

ClinicalTrials.gov
Protocol Registration System
User's Guide

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National Institute on Drug Abuse (NIDA)

Overview

What is *ClinicalTrials.gov*?

ClinicalTrials.gov provides patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Library of Medicine (NLM) has developed this site in collaboration with all NIH Institutes and the Food and Drug Administration (FDA). See <http://www.clinicaltrials.gov/ct/info/about> for the complete background on the development of the *ClinicalTrials.gov* database. The NIDA encourages the listing of all of the appropriate clinical trials that it sponsors in *ClinicalTrials.gov*. NIH and NIDA are firmly committed to their mission of improving the lives and health of the public. Through research all people can benefit from the knowledge compiled through testing medications, procedures, vaccines, behaviors, and devices from clinical trials.

Is it necessary to seek IRB approval for information listed in *ClinicalTrials.gov* records?

Please refer to Section L of the FDA's "Guidance for Industry Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions," which states:

"L. Is Institutional Review Board pre-approval of the protocol listing required?

No. Section 113 of the Modernization Act does not require prior IRB approval when submitting this information to the Clinical Trials Data Bank. Current FDA guidance recommends that IRB review of listings need not occur when, as here, the system format limits the information provided to basic information, such as title, purpose of the study, protocol summary, basic eligibility criteria, study site locations, and how to contact the site for further information. " <http://www.fda.gov/cder/guidance/4856fnl.htm>

Protocol Registration System (PRS)

The Protocol Registration System (PRS) is a Web-based tool developed by the National Library of Medicine for submitting clinical trials information to *ClinicalTrials.gov*. Records submitted through PRS (<http://register.clinicaltrials.gov>) are available to the public at <http://clinicaltrials.gov>

PRS users enter information about their clinical trials, ensuring that the information is correct, easily understood by members of the public, and updated in a timely manner. The *ClinicalTrials.gov* team maintains PRS and the *ClinicalTrials.gov* site and may make minor corrections to trial records.

The following information is for NIDA investigators and study personnel who want to submit summary information about their trials to be listed in the *ClinicalTrials.gov* database. You will find details about whom to contact and what the process is for getting started and how your trial can be listed in the database.

Administrative Procedures

User Definitions:

NIDA *ClinicalTrials.gov* Liaison: your liaison is your grant's Project Officer

PRS User: the User is the investigator or whomever they designate to enter trial data into the PRS

Process:

- 1) NIDA Liaison registers a new grantee in the PRS.
- 2) The grantee receives an e-mail generated by the PRS that includes information needed to log in to the PRS and enter trial data.
- 3) The grantee, following the PRS Data Element Definitions, provides data for the following mandatory fields:

Brief Title	Study Design
IND Protocol (if applicable)	Intervention Type
IND Grantor (if applicable)	Intervention Name
IND Number (if applicable)	Condition(s)
Brief Summary	Eligibility Criteria
Detailed Description	Gender
Study Phase	Age Limits
Study Type	Accepts Healthy Volunteers
Overall Study Status	Contact Information

On occasion, a single clinical trial is conducted at different sites under different Principal Investigators (PIs). In order to avoid the duplication of records in the *ClinicalTrials.gov* system, NIDA has determined that all information regarding multi-site trials will be obtained from a central contact person. This person will be identified by the Project Officer for the trial and will be responsible for updating the trial record as needed. PIs who are involved in a multi-site trial will be given the email address, phone number, or fax number of their central contact. PIs will be responsible for sending the central contact any updates that are related to their site.

- 4) User changes record status to [Complete] and the PRS automatically notifies the NIDA Liaison.
- 5) The NIDA Liaison reviews, approves, and releases currently recruiting records to *ClinicalTrials.gov*. Records whose trials are not recruiting will remain unreleased until their status changes.
6. NLM publishes the record within 2-5 days of release.

7. The NIDA Liaison will conduct verifications of all trial records assigned to them. Central Contacts will be contacted via email and asked to go into ClinicalTrials.gov to verify the accuracy of their record. Once a record has been completed, the NIDA Liaison may request that the Central Contact add publication information to the record as it becomes available.

Please note: Records are not released until all data has been reviewed. NIDA reserves the right to edit data entered by the User

PRS User Responsibilities

PRS users provide and maintain information about their clinical trials by entering information into PRS and ensuring that the information is correct, easy to understand, and updated in a timely manner.

Through PRS, a user may:

- Log-in to *ClinicalTrials.gov*.
- Enter information regarding clinical trials.
- Modify a record.
- View a record.
- Change a password.
- Preview a record as a *ClinicalTrials.gov* page.
- Complete and submit the trial data for approval.

Procedures for PRS Users

Logging In and Out of PRS:

1. Go to <http://register.Clinicaltrials.gov> to enter PRS.
2. Complete the three log-in fields
 - A. Organization: NIDA
 - B. User name: user login name*
 - C. Password: user password (case-sensitive)*
3. Click [Login] and to get to the **Main Menu** of PRS.
4. To log out of PRS, select [Logout] from the **Main Menu** screen.

** For security reasons, users are asked to please change their password after logging in the first time.*

Creating a Record:

1. Click [Create] from the **Main Menu** screen.
2. Enter the Unique Protocol ID and Brief Title for your record on the **Create New Protocol Record** screen.
3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
4. After clicking [Continue] on the final data entry screen, click [OK] on the **Study Completed** screen.

Tips:

The data entry screens contain text boxes, radio buttons, pull down menus, and other tools to facilitate data entry.

Data screens are clustered by topic for each clinical trial. These include: Title, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations, and Links.

Field definitions and examples can be viewed by clicking on the links associated with each field name.

A record may be completed during a single session or modified and saved for completion during later sessions.

Modifying Records:

1. Click [Modify] on the **Main Menu**.
2. On the **Select Protocol Record-Edit** screen, use the drop-down list under **Search** to choose the appropriate search information. If you want to search all records, check each option under **Records to include in the list** and click [OK] at the bottom of the screen.
3. Locate the data fields to be modified on the **Edit Protocol Screen**, click on the corresponding [Edit] for that field, and make necessary changes.
4. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
5. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

Viewing Records:

1. Click [View] on the **Main Menu**.
2. On the **Select Protocol Record-Edit** screen, use the drop-down list under **Search** to choose the appropriate search record. If you want to search all records, check each option under **Records to include in the list** and click [OK] at the bottom of the screen.
3. Click [View] next to record to be displayed.

* **View Protocol Record** is read-only. User must choose Edit from the Main Menu to modify record information.

Previewing Records as They Appear on *ClinicalTrials.gov*:

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be previewed
3. Click [Preview] to see the record displayed similar to how it appears on *ClinicalTrials.gov*.
4. Click [Continue] to return to the **Edit Protocol Record** screen.

Changing Your Password:

1. Click [Change password] on the **Main Menu**.
2. Enter:
 - Old password*
 - New password
 - New password again for verification

3. Click [Change Password] to save new password.

*Contact your NIDA Liaison if the password is forgotten or lost.

Completing and Submitting the Trial for Approval:

1. If modifying an existing record, click [Modify] from the **Main Menu**, then click the Edit link to the left of the record you wish to complete.
2. Proceed to the **Edit Protocol** Screen.
3. PRS automatically checks the data for any errors or potential problems. There are two types of messages that may be displayed for fields in the record:
 - A. Error: a problem has been found with the record that **MUST** be corrected. The record will not be released to *Clinicaltrials.gov* until the error is resolved.
 - B. Note: a potential problem has been found, that should be reviewed. The record can be released to *Clinicaltrials.gov* with a "Note."
4. After all available information has been entered into a record and there are no errors:
 - A. Click on the [Change Status] link on the record.
 - B. Click the Completed check box on the screen (this will generate an email to the NIDA Liaison).
 - C. Type any comments in the text that you wish to have the NIDA Liaison review when viewing the record.
 - D. Click [OK] to save the status change, or [Cancel] to retain the original status.

The NIDA Liaison will then review the clinical trial record. If no changes are needed, the record will be approved and sent to *ClinicalTrials.gov*.

Entering Your Trial Information:

Provide information about your trial by logging into the Protocol Registration System (PRS) and following these instructions:

1. Visit this web site: <https://register.clinicaltrials.gov/>
2. Log in with the information provided on the e-mail sent to you by the PRS:
Organization: NIDA
User Name: xxxxxx
Password: yyyyyyy
3. From the Main Menu screen, select Create.
4. Enter **Grant number** as the Unique Protocol ID.
5. Enter a Brief (lay) Title and select continue.
6. Provide as much information as possible in the available fields.
Include both a **brief summary** and **detailed description**.
List both **inclusion** and **exclusion criteria** in the eligibility criteria field.
4. When you have completed the record, select Next Action: Complete.

Please send an email to your NIDA Clinical Trials.gov Liaison once you have completed the record, to alert them to release your record to *ClinicalTrials.gov*. After your record has been completed, you may be contacted to request further information. Your record may be edited in order to maintain consistency in format and content across all NIDA records.

Data Element Definitions

1. Titles and Background Information

Organization's Unique Protocol ID

Submission: Required

Definition: Identification number assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Grants with a prefix of P50 indicate a project that may contain many sub-projects where maybe two of which (say 2 & 5) involve human subjects in clinical trials.

Example: IA0014; DA42931A

Secondary IDs

Submission: Optional

Definition: Other identification numbers assigned to the protocol, including any applicable NIH grant numbers. Provide up to 5 Secondary ID Numbers. Example: 5 R01-DA42931A; DA56224

Brief Title

Submission: Required

Definition: Protocol title intended for the lay public, usually found on line one of the grant application.

Example: Preventing Relapse to Substance Abuse in Adolescents

Official Title

Submission: Optional

Definition: Official name of the protocol provided by the principal investigator or sponsor.

Example: Maintaining Abstinence in Adolescents

Additional Information

IRB Approved?

Definition: Indicate if the protocol has received Institutional Review Board (IRB) approval. Select Yes/No.

Medicare: Organization is Deemed?

Definition: Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA, trials conducted at NCI cancer centers, and all trials of patients that are either conducted under an Investigational New Drug Application (IND) or are exempt from having an IND under 21 CFR 312.2(b)(1) are considered Medicare deemed. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

Medicare: Study Meets Requirements?

Definition: The subject of the trial must evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. See Medicare Coverage Policy ~ Clinical Trials: Final National Coverage Decision.

2. Investigational New Drug Application (IND) Information: Complete the following only if the protocol requires and Investigational New Drug Application (IND). (*Will not be made public- for administrative purposes only.*)

IND Protocol?

Submission: Required

Definition: Indicate if the protocol is being conducted under an Investigational New Drug Application (IND). If not, select "No" and continue. (*Will not be made public- for administrative purposes only.*)

IND Grantor

Submission: Required

Definition: FDA center to which the IND was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER). Select one. *(Will not be made public- for administrative purposes only.)*

IND Number

Submission: Required

Definition: Number assigned to an Investigational New Drug Application (IND). If not yet received, use "Not Yet Assigned". *(Will not be made public- for administrative purposes only.)* Example: 58-484

3. Sponsors

Sponsor

Submission: Required

Definition: Name of sponsoring organization that takes responsibility for and initiates a clinical investigation.

Example: National Institute of Drug Abuse (NIDA)

Collaborators

Submission: Optional

Definition: Full names of organizations co-sponsoring and/or providing financial support for the protocol. Provide up to 10 full names of collaborating organizations.

4. Study Description

Brief Summary

Submission: Required

Definition: Short description of the purpose of the protocol intended for the lay public.

Example: The purpose of this study is to assess the effectiveness and safety of both a nicotine patch each compared to a placebo, for the treatment of smoking in adolescents.

Detailed Description

Submission: Optional

Definition: Technical description of the protocol for health professionals, including information such as methodology and rationale, not already contained in other fields.

Example: Nicotine replacement continues to be the most promising treatment to date for tobacco addiction. Many questions remain, however, concerning how to optimize the effectiveness of nicotine replacement therapies. A major issue is how to prevent relapse to smoking after a quit-smoking attempt. Relapse rates are disappointingly high (typically 75 percent-80 percent), even for those receiving nicotine replacement treatment. We have planned a study very different from previous studies of nicotine replacement. Our study will be guided by the basic concept that generally characterizes medical management of any disorder: individualization of treatment based upon physiological characteristics unique to each person. Our plan is to test the efficacy of a procedure for tailoring the degree of nicotine replacement to match the smoker's usual nicotine intake using nicotine patches. We will randomly assign 750 smokers to one of 5 treatment conditions. 300 subjects will be given individualized treatment to replace either 50 percent or 100 percent of their pre-quit cotinine levels (cotinine is a major metabolite of nicotine that provides a stable measure of nicotine intake). A key feature of this treatment procedure involves close monitoring of cotinine levels after cessation and subsequent adjustment of dose if necessary. An additional 300 smokers will be given fixed standard or higher-dose patches rather than tailored nicotine replacement. These smokers will provide a dose-response control condition, which will allow us to compare individualization of treatment with a simpler model involving just standard or higher-dose patches. A final control group of 150 subjects will be given only placebo patches, to allow comparisons with a no-treatment condition.

Our central hypothesis is that those who receive tailored 100 percent replacement (i.e., matching their usual smoking nicotine intake with nicotine patches) will be the most likely to succeed in quitting. We will also measure relevant biological, behavioral, and withdrawal variables. These data will allow us to examine mechanisms by which greater nicotine replacement affects cessation rates, to study effects of greater nicotine replacement for important subgroups of smokers (e.g., women, depressed smokers, older smokers), and to investigate additional factors, besides degree of nicotine replacement, that may be related to abstinence or relapse. Results will provide a clear, definitive test of the hypothesis that matching the degree of nicotine replacement to usual nicotine intake improves cessation rates. If this hypothesis is supported, our findings will have major implications for the treatment of addicted smokers.

5. Status

Study Phase

Submission: Required

Definition: Phase of the Investigation. Select only one.

Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs or effects of behavioral intervention, the side effects associated with exposure to the intervention, and to gain early evidence of effectiveness; may include health participants and/or patients.

Phase 1/Phase 2

Phase 2: includes controlled clinical studies conducted to evaluate the effectiveness of the drug or behavioral intervention for a particular indication or indications in subjects or patients with the disease, condition, or behavior under the study and to determine the common short-term effects and risks

Phase 2/Phase 3

Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug/intervention has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug/intervention.

Phase 4: post-marketing studies to delineate additional information including the drug's or intervention's risks, benefits, and optimal use.

N/A: IND studies must not use this option

Study Type

Submission: Required

Definition: Nature of the investigation. Select one.

- Interventional: experimental studies in humans to investigate the safety and/or efficacy of a drug, gene therapy, vaccine, behavior, device, or procedure.
- Observational: studies in humans that record specific events occurring in a defined population without any intervention by the researcher, such as natural history, screening, and psychosocial studies.

Overall Study Status

Submission: Required

Definition: Overall protocol accrual activity for the protocol. Select one.

- Not yet recruiting: the protocol is not yet recruiting and enrolling participants
- Recruiting: the protocol is actively recruiting and enrolling participants

- No longer recruiting: the protocol is not recruiting or enrolling participants
- Complete: the protocol is no longer recruiting. Data analysis is complete.
- Suspended: recruiting or enrolling participants has halted but may potentially resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Verification Date

Submission: Required

Definition: Date the protocol information, including status, was verified, whether changes or made or not.

Start Date

Submission: Optional

Definition: Date that the protocol begins.

Completion Date

Submission: Optional

Definition: Expected or actual completion date of the protocol.

6. Study Design

Study Type (Interventional)

Submission: Required

Definition: Primary investigative techniques used in the protocol. Select the most appropriate term describing the protocol from each of six categories: Purpose, Allocation, Masking, Control, Assignment, and Endpoint.

Purpose: reason for the protocol

- **Treatment:** protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition
- **Prevention:** protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition
- **Diagnosis:** protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
- **Educational/Counseling/Training:** protocol designed to assess one or more interventions in an educational, counseling, or training environment

Allocation: participant selection

- Randomized Controlled Trial: participants are assigned to intervention groups by chance
- Nonrandomized Trial: participants are expressly assigned to intervention groups

Masking: knowledge of intervention assignments

- Open: no masking is used. All involved know the identity of the intervention assignment
- Single Blind: participants are unaware of the intervention assignment; investigators are aware.
- Double Blind: both participants and investigator s are unaware of the intervention assignment

Control: the nature of the intervention control

- Placebo: participants may receive **placebo only throughout** the course of the protocol
- Active: participants may receive some form of treatment (e.g., standard treatment) in place of the intervention under investigation
- None: no controls are used
- Historical: the control consists of results from past studies
- Dose Comparison: participants may receive one of several doses of the intervention

Assignment: intervention assignments

- Single or Group: all participants receive the **same** intervention throughout the protocol
- Parallel: participants receive **some** intervention throughout the protocol
- Cross-over: participants may receive **different** interventions sequentially during the protocol
- Factorial: participants may receive no intervention, **some** intervention, or **multiple** interventions **simultaneously**

Endpoint: overall outcome that the protocol is designed to evaluate. Select one.

- Safety: shows the drug is safe under conditions or proposed use.
- Efficacy: measure of an intervention's influence on a disease or health condition.
- Safety/Efficacy
- Bio-equivalence: scientific basis for comparing generic and brand name drugs.
- Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body
- Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound
- Pharmacokinetics: action of drugs in living systems
- Pharmacokinetics/Pharmacodynamics

Study Type (Observational)

Definition: Primary investigative techniques used in an observational protocol. Select the **most appropriate** term describing the protocol from each of the four categories:

Purpose, Duration, Selection, and Timing

Purpose: reason for the protocol

- Natural History: protocol designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention)
- Screening: protocol designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation)
- Psychosocial: protocol designed to observe the psychosocial impact of natural events

Duration: length of protocol

- Longitudinal: studies in which participants are evaluated over long periods of time, typically months or years
- Cross-sectional: studies in which participants are evaluated over short periods of time, typically up to 10 weeks

Selection: sample selection

- Convenience Sample; participants or populations are selected due to ease of recruitment
- Defined Population: participants or populations are selected based on predefined criteria
- Random Sample: participants or populations are selected by chance
- Case Control: participants or populations are selected to match the control participants or populations in all relevant factors excepts for the disease; only the participants or populations have the disease

Timing: time of protocol

- Retrospective: a protocol that observes events in the past
- Prospective: a protocol that observed events in real time (may occur in the future)
- Both: a protocol that combined retrospective and prospective observation

7. Conditions and Keywords

Conditions

Submission: Required

Definition: Primary diseases or conditions being studied, using the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary. The conditions are used to index studies in *ClinicalTrials.gov*. Select up to five disease or condition terms from the following MeSH categories: Diseases (c), Behavior and Behavior Modification (F01), and Mental Disorders (F03).

Keywords

Submission: Optional

Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

8. Interventions

Submission: Required

Definitions: Primary interventions being studied. Provide specific name and type for each intervention (up to 10 items).

Intervention Type: select one per intervention

- Drug
- Gene Transfer- including gene transfer and recombinant DNA
- Vaccine
- Behavior
- Device
- Procedure

Intervention Name

Definition: generic name of the precise intervention being studied.

Examples:

- Zidovudine (drug)
- Exercise (behavior)

9. Eligibility

Eligibility Criteria

Submission: Required

Definition: Summary criteria for participant selection

Example:

Inclusion Criteria:

- Clinical diagnosis of Alzheimer's Disease
- Must be able to swallow tablets

Exclusion Criteria:

- Current alcohol or drug abuse
- Thyroid disease

Gender

Submission: Required

Definition: Physical gender of individuals who may participate in the protocol. Select one.

- Both: both female and male participants are being studied

- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits

Minimum Age

Submission: Required

Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age

Submission: Required

Definition: Maximum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours, or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Acceptable Participants

Accepts Healthy Volunteers?

Submission: Required

Definition: Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.

Accepts Patients?

Definition: Indicate if persons who have or had the condition(s) being studied or otherwise specified in the eligibility requirements (e.g., specific symptoms), may participate in the study. Select Yes/No

Expected Total Enrollment

Submission: Optional

Definition: Estimated number of participants to be studied

10. Protocol Location, Contact and Investigator Information

Multiple locations may be specified. Location is composed of the following fields:

Facility

Submission: Required

-Name: Full name of the organization where the protocol is being conducted

Examples: UCLA Eye Institute; Springfield Memorial Hospital

-City

-State/Province

-Postal Code

-Country

Recruitment Status: protocol accrual activity at the facility. Select one.

Submission: Required (if Overall Status is "Recruiting")

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited or enrolled
- No longer recruiting: participants are no longer being recruited or enrolled
- Completed: participants are no longer being recruited; data analysis is complete
- Suspended: recruiting or enrolling participants has halted but potentially will resume
- Terminated: recruiting or enrolling participants has halted and will not resume

Facility Contact

Submission: Required (If Overall Status is recruiting)

- First Name
- Middle Name
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Facility Contact Backup

Submission: Optional

Definition: Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)

Submission: Optional

- First Name
- Middle Initial
- Last Name
- Degrees
- Role: Principal Investigator or Sub-Investigator (pick one)

Central Contact

Submission: Required (if a Facility Contact is not provided)

Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Central Contact Backup

Submission: Optional

Definition: Person to contact if Central Contact is not available.

Overall Study Officials

Submission: Optional

Definition: Person(s) responsible for the overall scientific leadership of the protocol.

- First Name
- Middle Initial
- Last Name
- Degree
- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Principal Investigator).
- Organizational Affiliation: Full name of the official's organization.

11. Related Information**References**

Submission: Optional

Definition: Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (**PMID**) of an article or enter the full bibliographic citation.

MEDLINE PMID

Definition: unique PubMed Identifier (**PMID**) for the citation

Example: **PMID**: 12000823

Citation

Definition: bibliographic reference in **NLM's MEDLINE** format

Example: Apolone G, Mosconi P, La Vecchia C. Post-traumatic stress disorder. N Engl J Med. 2002 May 9;346(19):1495-8; discussion 1495-8.