



IOWA

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ClinicalTrials.gov Checklist



TABLE OF CONTENTS

<u>ClinicalTrials.gov Registration</u>	3
<u>Applicable Clinical Trial Criteria</u>	3
<u>NIH Funding Requirements</u>	4
<u>Journal Requirements – ICMJE Journals</u>	4
<u>ClinicalTrial.gov Registration Requirements</u>	5
<u>Different Scenarios for Registration Requirements</u>	6
<u>ClinicalTrials.gov Registration Checklist</u>	7
<u>How to create a PRS account</u>	8
<u>Start a New Record</u>	8
<u>Study Identification</u>	8
<u>Study Status</u>	8
<u>Sponsor/Collaborators</u>	9
<u>Oversight</u>	9
<u>Study Description</u>	10
<u>Conditions</u>	10
<u>Study Design</u>	10
<u>Arms and Interventions</u>	14
<u>Outcome Measures</u>	14
<u>Eligibility</u>	15
<u>Contacts/Locations</u>	15
<u>IPD Sharing Statement</u>	15
<u>References</u>	16

ClinicalTrials.gov Results Reporting Checklist and Templates _____ **17**

Complete Result Section _____ 17

Participant Flow _____ 17

Baseline Characteristics _____ 17

Outcome Measures _____ 18

Adverse Events _____ 18

Required Documents _____ 19

ClinicalTrials.gov Good Cause Extension Request Checklist _____ **20**

ClinicalTrials.gov Registration

Task	Yes	No
Did PI initiate the study?	You are the Sponsor Investigator for the study.	You are not the sponsor. The sponsor is responsible for registering Applicable Clinical Trials and should provide you with the NCT number.

If “Yes” above continue below

There are 4 scenarios that require ClinicalTrials.gov registration.

- 1- Research Study fulfills the criteria of an Applicable Clinical Trial.
- 2- Clinical Trial has been funded by NIH.
- 3- Investigator wants to publish in ICMJE Journal.
- 4- To Upload ICF if ClinicalTrials.gov registration is not required but the study is conducted or supported by a Common Rule (45 CFR 46) department or agency.

Applicable Clinical Trial Criteria

Evaluate whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017

Questions	Yes	No
1. Is the study interventional (a clinical trial)? Study Type data element is “Interventional”		
2. Do ANY of the following apply (Is the answer “Yes” to at least one of the following sub-questions: 2a, 2b, OR 2c)? <ol style="list-style-type: none"> a. Is at least one study facility located in the United States or a U.S. territory? (Facility Location – Country data element is “United States,” “American Samoa,” “Guam,” “Northern Mariana Islands,” “Puerto Rico,” “U.S. Virgin Islands,” or other U.S. territory.) b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? (U.S. Food and Drug Administration IND or IDE Number data element is “Yes.”) c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? (Product Manufactured in and Exported from the U.S. data element is “Yes.”) 		

<p>3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? Studies a U.S. FDA-regulated Device Product data element is “Yes” and/or Studies a U.S. FDA-regulated Drug Product data element is “Yes.”</p>		
<p>4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, Study Phase data element is NOT “Phase 1” and for device product trials, Primary Purpose is NOT “Device Feasibility.”</p>		

If “Yes” is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT (Applicable Clinical trial) that is required to be registered under 42 CFR 11.22.

NIH Funding Requirements

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals submitted on or after January 18, 2017.

Check to see if NIH funded study is a Clinical Trial:

- a) Does the study involve human participants?
- b) Are the participants prospectively assigned to an intervention?
- c) Is the study designed to evaluate the effect of the intervention on the participants?
- d) Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answers to the 4 questions are “Yes”, the study meets the NIH definition of a clinical trial, and needs to register and submit results on ClinicalTrials.gov

Journal Requirements – ICMJE Journal

Investigators should be aware of their planned journals prior to beginning the study to assure that they meet the necessary requirements for registration.

Here is link to the Publication list: <https://www.icmje.org/journals-following-the-icmje-recommendations/#>

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

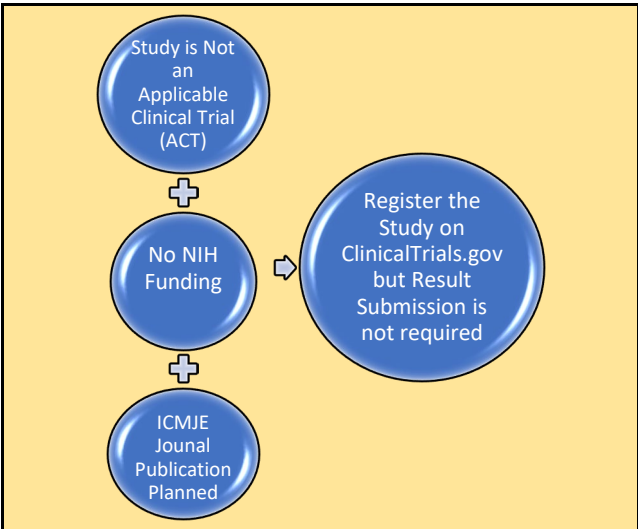
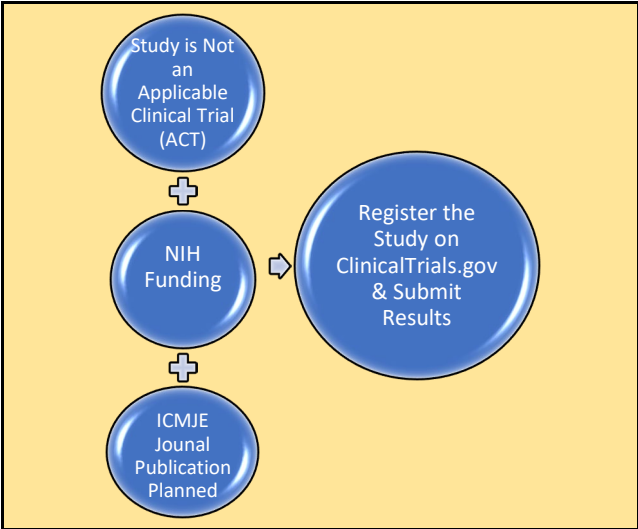
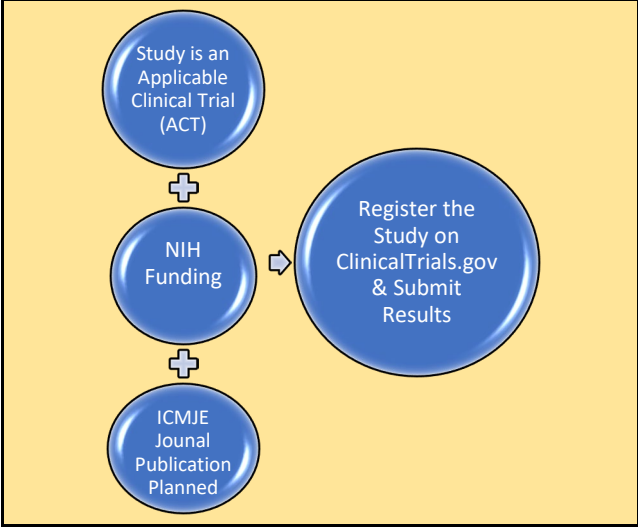
Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

ClinicalTrials.gov Registration Requirements

Question	Yes	No
Is the study <u>an Applicable Clinical Trial (ACT)</u>?	The study must be registered, and report results on ClinicalTrials.gov through the Protocol Registration and Results System (PRS).	If study is not an Applicable Clinical Trial based on FDA regulations. Continue using the checklist to see if other registration regulations may apply.
<u>NIH</u> Funded Clinical Trial?	NIH has their own requirements, definitions, and expectations for clinical trials that are conducted using NIH funding.	Check to see if Federal regulations or ICMJE conditions apply.
<u>ICMJE</u> journal publication planned?	ICMJE journals require all clinical trials wishing to publish in their journals to register on ClinicalTrials.gov prior to enrolling the first subject, and to disclose whether Individual Patient Data (IPD) will be shared. This may apply to research that does not meet the FDA definition of Applicable Clinical Trial or the NIH definition of a clinical trial, so check with your intended journal if you are unsure.	If you are not planning to publish in an ICMJE journal and the above FDA regulations or NIH requirements do not apply, ClinicalTrials.gov registration is not required.

If you answered 'Yes' to 1 or more of the above, you would need to register on [ClinicalTrials.gov](#).

Different Scenarios for Registration & Result Submission Requirements



ClinicalTrials.gov Registration Checklist

Task	Response
<p style="text-align: center; background-color: black; color: white; margin: 0;">How to create a PRS account</p> <p>Contact PRS Administrator @ ct-gov@uiowa.edu</p> <p><u>Required information to login:</u></p> <ul style="list-style-type: none"> a) Organization section: UIowa b) Username: HawkID c) Password: Will be sent through an automated email from the PRS 	
<p style="text-align: center; background-color: black; color: white; margin: 0;">General Review Items</p> <ul style="list-style-type: none"> <input type="checkbox"/> The person who will create a “New Record” will be the “Record Owner”. <input type="checkbox"/> If PI wants to change the “Record Owner”, contact PRS administrator @ ct-gov@uiowa.edu. <input type="checkbox"/> Record Owner can be the PI or the Coordinator. <input type="checkbox"/> PI on the record should match the PI listed on the IRB Application. <input type="checkbox"/> Record Status in ClinicalTrials.gov PRS include: <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Record Status —————</p> <p style="text-align: center;">In Progress ➡ Entry Completed ➡ Approved ➡ Released ➡ PRS Review ➡ Public</p> </div> <ul style="list-style-type: none"> <input type="checkbox"/> Record Owner can complete and approve the record. <input type="checkbox"/> PI/ Responsible party needs to “Release” the record every time after an update for PRS review. 	

Start a New Record

For Registration only the "Protocol Section" of the PRS Application needs to be completed.

There are 13 subsections of the protocol section.

Use the registration template to prepare for registration ([Study Protocol Registration Template](#)).

1) Study Identification

- a) **Unique Protocol ID:** Enter the HawkIRB ID # (digits Only)
- b) **Brief Title:** A short title of the clinical study written in language intended for the lay public.
- c) **Official Title:** Enter the HawkIRB project title
- d) **Secondary IDs:** Enter U.S. National Institutes of Health (NIH) Grant/Contract Award Number, Clinical Trial Registry Identifier, EudraCT Number or Other Grant/Funding Number.

2) Study Status

- a) **Record Verification:** Date on which the responsible party last verified the clinical study information. **Needs to be updated every 12 months even if no additional or updated information is being submitted.**
- b) **Overall Status:** The recruitment status for the clinical study as a whole, based upon the status of the individual sites.

Options are (Choose one)

- i. **Not yet recruiting:** Participants are not yet being recruited
- ii. **Recruiting:** Participants are currently being recruited, whether or not any participants have yet been enrolled
- iii. **Enrolling by invitation:** Participants are being (or will be) selected from a predetermined population
- iv. **Active, not recruiting:** Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
- v. **Completed:** The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred)
- vi. **Suspended:** Study halted prematurely but potentially will resume
- vii. **Terminated:** Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention
- viii. **Withdrawn:** Study halted prematurely, prior to enrollment of first participant

(In case of a multi-site clinical study if the Individual Site Status is "Recruiting," then the Overall Recruitment Status for the study must be "Recruiting").

- c) **Study Start:** Estimated date on which the clinical study will be open for recruitment of participants
- d) **Primary Completion Date:**
 - The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.

- **In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.**

e) Study Completion Date: The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant’s last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated.

3) Sponsor/Collaborators

a. Responsible Party - 3 options are listed

- i. Sponsor:** The entity (for example, corporation or agency) that initiates the study
- ii. Principal Investigator:** The individual designated as responsible party by the sponsor
- iii. Sponsor-Investigator:** The individual who both initiates and conducts the study

Choose “Sponsor-Investigator” option here.

b. Sponsor: The name of the entity or the individual who is the sponsor of the clinical study.

- When a clinical study is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder is considered as the sponsor.
- When a clinical study is not conducted under an IND or IDE, the single person or entity who initiates the study, by preparing or planning the study, and who has authority and control over the study, is considered the sponsor.

c. Collaborators: Other organizations (if any) providing support. Support may include funding, design, implementation, data analysis or reporting.

4) Oversight

a. U.S. FDA-regulated Drug: Indication that a clinical study is studying a drug product

b. U.S. FDA-regulated Device: Indication that a clinical study is studying a device product

c. U.S. FDA IND/IDE: Indicate whether the clinical study is being conducted under an IND or IDE application filed with the FDA.

- If there is an IND or IDE filed with the FDA for a clinical study, the following information is required:
 - i. Name or abbreviation of the FDA Center with which the IND or IDE is filed.**
 - ii. IND or IDE number assigned by the FDA Center.**

d. Product Exported from U.S: Whether any drug product (including a biological product) or device product studied in the clinical study is manufactured in the United States or one of its territories and exported for study in a clinical study in another country.

e. Human Subjects Protection Review:

- **Board status:** Choose appropriate option. Options are
 - i. Request not yet submitted:** Review board approval is required but has not yet been requested
 - ii. Submitted, pending:** Review board approval has been requested but not yet granted
 - iii. Submitted, approved:** Review board approval has been requested and obtained

- iv. **Exempt:** An exemption in accord with applicable law and regulation has been granted
- v. **Submitted, denied:** Review board has denied the approval request
- vi. **Submission not required:** Review board approval is not required because the study is not subject to laws, regulations, or applicable institutional policies requiring human subjects review

Enter information as

Board Name: University of Iowa Hawk IRB-01

Board Affiliation: University of Iowa

Board Contact: Human Subjects Office

Hardin Library for the Health Sciences

600 Newton Road, Suite 105.

Iowa City, IA 52242

irb@uiowa.edu

319-335-6564

f. Data Monitoring Committee: Indicate whether a data monitoring committee has been appointed for this study.

g. FDA Regulated Intervention: Indicate whether this study includes an intervention subject to U.S. FDA regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug, and Cosmetic Act: 505, 510(k), 515, 520(m), and 522.

h. Section 801 Clinical Trial: If this study includes an FDA regulated intervention, indicate whether this is an applicable clinical trial as defined in U.S. Public Law 110-85, Title VIII, Section 801.

5. Study Description

- a. **Brief Summary:** A short description of a clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public.
Limit: 5000 characters.
- b. **Detailed Description:** Enter extended description of the protocol, including more technical information (as compared to the Brief Summary), if desired.
 - Do not include the entire protocol
 - Do not duplicate information recorded in other data elements, such as Eligibility Criteria or outcome measures.**Limit: 32,000 characters.**

6) Conditions

- a. **Conditions:** Enter Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study
- b. **Keywords:** Enter words or phrases that best describe the protocol. Keywords help users find studies in the database.

Avoid acronyms and abbreviations.

7) Study Design

- **Study Type:** Will be auto populated as entered while creating the new record in the PRS.
- **Primary Purpose:** The main objective of the intervention(s) being evaluated by a clinical trial.

Select one.

<ul style="list-style-type: none"> i. Treatment: One or more interventions are being evaluated for treating a disease, syndrome, or condition. ii. Prevention: One or more interventions are being assessed for preventing the development of a specific disease or health condition. iii. Diagnostic: One or more interventions are being evaluated for identifying a disease or health condition. iv. Supportive Care: One or more interventions are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function. v. Screening: One or more interventions are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor. vi. Health Services Research: One or more interventions for evaluating the delivery, processes, management, organization, or financing of healthcare. vii. Basic Science: One or more interventions for examining the basic mechanism of action (for example, physiology or biomechanics of an intervention). viii. Device Feasibility: An intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. ix. Other: None of the other options applies. <p>➤ Study Phase: For a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21 and in 21 CFR 312.85 for phase 4 studies.</p> <p>Select only one as entered in HawkIRB</p> <ul style="list-style-type: none"> i. N/A: Trials without phases (for example, studies of devices or behavioral interventions). ii. Early Phase 1 (Formerly listed as "Phase 0"): Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). iii. Phase 1: Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients. iv. Phase 1/Phase 2: Trials that are a combination of phases 1 and 2. v. Phase 2: Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks. vi. Phase 2/Phase 3: Trials that are a combination of phases 2 and 3. vii. Phase 3: Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug. viii. Phase 4: Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use. <p>➤ Interventional Study Model:</p> <p>The strategy for assigning interventions to participants.</p> <ul style="list-style-type: none"> i. Single Group: Clinical trials with a single arm 	
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ii. Parallel: Participants are assigned to one of two or more groups in parallel for the duration of the study

iii. Crossover: Participants receive one of two (or more) alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study

iv. Factorial: Two or more interventions, each alone and in combination, are evaluated in parallel against a control group

v. Sequential: Groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies

Model Description: Provide details about the Interventional Study Model. **Limit: 1000 characters.**

- **Number of Arms:** The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, it will include the maximum number of arms during all periods or phases.
 - **Masking:** The group involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual participants.
 - Select all that apply.
 - **Roles, if Masking:**
 - **Participant**
 - **Care Provider**
 - **Investigator**
 - **Outcomes Assessor:** The individual who evaluates the outcome(s) of interest
 - **No Masking**
 - **Masking Description:** Provide information about other parties who may be masked in the clinical trial, if any. Limit: 1000 characters.
 - **Allocation:** The method by which participants are assigned to arms in a clinical trial.
 - **N/A:** For a single-arm trial
 - **Randomized:** Participants are assigned to intervention groups by chance.
 - **Nonrandomized:** Participants are expressly assigned to intervention groups through a non-random method, such as by physician choice
 - **Observational Study Design** (For observational studies only)
 - **Observational Study Model:** Primary strategy for participant identification and follow-up.
- Select one.
- **Cohort:** Group of individuals, initially defined and composed, with common characteristics (for example, condition, birth year), who are examined or traced over a given time period.
 - **Case-Control:** Group of individuals with specific characteristics (for example, conditions or exposures) compared to group(s) with different characteristics, but otherwise similar.
 - **Case-Only:** Single group of individuals with specific characteristics.
 - **Case-Crossover:** Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (that is, control period).
 - **Ecologic or Community Studies:** Geographically defined populations, such as countries or regions within a country, compared on a variety

of environmental (for example, air pollution intensity, hours of sunlight) or global measures not reducible to individual level characteristics (for example, healthcare system, laws or policies median income, average fat intake, disease rate).

- **Family-Based:** Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment.
- **Other:** Explain in Detailed Description section.
- **Time Perspective:** Temporal relationship of observation period to time of participant enrollment.

Select one.

- **Retrospective:** Look back using observations collected predominantly prior to subject selection and enrollment
- **Prospective:** Look forward using periodic observations collected predominantly following subject enrollment
- **Cross-sectional:** Observations or measurements made at a single point in time, usually at subject enrollment
- **Other:** As Explained in Detailed Description
- **Biospecimen Retention:** Indicate whether samples of material from research participants are retained in a biorepository.

Select one.

- **None Retained:** No samples retained
- **Samples With DNA:** Samples retained, with potential for extraction of DNA from at least one of the types of samples retained (e.g., frozen tissue, whole blood)
- **Samples Without DNA:** Samples retained, with no potential for DNA extraction from any retained samples (e.g., fixed tissue, plasma)
- **Biospecimen Description:** Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).

Limit: 1000 characters.

- **Enrollment:** The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study.
 - "Enrolled" means a participant's, or their legally authorized representative's, agreed to participate in a clinical study following completion of the informed consent process.
 - Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.
- **Target Follow-Up Duration:** For Patient Registries, the anticipated time period over which each participant is to be followed. Provide a number and select a Unit of Time (years, months, weeks, days).
- **Number of Groups/Cohorts:** Number of study groups/cohorts.

8) Arms and Interventions

Enter description of each arm of the clinical trial that indicates its role in the clinical trial, including

a. Arms:

i. Arm Title

ii. Arm Type: The role of each arm in a clinical trial.

- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No Intervention
- Other

iii. Arm Description: Enter additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

Limit: 999 characters.

b. Interventions:

i. Specify the intervention(s) associated with each arm or group; at least one intervention must be specified for interventional studies.

ii. For observational studies specify the intervention(s)/exposure(s) of interest, if any.

- a. If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.**

iii. For each intervention studied in the clinical study, the general type of intervention.

Select one

- **Drug:** Including placebo
- **Device:** Including sham
- **Biological/Vaccine**
- **Procedure/Surgery**
- **Radiation**
- **Behavioral:** For example, psychotherapy, lifestyle counseling
- **Genetic:** Including gene transfer, stem cell and recombinant DNA
- **Dietary Supplement:** For example, vitamins, minerals
- **Combination Product:** Combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device
- **Diagnostic Test:** For example, imaging, in-vitro
- **Other**

Provide Intervention name and brief description. If multiple Arms or Groups have been specified in the study, indicate which Interventions will be used in each Arm or Group of the study, using the Cross-Reference check boxes.

9) Outcome Measures

- a. Primary Outcome Measures:** Enter description of each primary outcome measure including **Title**, **Description**, and **time frame** at which the measurement is assessed for the specific metric used.

- b. **Secondary Outcome Measures:** Enter description of each secondary outcome measure including **Title, Description,** and **time frame** at which the measurement is assessed for the specific metric used.

10) Eligibility

- a. **Min/ Max. Age,** and **Sex** as entered in HawkIRB Application section VI.
- b. **Gender based Trial:** Indicate whether participant eligibility is based on a gender.
- c. **Accepts Healthy Volunteers:** indicate if study is enrolling healthy volunteers
- d. **Inclusion/ Exclusion Criteria** as entered in HawkIRB application section VI.13

11) Contacts/ Locations

- a. **Central Contact Person:** name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed.
- b. **Central Contact Backup:** Person to contact if Central Contact is not available. Include the following information: First Name, Middle Initial, Last Name or Official Title, Degree, Phone
- c. **Study Officials:** Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator. **Include the following information: First Name, Middle Initial, Last Name, Degree, Organizational Affiliation, Official's Role.**
- d. **Locations:** Enter location for each participating facility in a clinical study along with facility contact and facility contact back up information. Enter information of a person to whom questions concerning the study and enrollment at that site can be addressed.

12) IPD Sharing Statement

- a. **Plan to Share IPD:** Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study).

Select one.

- **Yes:** There is a plan to make IPD and related data dictionaries available.
- **No:** There is not a plan to make IPD available.
- **Undecided:** It is not yet known if there will be a plan to make IPD available.

IPD Sharing Plan Description:

- If Plan to Share IPD is "Yes," briefly describe what specific individual participant data sets are to be shared.
- If the Plan to Share IPD is "No" or "Undecided," an explanation may be provided for why IPD will not be shared or why it is not yet decided.
Limit: 1000 characters.

If Plan to Share IPD is "Yes," provide the following information.

- b. **Supporting Information:** The type(s) of supporting information that will be shared, in addition to the individual participant data set and data dictionaries for the IPD itself.

Select all that apply.

- Study Protocol
- Statistical Analysis Plan (SAP)
- Informed Consent Form (ICF)
- Clinical Study Report (CSR)
- Analytic Code

- c. **Time Frame:** A description of when the IPD and any additional supporting information will become available and for how long, including the start and end dates or period of availability.
- d. **Access Criteria:** Describe by what access criteria IPD and any additional supporting information will be shared, including with whom, for what types of analyses, and by what mechanism. Information about who will review requests and criteria for reviewing requests may also be provided. **Limit: 1000 characters.**
- e. **URL:** The web address, if any, used to find additional information about the plan to share IPD.

13) References

- a. **Citations:** Citations to publications related to the protocol, background, or the results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.
- b. **Links:** A web site directly relevant to the protocol may be entered. Links to the educational, research, government, and other non-profit web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

ClinicalTrials.gov Results Reporting Checklist

For submitting results and required documents, use the checklists below.

For applicable clinical trials (ACTs) that are subject to 42 CFR 11.42, and NIH funded clinical trials the standard submission deadline for results information is no later than 1 year after the study's Primary Completion Date, as described in 42 CFR 11.44(a) of the Final Rule.

Result submission process has 2 components: Responsible Parties must submit scientific and administrative information about the results of the trial to the ClinicalTrials.gov results database.

Complete Result Section

a. Scientific information is submitted as four separate modules: Participant Flow, Baseline Characteristics, Outcome Measures and Statistical Analyses, and Adverse Events.

b. Administrative Information consists of the study results point of contact and any agreement between the sponsor and principal investigator (PI) restricting the ability of the PI to discuss the results after the completion of the study.

c. Limitations and Caveats: Describe significant limitations of the study. Such limitations may include not reaching the target number of participants needed to achieve target power and statistically reliable results or technical problems with measurements leading to unreliable or uninterpretable data. **Limit: 500 characters.**

Result Section Components	Checklists	Simple Results Templates and Examples
Participant Flow A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group. It includes the numbers of participants who started, completed, and dropped out of each period of the study based on the sequence in which interventions were assigned	Participant Flow Data Preparation Checklist	Participant Flow Template
Baseline Characteristics A table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of participants in the clinical study	Baseline Characteristics Data Preparation Checklist	Age Sex/Gender Race, Ethnicity, and Region Study Specific Measures

<p>Outcome Measure and Statistical Analysis</p> <p>a. Outcome Measures: A table of data for each primary and secondary outcome measure by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any</p> <p>b. Statistical Analyses: Result(s) of scientifically appropriate tests of statistical significance of the primary and secondary outcome measures, if any. Such analyses include pre- specified in the protocol or in statistical analysis plan; made public by the sponsor or responsible party; conducted on a primary outcome measure in response to a request made by FDA.</p>	<p>When results are first created, information about outcome measures from the Protocol Section of the record will be copied into the Results Section.</p> <p>Outcome Measure and Statistical Analysis Data Preparation Checklist</p>	<p>Outcome Measure Template Outcome Measure</p> <p>Template Examples Statistical Analysis Template</p>
<p>Adverse Events</p> <p>Information for completing three tables summarizing adverse events.</p> <p>All-Cause Mortality: A table of all anticipated and unanticipated deaths due to any cause, with the number and frequency of such events by arm or comparison group of the clinical study.</p> <p>Serious Adverse Events: A table of all anticipated and unanticipated serious adverse events, grouped by organ system, with the number and frequency of such events by arm or comparison group of the clinical study.</p> <p>Other (Not Including Serious) Adverse Events: A table listing anticipated and unanticipated events (not listed in the serious adverse event table) that occur more frequently than a predetermined threshold (for instance, 5 percent) in any clinical study arm, organized by organ system, along with the quantity and frequency of such events by study arm or comparison group.</p>	<p>Adverse Event Data Preparation Checklist</p>	<p>SAEs</p> <p>Other (Not Including Serious) AEs</p>

Required Documents

Required Documents include

1- Protocol

2- Statistical Analysis Plan

- Documents must be in English and in PDF Archive (PDF/A) format.
- A cover page with official title, NCT number and document date must be included in each document.

Ensure the names of research participants are not included in an uploaded document.

Study Protocol and Statistical Analysis Plan are only required with results information for studies with a Primary Completion Date on or after January 18, 2017

3- Informed Consent Document:

Optional under 42 CFR Part 11, but may be required by funder, including if the study is conducted or supported by a Common Rule (45 CFR 46) department or agency.

ClinicalTrials.gov Good Cause Extension Request Checklist

According to 42 CFR 11.44(e)(1)(i), a responsible party may ask for a delay in the deadline for submitting clinical trial results information if they have a valid reason. So, submit a "Good Cause Extension Request" if a PI anticipates a delay in the submission of Results information.

Required Task	Response
<p>1) Submit extension request via the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to the date (i.e., the day before) that results information would otherwise be due according to 42 CFR 11.44(a) through (f).</p> <p>For applicable clinical trials (ACTs) that are subject to 42 CFR 11.42, the standard submission deadline for results information is no later than 1 year after the study's Primary Completion Date, as described in 42 CFR 11.44(a) of the Final Rule.</p> <p>2) Include a description of the reasons that the PI believes constitute good cause to justify an extension with sufficient detail to allow for evaluation of the request.</p> <p>3) Provide an estimated date on which the results information will be submitted.</p>	

There is not a certain situation that justifies a good cause. The director of NIH evaluates each extension request individually.

[Here](#) are a few instances that would qualify as a good reason under section 402(j)(3)(E)(vi) of the PHS Act.

The potential choices are

- 1- The need to protect the scientific integrity of a relevant clinical trial for which data collection is still ongoing, particularly in circumstances where the submission of results information for the primary outcome(s) of a relevant clinical trial would impede or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome (s).

NIH has indicated that an extension should be granted only in those situations in which the following could be demonstrated:

- Data collection for the secondary outcome(s) of interest extends more than 1 year beyond the completion date, the secondary outcome(s) is pre-specified in

the protocol or SAP, and the planned analysis of the outcome measure is also described in the protocol or SAP.

- The responsible party could provide this information either by voluntarily submitting copies of the protocol or statistical analysis plan with the extension request or describing them in the extension request itself in the PRS.
- 2- Emergency scenarios, such as those where one or more data collection sites were impacted by natural disasters or other catastrophes beyond the control of the responsible party or sponsor, could prohibit the timely submission of clinical trial outcomes information. In certain situations, an initial extension of up to 6 months is typically given, followed by further extensions as needed.
 - 3- Events that might have been reasonably averted or foreseen through regular contingency planning (such as transition planning for important staff employees leaving an organization) do not qualify as justification of a request for an extension.