

Clinical Intervention Study Protocol Template

FULL PROTOCOL TITLE

(If not obvious from the protocol title, consider adding a subtitle that briefly summarizes the trial, such as: A randomized, placebo-controlled, double-masked, 2100-subject clinical trial of X in the treatment of Z.)

Study Chairman or Principal Investigator:

(List Study Chairman's or Principal Investigator's name, degree, position and affiliation)

Supported by:

(Include application or grant number(s) when available)

Study Intervention Provided by:

(Name of pharmaceutical company or device manufacturer, if any, providing support)

Sponsor of IND (IDE):

(Official sponsor, i.e., IND or IDE holder, if any. Include IND/IDE # when available)

(Any modification to the protocol should be annotated on the coversheet or in an appendix. The annotation should note the exact words that are changed, the location in the protocol, the date the modification was approved by the Executive Committee, and the date it became effective.)

Version 1 (Please change version number with each amendment)
Month Day, Year

PROTOCOL SYNOPSIS

TITLE

PRINCIPAL INVESTIGATOR

OBJECTIVE

STUDY DESIGN

SAMPLE SIZE

SUBJECT SELECTION

INTERVENTION(S)

FORMULATION

DOSAGE

ROUTE OF ADMINISTRATION

PRIMARY OUTCOME VARIABLES

PROCEDURES

STATISTICAL ANALYSIS

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I. Procedures Schedule

II. Informed Consent Form Template

8/22/13 Adapted from: Protocol Template- 6/10/2008
www.ppru.org/Doc/StudyManagement/ProtocolTemplate.doc

III. Other (*add as many appendices as necessary*)

GLOSSARY OF ABBREVIATIONS

TEAM ROSTER

List individuals who play key roles in the development and execution of the study, especially those who may need to be contacted by the sites during the course of the study. Include address, telephone, fax and e-mail address of each individual listed.

PARTICIPATING STUDY SITES

List the name and address of each study site investigator, including telephone and fax numbers and e-mail address.

1. STUDY OBJECTIVES

1.1 Primary Objective

The primary objective should always address a specific hypothesis. State the hypothesis in quantifiable terms; e.g., “the experimental treatment will result in 12 months of additional survival compared to the control treatment.” The primary objective must match the one used in section 9, Statistical Design.

1.2 Secondary Objectives

Secondary objectives may or may not be hypothesis-driven, may include secondary outcomes, and may include more general non-experimental objectives (e.g., to develop a registry, to collect natural history data).

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Describe the need, relevance and priority for the study. For example, autism is a disorder of brain development and affects N children. Symptoms are characterized by....

2.2 Study Rationale

Describe the scientific and medical data (e.g., results of observational studies and early clinical trials) that justifies the study, its design, and the intervention groups. Include any data from animal and human studies relevant to mechanism of action, effect size, and possible effects of the intervention on selected outcomes.

Name and describe the intervention regimen(s) and justify why the intervention(s) have been chosen. Describe and justify the route of administration, dosage regimen, intervention period, frequency and intensity, etc. Summarize the known and potential risks of the interventions.

3. STUDY DESIGN

Briefly describe the study design and indicate, in general terms, how the design will answer the question posed by the study. Use diagrams to explain design

complexities.

A description of the study design should include:

- *Type/design of study (e.g., pharmacokinetic/pharmacodynamic, pharmacogenetics, dose escalation, dose-ranging, placebo-controlled, double-mask, parallel design, open-label).*
- *Specific statement of the primary and secondary outcomes (must be consistent with Study Objectives)*
- *Study population and groups/arms including sample size (including a table, if appropriate)*
- *Study location (e.g., in-patient or out-patient, clinic, community)*
- *Approximate duration of enrollment period and follow-up (specify individual participant vs. entire trial)*
- *Description of intervention and administration*
- *Randomization, blinding(masking) and any stratification*
- *Other protocol specific details, such as centralization of evaluations (e.g., central laboratory or central reading center for clinical scans)*

4. SUBJECT SELECTION AND ENROLLMENT

Key components of the success of a clinical study are the selection and enrollment of subjects who are reasonably representative of the population or characteristics under investigation to allow for sufficient generalizability. This section should define and describe the study population.

4.1 Inclusion Criteria

Provide a statement that individuals must meet all of the inclusion criteria to participate in this study and then list each criterion. List as many criteria as necessary to clearly define your study population.

- *Demographic characteristics (e.g. gender, age) and the health state, presence or absence of a medical condition/disease.*
- *Required laboratory results, diagnostic methods, criteria for classification of current status, as measured within XX days prior to randomization. List specific tests and documentation methods.*
- *Prior therapy, if any. Consider listing specific prior treatments. Consider listing the allowable duration of prior therapy for the specific population to be studied (e.g., treatment-naïve, treatment-experienced or prior-treatment-failed “salvage” subjects).*

- *Ability to understand study procedures and to comply with them for the entire length of the study.*
- *If adolescents of reproductive capability will be enrolled, indicate whether contraception is necessary and required. If yes, include details of allowable contraception methods for trial.*

4.2 Exclusion Criteria

Provide a statement that all candidates meeting any of the exclusion criteria at baseline will be excluded from study participation and then list each criterion.

List as many criteria as necessary to clearly define your study population.

- *Specify health status or any clinical conditions (e.g., life expectancy, co-existing disease) or other characteristics that precludes appropriate diagnosis, treatment or follow-up in the trial.*
- *Clinical/laboratory indicators of current status, obtained within XX days prior to randomization. List the specific tests to be performed and the narrowest acceptable range of laboratory values for exclusion, consistent with disease and/or safety. Include as many as necessary.*
- *Specify any exclusion related to pregnancy, lactation, or plans to become pregnant. Specify methods for assessing current status and willingness to use contraception, if applicable. Include as many as necessary.*
- *Use of [excluded drugs, behavioral interventions, devices, etc.] within XX days prior to study entry. Treatment with another investigational drug or intervention (with time frame).*
- *For drug studies: allergy/sensitivity to study drugs or their ingredients.*
- *Cancer*
- *Current drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to study requirements.*
- *Inability or unwillingness of individual or legal guardian/representative to give written informed consent.*

4.3 Study Enrollment Procedures

- *Do not repeat inclusion or exclusion criteria but describe the method for identifying and recruiting candidates for the trial.*
- *Describe procedures for documentation of reasons for ineligibility and for non-participation of eligible candidates (e.g. Screening Log).*

- Describe consent procedures, including any special requirements (e.g., consent for individuals who are unable to consent for themselves),
- Describe the randomization procedure for assigning a participant to an intervention group.

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Indicate each study intervention, including how it is administered and the dosing schedule, as well as potential adverse effects. Indicate where the intervention will be administered (e.g., outpatient, exercise laboratory, intensive care unit). State guidelines for use of appropriate supportive care, medications or treatments.

Describe dosing procedures (e.g. dose escalation) if relevant.

Include instructions for modifications to the study interventions, if appropriate and clearly explain modification of dose due to toxicity or any other reason. Address dose modifications for specific abnormal laboratory values of concern or other adverse events that are known to be associated with the planned intervention regimen.

For drug studies, package insert information can be referred to, but does not need to be included unless there is a new, significant change. Justify any aspects of the study that are not FDA-approved (e.g., different dosing schedule, new combination of drugs, new drug formulation).

5.2 Handling of Study Interventions

For studies involving drugs and dietary or nutritional supplements, describe how their interventions are to be acquired by the clinical sites (e.g., the pharmaceutical company will distribute the drug in bulk to the site pharmacist), and how they are to be stored, prepared, dispensed and, if applicable, how unused study products are destroyed or to be returned to the company supplying them.

Provide instructions for completing study intervention accountability records. If appropriate, reference the study Manual of Operations for detailed instructions on these issues.

For behavioral interventions, describe the intervention and general approach for delivering the intervention (e.g., manual describing procedures).

Note mechanisms (if any) for masking (i.e., blinding) study interventions. For example, if a placebo is being used in a drug trial, note whether it has similar

color, taste, etc., as the active drug.

5.3 Concomitant Interventions

Allowed, required, and prohibited interventions (e.g., medications) will depend upon the study interventions and outcomes.

This section should be consistent with the medications and interventions restrictions in the inclusion/exclusion criteria.

5.3.1 Allowed Interventions

List all drugs and/or treatments/interventions that are allowed, including rescue medications, while on study.

5.3.2 Prohibited Interventions

Include classes of medications, devices, etc. from the exclusion criteria (section 4.2) if they are also prohibited while the participant is on study. If necessary, provide a list of prohibited medications in appendix.

5.4 Adherence Assessment

Adherence to a study regimen is generally defined as the extent to which subjects take medications or comply with other study requirements as prescribed by the investigators. Define adherence (e.g., at least 80% of treatment intervention pills taken, 85% of exercise sessions attended). Provide details as to how adherence to study intervention will be assessed (e.g., pill counts, electronic monitoring devices, attendance at counseling sessions) and in the section on Data Analyses (Section 9.5), describe how this information will be incorporated into the analysis of the study results.

6. STUDY PROCEDURES

The Schedule of Evaluations in section 6.1 should include all study evaluations. Use an 'X' in a cell to indicate that a particular evaluation is to be performed at a particular study visit. The evaluations listed and their order in the table are only examples. The evaluations should reflect the protocol and should be arranged for clearest presentation. Additional columns may be needed to specify evaluations at intervention failure, at early discontinuation of study interventions, or at other special time points that require a different set of evaluations. In complicated studies with multiple study steps or multiple randomization points, it may be useful to include in the table the time of each step/randomization and the time that study intervention is given to the participant.

6.1 Schedule of Evaluations

Assessment	Screening	Baseline, Enrollment, Randomization	Treatment					Follow-up
	Visit-1	Visit 1	2	3	4	5	6	Final Visit
	Day-14 to Day -1	Day 0	W1	W2	W3	W4	W8	W10
Informed Consent Form	X							
Demographics	X							X
Medical History	X							
General Physical Examination	X	X	X				X	X
Current Medications	X	X						
Blood Chemistries	X	X	X			X		X
Hematology	X	X	X			X		X
Urine Analysis	X	X	X			X		X
Vital Signs	X	X	X	X	X	X	X	X
Inclusion/Exclusion Criteria		X						
Enrollment/Randomization		X						
Treatment Administration Form			X	X	X	X	X	
Concomitant Medications		X	X	X	X	X	X	X
Adverse Events		X	X	X	X	X	X	X

6.2 Description of Evaluations

Descriptions for the Schedule of Evaluations define what is to be done at each study period and include special considerations or instructions for evaluations.

This section should include definitions of the column headings in the Schedule of Evaluations and any special instructions.

6.2.1 Screening Evaluation

These evaluations occur to determine if the candidate is eligible for the study.

Consenting Procedure

Before any screening procedure is performed, informed consent/assent must be obtained. Indicate whether there will be two consenting processes or a single informed consent form that describes both the screening and study procedures.

State which study staff (including educational level) will conduct the consent process and how it will be implemented.

Describe informed consent/assent process; any plan for review of consent document in case changes may be required; and how documentation of signed consent will be maintained by the study.

Screening

Specify allowable range of time prior to study entry during which all screening evaluations to determine eligibility must be completed. List and briefly describe all screening evaluations in bulleted format.

Include only those evaluations that are necessary to assess whether an individual meets enrollment criteria. Discuss the sequence of events that should occur during screening and the decision points regarding eligibility. List the time frame prior to enrollment within which screening tests and evaluations must be done. For example, ambulatory monitoring during 30 prior days of study enrollment.

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

The act of enrolling a study participant should be defined. Since informed consent must be obtained if screening procedures are not a part of routine care, some studies use two informed consents: one for screening and one for enrollment. In this case the enrollment date is day the individual has met all the screening criteria and signs the second informed consent form.

Some studies utilize a single informed consent form that describes both screening and study procedures. In these studies enrollment is defined as the randomization date or as the date all of the screening criteria are met and the individual agrees to participate

In any case the enrollment date should be defined and recorded on a case report form along with the allowable window between screening and study start (e.g. randomization, first dose of study intervention).

Baseline Assessments

For individuals who have successfully been screened for eligibility and are enrolled into the study, baseline assessments are performed against which to measure the study outcome. They also ensure that the groups are balanced with respect to baseline characteristics. For example if the study hypothesis is “study drug will reduce seizure activity, seizure occurrence will be documented.

List and briefly describe all baseline evaluations in a bulleted format.

Randomization

Randomization must precede intervention administration in a randomization study.

Specify time window for (a) randomization relative to completion of screening and baseline and (b) initiation of study intervention relative to randomization.

6.2.3 Treatment and Follow-up Visits

Indicate treatment and follow-up visit assessments for each visit. List all measurements and procedures in bulleted format.

Include allowable time window in which evaluations may take place, e.g., study visits must be performed on the weeks indicated in the Schedule of Evaluations \pm X days. The evaluation time window should be as narrow as technically feasible.

For example:

- Visit 3:
 - Vital Signs
 - Treatment Administration Form
 - Concomitant Medications
 - Adverse Events

- Visit 6:
 - General Physical Examination
 - Vital Signs
 - Treatment Administration Form

- Concomitant Medication
- Adverse Events

6.2.4 Completion/Final Evaluation

List each assessment to be performed at the participant's final visit.

Specify evaluations needed for subjects who discontinue study intervention early. Specify potential reasons for early termination. Specify any requirements (e.g., related to monitoring and reporting of adverse experiences) for follow-up on subjects once they have stopped using the study intervention.

7. SAFETY ASSESSMENTS

Identify time from which adverse events will be captured (e.g., participant signs informed consent, enrollment, first dose of study medication). To assure comprehensive review of potential safety events, include an alphabetical list of expected adverse experiences for each study intervention, criteria for management and modification of the study intervention regimen or participant assessments if an adverse event occurs.

For investigational drug studies the section should identify toxicities that have been seen in previous studies.

7.1 Specification of Safety Parameters

Include examples of safety measures such as specific laboratory findings.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

This section should be based on the risk profile of the study intervention. Include a review of relevant literature, which should be referenced.

7.3 Adverse Events and Serious Adverse Events

Provide definitions for adverse events (AEs) and serious adverse events (SAEs).

*An **adverse event (AE)** is generally defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recording regardless of their relationship to the study intervention.*

*A **serious adverse event (SAE)** is generally defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.*

Describe any laboratory values that will be collected to assess safety. Abnormal laboratory values should be defined (e.g. two times the normal limit or outside the reference range for a laboratory).

Describe which AEs will be collected as solicited events. Describe how unsolicited events will be captured. Assure that the reporting and data collection systems avoid double capture.

Describe time frames for reporting and collecting AEs and SAEs.

In addition, protocols may specify other events that require reporting in an expedited time frame (e.g., abnormal laboratory values). Include time period of collection.

7.4 Reporting Procedures

All clinical trials must have a safety reporting system in place. Include details of the reporting procedures and time lines, including the individual responsible for each step (e.g., the Investigator, the Medical Monitor, etc.), how decisions will be made regarding determining relatedness and severity, which forms should be completed, (specific information on where to send this form is included), how reports will be distributed and what follow-up is required.

7.5 Follow-up for Adverse Events

Describe how AEs will be followed until resolved or considered stable. Specify duration of follow-up.

7.6 Safety Monitoring

Indicate whether a Data and Safety Monitoring Board or Safety Officer will monitor the study.

8. INTERVENTION DISCONTINUATION

List criteria for discontinuing intervention for a participant and methods for determining when criteria are met.

List possible reasons for discontinuation of the study intervention/product, e.g., development of laboratory toxicities, study closure by institute.

Note that subjects will continue to be followed with their permission if study intervention is discontinued. Discuss any modifications to the schedule and duration of continued follow-up.

If relevant, include criteria for temporary discontinuation of treatment and define its length.

Indicate the evaluations to be completed while the participant is either temporarily or permanently discontinued from study intervention but followed for outcomes, if applicable.

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

State the statistical hypotheses.

Describe the reasons for choice of study design (e.g., dose escalation, single/multi dose, crossover); why certain design features were chosen (e.g., for a dose escalation study, crossover trial, how the number of subjects at each dose was chosen).

Describe the primary and secondary hypotheses and the primary and secondary outcome measures as well as their validity and reliability.

9.2 Sample Size and Randomization

Describe sample size calculation and effect size with respect to power. Specify the test statistic; assumed rates of drop-out, withdrawal, cross-over to other study arms, missing data, etc.; and approach to handling withdrawals and protocol violations, in terms of an “intent to treat” approach. If sample size was not calculated, justify reason.

9.2.1 Treatment Assignment Procedures

Describe the treatment assignment procedures (randomization, minimization, relevant criteria, etc). If such procedures are proposed describe rationale as well as the procedure.

Plans for the maintenance of trial randomization codes and maintaining appropriate masking for the study should be discussed, including the timing and procedures for planned and unplanned breaking of randomization codes should be included. Include a statement regarding when unmasking may occur and who may unmask.

If the randomization will be stratified, indicate whether (and why) there is a sample size goal for each stratum. Identify what factors (if any) will be used to stratify the randomization.

9.3 Interim analyses and Stopping Rules

If an interim analysis is planned, describe the rationale, effect on “spending” the Type I error, and method for adjusting calculations. As relevant, provide guidelines for stopping the study for reasons of efficacy, safety, futility, or poor study performance (e.g., slow accrual, high losses-to-follow-up, and poor quality control).

Describe safety findings and statistical rules that would temporarily suspend enrollment and/or study intervention until a safety review is convened (either

routine or ad hoc) to determine whether the study should continue per protocol, proceed with caution, be further investigated, be discontinued, or be modified and then proceed.

Examples of findings that might trigger a safety review are the number of SAEs overall, the number of occurrences of a particular type of SAE, severe AEs/reactions, or increased frequency of events. Such findings are presented to the study statistician or to the Data and Safety Monitoring Board (DSMB) statistician to review the events by group to determine whether there are statistical as well as clinical concerns. The statistician reports his findings to a closed session of the DSMB or to the Safety Officer and/or NICHD. The findings are used to determine what steps will be taken.

9.4 Outcomes

Discuss how the outcomes will be analyzed

9.4.1 Primary outcome

State and define the primary outcome measure and specify at which study visit the outcome assessments will be performed.

9.4.2 Secondary outcomes

State and define the secondary outcome measures.

9.5 Data Analyses

Describe the descriptive and inferential statistical methods that will be used to analyze the outcomes and other study data. Specify any confounding variables for which it is anticipated adjustment will be made.

In accordance with NIH policy, if data from prior studies do not negate strongly the existence of significant differences of clinical or public health importance in the intervention effect between gender and racial/ethnic subgroups, a statement should be included noting that a valid analysis of the intervention effect will be performed in these subgroups. If data from prior studies do not strongly support the existence of significant differences in the intervention effect between subgroups, then the analyses does not require high statistical power for detecting clinically meaningful differences.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Indicate how information will be collected for each participant and by whom. For example if a blinded observer will perform outcome assessments, state who this person will be. Describe methods for maintaining confidentiality of participant records. Refer to Manual of Procedures (MOP) for description of study forms (also called Case Report Forms).

10.2 Data Management

Briefly describe clinical site responsibilities in data collection and management.

Briefly describe Coordinating Center (or Data Management/Statistical Center) responsibilities in data management.

Briefly describe data collection forms.

10.3 Quality Assurance

10.3.1 Training

Describe types and mechanisms of training of staff for the study.

10.3.2 Quality Control Committee

If there is a study quality control committee, describe membership and list the reports that they review.

10.3.3 Metrics

Provide quality control metrics for outcome measures.

10.3.4 Protocol Deviations

Describe how protocol deviations will be captured, documented, and reviewed.

10.3.5 Monitoring

Briefly describe methods (e.g., site monitoring) for assuring protocol compliance, and data quality at the clinical sites, including review of records, consent forms, etc. The types of materials to be reviewed; who is responsible, and the schedule for reviews may be specified or referenced in the Manual of Procedures (MOP).

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

The texts in this section are examples only.

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document (Appendix XX) and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study. The consent form should be separate from the protocol document.

11.2 Informed Consent Forms

This section describes the procedures for obtaining and documenting informed consent of study subjects. Make provisions for special populations, e.g., non-English speakers, children illiterate or non-writing individuals, vulnerable populations.

A signed consent form will be obtained from each subject. Subjects who are not of majority age and who can read and write will sign assent forms. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant or legal guardian and this fact will be documented in the participant's record.

11.3 Data Security and Confidentiality

Include procedures for maintaining subjects' confidentiality according to the Health Insurance Portability and Accountability Act (HIPAA), any special data security requirements, and record retention per the sponsor's requirements.

Any data, specimens, forms, reports, video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NICHD, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NICHD, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research subjects are protected.

12. COMMITTEES

Provide a list of the committees (Steering Committee or Executive Committee, Publication Committee, Adjudication Committee, etc.) and describe their roles.

13. PUBLICATION OF RESEARCH FINDINGS

Sample text:

Publication of the results of this trial will be governed by the policies and procedures developed by the Steering Committee. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NICHD prior to submission.

14. REFERENCES

Provide the citations for all publications and presentations referenced in the text of the protocol.

15. SUPPLEMENTS/APPENDICES