NCI CTRP Attachment 3a

NCI CTRP Registration 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

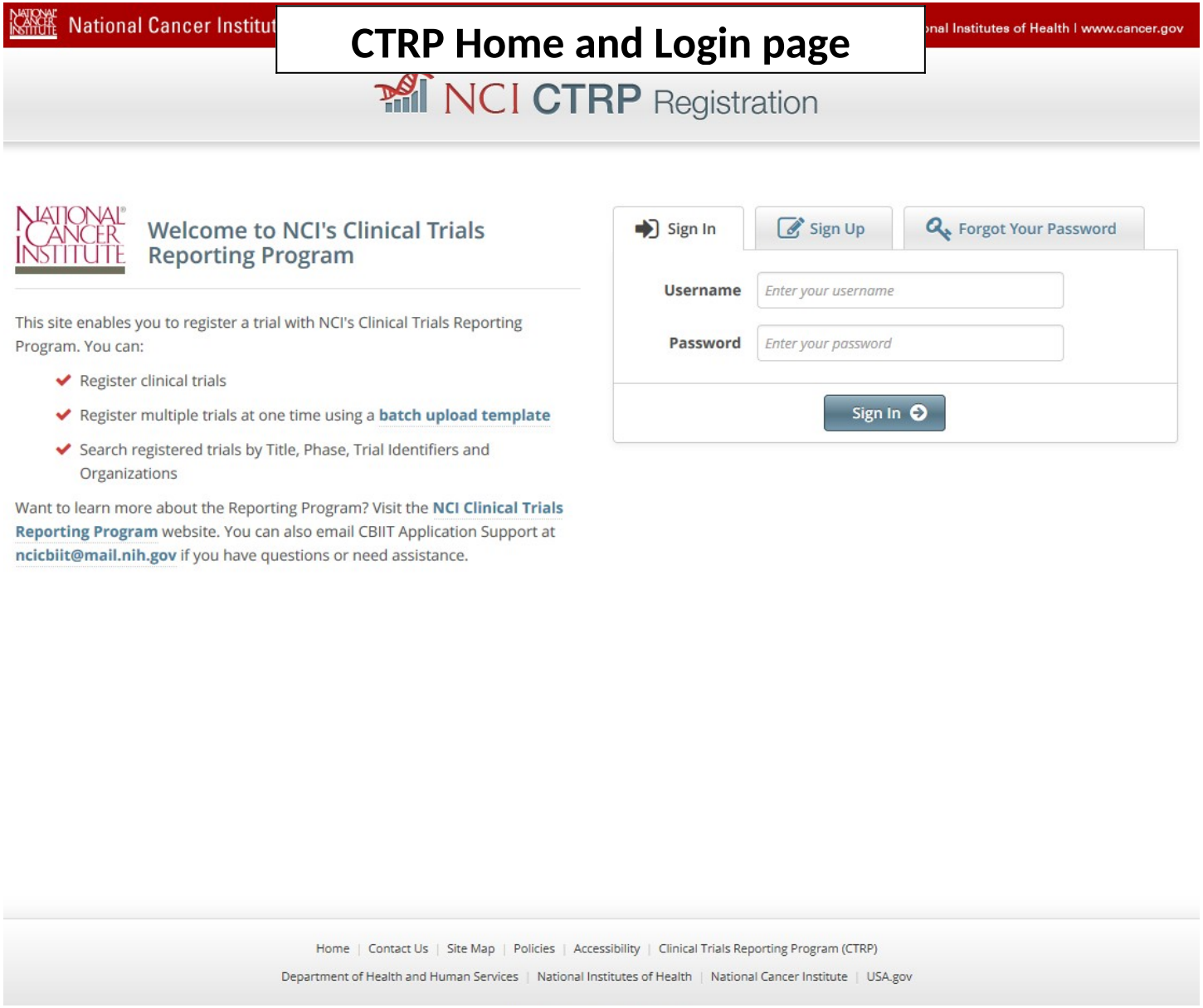
Step 2: User enters “Username” and “Password” – see screenshot, page 2

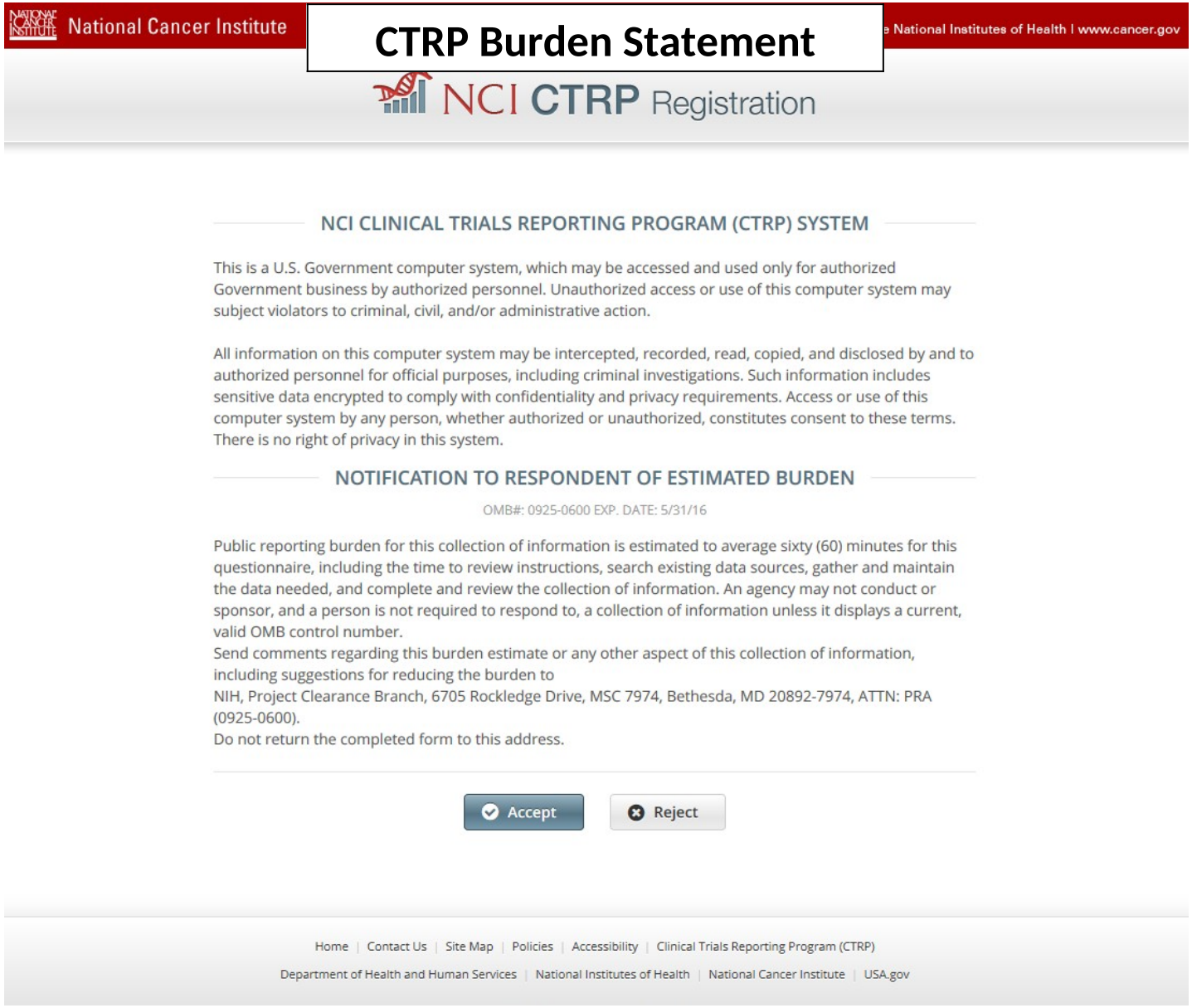
Step 3: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 3

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

Step 5: User selects to perform “Initial Trial Registration” and completes initial registration – see screenshots, pages 5 - 7

CTRP Home and Login page




National Cancer Institute
National Institutes of Health | www.cancer.gov
CTRP Burden Statement
NCI CTRP Registration
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
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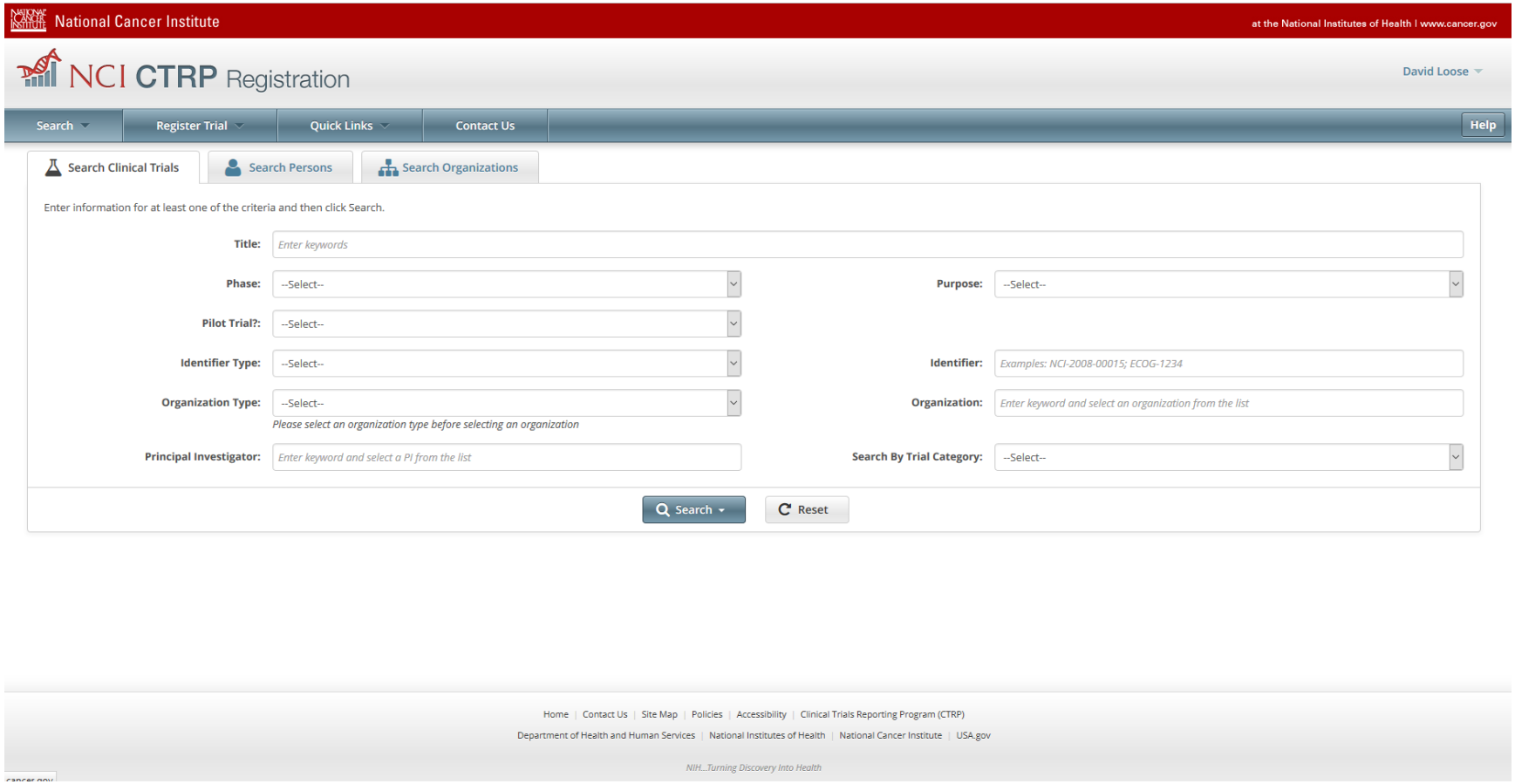
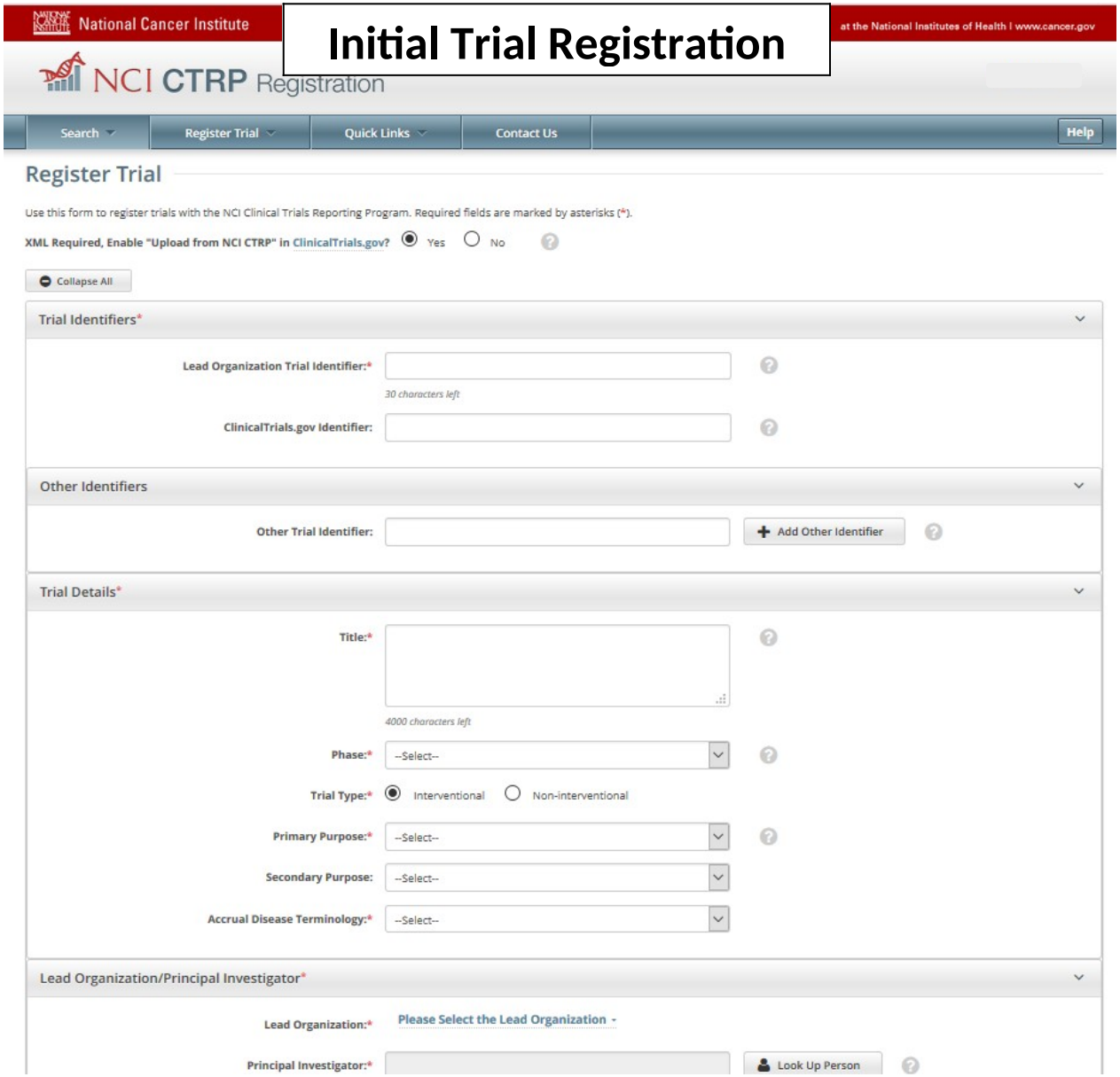
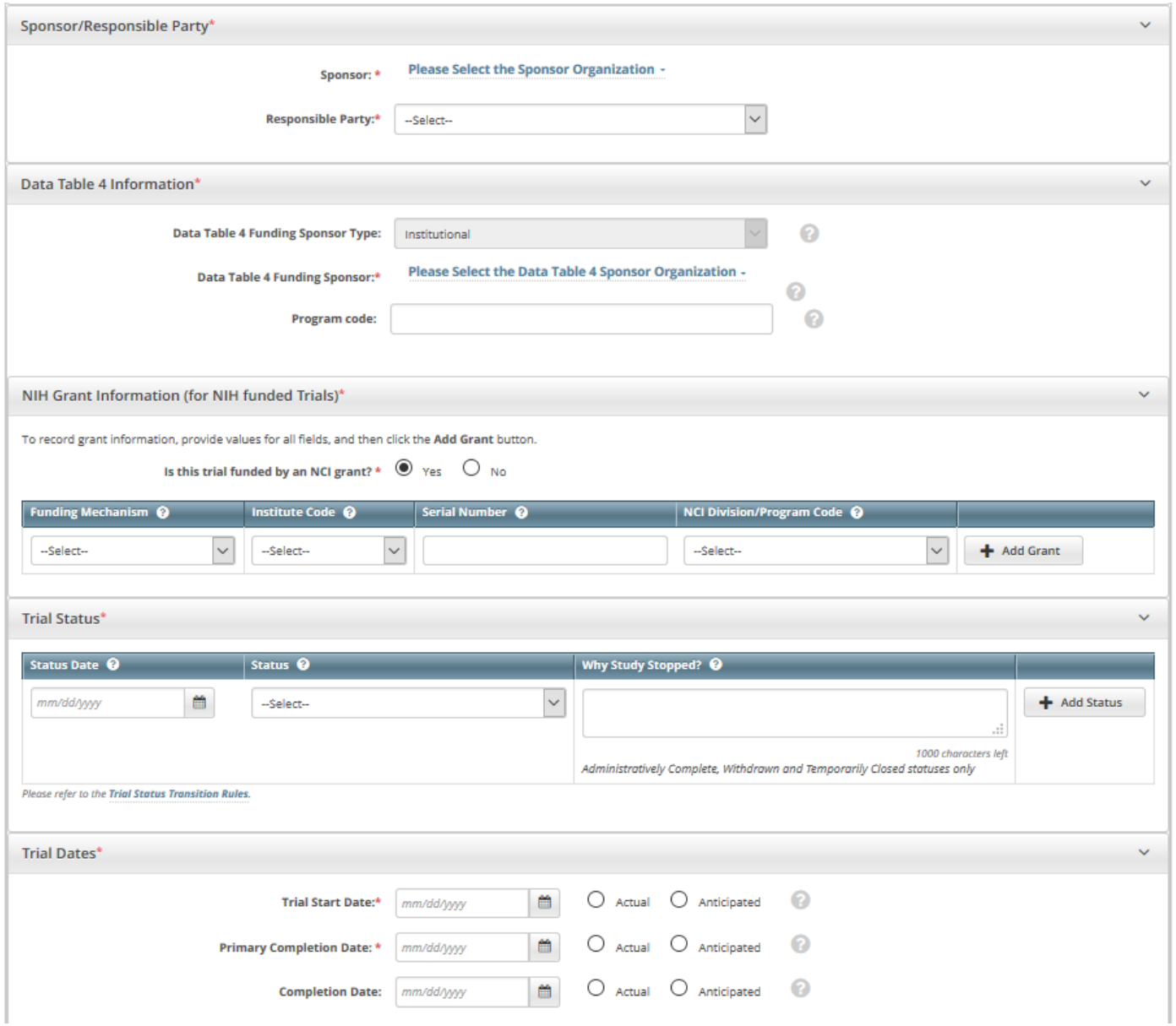
Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov

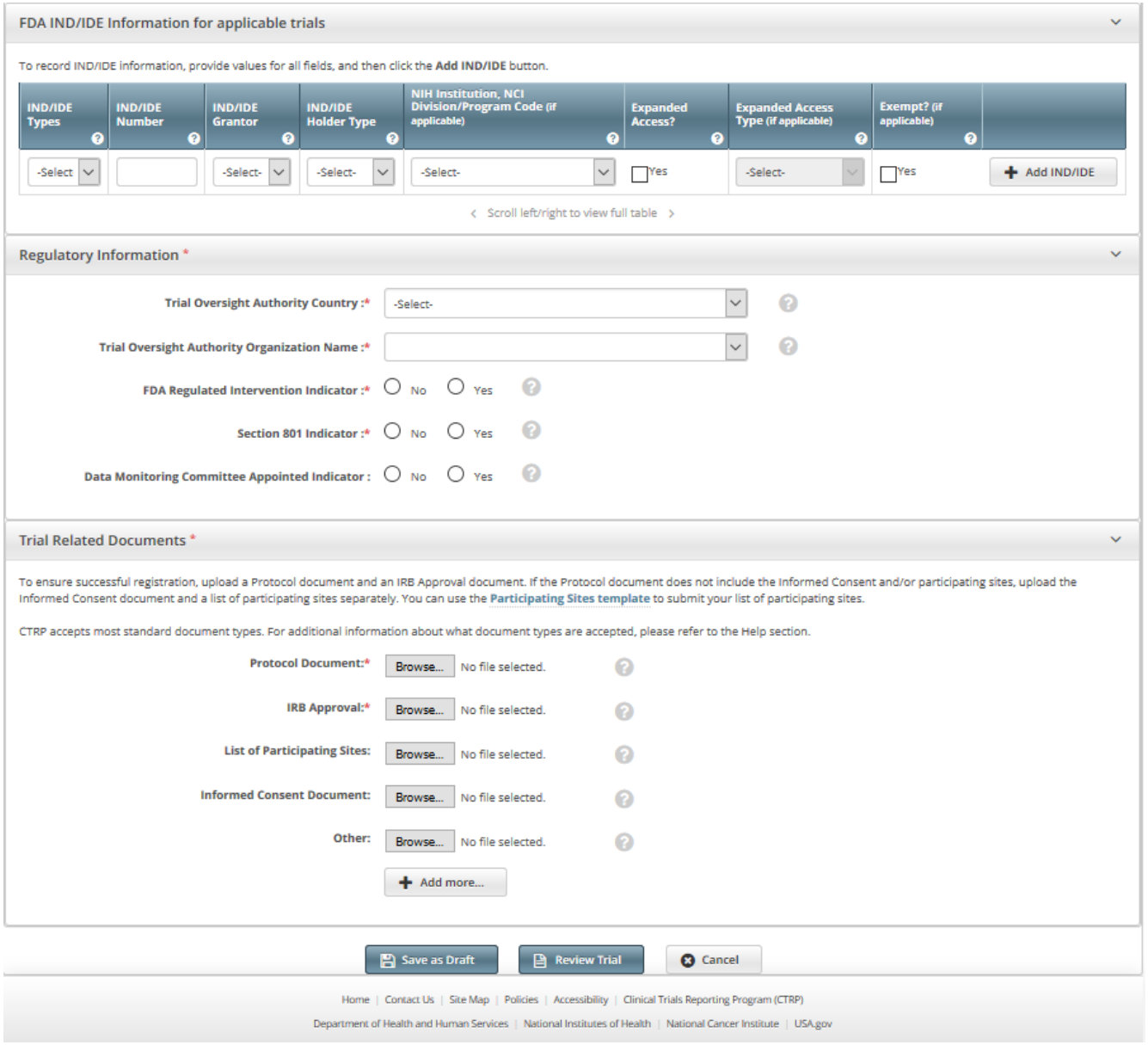
Search Submitted Clinical Trials



Initial Trial Registration




Sponsor/Responsible Party*
Sponsor: *
Please Select the Sponsor Organization
Responsible Party:*
--Select--
Data Table 4 Information*
Data Table 4 Funding Sponsor Type:
Institutional
Data Table 4 Funding Sponsor:*
Please Select the Data Table 4 Sponsor Organization
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--
Add Grant
Trial Status*
Status Date
Status
Why Study Stopped?
mm/dd/yyyy
--Select--
1000 characters left
Administratively Complete, Withdrawn and Temporarily Closed statuses only
Add Status
Please refer to the Trial Status Transition Rules.
Trial Dates*
Trial Start Date:*
Primary Completion Date: *
Completion Date:
mm/dd/yyyy
Actual
Anticipated


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
Add IND/IDE
Scroll left/right to view full table
Regulatory Information *
Trial Oversight Authority Country :*
-Select-
Trial Oversight Authority Organization Name :*
FDA Regulated Intervention Indicator :*
No
Yes
Section 801 Indicator :*
No
Yes
Data Monitoring Committee Appointed Indicator :
No
Yes
Trial 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:*
Browse...
No file selected.
IRB Approval:*
Browse...
No file selected.
List of Participating Sites:
Browse...
No file selected.
Informed Consent Document:
Browse...
No file selected.
Other:
Browse...
No file selected.
Add more...
Save as Draft
Review Trial
Cancel
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Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov