National Institute of Mental Health
ClinicalTrials.gov
Reference Guide for NIMH Researchers
Revised April 2009

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Background

What is *ClinicalTrials.gov*?

ClinicalTrials.gov is an online registry (http://clinicaltrials.gov), developed and maintained by the National Library of Medicine (NLM), that makes basic information on human research studies available to the public. This free registry currently contains descriptions of more than 71,000 federally and privately supported trials from 165 countries. Each record reflects a single unique protocol (e.g., a single record for a multi-site study), and includes a protocol summary describing the purpose of the study, recruiting status, criteria for patient participation, responsible party (Principal Investigator/institution), sponsor (NIMH), all location(s) of the trial, a contact for additional information, and basic results. All trials, regardless of study design, sponsor, and intervention types (e.g., drug, device, observational, behavioral), are accepted by *ClinicalTrials.gov*.

NIMH researchers should register "applicable" clinical studies as federally mandated (see FDA Amendments Act of 2007, http://prsinfo.clinicaltrials.gov/fdaaa.html; NIH Guidance, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html and http://grants.nih.gov/grants/policy/hs/faqs_aps_clinical_trials.htm). Registration of the study in *ClinicalTrials.gov* also fulfills the International Committee of Medical Journal Editors (ICMJE) requirement that studies be registered as a prerequisite to publication of the trial results (N Engl J Med 2004; 351:1250-1; http://www.icmje.org).

Once the study is registered, a unique National Clinical Trials **NCT No. (e.g., NCT000XXXX)** will be assigned to the clinical trial record. The NCT No. is important for reporting and identification purposes as described above. You can also use this No. as a search criteria to easily locate your study in *ClinicalTrials.gov*.

Although registration of "applicable" studies is mandatory, there is an added benefit that these studies have the potential to be seen by a large audience of referring clinicians and potential trial participants and their family members. *ClinicalTrials.gov* receives more than 40 million page views per month, with 50,000 visitors daily. The registry also enables visitors to search for clinical trials by location, thus facilitating instant results for regional queries.

Additional Resources:

- Information for NIMH investigators conducting studies: http://www.nimh.nih.gov/health/trials/researchers/index.shtml
- *ClinicalTrials.gov* FAQs: http://www.nlm.nih.gov/services/faqctgov.html
- About *ClinicalTrials.gov*: http://www.clinicaltrials.gov/ct2/info/about
- Center for Drug Evaluation and Research (CDER) Guidelines: http://www.fda.gov/cder/guidance/4856fnl.htm

Registering and Maintaining Your NIMH-Sponsored *ClinicalTrials.gov* Record

Getting Started

Study records are registered and maintained through the Protocol Registration System (PRS), (http://register.clinicaltrials.gov) a web-based tool developed for managing clinical trial information submissions. Each record consists of a protocol section and a results section. Records submitted through the PRS will be made public, after review and approval, in the NLM's *ClinicalTrials.gov* website (http://clinicaltrials.gov). From the time the record is released, it usually takes between **2 and 5 business days** for internal quality assurance review and processing for publication on *ClinicalTrials.gov*. Records that report results may take **up to 30 days**.

The NIMH *ClinicalTrials.gov* Records Coordinator (Alex Danvers, email: update@clinicaltrials.gov) can help facilitate the registration and/or maintenance of a clinical study record in *ClinicalTrials.gov*. If the Principal Investigator (PI) or study designee is a first-time user of the PRS, the PI will be contacted by the Records Coordinator via email, with information about content requirements, instructions about how to register, and a User Name and Password for logging into the PRS.

PRS users enter their own information about their clinical trials. Users should ensure that the information is correct, readily understood by members of the public, and updated in a timely manner. The *ClinicalTrials.gov* team maintains PRS and the *ClinicalTrials.gov* website and may make minor modifications to trial records for clarity.

After the PI or designated study official registers with PRS, he/she may open his/her record and, following the PRS Data Element Definitions, provide information for the mandatory fields. See **Appendix 1** for additional information on these fields.

SPECIAL NOTE:
Multi-site Studies
Please note that for clinical trials being conducted at **multiple study sites** (linked R01s or cooperative agreements), only one record should be created in *ClinicalTrials.gov*. In order to avoid the duplication of records, a Central Contact (a PI or another study official) needs to be designated to take primary responsibility for entering information from all of the study sites. All PIs involved in a multi-site trial will be given the contact information for the Central Contact. PIs will be responsible for sending the Central Contact any updates related to their respective sites.

Completing the Study Record

Once the clinical trial record fields are completed, the updater should select **[Complete]** at the top of the screen to indicate that the record is ready to be reviewed and released. PRS will then automatically notify the NIMH *ClinicalTrials.gov* Records Coordinator, who will review the record for completeness. The record is then sent to the NIMH *ClinicalTrials.gov* Administrator for approval. After the record is released by NIMH, the NLM publishes it on the *ClinicalTrials.gov* website. See **Appendix 2** for an overview of the NIMH process for registering trials.

Frequently Asked Questions and Answers

When should a study be registered?

In general, applicable clinical studies *must* be registered before the study starts recruiting participants. However, as long as the study has been funded and the protocol has IRB approval(s), you can begin registering the study.

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

The information submitted for the *ClinicalTrials.gov* record that describes and summarizes the clinical trial does not require IRB approval. 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:

> ***"Is Institutional Review Board preapproval 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

Once an NIMH-sponsored study is registered in *ClinicalTrials.gov*, who is responsible for maintaining and updating the information about that study?

The PI (responsible party) or a designated study representative is the most appropriate person for updating and maintaining data about the study. The study officials are responsible for the completeness and maintenance of the record once it becomes part of the system. They serve as a point of contact for the *ClinicalTrials.gov* team and resolve questions associated with the information that is provided. When any information in the record changes, it is the responsibility of the PI or study representative to update the record to reflect the change as soon as possible.

> NOTE: Each *ClinicalTrials.gov* record has one "owner". This owner is the only study individual responsible for and authorized to make changes to the record. If the owner of a study record changes, the "owner" must contact the Records Coordinator or the NIMH Administrator to change the record ownership. The record owner should designate the new person who will be responsible for maintaining the study record, whether this person is the PI, study coordinator, or central contact of the study. Ownership of the account will then be transferred to the designated person.

Does study information need to be updated after a trial has closed?

Yes, a *ClinicalTrials.gov* record is permanent and will always be available from *ClinicalTrials.gov*, regardless of the trial's status. However, after a trial's status has been changed to "completed," study contact information will no longer be displayed. Additionally,

trial results should be reported no later than a year after the date on which the last measurement concerning the primary outcome has been completed (http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf). The results reporting requirements include baseline characteristics, primary and secondary outcomes, statistical analyses, and a point of contact for scientific information.

For more information about key reporting dates, *see also*:
http://grants.nih.gov/grants/policy/hs/faqs_aps_clinical_trials.htm#q4

It is the investigator's responsibility to make sure the *ClinicalTrials.gov* record is accurate, even if the study has closed. This includes adding journal citations of the study's results. If the Journal in which the relevant article is published is indexed in PubMed, an automatic link to the publication will appear on your study's *ClinicalTrials.gov* page after you have added the citation's PubMed Identifier (PMID) to your study record. If the journal in which your results are published is not indexed in PubMed, you may still add the citation, but it will not produce a link to the publication.

Reminders about updating records are periodically sent to record owners. For trials listed as "Not Yet Recruiting" "Recruiting," and "Suspended," reminders are sent twice a year. Reminders are sent to records with the recruiting status "Active, Not Recruiting" once a year.

How do I report results of a clinical trial?

As explained above, results of certain clinical trials must be reported to *ClinicalTrials.gov* in order to comply with Public Law 110-85. Results of these trials should be entered through the original study record. To post results, select the hyperlinked text near the top of the record labeled "Post Results." There are multiple results data fields to fill in, and they function in the same way as the other parts of the record. The PI or designated representative must post all mandatory data in each section and then select **[Complete]** at the top of the study record to submit it for review and publication on the *ClinicalTrials.gov* website. For more information on Results reporting, see **Appendix 1.**

Additional Resources:

- *ClinicalTrials.gov* Basic Results Data Element Definitions:
  https://register.clinicaltrials.gov/prs/html/results_definitions.html

- More details about the Basic Results Database:
  http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf

Appendix 1: Selected PRS Data Element Definitions with NIMH-Specific Examples

The following information has been adapted from the NLM's online PRS User's Guide and is available in full in the *ClinicalTrials.gov* PRS Guidelines (**http://prsinfo.clinicaltrials.gov/definitions.html**).

User Definitions

PRS Administrators

- NIMH *ClinicalTrials.gov* PRS Records Coordinator: responsible for working with Principal Investigator (PI) to create, manage, and maintain *ClinicalTrials.gov* records (Alexander Danvers: **update@clinicaltrials.gov**)

- NIMH *ClinicalTrials.gov* Administrator: responsible for reviewing, approving, and releasing records for publication on *ClinicalTrials.gov* (Jean Baum: **jbaum@mail.nih.gov** and Christine Ulbricht: **uchristi@mail.nih.gov**)

PRS Users

- Owner: responsible for creating and updating the record as necessary (the responsible party or designated primary updater of the record)

- Updater: the person who last updated the record (usually the owner, the Records Coordinator, or the Administrator)

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:

- Enter information regarding clinical trials
- Modify a record
- View a record
- Change a password
- Preview a record as it will appear on *ClinicalTrials.gov*
- Complete and submit the trial data for approval
- Report results of a study

Special Cases

Multi-site Studies

For trials being conducted at multiple study sites under different PIs, only one record should be created in *ClinicalTrials.gov*. In order to avoid the duplication of records, a Central Contact (a PI or another study official) needs to be designated to take primary responsibility for entering information from all of the study sites. All PIs involved in a multi-site trial will be given the contact information for the Central Contact. PIs will be responsible for sending the Central Contact any updates related to their respective sites.

Continuation Awards
For studies that are recipients of awards covering multiple years of work, a record may already have been created for a previous year. Please check in *ClinicalTrials.gov* to ensure that there are no duplicates before you create a record. You can search by entering any of the following into the search field on the *ClinicalTrials.gov* home page: title of the study, the grant number, a study official's name, or any other information that is unique to your study.

I. Titles and Background Information

Organization's Unique Protocol ID
Definition: Unique identification assigned to the protocol by the sponsoring organization, which will be the NIMH grant, contract, or cooperative agreement number. Multiple studies conducted under the same grant or contract must each have a unique number. The grant/contract number should be formatted in the following manner:

For a grant funding only one study: R01 MH12345
For a contract: N01 MH90003

For a multi-site study, enter the grant/contract number for the main study site as the Unique Protocol ID. Grant/contract numbers from other sites should be listed as secondary IDs.

Secondary IDs
Definition: Other identification numbers assigned to the protocol, including any applicable NIH grant numbers.

Examples: **R01 MH61686-05; R01 MH059542; R01 MH059552; R01 MH075131; R01 MH059541; R01 MH060912; DNBBS 7G-GRR***

*Please note: NIMH will add the applicable division name and program class code (PCC) to the record.

Brief Title
Definition: Protocol title written in plain language for the general public.

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

Examples:

1. ***Brief Title:*** Stimulant Versus Nonstimulant Medication for Attention Deficit Hyperactivity Disorder in Children
   Official Title: Measuring and Predicting Response to Atomoxetine and Methylphenidate

2. ***Brief Title:*** Behavioral Treatments for Acute Stress Disorder In Firefighters
   Official Title: Developing Group Treatments for Acute Stress Disorder

3. ***Brief Title:*** Characteristics of Sleep Patterns in Young Adults With and Without Insomnia
   Official Title: Psychobiology and Treatment Response in Primary Insomnia

4. ***Brief Title:*** Treatment of Mania Symptoms With Drug Therapy
   Official Title: Divalproex Extended Release and Placebo, Lithium, or Quetiapine for Mania

5. ***Brief Title:*** Effectiveness of Behavioral Treatments for Obesity and Major Depression in Women
   Official Title: Treating Co-Morbid Obesity and Major Depressive Disorder

Study Type
Definition: Nature of the investigation. Select one.

- *Interventional*: studies in human beings in which individuals are assigned to receive specific interventions. Subjects may receive diagnostic, therapeutic, or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
- *Observational*: studies in human beings in which biomedical and/or health outcomes are assessed in a predefined group of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.
- *Expanded Access*: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are used to register all types of non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access, and parallel track.

II. Sponsors

Sponsor
Definition: Name of organization that is funding the clinical investigation.

Note: **National Institute of Mental Health** should be listed as the sponsor for all NIMH studies registered in PRS.

Responsible Party
Definition: As defined in **US Public Law 110-85**, Title VIII, Section 801, the term "responsible party," with respect to a clinical trial, means

1. the sponsor of the clinical trial (as defined in 21 CFR 50.3) or

2. the principal investigator of the clinical trial if designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

Provide the following information for the designated responsible party:

1. Name/Official Title - for either the principal investigator or sponsor contact
2. Organization - the sponsor or the principal investigator's organizational affiliation
3. Contact Information - telephone number and/or email address *(required for internal administrative use only; not revealed to public)*

Example: Name/Official Title: John Smith, PhD
Organization: Mount Sinai School of Medicine
Phone: 555-920-1552 Ext: Email: john.smith@mssm.edu

III. Human Subjects Review

Submitted studies must have approval from a human subjects review board, such as an Institutional Review Board (IRB), ethics committee, or equivalent group that is responsible for reviewing and monitoring human subjects in this protocol.

Review board information is not required for trials associated with U.S. FDA IND or IDE applications.

Review board information is required for internal administrative use and is not revealed to the public. Oversight authority information is displayed on *ClinicalTrials.gov.* For more details on this, please refer to the PRS *ClinicalTrials.gov* User's Guide online Data Element Definitions in the PRS HELP function.

Oversight Authorities
Definition: The name of each national or international health organization with authority over the protocol. Use the following format for each authority:

Country: Organization Name
Example:
United States: Federal Government

IV. Study Description

Brief Summary (known as Purpose in the published record)
Definition: Short description of the primary purpose of the protocol intended for the lay public.

> ***Example 1:*** **A Behavioral Intervention**
> This study will determine the effectiveness of a group-based behavioral program for weight reduction in overweight and obese people with schizophrenia.
> ***Example 2:*** **A Drug Intervention**
> This study will compare two different antidepressant treatment regimens to determine which is more effective in reducing symptoms of bipolar depression.
> ***Example 3:*** **An Observational Study**
> This study will examine brain responses associated with reinforcement and reward tasks in individuals with major depressive disorder (MDD).

Detailed Description
Definition: Extended description of the protocol, including information not already contained in other fields. Generally, the description should contain two paragraphs. The first paragraph should include the rationale for the study, and the second paragraph should outline the methodology and duration of the study.

Example 1: **A Behavioral Intervention**
Somatization disorder is a chronic psychological condition that causes numerous physical complaints for which no underlying physical problem can be identified. The disorder often lasts for several years and results in substantial functional impairment. The physical complaints most frequently involve chronic pain and problems with the digestive, nervous, and reproductive systems. Neither pharmacological nor psychosocial treatments for this disorder have been successful in suppressing symptoms. Cognitive behavioral therapy (CBT) is a treatment that focuses on maladaptive patterns of thinking and the beliefs that underlie

such thinking. This study will examine the long-term effects of CBT on the physical symptoms, functioning, and health care utilization of people with somatization disorder.

Participants in this open label study will be randomly assigned to receive either CBT supplemented with augmented standard medical care (ASMC) as indicated by a psychiatric consultation letter or ASMC alone. Participants assigned to CBT plus ASMC will receive CBT for 10 weeks. Somatic symptomatology, functional impairment, and health care costs will be assessed at study visits at baseline and Months 3, 9, and 15. The visits at Months 9 and 15 will assess specifically the long-term efficacy of the treatment.

Example 2: **A Drug Intervention**

Generalized social anxiety disorder (GSAD) is one of the most common psychiatric disorders, and often causes significant distress and dysfunction in affected individuals. Although currently available treatments for GSAD are effective, most individuals have residual symptoms after initial psychosocial or psychopharmacologic intervention. Further treatment is necessary for such individuals, but sufficient research has not been done to guide clinicians on what the safest and most effective next step may be. This study will compare the effectiveness of either combining clonazepam or placebo with sertraline or completely switching to venlafaxine in treating GSAD in individuals who have not responded to treatment with sertraline. This study will also examine predictors of treatment response, including factors such as age at disease onset, duration of illness, comorbidities, and genes that influence serotonin and catecholamine metabolism.

Participants in this double-blind study will first partake in an initial 10-week phase in which they will be treated with sertraline. Participants who do not respond to sertraline treatment will proceed to phase two of the study, in which they will be randomly assigned to one of three treatment groups. One group will receive both sertraline and clonazepam, another group will receive both sertraline and placebo, and the third group will receive only venlafaxine. All treatments will continue for 12 weeks. Sertraline and venlafaxine are both FDA-approved for the treatment of GSAD. Clonazepam is widely used for the treatment of anxiety, but is not FDA-approved for the treatment of GSAD. All participants will attend weekly study visits at Weeks 1, 2, 4, 6, 8, and 10. Participants who continue into phase two will attend weekly study visits at Weeks 11 – 14, 16, 18, 20, and 22. Symptom remission rates and post-treatment social phobia severity will be assessed at Week 20.

Example 3: **An Observational Study**

Bipolar disorder (BPD), also known as manic-depressive illness, is a disorder that causes frequent shifts in an individual's mood, energy, and ability to function. An individual with BPD may go through periods of mania, which are characterized by increased energy, irritability, and an excessively "high" euphoric mood. The manic periods are followed by periods of depression, which are characterized by decreased energy, feelings of hopelessness, and anxiety. BPD is a persistent and severe mental illness with a high suicide rate; it must be strictly managed through medication and therapy. Many BPD medications have been developed recently; however, there are still many individuals who do not respond well to medication treatment. Research has shown that the way individuals experience illness has an effect on their response to medication. The purpose of this study is to gain insight into how individuals with BPD perceive and respond to medication treatment. Factors such as gender, degree of social support, drug and alcohol usage, and attitudes toward medication will be evaluated to understand how they affect medication and treatment adherence.

This 6-month study will consist of 3 interviews. Each interview will last approximately 2 and ½ hours and will include numerous standardized psychological questionnaires. The

questionnaires will assess participants' attitudes toward BPD treatment; psychiatric illness severity, including symptoms of mania and depression; level of addiction to alcohol and drugs; availability of social support resources; and medication adherence.

V. Key Dates

Record Verification Date
Definition: Date the protocol information, including recruiting status, was last verified, whether changes were made or not.

Study Start Date
Definition: Date that enrollment to the protocol begins.

Primary Completion Date
Definition: As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study.

NOTE: The deadline for reporting results data, for clinical trials required to report it by Public Law 110-85, is one year after the primary completion date. It is therefore important that the primary completion date is reported accurately and separately from the study completion date. (http://prsinfo.clinicaltrials.gov/DelayedSubmission.html)

Study Completion Date
Definition: Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.

VI. Outcome Measures

Primary Outcome Measure
Definition: Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors, or treatment.

Time Frame
Definition: Time point(s) at which outcome measure is assessed.

Safety Issue?
Definition: Is this outcome measure assessing a safety issue? Select: Yes/No.

Secondary Outcome Measures
Definition: Other key measures that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. Specify Outcome Measure, Time Frame, and Safety Issue (See above).

Example 1:
Primary Outcome Measure:

Measure: Clinician Severity Rating on the Anxiety Disorders Interview Schedule for Children (ADIS C/P)
Time Frame: Measured at pretreatment, midtreatment, and Year 1 follow-up post-treatment
Safety Issue?: No

Secondary Outcome Measures:
Measure: Child Manifest Anxiety Scale for Children, Revised
Time Frame: Measured at pretreatment and Year 1 follow-up post-treatment
Safety Issue?: No

Example 2:
Primary Outcome Measure:
Measure: Time to medication discontinuation
Time Frame: Measured at Year 1
Safety Issue?: No

Secondary Outcome Measures:
Measure: Psychiatric symptoms, hospitalization, and medication side effects
Time Frame: Measured at Year 1
Safety Issue?: Yes

Example 3 **(Observational Study):**
Primary Outcome Measure:
Measure: Social and emotional development of infants who have mothers with depression and anxiety, during or soon after pregnancy
Time Frame: Measured at Months 6 and 12 post-pregnancy
Safety Issue?: No

VII. Arms, Groups, and Interventions

For interventional studies specify the arms:

Arm Number or Label
Definition: The number, letter, or name used to identify the arm.
Examples: A, 2, III

Arm Type
Select one:
- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No Intervention
- Other

Arm Description
Definition: Brief description of the arm.

Example 1:
Participants will receive cognitive behavioral therapy (Arm 1: Experimental)
Participants will receive treatment as usual (Arm 2: Active Comparator)

Example 2:

Participants will receive treatment with sertraline (Arm I: Experimental)
Participants will receive treatment with placebo (Arm II: Placebo Comparator)

For observational studies specify the predefined participant groups (cohorts) to be studied. Do not use this section to specify strata (Detailed Design can be used for that purpose, if desired).

Group/Cohort Number or Label
Definition: The number, letter, or name used to identify the group.
Examples: A, 2, III, Surgical, Observation

Group/Cohort Description
Definition: Explanation of the nature of the study group (e.g., those with a condition and those without a condition; those with an exposure and those without an exposure). Note that the overall study population should be described under Eligibility.
Examples: Participants with depression (Group 1)
Healthy participants without depression (Group 2)

For all studies, and for expanded access records, specify the associated intervention(s).

Intervention Type
Select one per intervention:
- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., psychotherapy, lifestyle counseling)
- Genetic (including gene transfer, stem cell, and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Other

Intervention Name
Definition: For drugs use generic name; for other types of interventions provide a brief descriptive name.

For investigational new drugs that do not yet have a generic name, a chemical name, company code, or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly.

For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.
Examples: Cognitive behavioral therapy (CBT) (Behavioral)
Fluoxetine (Drug)
Placebo (Drug)

Intervention Description
Definition: Cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac

defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.

Example 1: Dosage ranging from 50 mg to 200 mg once a day for 12 weeks

Example 2: Participants will receive 16 interpersonal therapy (IPT) sessions, which will address adjustment to pregnancy, concerns about interpersonal relationships, and parenting issues.

Arms/Groups

Definition: If arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.

Other Names

Definition: List other names used to identify the intervention, past or present (e.g., brand name for a drug). These names will be used to improve search results in *ClinicalTrials.gov*.

***Example 1* - Arms, Groups, and Interventions (Interventional Study):**

Arms:

1: Experimental
Participants will receive sertraline and cognitive behavioral therapy

2: Active Comparator
Participants will receive placebo and cognitive behavioral therapy

Interventions:

Drug: Sertraline
Sertraline will be administered in standard dosing or slow titration. Treatment with sertraline will last 18 weeks.
Arms: 1
Other Names: Zoloft

Drug: Placebo
The placebo will be administered in the same manner as sertraline. Treatment with placebo will last 18 weeks.
Arms: 2

Behavioral: Cognitive behavioral therapy (CBT)
CBT treatment will begin at Week 4 of antidepressant treatment. CBT will include education, training, and identifying repetitive behaviors of participants. Participants will learn how to respond to repetitive behaviors in a positive manner.
Arms: 1, 2

***Example 2* - Arms, Groups, and Interventions (Observational Study):**

Groups/Cohorts:

1: Smokers with schizophrenia
2: Smokers with bipolar disorder
3: Smokers without any mental illness

Interventions:

Device: CReSSmicro handheld topography device

The CReSSmicro device represents the state-of-the-art technology for measurements of ambulatory puff topography taken in the smoker's natural environment. Although all topography measurements are limited, at least to some degree, by the artificial act of smoking while using a device, or smoking through a mouthpiece, this small, lightweight, and portable device is easy to use outside of the laboratory setting to capture more naturalistic smoking behavior and allows for less intrusion from the research team and research environment.
Groups: 1, 2, and 3

VIII. Conditions and Keywords

Conditions or Focus of Study
Definition: Primary disease or condition being studied, or focus of the study. When naming diseases or conditions, the NLM's Medical Subject Headings (MeSH) controlled vocabulary should be used when possible.

Examples: Anxiety Disorders
Depression
Bipolar Disorder
Eating Disorders
Generalized Anxiety Disorder

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

Examples: Major Depressive Disorder
Psychosocial Intervention
Anorexia

IX. Related Information

References
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 Identifier
Definition: Unique PubMed Identifier (PMID) for the citation.
Example: PMID: 12000823

Citation
Definition: Bibliographic reference in NLM's MEDLINE format.
Example: Tolin, D.F., Diefenbach, G.J., Maltby, N., & Hannan, S. (2005). Stepped care for obsessive-compulsive disorder: A pilot study. Cognitive and Behavioral Practice, 12, 403-414.

References
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.

NOTE: Currently active studies should not have results references. Results references should be added after study completion.

Links
Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by *ClinicalTrials.gov.*

URL
Definition: complete URL, including http://

Description
Definition: Title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol.

Example:
http://www.catie.unc.edu/ (Click here for more information about this study)

Examples of NIMH study records in *ClinicalTrials.gov*
http://www.clinicaltrials.gov/show/NCT00611975
http://www.clinicaltrials.gov/show/NCT00601393
http://www.clinicaltrials.gov/show/NCT00601653
http://www.clinicaltrials.gov/show/NCT00601965
http://www.clinicaltrials.gov/show/NCT00614068
http://www.clinicaltrials.gov/show/NCT00611806

X. Results

Study records now include a basic results section, as called for by U.S. Public Law 110-85. Basic results include baseline characteristics, primary and secondary outcomes, and tests of statistical significance. The reporting of basic results is a relatively new requirement in *ClinicalTrials.gov* and is anticipated to evolve over the new few years. Detailed information on the current results data element definitions is available at https://register.clinicaltrials.gov/prs/html/results_definitions.html. To receive occasional email announcements with information about US Public Law 110-85, join the NIH FDAAA Update LISTSERV.

Additional Resources:

- Background information on the current results reporting requirements: http://prsinfo.clinicaltrials.gov/fdaaa.html
- Federally-funded studies registered in *ClinicalTrials.gov* that have reported results
- Helpful hints for the Basic Results Database: http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf

For questions about this resource guide, email NIMHCTgov@mail.nih.gov.

Appendix 2: Process for Registering Trials in *ClinicalTrials.gov*