ClinicalTrials.gov
Protocol Registration System

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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Protocol Registration System

Main Menu

Important Information on U.S. Public Law 110-85 Dec 12, 2007

Protocol Records
- Create
- Modify
- View
- Check my records
- Undelete

User Account
- Change password
- PRS Administrator(s)

Help
- **Quick Start Guide**
- Frequently Asked Questions
- What's New Dec 18, 2007
- User's Guide
- Data Element Definitions
- FDAMA 113 Requirements

Session
- Logout

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Protocol Registration System

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

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Protocol Registration System

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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: –Select– Approval Number:

Board Name: *

Board Affiliation: *

Board Contact: *
(Not made public)

NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.

Business Phone: Extension:
Business Email:
Business Address:

Data Monitoring Committee?

Has a group been appointed to monitor safety and scientific integrity of the study?
–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

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Sponsor: * Test Organization

Collaborators:
(One per line)

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Record Verification Date: *	–Select– Year:
Overall Recruitment Status: *	–Select–
Why Study Stopped:	For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.

Key Trial Dates

Study Start Date: *	–Select– Year:
Study Completion Date:	–Select– Year: Type: –Select–
Primary Completion Date: *	Final data collection date for primary outcome measure. –Select– Year: Type: –Select–

Continue Quit * Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

Primary Purpose: *	–Select–
Study Phase: *	–Select–
Intervention Model: *	Formerly referred to as Study Design or Assignment. –Select–
Number of Arms: *	
Masking: *	–Select– Masked Roles: ☐ Subject ☐ Caregiver ☐ Investigator ☐ Outcomes Assessor
Allocation: *	–Select–
Control:	Control is being phased out. Specify study arms instead. –Select–
Study Endpoint Classification:	–Select–
Enrollment: *	Number of Subjects: Type: –Select–

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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: *	Number of Subjects: Type: –Select–
Number of Groups/Cohorts: *	

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Primary Outcome Measure

Outcome Measure: * Enter only one distinct outcome measure.

Time Frame: *

Safety Issue? * Does this outcome measure assess a safety issue?
–Select–

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Secondary Outcome Measure

Outcome Measure: *	Enter only one distinct outcome measure.
Time Frame: *	
Safety Issue? *	Does this outcome measure assess a safety issue? –Select–

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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.

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

* Required

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Arm Number or Label: *	Examples: A, 2, III
Arm Type: *	–Select–
Arm Description:	

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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.

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

* Required

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Intervention Type: *	–Select–
Intervention Name: *	Use the generic name if it has been established.
Intervention Description: *	Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
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".

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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.

Conditions or Focus of Study: * (Enter 1 to 5 items)	Enter only condition or focus (no numbers, dashes, bullets, etc.), one per line.
Keywords:	Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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.

–Select–

Facility Contact: *

Facility contact is required for locations that are recruiting, but may be ommitted 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:

Continue Cancel

* Required

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

Continue Quit

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Study Official's Name:	First: [ ] MI: [ ] Last: [ ] Degree: [ ]
Official's Role:	–Select–
Organizational Affiliation:	[ ]

OK Cancel

* Required fields

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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

Continue Quit Add a Citation to this study, if applicable.

Citations: There are no Citations currently listed for this study.

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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–

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

OK Cancel

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

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.

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

Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

URL:	http://
Description:	

OK Cancel

ClinicalTrials.gov
Protocol Registration System

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