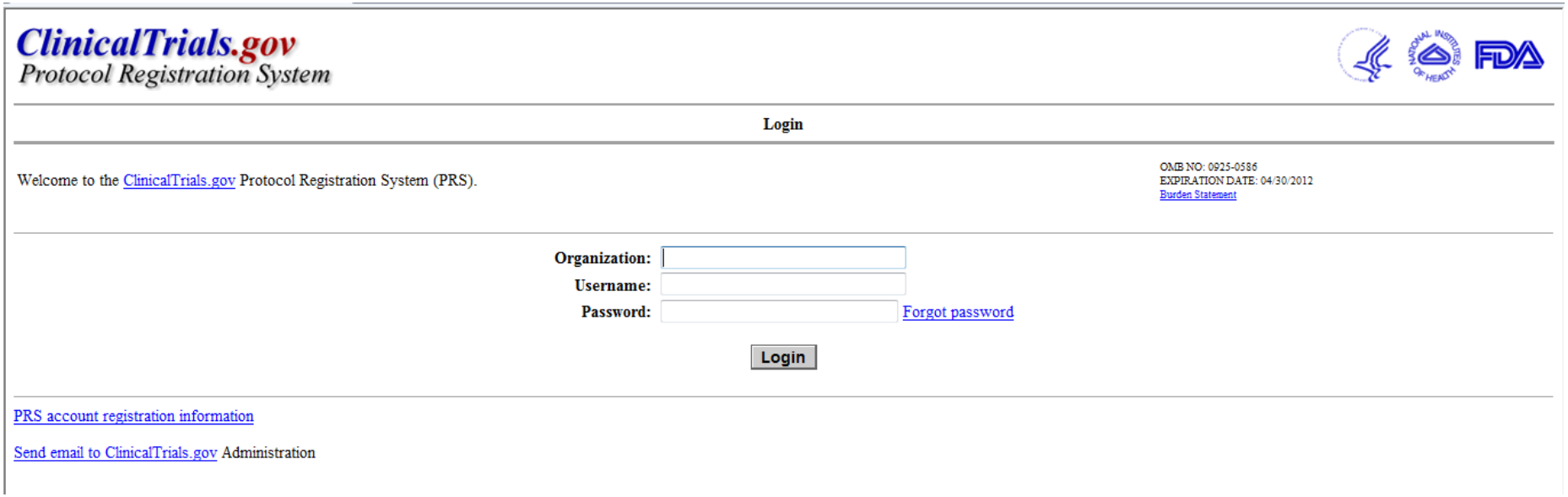
OVERVIEW

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (http://register.clinicaltrials.gov) are available to the public at ClinicalTrials.gov (http://clinicaltrials.gov). A guided tour of the PRS and account application information are available at http://prsinfo.clinicaltrials.gov/

The screen shots provided below for your review and assistanceare step by step guidance to enter a protocol record.



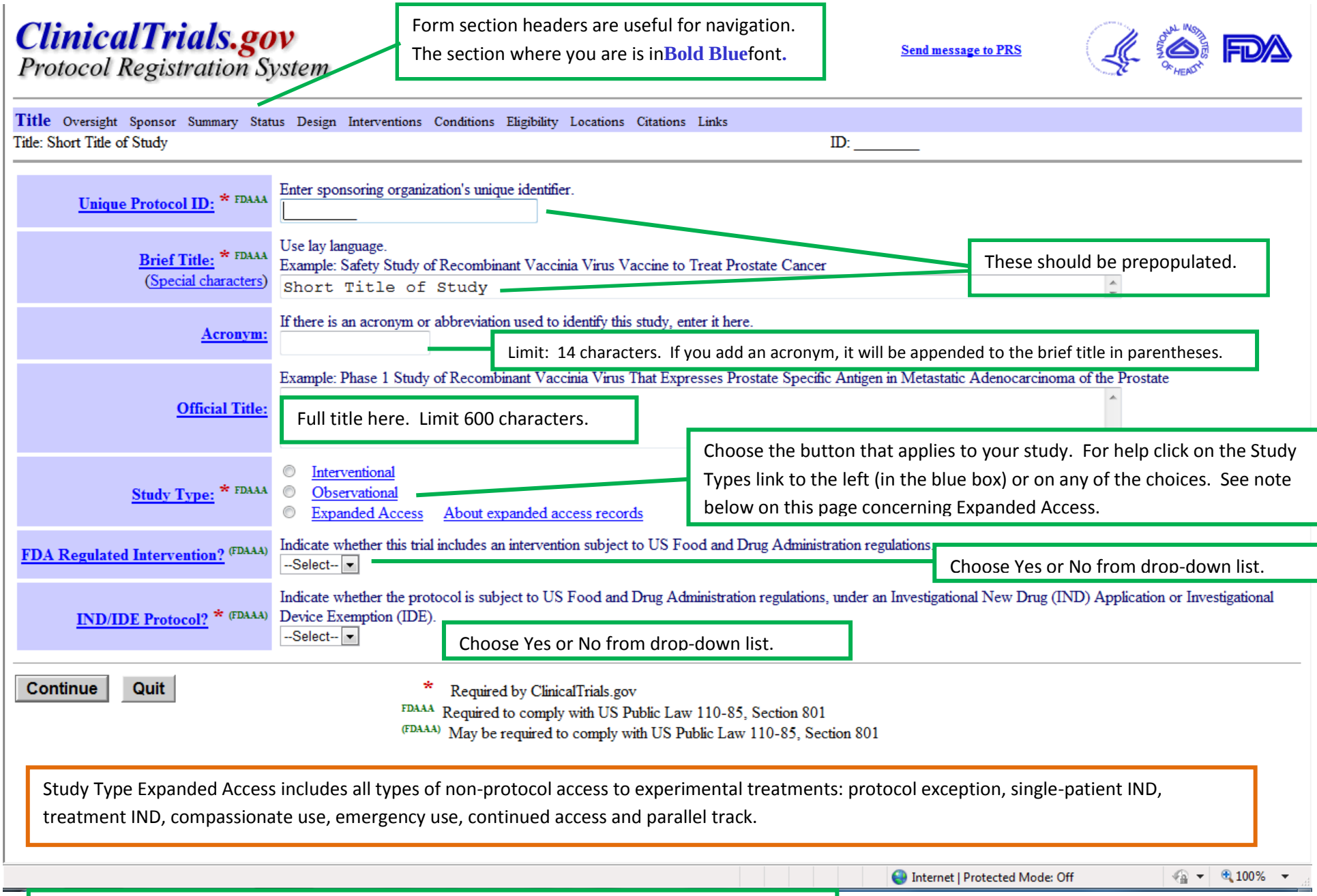
Color Key Code used on subsequent pages:

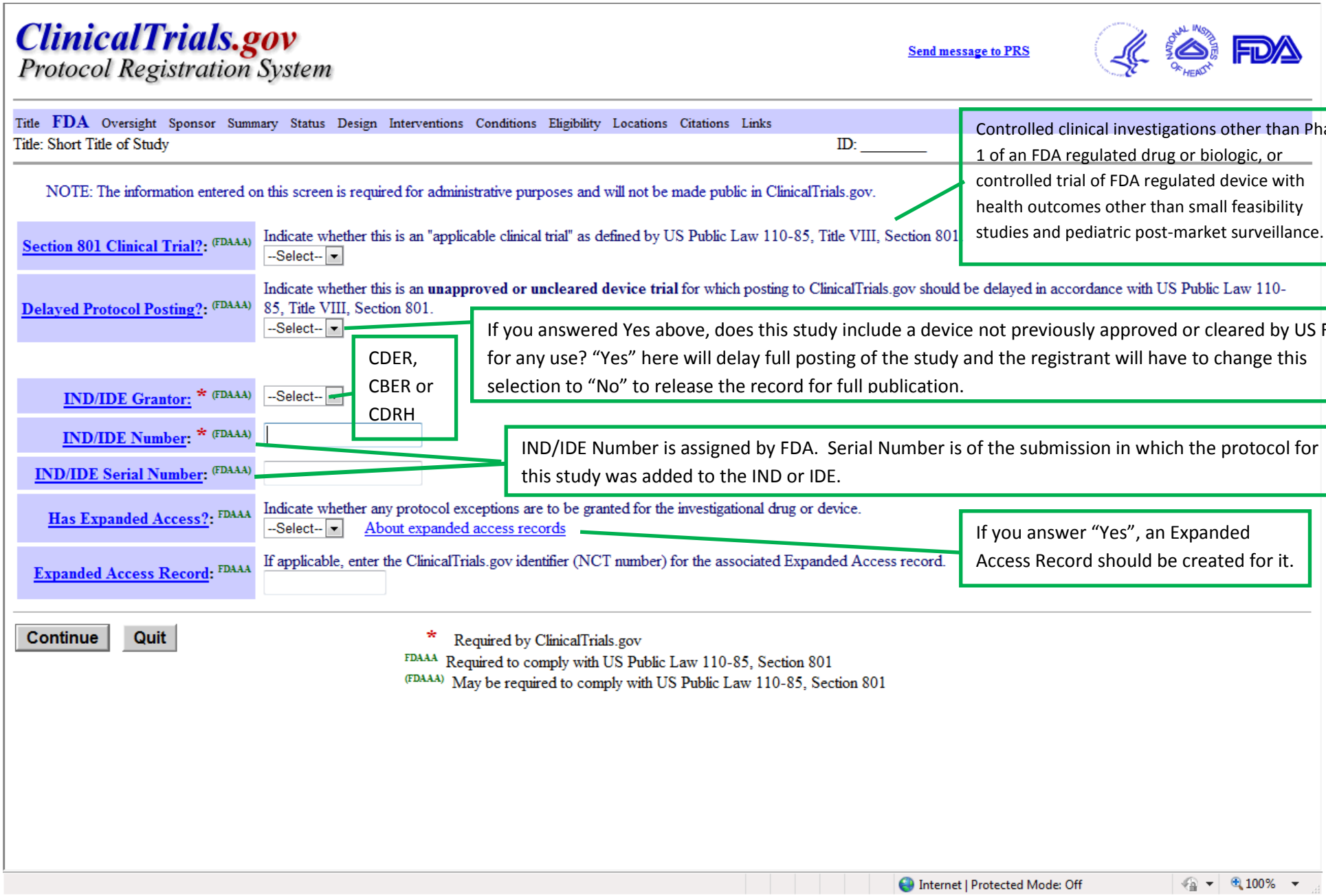
Green = Text explanation

Orange = Highlighted information on form

RED = Please take note


ClinicalTrials.gov
Protocol Registration System
START SCREEN FOR REGISTRATION OF A PROTOCOL
Send message to PRS
Create New Protocol Record
This "send message" shows on all screens, however it's better to consult your Organizational contact prior to sending emails to this external group.
To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:
1. Section 801 studies may only be registered by the Responsible Party. If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.
2. IND/IDE studies may only be registered by the IND/IDE holder. If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.
3. For NIH-funded studies, coordinate with the relevant Institute or Center. If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.
4. Multi-site studies are NOT registered by individual sites. If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).
5. Coordinate with all collaborators before registering. If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.
6. Refer to the ClinicalTrials.gov Review of Protocol Submissions document for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.
Sponsor provided protocol number. This is not the IRB number. If you do not have one, contact your administrator.
Unique Protocol ID: *
Enter the Study "Short Title"; the full title is entered later. The Brief Title put here is to be in lay language and include the condition and intervention evaluated in the study. 300 character limit.
Brief Title: *
Continue
Cancel
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Look for the asterisks as you go through the various screens.
Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.


ClinicalTrials.gov
Protocol Registration System
Form section headers are useful for navigation.
The section where you are is inBold Bluefont.
Send message to PRS
Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID: _____
Unique Protocol ID: * FDAAA
Enter sponsoring organization's unique identifier.
Brief Title: * FDAAA
(Special characters)
Use lay language.
Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
Short Title of Study
These should be prepopulated.
Acronym:
If there is an acronym or abbreviation used to identify this study, enter it here.
Limit: 14 characters. If you add an acronym, it will be appended to the brief title in parentheses.
Official Title:
Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
Full title here. Limit 600 characters.
Study Type: * FDAAA
Interventional
Observational
Expanded Access
About expanded access records
Choose the button that applies to your study. For help click on the Study Types link to the left (in the blue box) or on any of the choices. See note below on this page concerning Expanded Access.
FDA Regulated Intervention? (FDAAA)
Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations
--Select--
Choose Yes or No from drop-down list.
IND/IDE Protocol? * (FDAAA)
Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE).
--Select--
Choose Yes or No from drop-down list.
Continue
Quit
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Study Type Expanded Access includes all types of non-protocol access to experimental treatments: protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.
Internet | Protected Mode: Off
100%
This is a smart form - the choices you made on previous screens affect future screens.



Controlled clinical investigations other than Phase 1 of an FDA regulated drug or biologic, or controlled trial of FDA regulated device with health outcomes other than small feasibility studies and pediatric post-market surveillance.

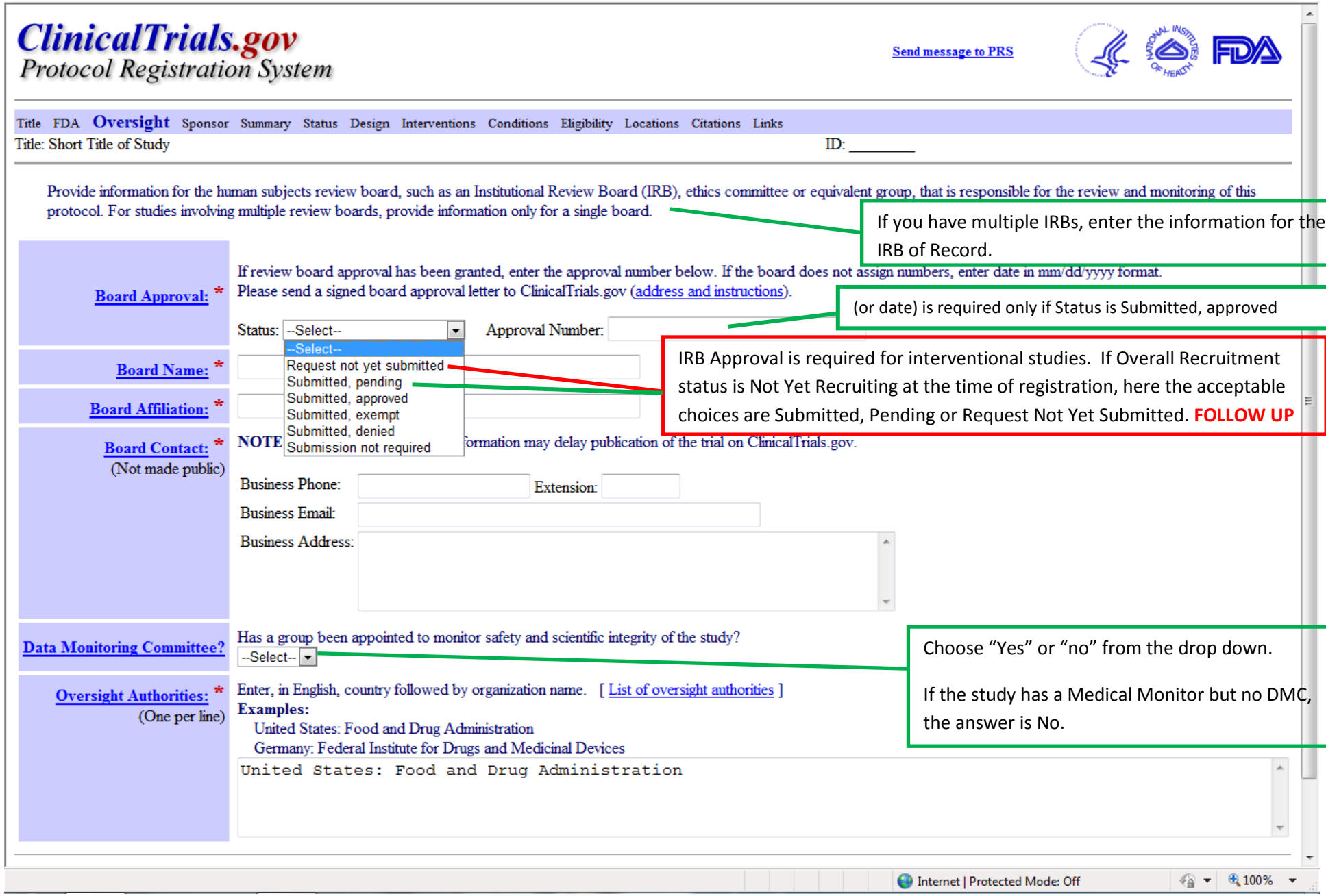
If you answered Yes above, does this study include a device not previously approved or cleared by US FDA for any use? "Yes" here will delay full posting of the study and the registrant will have to change this selection to "No" to release the record for full publication.

CDER, CBER or CDRH

IND/IDE Number is assigned by FDA. Serial Number is of the submission in which the protocol for this study was added to the IND or IDE.

If you answer "Yes", an Expanded Access Record should be created for it.

FDA screen comes up if you say Yes.



If you have multiple IRBs, enter the information for the IRB of Record.

(or date) is required only if Status is Submitted, approved

IRB Approval is required for interventional studies. If Overall Recruitment status is Not Yet Recruiting at the time of registration, here the acceptable choices are Submitted, Pending or Request Not Yet Submitted. **FOLLOW UP**

Choose "Yes" or "no" from the drop down.

If the study has a Medical Monitor but no DMC, the answer is No.

Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Required ID: Test2

Responsible Party: FDAAA
NOTE: The **Sponsor** option should be selected, unless the Investigator has been designated as Responsible Party as permitted under US Public Law 110-85, the FDA Amendments Act (FDAAA).
Sponsor [About Responsible Party...]

Sponsor: * FDAAA

Collaborators: (One per line)
Include all additional funding sources.
Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).

Three choices: Sponsor, Sponsor-Investigator or Principal Investigator.
If not the Sponsor, additional information will be asked for.

Name of primary organization that oversees implementation of the study and is responsible for data analysis. For applicable trials, Sponsor is defined in 21 CFR 50.3.
Limit: 160 characters.

Continue Quit

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

Up to 10 names if applicable to the study. The person who fills in this field is responsible for confirming any Collaborator before listing them here.

Limit 160 characters per name.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title FDA Oversight Sponsor **Summary** Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Short Title of Study ID: _____

Brief Summary: * FDAAA

(Formatting tips)

Use lay language. Include a statement of the study hypothesis.

Can cut and paste into this field from a study document. Suggest in from the Informed Consent Form as must use lay language.

5000 character limit.

Detailed Description:

(Formatting tips)

Provide a more extensive description, if desired.
Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcome measures.

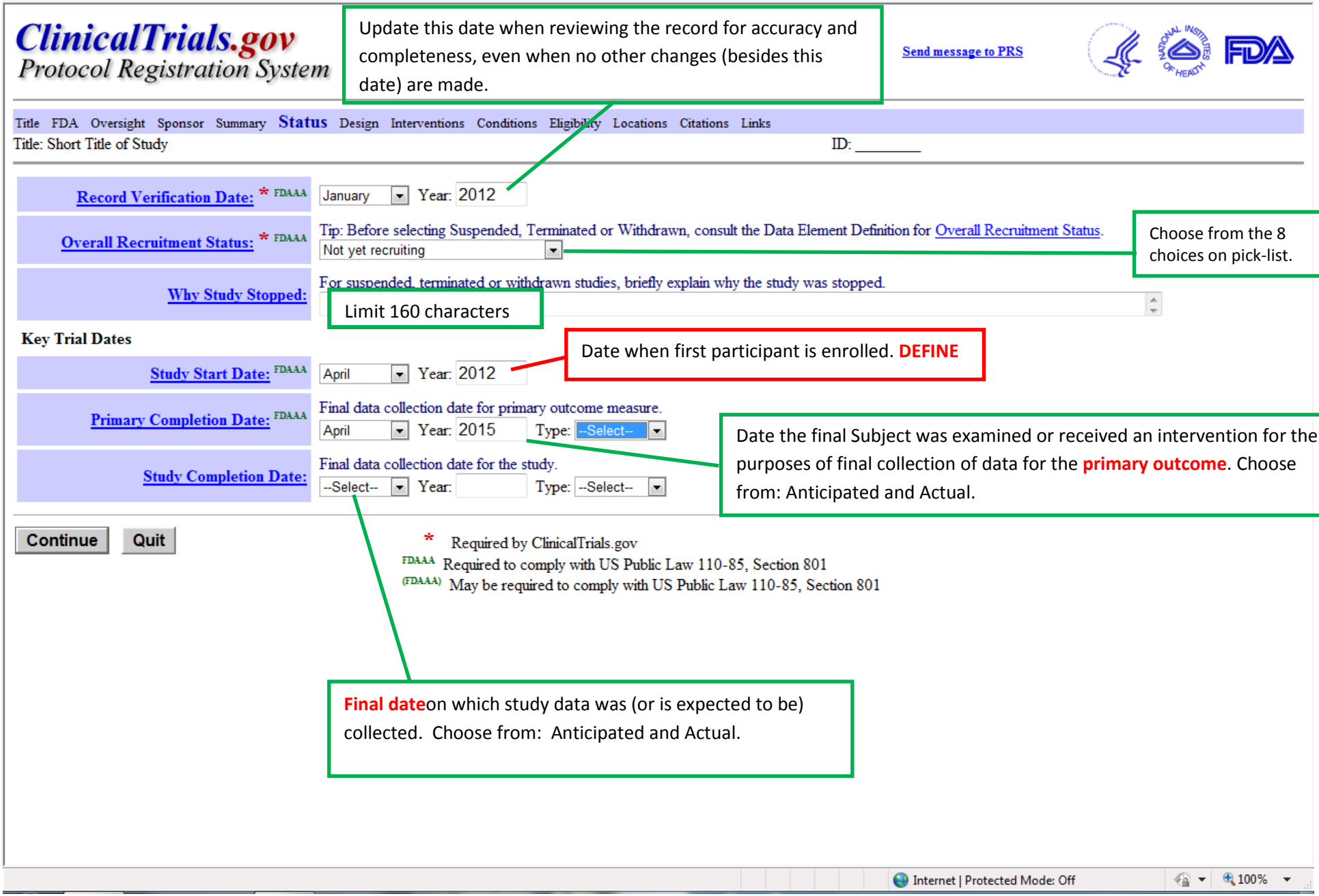
This field is NOT asterisked in red, so is optional. May be left blank.

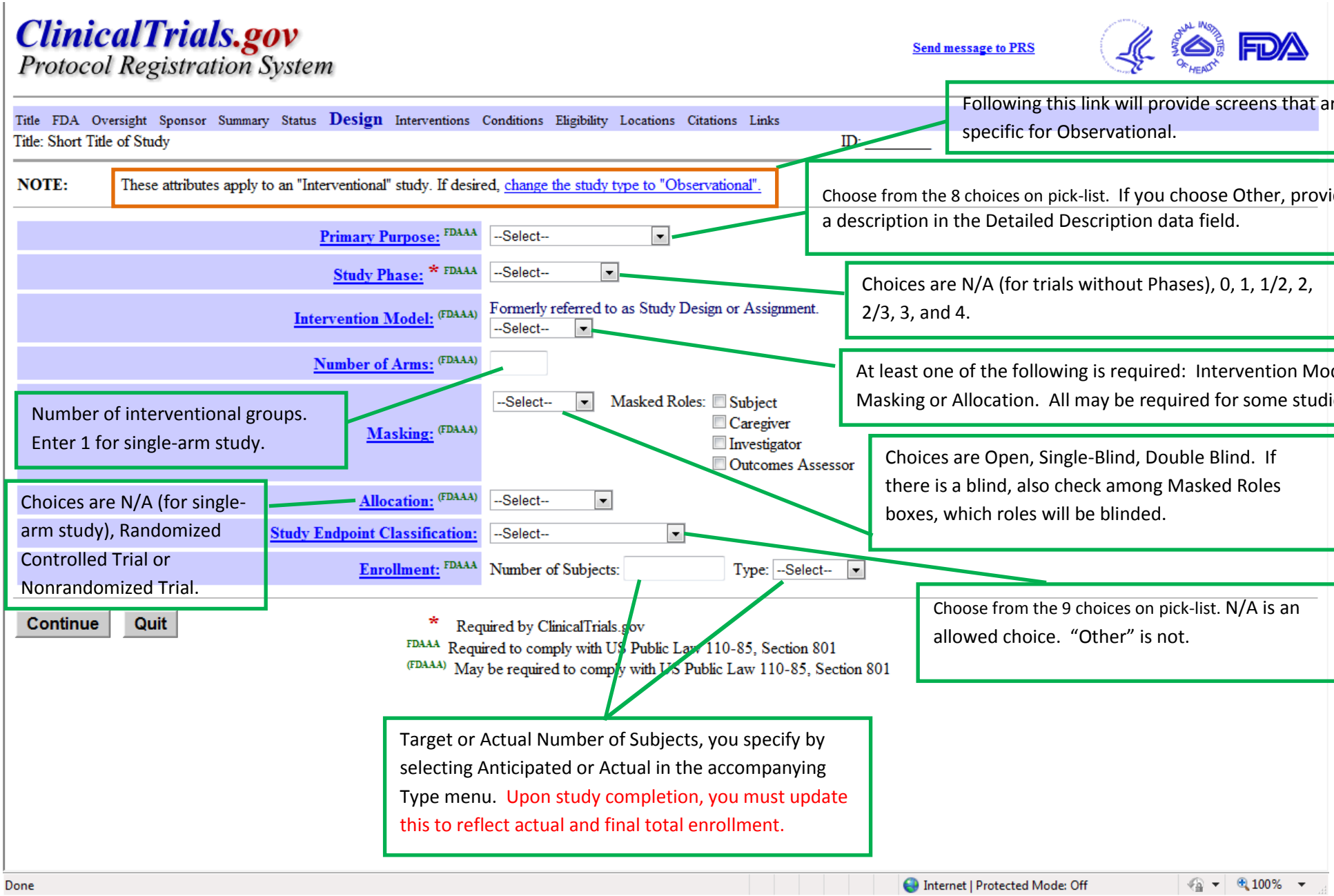
Extended description of the protocol including more technical information as compared to the Brief Summary. Do not include the entire protocol or duplicate information recorded in other data elements of the submission form (such as eligibility criteria or outcome measures). Limit 32,000 characters.

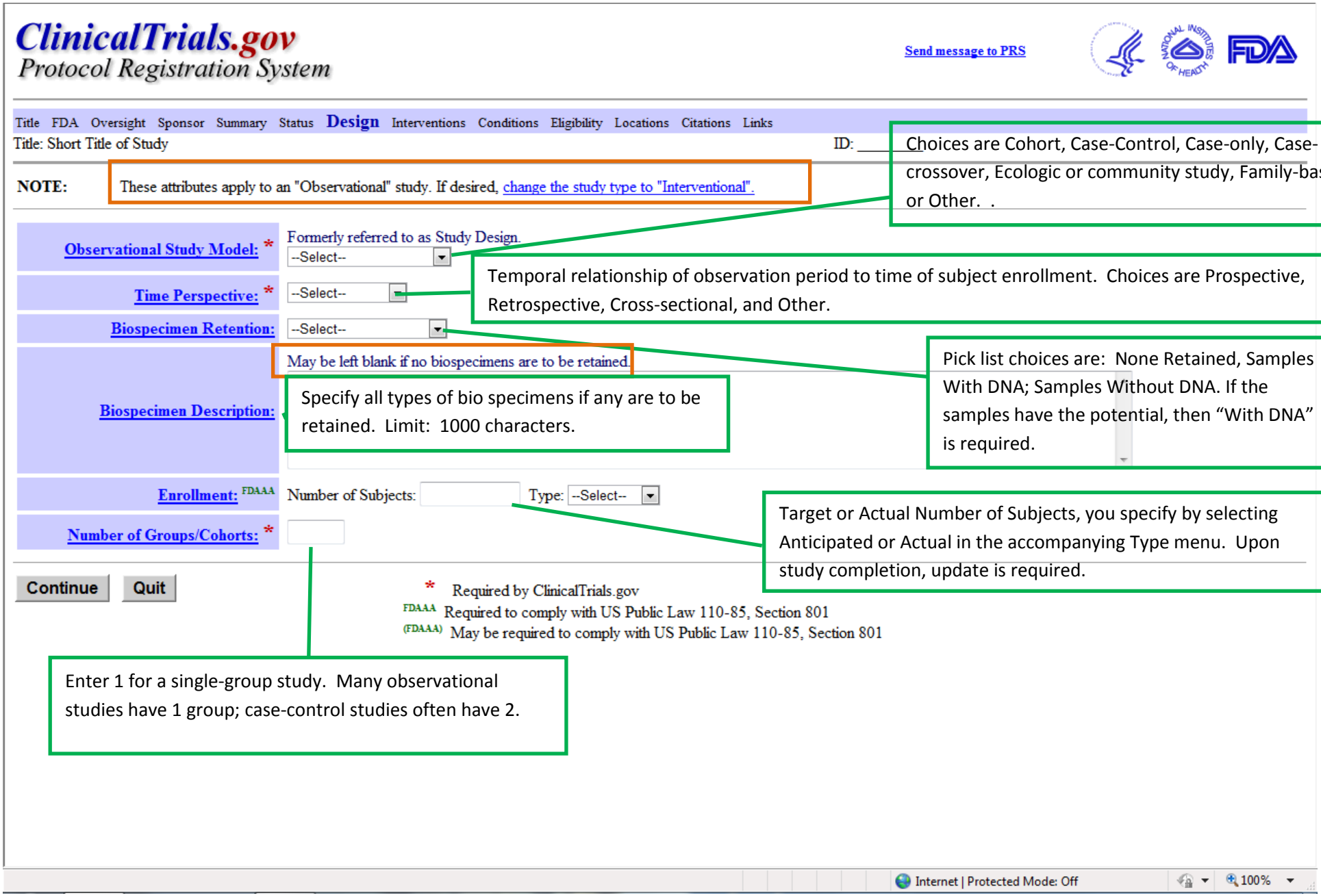
Continue Quit

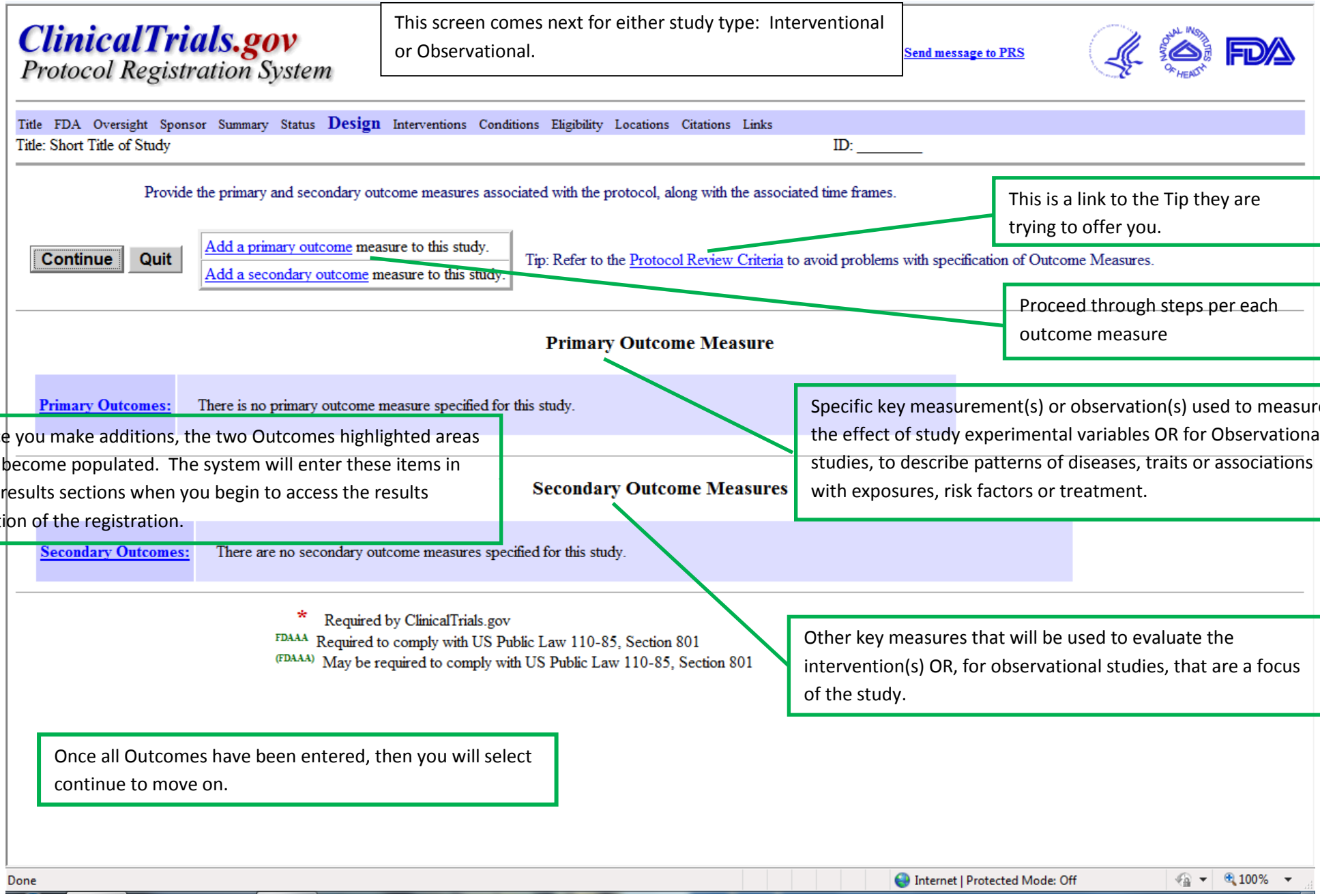
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

Internet | Protected Mode: Off 100%

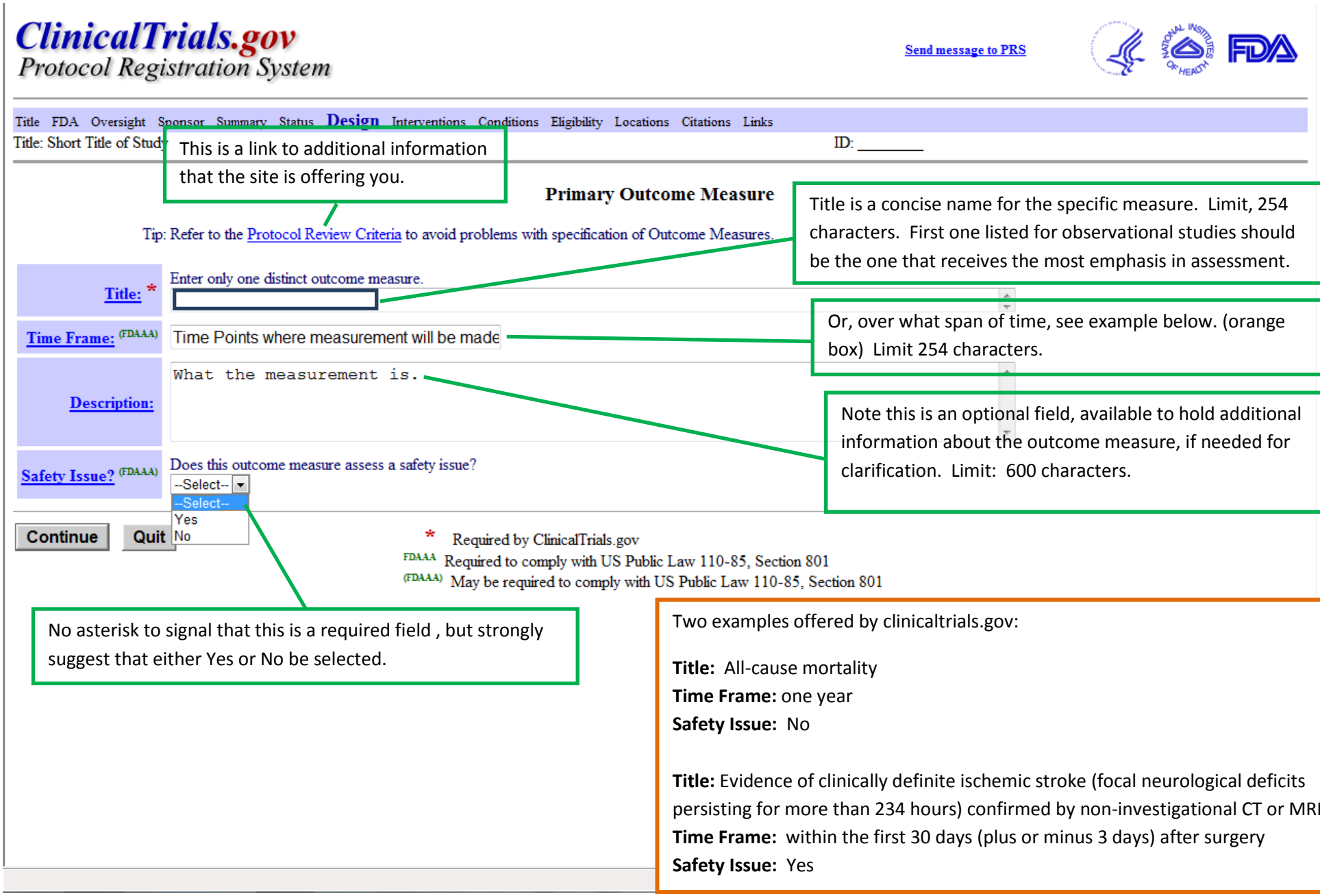

ClinicalTrials.gov
Protocol Registration System
Update this date when reviewing the record for accuracy and completeness, even when no other changes (besides this date) are made.
Send message to PRS
Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID: _____
Record Verification Date: * FDAAA
January Year: 2012
Overall Recruitment Status: * FDAAA
Tip: Before selecting Suspended, Terminated or Withdrawn, consult the Data Element Definition for Overall Recruitment Status.
Not yet recruiting
Choose from the 8 choices on pick-list.
Why Study Stopped:
For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.
Limit 160 characters
Key Trial Dates
Study Start Date: FDAAA
April Year: 2012
Date when first participant is enrolled. DEFINE
Primary Completion Date: FDAAA
Final data collection date for primary outcome measure.
April Year: 2015 Type: --Select--
Date the final Subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. Choose from: Anticipated and Actual.
Study Completion Date:
Final data collection date for the study.
--Select-- Year: Type: --Select--
Continue
Quit
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Final dateon which study data was (or is expected to be) collected. Choose from: Anticipated and Actual.
Internet | Protected Mode: Off
100%


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID:
NOTE:
These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".
Primary Purpose: FDAAA
--Select--
Study Phase: * FDAAA
--Select--
Intervention Model: (FDAAA)
Formerly referred to as Study Design or Assignment.
--Select--
Number of Arms: (FDAAA)
Masking: (FDAAA)
--Select--
Masked Roles:
Subject
Caregiver
Investigator
Outcomes Assessor
Allocation: (FDAAA)
--Select--
Study Endpoint Classification:
--Select--
Enrollment: FDAAA
Number of Subjects:
Type: --Select--
Continue
Quit
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Following this link will provide screens that are specific for Observational.
Choose from the 8 choices on pick-list. If you choose Other, provide a description in the Detailed Description data field.
Choices are N/A (for trials without Phases), 0, 1, 1/2, 2, 2/3, 3, and 4.
At least one of the following is required: Intervention Model, Masking or Allocation. All may be required for some studies.
Number of interventional groups. Enter 1 for single-arm study.
Choices are Open, Single-Blind, Double Blind. If there is a blind, also check among Masked Roles boxes, which roles will be blinded.
Choices are N/A (for single-arm study), Randomized Controlled Trial or Nonrandomized Trial.
Choose from the 9 choices on pick-list. N/A is an allowed choice. "Other" is not.
Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, you must update this to reflect actual and final total enrollment.
Done
Internet | Protected Mode: Off
100%

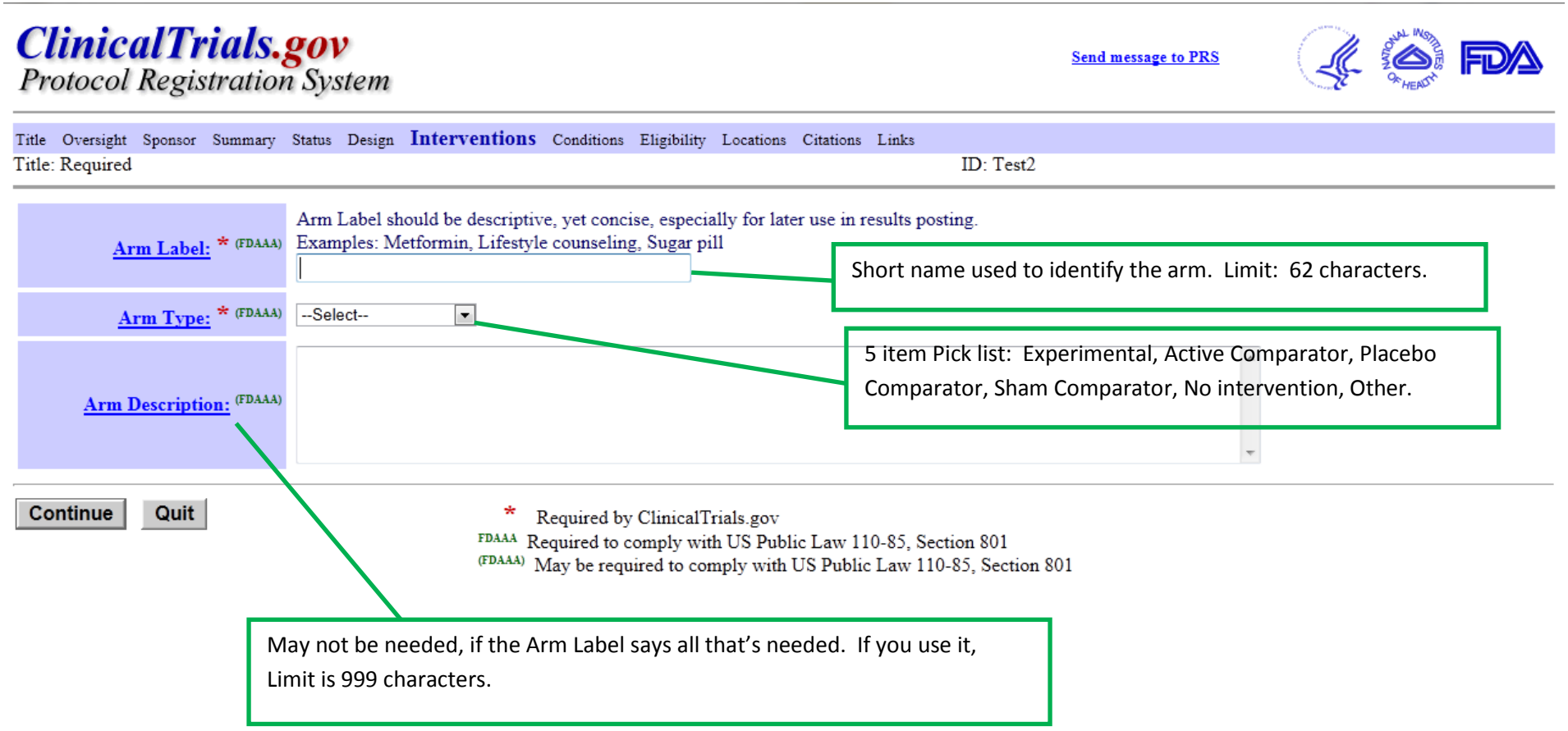

ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID:
NOTE:
These attributes apply to an "Observational" study. If desired, change the study type to "Interventional".
Observational Study Model: *
Formerly referred to as Study Design.
--Select--
Time Perspective: *
--Select--
Biospecimen Retention:
--Select--
Biospecimen Description:
May be left blank if no biospecimens are to be retained.
Enrollment: FDAAA
Number of Subjects:
Type: --Select--
Number of Groups/Cohorts: *
Continue
Quit
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Choices are Cohort, Case-Control, Case-only, Case-crossover, Ecologic or community study, Family-based or Other. .
Temporal relationship of observation period to time of subject enrollment. Choices are Prospective, Retrospective, Cross-sectional, and Other.
Pick list choices are: None Retained, Samples With DNA; Samples Without DNA. If the samples have the potential, then "With DNA" is required.
Specify all types of bio specimens if any are to be retained. Limit: 1000 characters.
Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, update is required.
Enter 1 for a single-group study. Many observational studies have 1 group; case-control studies often have 2.
Internet | Protected Mode: Off
100%



The next two pages demonstrate screens you will see once Outcomes Measures has been chosen.



Interventional studies have Arms:



For each Arm, specify the Intervention, see next page.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design **Interventions** Conditions Eligibility Locations Citations Links

Title: Required ID: Test2

Intervention Type: * FDAAA	--Select--
Intervention Name: * FDAAA	Enter the specific name of the intervention. For a drug, use the generic equivalent name if it has been established.
Intervention Description: (FDAAA)	Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
Arms: * (FDAAA)	: : :
Other Names: (One per line)	Include brand names, serial numbers and code names, if applicable. Other names are used to improve search results on the ClinicalTrials.gov web site.

9 item Pick List, select one per intervention:

Generic name for drugs, descriptive name for others. Limit: 1000 characters.

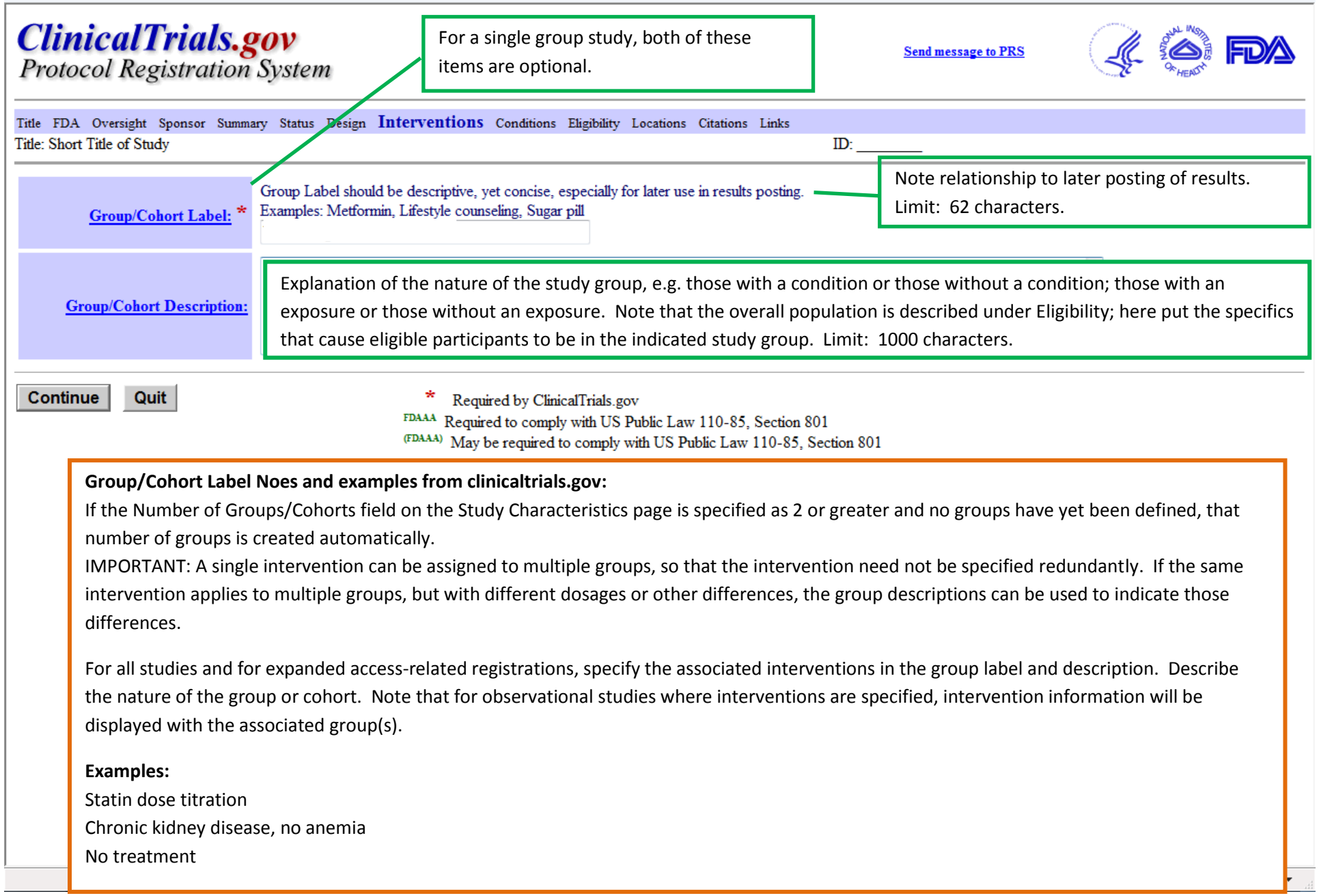
Limit: 1000 characters.

There are as many boxes here, with the labels you entered, as you told the system the number of arms your protocol has. You'll be filling in a screen for each study Intervention, indicating which Arms receive it.

Other names used to identify the intervention, past or present. These names will be used to improve search results. Limit: 160 characters per name.

Continue Quit

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801



Group/Cohort Label Noes and examples from clinicaltrials.gov:

If the Number of Groups/Cohorts field on the Study Characteristics page is specified as 2 or greater and no groups have yet been defined, that number of groups is created automatically.

IMPORTANT: A single intervention can be assigned to multiple groups, so that the intervention need not be specified redundantly. If the same intervention applies to multiple groups, but with different dosages or other differences, the group descriptions can be used to indicate those differences.

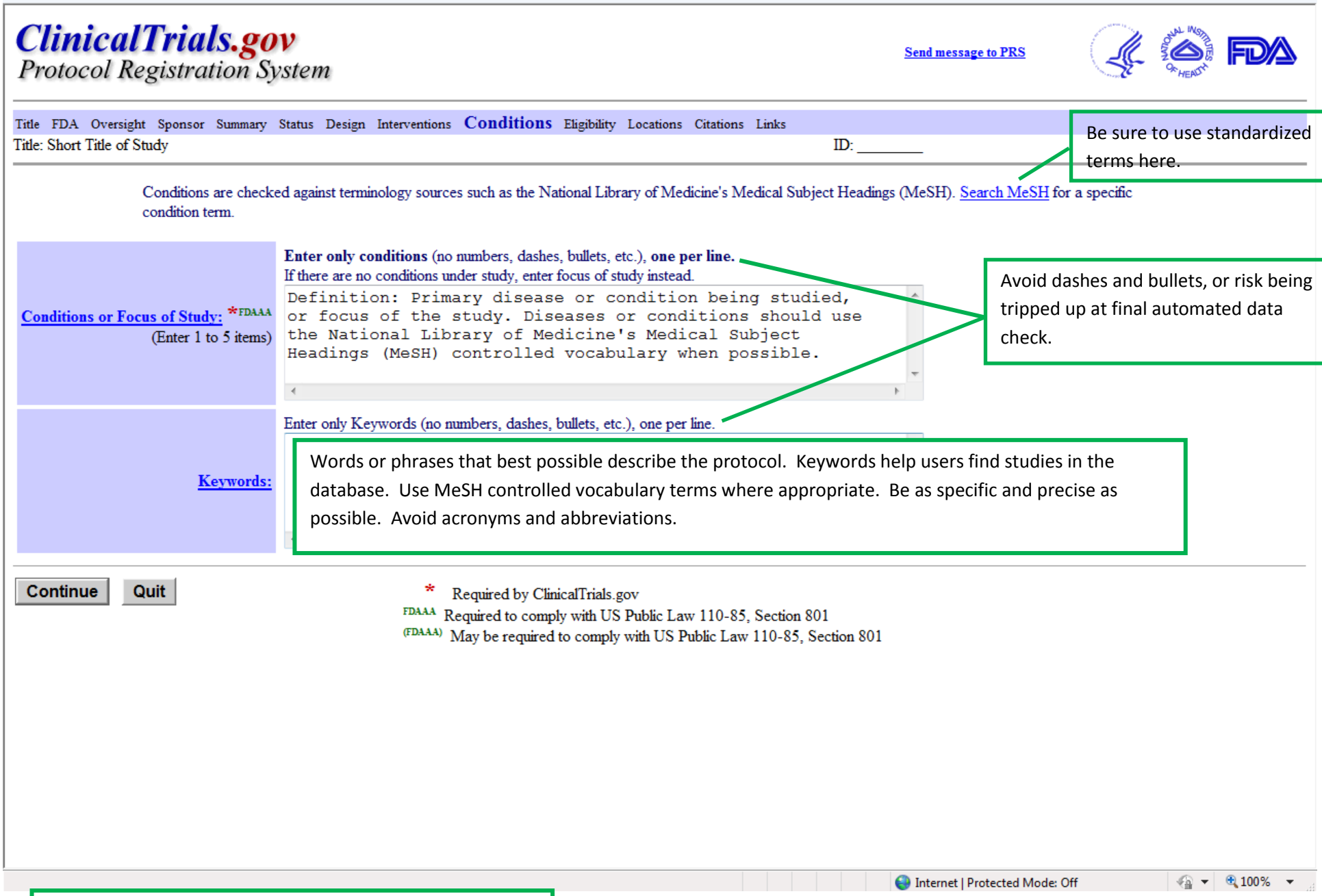
For all studies and for expanded access-related registrations, specify the associated interventions in the group label and description. Describe the nature of the group or cohort. Note that for observational studies where interventions are specified, intervention information will be displayed with the associated group(s).

Examples:

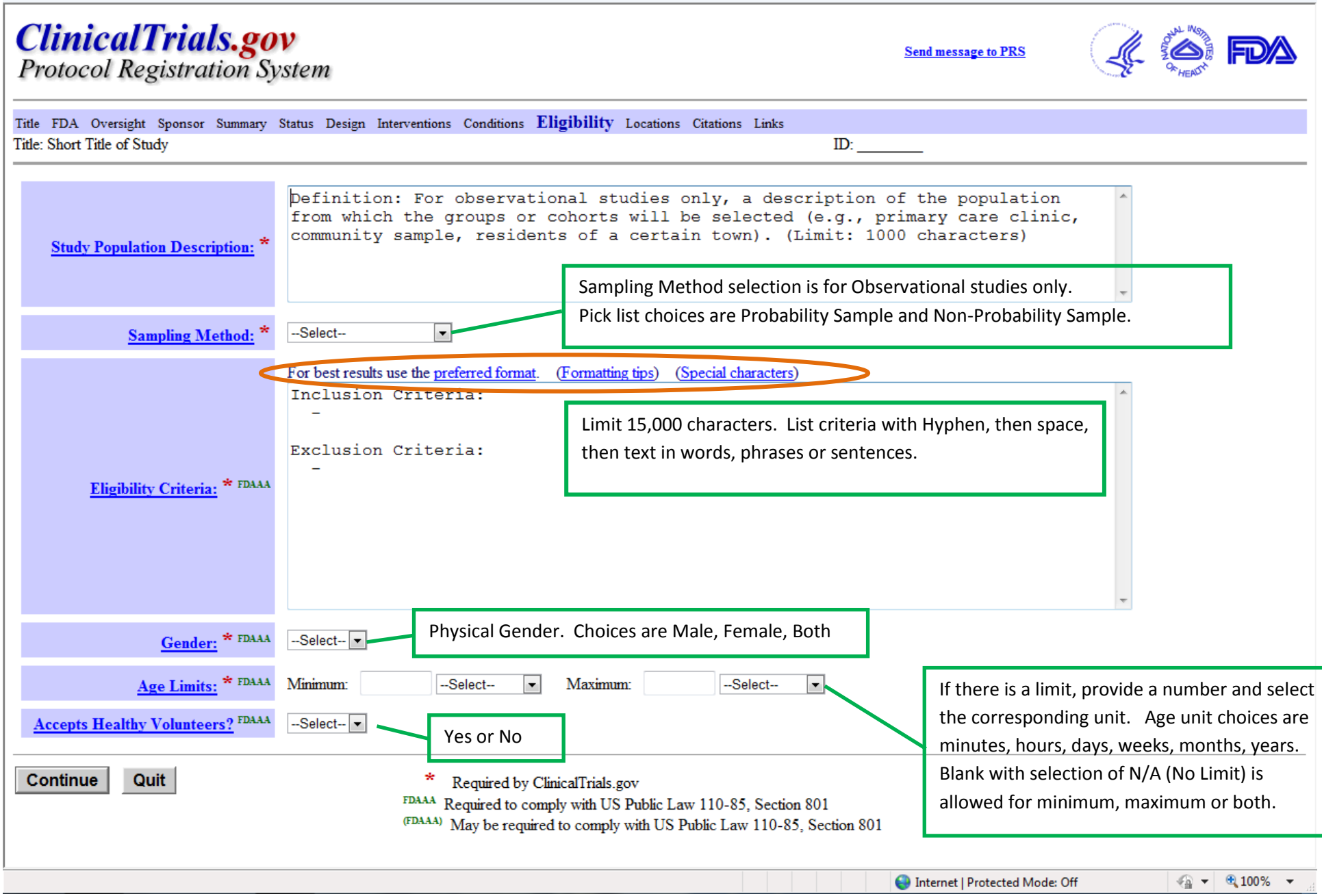
Statin dose titration

Chronic kidney disease, no anemia

No treatment



Observational studies have Groups/Cohorts


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID: _____
Study Population Description: *
Definition: For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town). (Limit: 1000 characters)
Sampling Method: *
--Select--
Sampling Method selection is for Observational studies only.
Pick list choices are Probability Sample and Non-Probability Sample.
Eligibility Criteria: * FDAAA
For best results use the preferred format. (Formatting tips) (Special characters)
Inclusion Criteria:
-
Exclusion Criteria:
-
Limit 15,000 characters. List criteria with Hyphen, then space, then text in words, phrases or sentences.
Gender: * FDAAA
--Select--
Physical Gender. Choices are Male, Female, Both
Age Limits: * FDAAA
Minimum:
--Select--
Maximum:
--Select--
If there is a limit, provide a number and select the corresponding unit. Age unit choices are minutes, hours, days, weeks, months, years.
Blank with selection of N/A (No Limit) is allowed for minimum, maximum or both.
Accepts Healthy Volunteers? FDAAA
--Select--
Yes or No
Continue
Quit
* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801
Internet | Protected Mode: Off
100%

This section begins illustration for completing Contact/Facility Information, next 7 pages.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

Continue Quit

Specify the Central Contact * (FDAAA) with overall recruiting responsibility for this study.
Specify the Study Officials/Investigators with overall scientific responsibility for this study.
Add a location * (FDAAA) to this Study.
Copy locations from a master list, extracted from this organization's records.

Locations: *

There are no Locations currently listed for this study.

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

Study officials, including the principal investigator, are the persons responsible for the overall scientific leadership of the protocol.

OK Add a Study Official to this study.

Study Officials: There are no Study Officials currently listed for this study.

NOTE: Study Official is required by the WHO and ICMJE.

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

Study Official is the person with overall scientific leadership of the study. Select this and you get the next page.

ICJME: International Council of Medical Journal Editors. This item relates to your ability to publish the study results.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

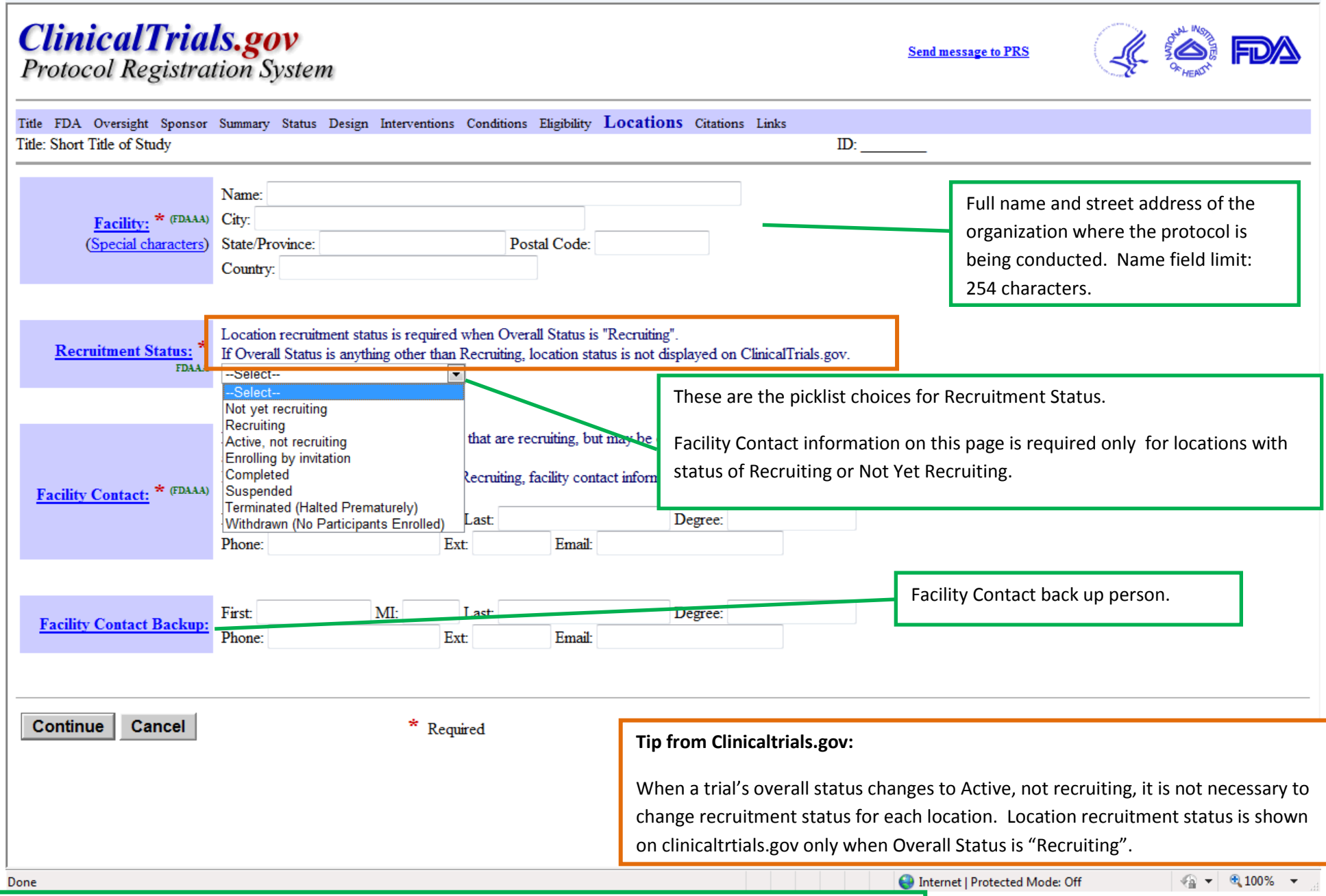
Study Official's Name:	First: MI: Last: Degree:
Official's Role:	--Select--
Organizational Affiliation:	

OK Cancel

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

Pick list choices are: Study Chair, Study Director, Principal Investigator.

Once OK is selected here, the system will return you to the first Locations page. If "Add Location" is chosen the next screen shot will appear.



Repeat of previous page, to illustrate boxes covered by the pick list.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

Facility: * (FDAAA) (Special characters)
Name:
City:
State/Province: Postal Code:
Country:

Multiple locations may be specified by invoking this page more than once.

Recruitment Status: * FDAAA
Location recruitment status is required when Overall Status is "Recruiting".
If Overall Status is anything other than Recruiting, location status is not displayed on ClinicalTrials.gov.
--Select--

Facility Contact: * (FDAAA)
Facility contact is required for locations that are recruiting, but may be ommitted if a Central Contact is provided for the trial. At a minimum, last name and either phone or email are required.
If Overall Status is anything other than Recruiting, facility contact information is not displayed on ClinicalTrials.gov.
First: MI: Last: Degree:
Phone: Ext: Email:

Office phone ***OR*** email is required. In the US and Canada, phone number should include area code and be in the format 123-555-5555. Otherwise, include the country code. Extension can be left blank if not needed.

Facility Contact Backup:
First: MI: Last: Degree:
Phone: Ext: Email:

A Backup for the Facility Contact is not required.

Continue Cancel

* Required

After you fill in Location you then have the opportunity to Add one or multiple Investigator(s) at this location. (See next page).

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

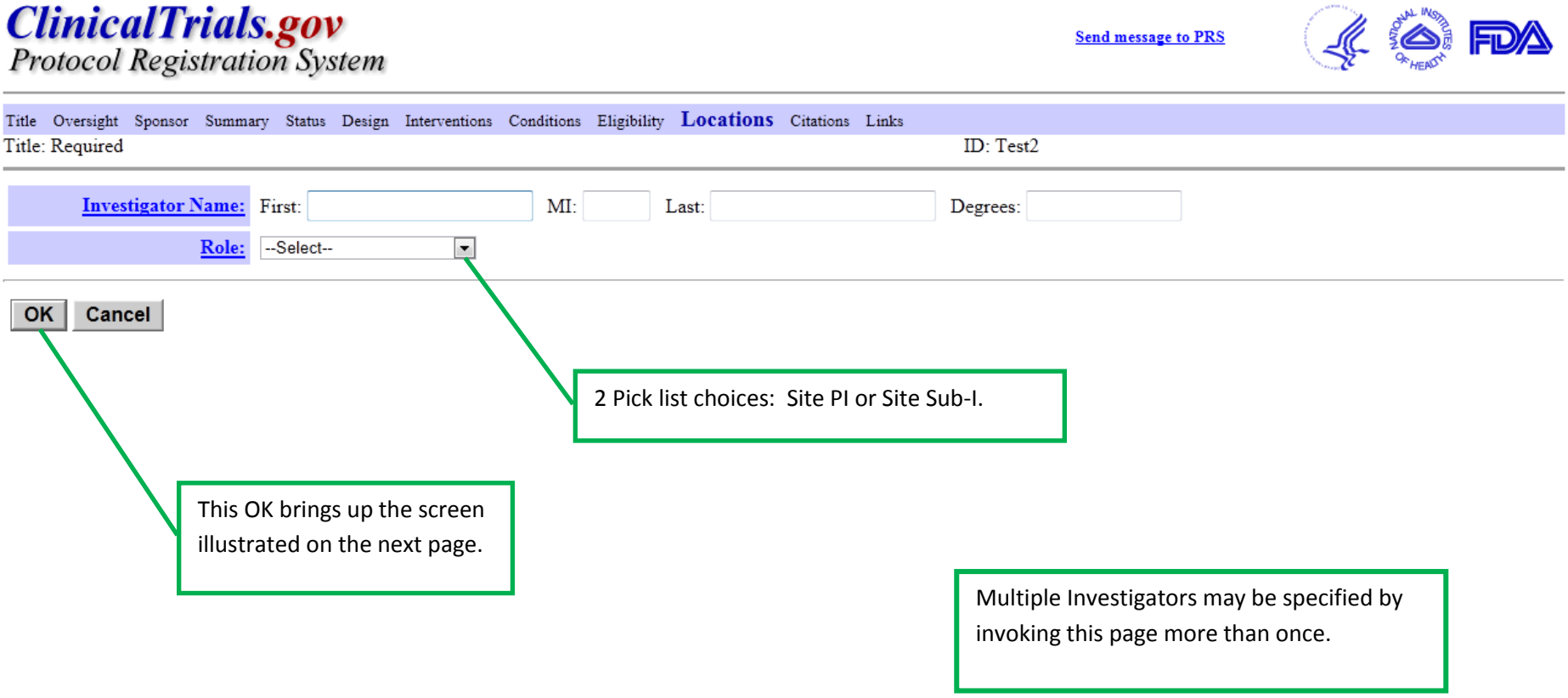
Location:

The Facility name and address that you added is brought into this area for you.

OK Add an Investigator to this Location.

Choose this Add button and the following screen comes up.

Investigators:	There are no Investigators currently listed for this location.


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Required
ID: Test2
Investigator Name: First: MI: Last: Degrees:
Role: --Select--
OK Cancel
2 Pick list choices: Site PI or Site Sub-I.
This OK brings up the screen illustrated on the next page.
Multiple Investigators may be specified by invoking this page more than once.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Required ID: Test2

Continue Quit

Specify the Central Contact * (FDAAA) with overall recruiting responsibility for this study.
Specify the Study Officials/Investigators with overall scientific responsibility for this study.
Add a location * (FDAAA) to this Study.
Copy locations from a master list, extracted from this organization's records.

You can attach additional Investigators or additional Locations from here. Choose Continue button to the left if you are finished adding both Investigators and Locations for the study.

Edit Delete	Facility: Recruitment Status: Contact: Contact Backup:	Information you previously added populates here for you to review. The system provides Edit and Delete links for your convenience just to the left of these entries.
Edit Investigators	Investigators:	Francisco K Fermata , MD Role: Site Sub-Investigator

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Short Title of Study ID: _____

Central Contact is the person with overall recruitment responsibility for this study.
If contact information is provided for all recruiting locations, Central Contact may be left blank.

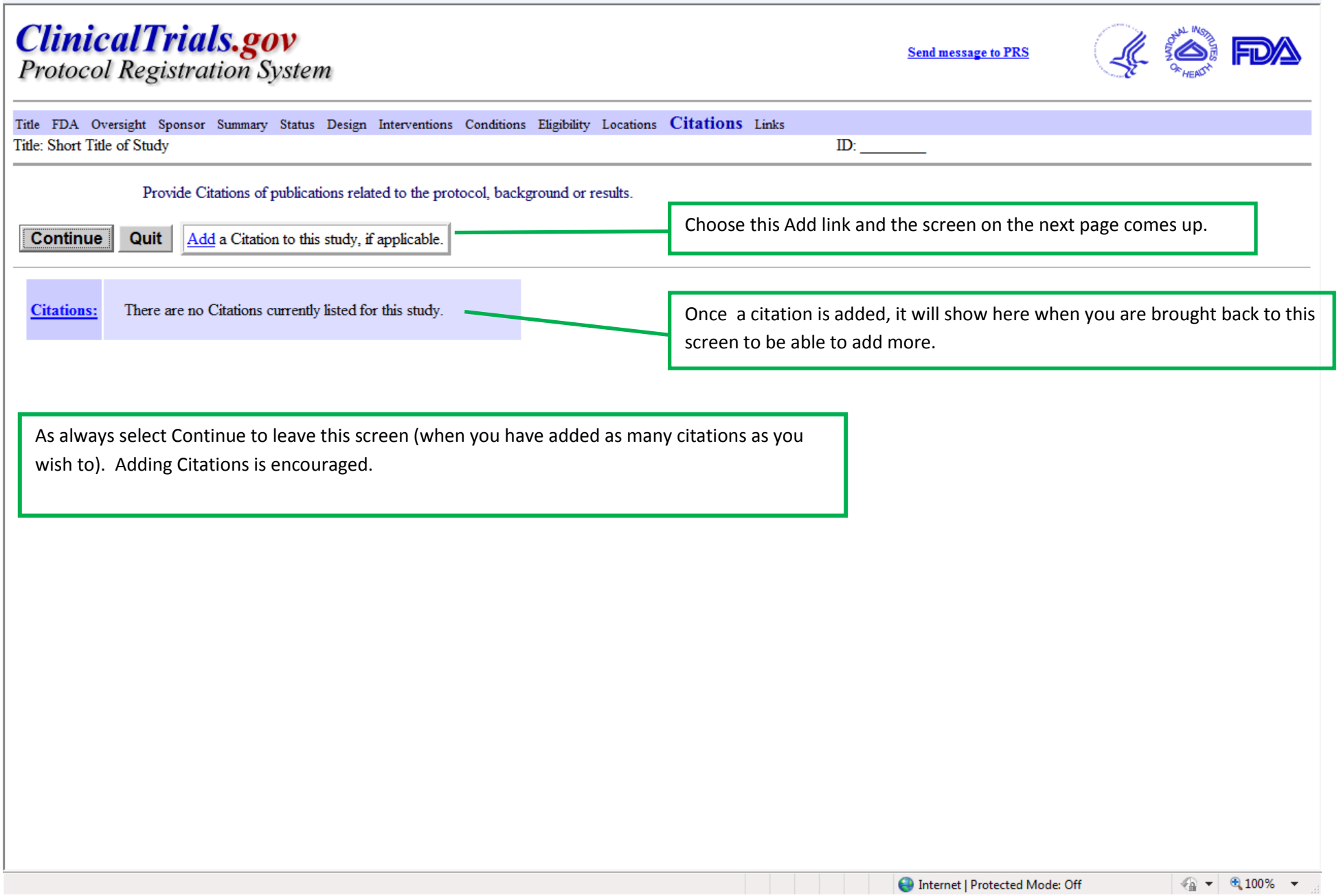
Central Contact: * (FDAAA)	First:		MI:	Last:	Degree:	
	Phone:		Ext:	Email:		
Central Contact Backup:	First:		MI:	Last:	Degree:	
	Phone:		Ext:	Email:		

Continue Quit

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

Phone if given for Central Contact (and Central Contact Backup if one is entered), must be a toll-free number. Phone format in the US and Canada to be used is 800-555-5555. Otherwise, provide the country code. Extension may be left blank.

Done Internet | Protected Mode: Off 100%


ClinicalTrials.gov
Protocol Registration System
Send message to PRS
Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study
ID: _____
Provide Citations of publications related to the protocol, background or results.
Continue
Quit
Add a Citation to this study, if applicable.
Choose this Add link and the screen on the next page comes up.
Citations:
There are no Citations currently listed for this study.
Once a citation is added, it will show here when you are brought back to this screen to be able to add more.
As always select Continue to leave this screen (when you have added as many citations as you wish to). Adding Citations is encouraged.
Internet | Protected Mode: Off
100%

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations **Citations** Links

Title: Required ID: Test2

Provide the unique PubMed Identifier (PMID) for the citation.

Search for a citation in MEDLINE, using the PubMed browser.

MEDLINE Identifier:	Enter PubMed Identifier (PMID)
Results Reference?	Does the publication report on results of this study? --Select--

Yes or No.

If the publication was not found in MEDLINE, enter the citation text.

OK Cancel

This OK will take you back to the screen on the previous page, where you confirm that you are done adding citations by choosing Continue.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title FDA Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations **Links**

Title: Short Title of Study ID: _____

Use this screen to provide pointers to web pages directly relevant to the protocol. Provide up to 5 suggested links.

Continue Quit Add a Link to a related web page to this study, if applicable.

If you choose this Add link and the screen on the next page comes

Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

Links: There are no Links to related web pages currently listed for this study.

Once one is added, it will show here and you are brought back to this screen to be able to add more, up to 5 allowed.

Cautionary Tip from Clinicaltrials.gov:

Do not include sites whose primary goal is to advertise or sell commercial products or services.

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations **Links**

Title: Required ID: Test2

URL: http://

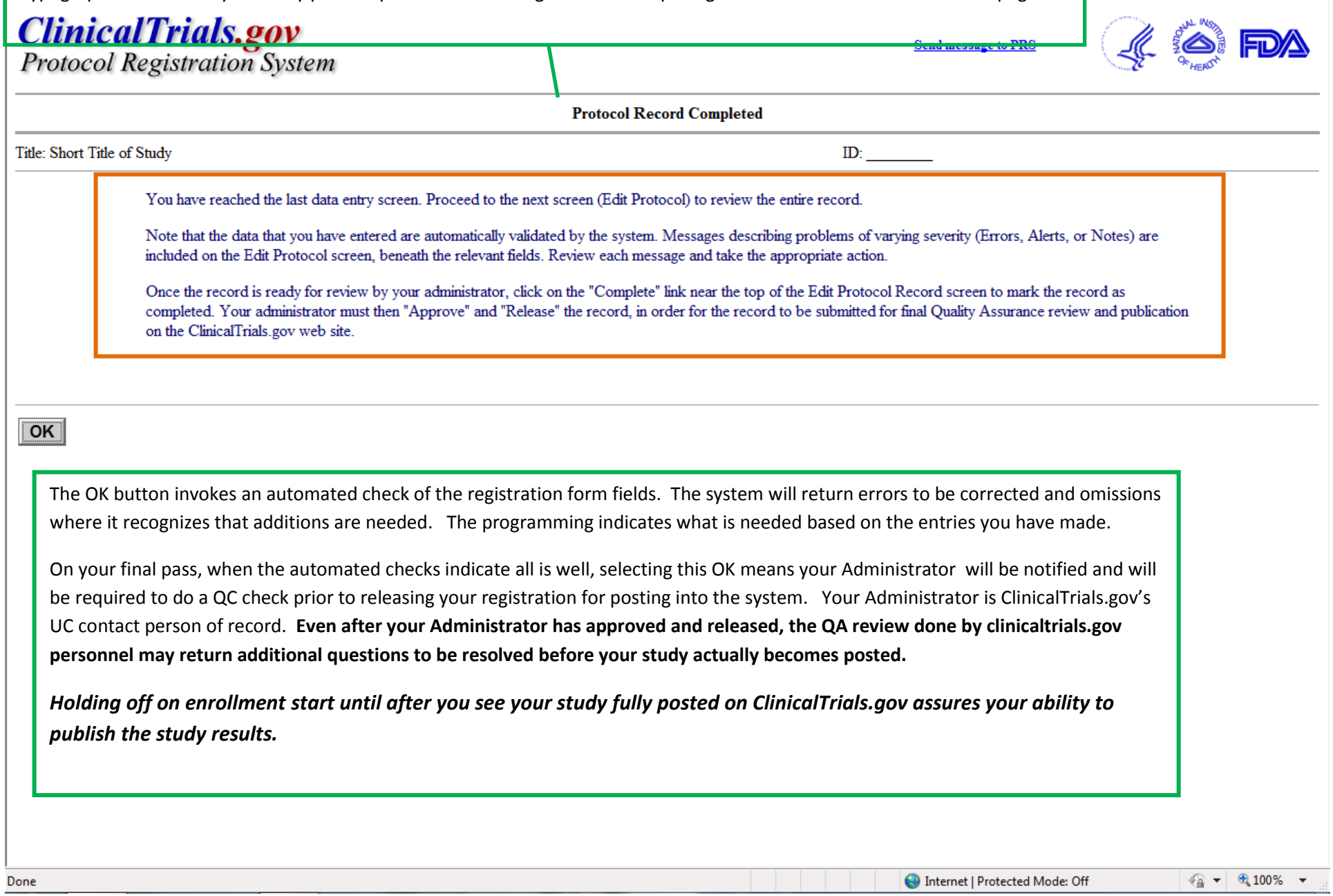
Description: Enter desired link text. Default: Related Info

OK Cancel

Complete URL, Limit 254 characters, includes the http://.

Limit: 254 characters.

Typographical errors may be easily picked up at this review stage. There is a spelling tool on the View Protocol Record page.



The OK button invokes an automated check of the registration form fields. The system will return errors to be corrected and omissions where it recognizes that additions are needed. The programming indicates what is needed based on the entries you have made.

On your final pass, when the automated checks indicate all is well, selecting this OK means your Administrator will be notified and will be required to do a QC check prior to releasing your registration for posting into the system. Your Administrator is ClinicalTrials.gov's UC contact person of record. **Even after your Administrator has approved and released, the QA review done by clinicaltrials.gov personnel may return additional questions to be resolved before your study actually becomes posted.**

Holding off on enrollment start until after you see your study fully posted on ClinicalTrials.gov assures your ability to publish the study results.