
Login

Welcome to the ClinicalTrials.gov Protocol Registration System (PRS).

OMB NO: 0910-0459
EXPIRATION DATE: 11/30/2007
[Burden Statement](#)

Organization:

User Name:

Password: [Forgot password](#)

Login

[PRS account registration information](#)

[Send email to ClinicalTrials.gov Administration](#)

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[Important Information on U.S. Public Law 110-85](#) Dec 12, 2007

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Create New Protocol Record

Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov.

All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.

Unique Protocol ID: *

123456789

Brief Title: *

FDA Amendments Act of 2007, Title VIII, Screenshots

Continue

Cancel

* Required fields

| | |
|---|--|
| Unique Protocol ID: * | Enter sponsoring organization's unique identifier. <input type="text" value="123456789"/> |
| Brief Title: * (Special characters) | Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer <input type="text" value="FDA Amendments Act of 2007, Title VIII, Screenshots"/> |
| Acronym: | If there is an acronym or abbreviation used to identify this study, enter it here. <input type="text"/> |
| Official Title: | Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate <input type="text"/> |
| Secondary ID's: * (One ID per line) | Include ISRCTN, NIH grant or contract numbers. <input type="text"/> |
| Study Type: * | <input type="radio"/> Interventional <input type="radio"/> Observational <input type="radio"/> Expanded Access About expanded access records |
| FDA Regulated Intervention? * | Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. <input type="text" value="-Select-"/> |
| IND/IDE Protocol? * | 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). <input type="text" value="-Select-"/> |

* Required fields

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

| | |
|---|--|
| Board Approval: * | If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format. Please send a signed board approval letter to ClinicalTrials.gov (address and instructions). |
| | Status: <input type="text" value="-Select-"/> Approval Number: <input type="text"/> |
| Board Name: * | <input type="text"/> |
| Board Affiliation: * | <input type="text"/> |
| Board Contact: * (Not made public) | NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov. Business Phone: <input type="text"/> Extension: <input type="text"/> Business Email: <input type="text"/> Business Address: <input type="text"/> |
| Data Monitoring Committee? | Has a group been appointed to monitor safety and scientific integrity of the study? <input type="text" value="-Select-"/> |
| Oversight Authorities: * (One per line) | Enter, in English, country followed by organization name. [List of oversight authorities] Examples: United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medicinal Devices <input type="text"/> |

* Required fields

Sponsor: *

Collaborators:
(One per line)

Test Organization

Include all additional funding sources.

Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).

Responsible Party: *

Sponsor or principal investigator, as defined in US Public Law 110-85, Title VIII, Section 801.

If responsible party is an organization enter the contact person by name or official title.

Name/Official Title:

If responsible party is an individual enter organizational affiliation.

Organization:

Contact information will not be made public.

Phone: Extension:

Email:

Continue

Quit

* Required fields

Brief Summary: *

[\(Formatting tips\)](#)

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

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.

Continue

Quit

* Required fields

Record Verification Date: * -Select- v Year:

Overall Recruitment Status: * -Select- v

Why Study Stopped:
For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.

Key Trial Dates

Study Start Date: * -Select- v Year:

Study Completion Date: -Select- v Year: Type: -Select- v

Primary Completion Date: *
Final data collection date for primary outcome measure.
-Select- v Year: Type: -Select- v

* Required fields

NOTE: These attributes apply to an "Interventional" study. If desired, [change the study type to "Observational"](#).

| | |
|---------------------------------------|---|
| Primary Purpose: * | <input type="text" value="-Select-"/> |
| Study Phase: * | <input type="text" value="-Select-"/> |
| Intervention Model: * | Formerly referred to as Study Design or Assignment. <input type="text" value="-Select-"/> |
| Number of Arms: * | <input type="text"/> |
| Masking: * | <input type="text" value="-Select-"/> Masked Roles: <input type="checkbox"/> Subject <input type="checkbox"/> Caregiver <input type="checkbox"/> Investigator <input type="checkbox"/> Outcomes Assessor |
| Allocation: * | <input type="text" value="-Select-"/> |
| Control: | Control is being phased out. Specify study arms instead. <input type="text" value="-Select-"/> |
| Study Endpoint Classification: | <input type="text" value="-Select-"/> |
| Enrollment: * | Number of Subjects: <input type="text"/> Type: <input type="text" value="-Select-"/> |

* Required fields

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. <input type="text"/> |
| Enrollment: * | Number of Subjects: <input type="text"/> Type: -Select- ▼ |
| Number of Groups/Cohorts: * | <input type="text"/> |

* Required fields

Provide the primary and key secondary outcome measures associated with the protocol, along with the associated time frames.

Continue

Quit

[Add a primary outcome](#) measure to this study.

[Add a secondary outcome](#) measure to this study.

Primary Outcome Measure

Primary Outcomes:

There is no primary outcome measure specified for this study.

Key Secondary Outcome Measures

Secondary Outcomes:

There are no secondary outcome measures specified for this study.

* Required

Primary Outcome Measure

| | |
|---------------------------|---|
| Outcome Measure: * | Enter only one distinct outcome measure. <input type="text"/> |
| Time Frame: * | <input type="text"/> |
| Safety Issue? * | Does this outcome measure assess a safety issue? <input type="text" value="-Select-"/> |

* Required fields

Provide the primary and key secondary outcome measures associated with the protocol, along with the associated time frames.

Continue

Quit

[Add a primary outcome](#) measure to this study.

[Add a secondary outcome](#) measure to this study.

Primary Outcome Measure

Primary Outcomes:

There is no primary outcome measure specified for this study.

Key Secondary Outcome Measures

Secondary Outcomes:

There are no secondary outcome measures specified for this study.

* Required

Secondary Outcome Measure

| | |
|---------------------------|---|
| Outcome Measure: * | Enter only one distinct outcome measure. <input type="text"/> |
| Time Frame: * | <input type="text"/> |
| Safety Issue? * | Does this outcome measure assess a safety issue? <input type="text" value="-Select-"/> |

* Required fields

Specify the arms, if any, and their associated interventions ([Specifying Study Arms](#)).

Continue

Quit

[Add an arm](#)

[Add an Intervention](#)

Study Arms

[Arm:](#) *

There are no arms currently listed for this study.

Interventions

[Interventions:](#) *

There are no Interventions currently listed for this study.

STOP ERROR: At least one Intervention must be specified for an Interventional study.

* Required

Arm Number or Label: *
Examples: A, 2, III

Arm Type: *
-Select-

Arm Description:

* Required fields

Specify the arms, if any, and their associated interventions ([Specifying Study Arms](#)).

Continue

Quit

[Add an arm.](#)

[Add an Intervention.](#)

Study Arms

[Arm:](#) *

There are no arms currently listed for this study.

Interventions

[Interventions:](#) *

There are no Interventions currently listed for this study.

STOP ERROR: At least one Intervention must be specified for an Interventional study.

* Required

| | |
|---------------------------------------|--|
| Intervention Type: * | <input type="text" value="-Select-"/> |
| Intervention Name: * | Use the generic name if it has been established. <input type="text"/> |
| Intervention Description: * | Key details, e.g., for drugs include dosage form, dosage, frequency and duration. <input type="text"/> |
| Other Names: (One per line) | Include brand names, serial numbers and code names, if applicable. If there are no other names for the intervention, enter "n/a". <input type="text"/> |

* Required fields

Specify the primary condition or disease being studied, or the primary focus of the study.

Conditions are checked against the National Library of Medicine's Medical Subject Headings (MeSH).

[Search MeSH](#) for a specific condition term.

Enter only condition or focus (no numbers, dashes, bullets, etc.), one per line.

Conditions or Focus of Study: *

(Enter 1 to 5 items)

Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.

Keywords:

Continue

Quit

* Required fields

Study Population Description: *

Sampling Method: *

-Select-

Eligibility Criteria: *

(Special characters)

For best results use the [preferred format](#).

Inclusion Criteria:
-

Exclusion Criteria:
-

Gender: *

-Select-

Age Limits: *

Minimum: -Select- Maximum: -Select-

Accepts Healthy Volunteers? *

-Select-

Continue

Quit

* Required fields

Continue

Quit

[Specify the Central Contact](#) * with overall recruiting responsibility for this study.

[Specify the Study Official/Investigators](#) * with overall scientific responsibility for this study.

[Add a location](#) to this Study.

[Copy locations](#) from the master list for this organization.

Locations: *

There are no Locations currently listed for this study.

* Required

Facility: *
(Special characters)

Name:
City:
State/Province: Postal Code:
Country:

Recruitment Status: *

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.

Facility Contact: *

Facility contact is required for locations that are recruiting, but may be omitted if a Central Contact is provided for the trial.

First: MI: Last: Degree:
Phone: Ext: Email:

Facility Contact Backup:

First: MI: Last: Degree:
Phone: Ext: Email:

* Required

[Specify the Central Contact](#) * with overall recruiting responsibility for this study.

[Specify the Study Officials/Investigators](#) * with overall scientific responsibility for this study.

[Add a location](#) to this Study.

[Copy locations](#) from the master list for this organization.

Continue

Quit

Locations: *

There are no Locations currently listed for this study.

* Required

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.

| | | | | |
|---------------------------------------|-----------------------------|---------------------------|-----------------------------|------------------------------|
| <u>Central Contact:</u> * | First: <input type="text"/> | MI: <input type="text"/> | Last: <input type="text"/> | Degree: <input type="text"/> |
| | Phone: <input type="text"/> | Ext: <input type="text"/> | Email: <input type="text"/> | |
| <u>Central Contact Backup:</u> | First: <input type="text"/> | MI: <input type="text"/> | Last: <input type="text"/> | Degree: <input type="text"/> |
| | Phone: <input type="text"/> | Ext: <input type="text"/> | Email: <input type="text"/> | |

* Required fields

Continue

Quit

[Specify the Central Contact *](#) with overall recruiting responsibility for this study.

[Specify the Study Officials/Investigators *](#) with overall scientific responsibility for this study.

[Add a location](#) to this Study.

[Copy locations](#) from the master list for this organization.

Locations: *

There are no Locations currently listed for this study.

* Required

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.

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

* Required

Study Official's Name: First: MI: Last: Degree:

Official's Role:

Organizational Affiliation:

* Required fields

Provide Citations of publications related to the protocol, background or results.

Citations:

There are no Citations currently listed for this study.

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) <input type="text"/> |
| Results Reference? | Does the publication report on results of this study? -Select- <input type="button" value="v"/> |

If the publication was not found in MEDLINE, [enter the citation text](#).

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.

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.

[Title](#) [Oversight](#) [Sponsor](#) [Summary](#) [Status](#) [Design](#) [Interventions](#) [Conditions](#) [Eligibility](#) [Locations](#) [Citations](#) **Links**

Title: FDA Amendments Act of 2007, Title VIII, Screenshots

ID: 123456789

| | |
|---------------------|--------------------------------------|
| URL: | <input type="text" value="http://"/> |
| Description: | <input type="text"/> |

Protocol Record Completed

Title: FDA Amendments Act of 2007, Title VIII, Screenshots

ID: 123456789

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen, beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator must then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov web site.

OK