Cancer Center
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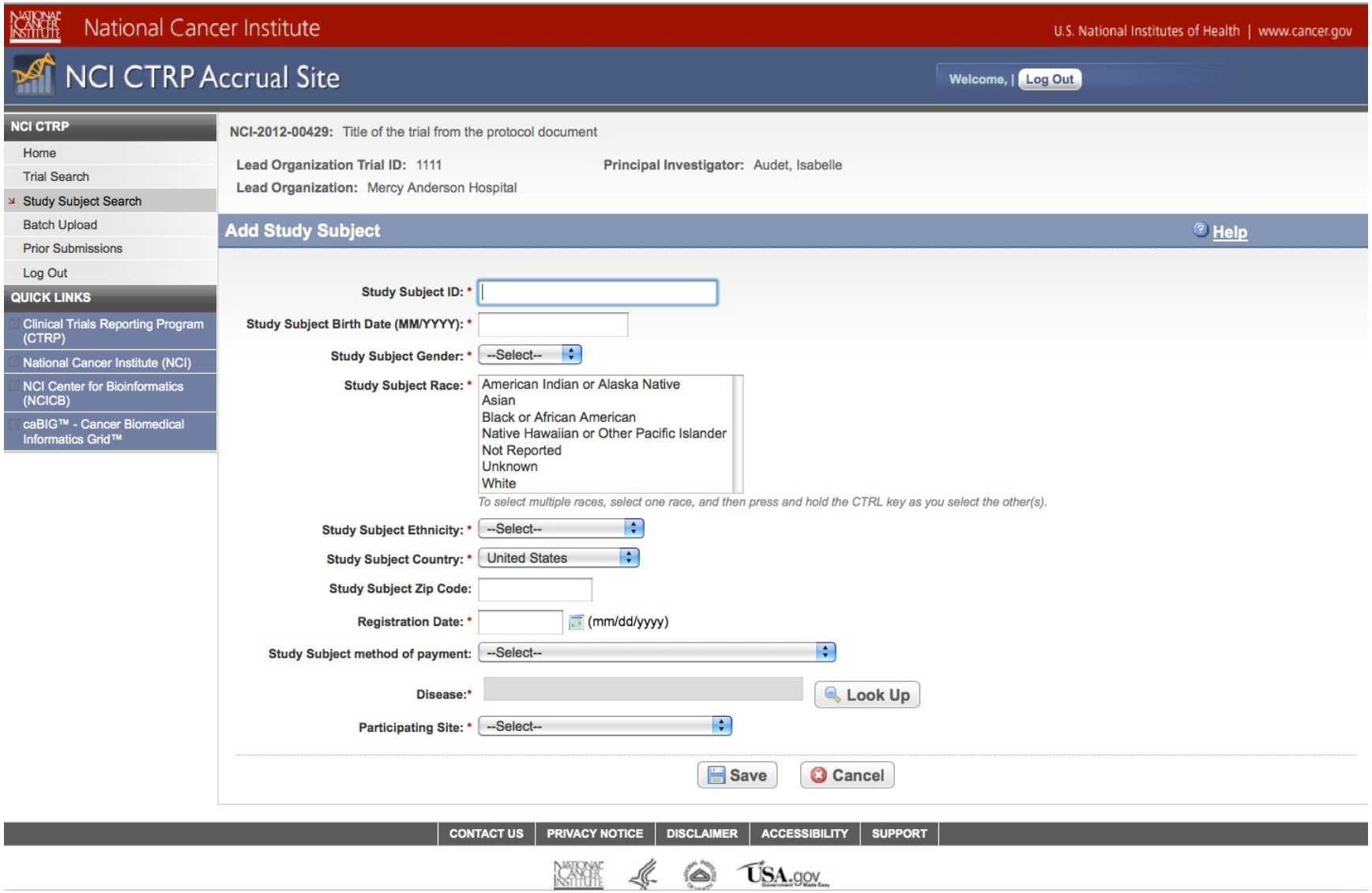
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NCI-2012-00429: Title of the trial from the protocol document
Lead Organization Trial ID: 1111
Principal Investigator: Audet, Isabelle
Lead Organization: Mercy Anderson Hospital
Add Study Subject
Help
Study Subject ID: *
Study Subject Birth Date (MM/YYYY): *
Study Subject Gender: * --Select--
Study Subject Race: *
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
Not Reported
Unknown
White
To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).
Study Subject Ethnicity: * --Select--
Study Subject Country: * United States
Study Subject Zip Code:
Registration Date: * (mm/dd/yyyy)
Study Subject method of payment: --Select--
Disease:*
Look Up
Participating Site: * --Select--
Save
Cancel
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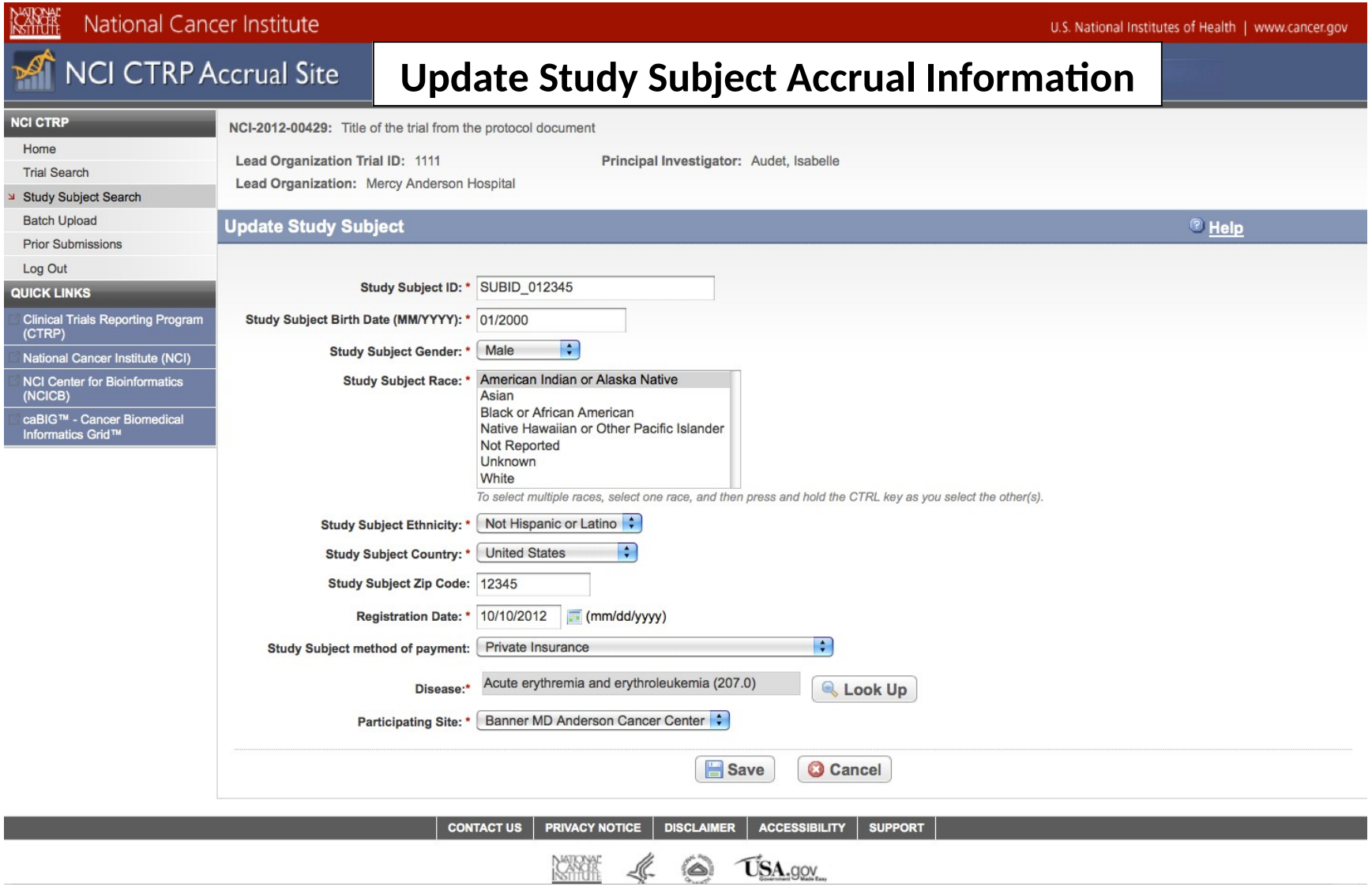
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NCI-2012-00429: Title of the trial from the protocol document
Lead Organization Trial ID: 1111
Principal Investigator: Audet, Isabelle
Lead Organization: Mercy Anderson Hospital
Update Study Subject
Help
Study Subject ID: * SUBID_012345
Study Subject Birth Date (MM/YYYY): * 01/2000
Study Subject Gender: * Male
Study Subject Race: * American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
Not Reported
Unknown
White
To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).
Study Subject Ethnicity: * Not Hispanic or Latino
Study Subject Country: * United States
Study Subject Zip Code: 12345
Registration Date: * 10/10/2012 (mm/dd/yyyy)
Study Subject method of payment: Private Insurance
Disease:* Acute erythremia and erythroleukemia (207.0) Look Up
Participating Site: * Banner MD Anderson Cancer Center
Save
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Submit Aggregate Study Subject Accrual Information