NCI CTRP Attachment 2B

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 clicks “Login”

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

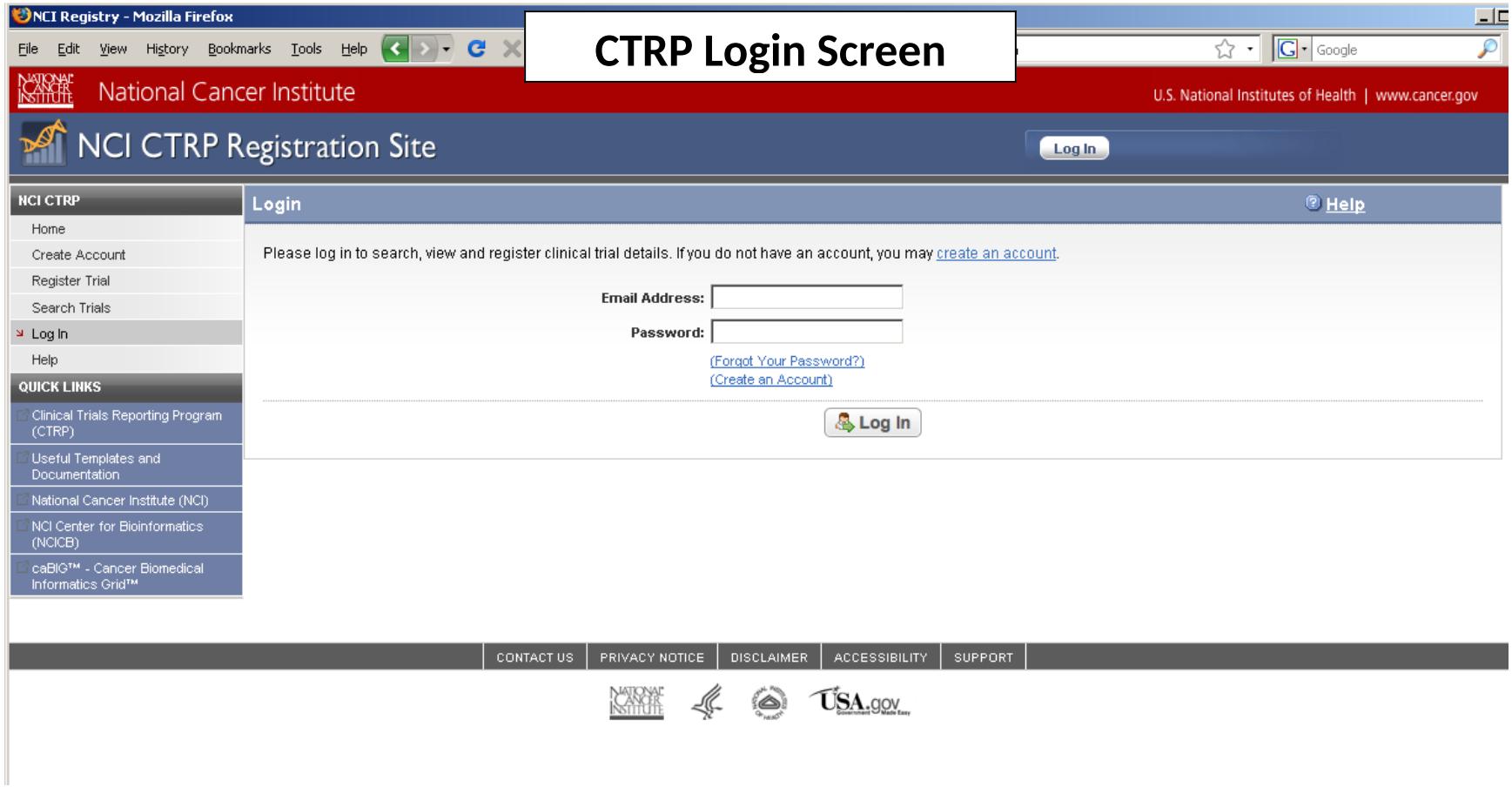
Step 4: User reviews NCI Clinical Trials Reporting Program burden statement – see screenshot, page 4

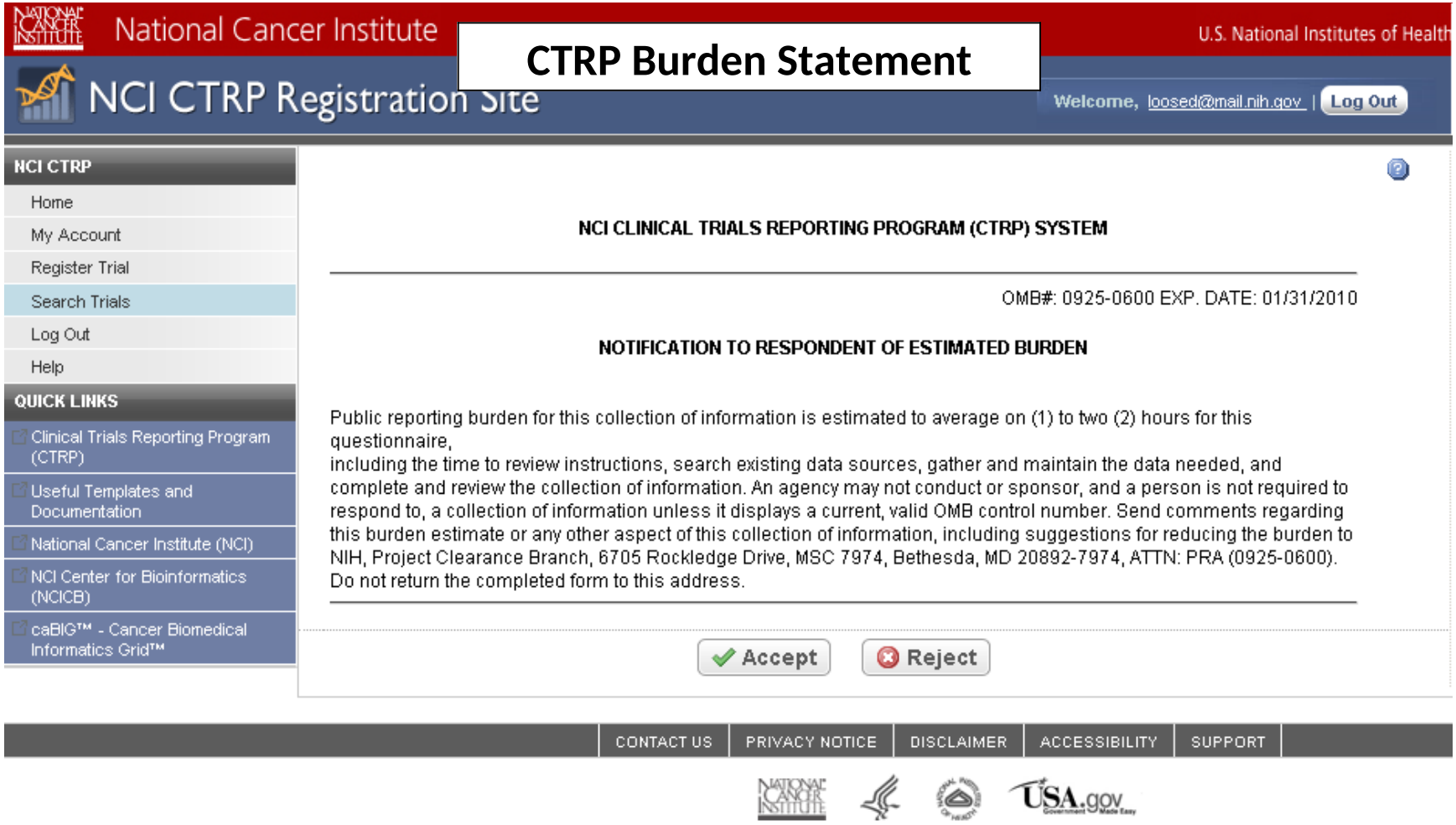
Step 5: System displays “Search Submitted Clinical Trials” page – see screenshot, page 10

Step 6: User selects to “Submit Trial Amendment” and amends an existing trial record – see screenshots, pages 5 - 9

CTRP Home page

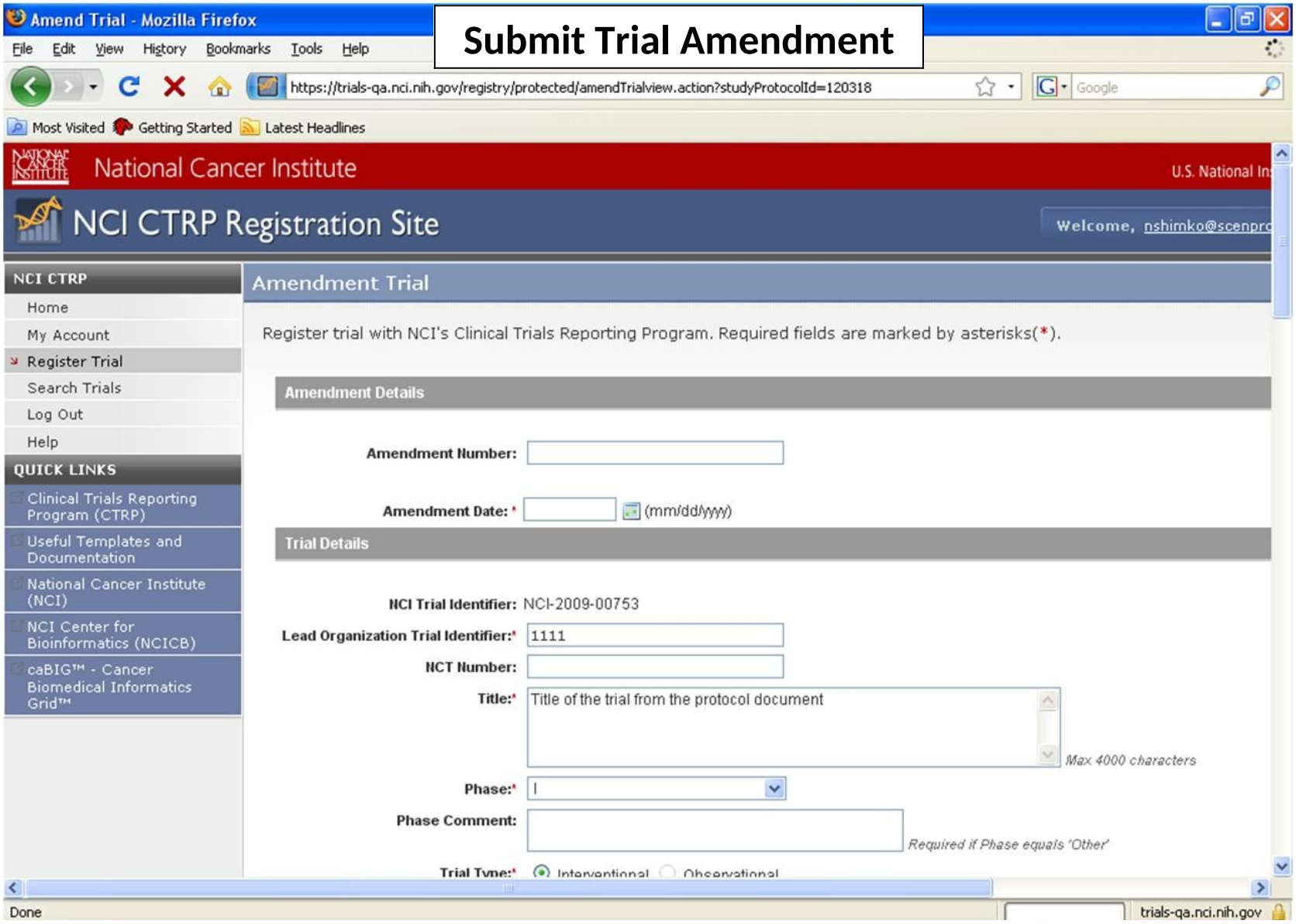
CTRP Login Screen

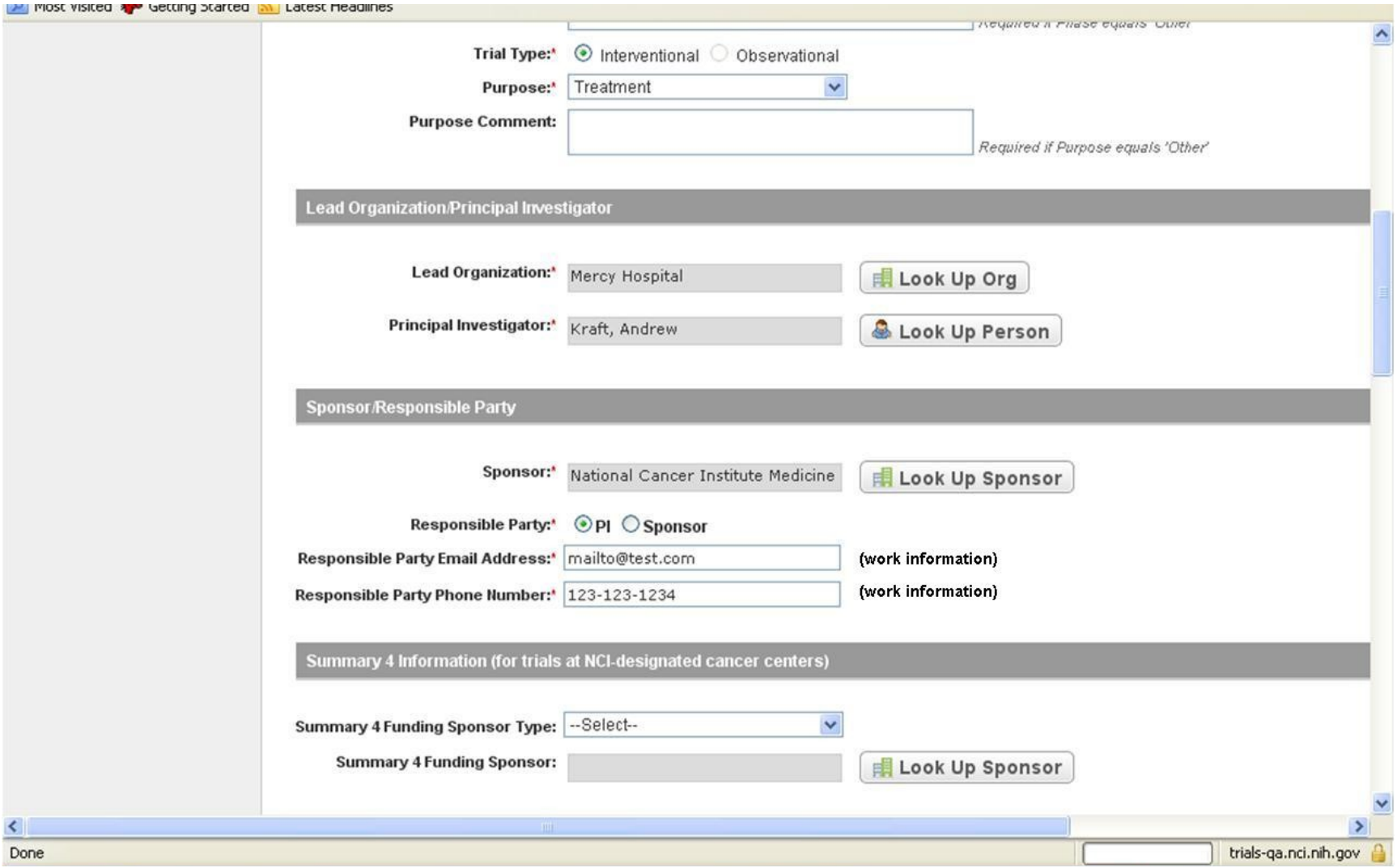


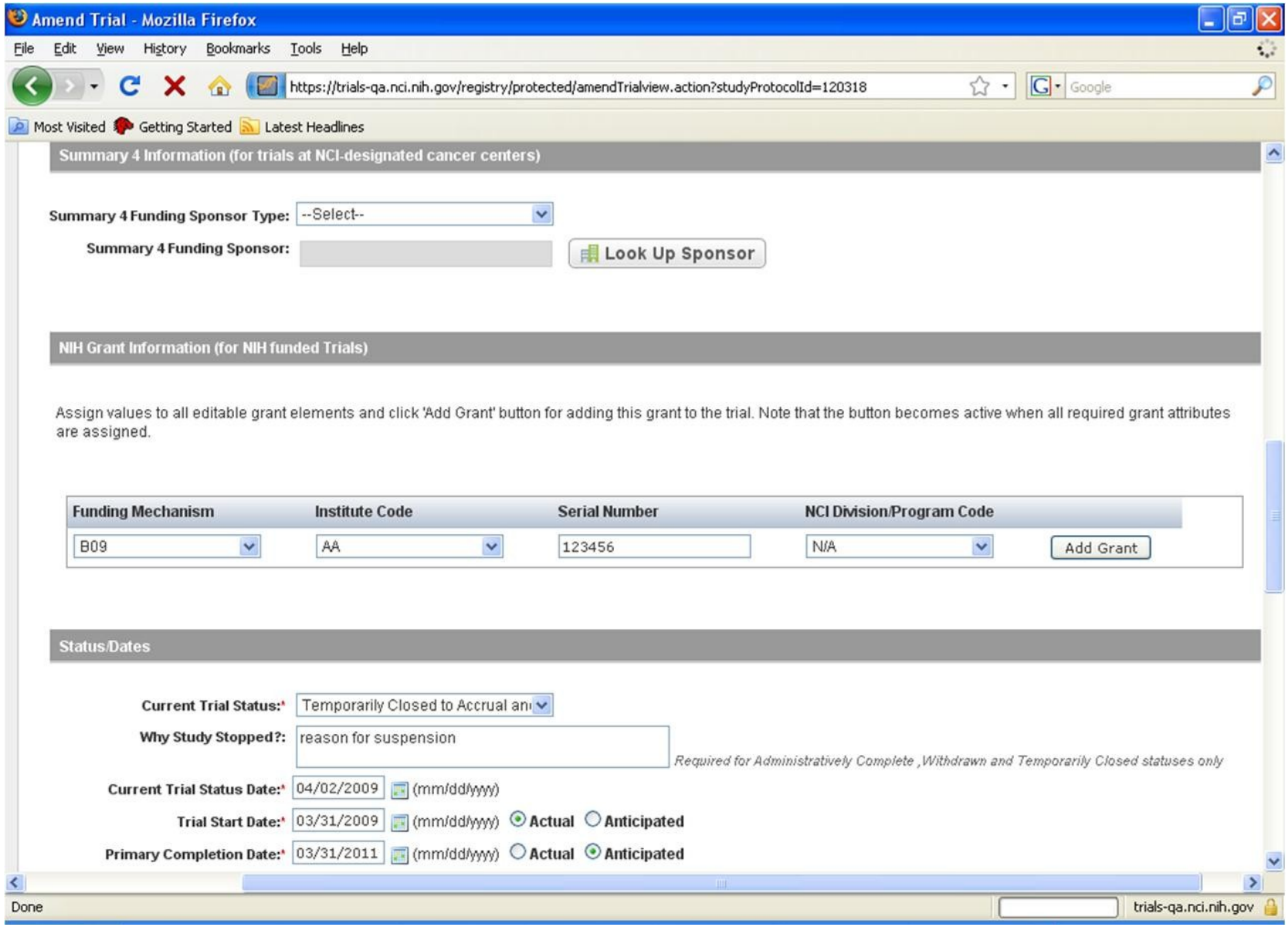


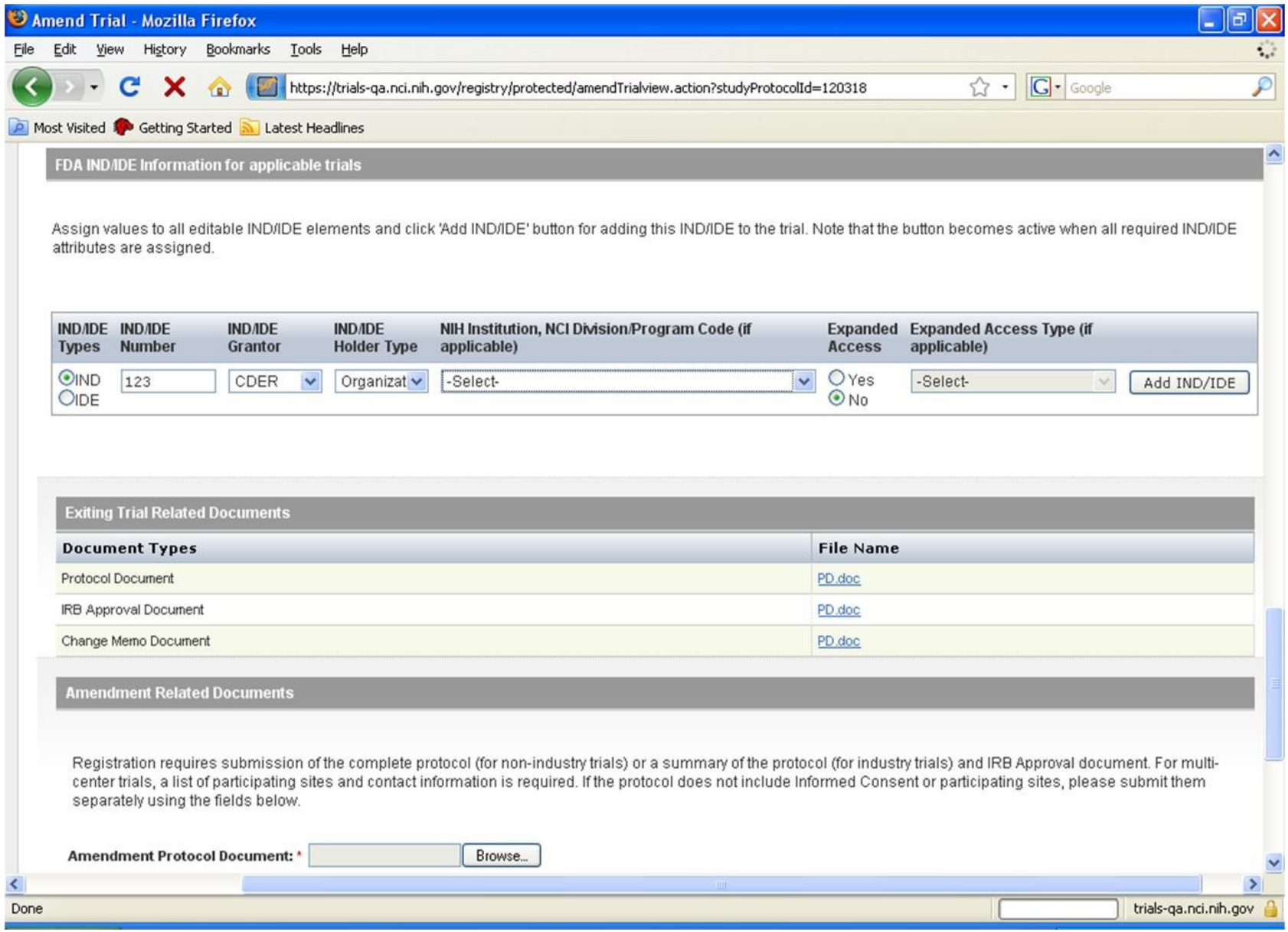
CTRP Burden Statement

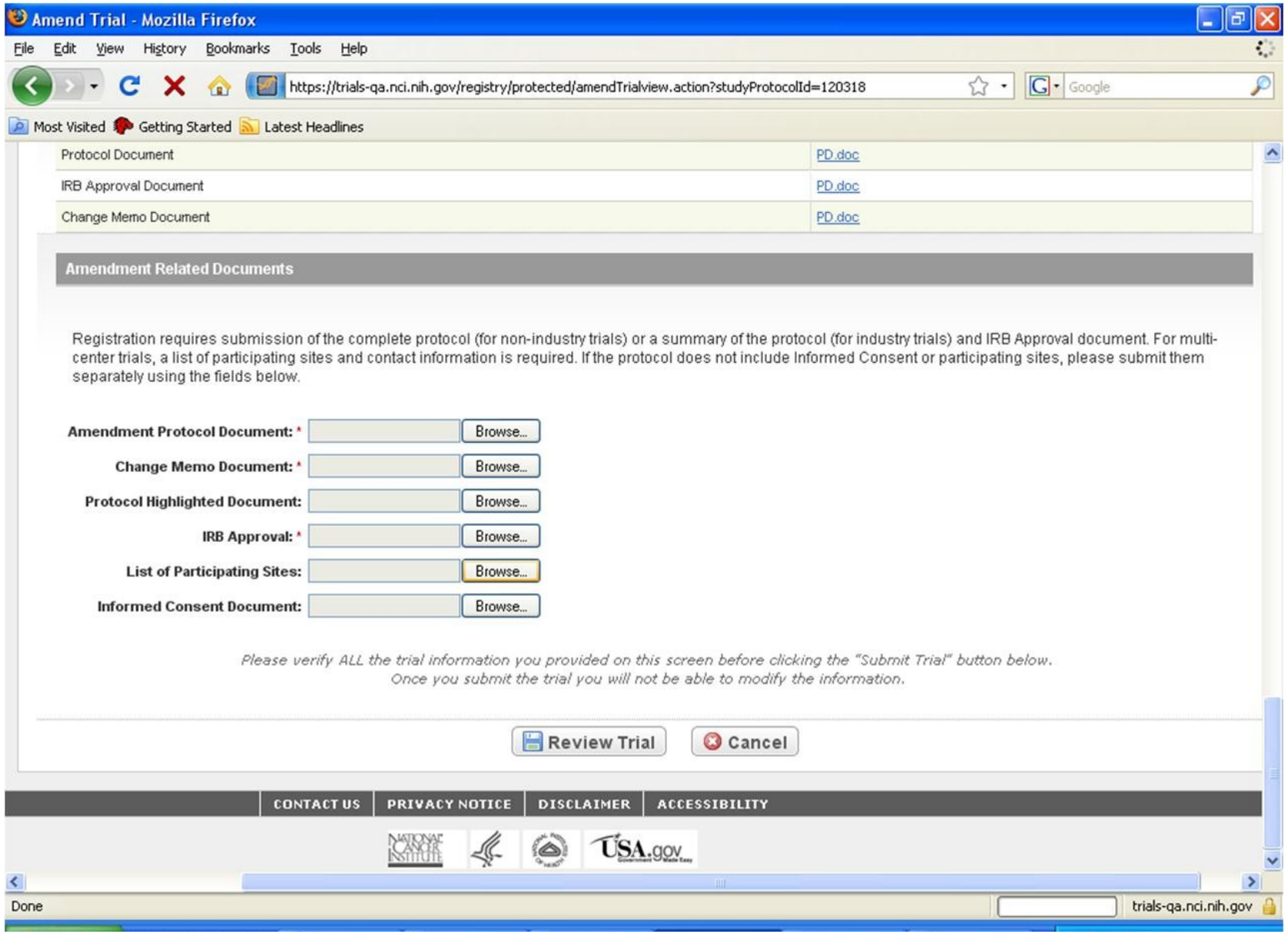
Submit Trial Amendment




Most Visited
Getting Started
Latest Headlines
Trial Type:*
Interventional
Observational
Purpose:*
Treatment
Purpose Comment:
Required if Purpose equals 'Other'
Lead Organization/Principal Investigator
Lead Organization:*
Mercy Hospital
Look Up Org
Principal Investigator:*
Kraft, Andrew
Look Up Person
Sponsor/Responsible Party
Sponsor:*
National Cancer Institute Medicine
Look Up Sponsor
Responsible Party:*
PI
Sponsor
Responsible Party Email Address:*
mailto@test.com
(work information)
Responsible Party Phone Number:*
123-123-1234
(work information)
Summary 4 Information (for trials at NCI-designated cancer centers)
Summary 4 Funding Sponsor Type:
--Select--
Summary 4 Funding Sponsor:
Look Up Sponsor
Done
trials-qa.nci.nih.gov


Amend Trial - Mozilla Firefox
File Edit View History Bookmarks Tools Help
https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318
Most Visited Getting Started Latest Headlines
Summary 4 Information (for trials at NCI-designated cancer centers)
Summary 4 Funding Sponsor Type: --Select--
Summary 4 Funding Sponsor:
Look Up 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
Add Grant
Status/Dates
Current Trial Status:*
Temporarily Closed to Accrual an
Why Study Stopped?:
reason for suspension
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
File Edit View History Bookmarks Tools Help
https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318
Most Visited Getting Started Latest Headlines
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)
IND
IDE
123
CDER
Organizat
-Select-
Yes
No
-Select-
Add IND/IDE
Exiting Trial Related Documents
Document Types
File Name
Protocol Document
PD.doc
IRB Approval Document
PD.doc
Change Memo Document
PD.doc
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: *
Browse...
Done
trials-qa.nci.nih.gov


Amend Trial - Mozilla Firefox
File Edit View History Bookmarks Tools Help
https://trials-qa.nci.nih.gov/registry/protected/amendTrialview.action?studyProtocolId=120318
Most Visited Getting Started Latest Headlines
Protocol Document PD.doc
IRB Approval Document PD.doc
Change Memo Document PD.doc
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:
Browse...
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
CONTACT US
PRIVACY NOTICE
DISCLAIMER
ACCESSIBILITY
USA.gov
Done
trials-qa.nci.nih.gov

Search Submitted Clinical Trials