CASE WESTERN RESERVE UNIVERSITY

Registering Your CWRU Study on ClinicalTrials.gov

IMPORTANT NOTE: clinicaltrials.gov has recently been modernized by the NIH ("Modernized PRS"); however, not all bugs have been resolved on the modernized site. To avoid technical difficulties, after logging in, click the blue link on the top center of the webpage that says, "**Go to Classic PRS**," as shown below, before creating a new record or completing record updates.

All Applicable Clinical Trials MUST be registered in ClinicalTrials.gov no later than 21 days after enrollment of the first participant. However, **the WHO-defined clinical trial/ICMJE registration policy requires prospective registration** (i.e., registration prior to first person enrolled) of all interventional clinical studies. If an investigator fails to register an Applicable Clinical Trial (ACT) this could result in future research approval delays, departmental fines, loss of funding, and/or publication restrictions. If a non-ACT interventional study fails to register prior to enrolling participants, this could result in publication restrictions.

For more information regarding what is an Applicable Clinical Trial and/or which studies must register with ClinicalTrials.gov, see CHAPTER 26 – Overview of ClinicalTrials.gov Records in the CWRU Investigator Manual. For more information on WHO-defined clinical trial ICMJE requirements, see ICMJE | Recommendations | Clinical Trials.

If you do not yet have a ClinicalTrials.gov account, please email irbqip@case.edu. An account will be created for you by a CWRU ClinicalTrials.gov PRS administrator. ClinicalTrials.gov will then send you an email with an auto-generated password. You can change this password when you log in for the first time. You will log in with the CaseWestern organization name (case sensitive, so type in *exactly* as CaseWestern) your username, and password. **Note that University Hospitals has its own PRS administrators and organization name. All CWRU IRB-approved studies or UH IRB-approved studies with federal funding that is managed by CWRU must register their studies under the CaseWestern PRS organization.**

In addition to the guidance below, ClinicalTrials.gov has very helpful tutorials here: https://clinicaltrials.gov/submit-studies/prs-help/prs-guided-tutorials#/

Creating a New Record in ClinicalTrials.gov

Before starting this process, it may be helpful to have the IRB-approved protocol, informed consent document, and study team contact information on hand. Additionally, ***the person who creates the record becomes the Record Owner***. All email messages about the record will be sent to this person.

The process for creating a new record takes 2 hours on average. However, you may save your changes by selecting "Quit," and return to complete the registration at another time.

1. Login at https://register.clinicaltrials.gov/ with the information from your account registration using your one-word organization name (CaseWestern), username, and password.
2. Select **New Record** in the top left dialogue box or use the dropdown "Records" menu. A "Create New Record" page will be displayed. At the top of the page are two links: *Help* and *Definitions*. The *Help* link contains examples and data entry tips, and the *Definitions* link contains information about terms and field lengths. These will open in a pop-up window and can be used at any time without altering or suspending your New Record entry. Proceed as listed below:

    a. Enter the study's **Unique Protocol ID** using the assigned CWRU or UH IRB number, e.g., STUDY12345678. Do NOT enter the grant number here; grant numbers are Secondary IDs (see 3.b below). *Limit: 30 characters*
    b. In the **Brief Title** box, enter the study title written in language intended for lay public. If possible, the title should provide some idea of the condition being evaluated and intervention(s) studied. The Brief Title can be the same as the Official Title (see 3.a below) if that is preferable. However, if the Official Title is longer than 300 characters or contains language or jargon that would be difficult for the lay public to understand, a simplified Brief Title is recommended. ***Note that this title will be displayed in search results***. Therefore, ensure that it is both accurate and free from typographical and grammatical errors. Also, DO NOT add the study acronym here (see step 2.c below). *Limit: 300 characters*
    c. **Acronym** (if any): If the study utilizes an acronym, enter it here. If an acronym is entered here, it will be included at the end of the Brief Title in parentheses on the public-facing site. *Limit: 14 characters*
    d. Select the appropriate **Study Type**:
    (1) Interventional – participants assigned to an intervention based on a protocol.
    For the Study Types below, see ClinicalTrials.gov Observational Study Registration Guide or ClinicalTrials.gov Expanded Access Study Registration Guide
    (2) Observational – participants NOT assigned to intervention(s) based on a protocol; typically, in context of routine care.
    (3) Expanded Access – availability of an experimental drug or device outside of a clinical trial protocol. These types of records are usually registered by the product manufacturer.

    If you are unsure which Study Type you are registering, please consult the Protocol Registration Data Element Definitions and/or contact irbqip@case.edu for assistance. Note that when the Study Type is selected, the rest of the registration template will prepopulate based on the selected study type of Interventional, Observational, or Expanded Access.

3.

Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Study Identification** module will open. Proceed with the following steps:

a. Enter the **Official Title**. This may be the same as the Brief Title (see 2.b above) but MUST be the exact name of the study as it appears on the IRB-approved protocol and informed consent document. Please note that ICMJE requires an Official Title be entered in the ClinicalTrials.gov record as a condition of publication. *Limit: 600 characters*
b. Enter the **Secondary ID**, if applicable. If the clinical study is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID. Additionally, if the study has unique clinical study identifiers assigned by other publicly available clinical trial registries (other than ClinicalTrials.gov), that should be entered here. More than one Secondary ID can be entered. *Limit: 30 characters*
c. **Secondary ID Type** (if applicable, see above, 4.b.): If you have entered a Secondary ID, a descriptor must be entered here. Select from "U.S. National Institutes of Health (NIH) Grant/Contract Award Number," "EudraCT Number," "Other Grant/Funding Number," "Other Identifier," or "Registry Identifier."
d. **Secondary ID Type Description**: If a Secondary ID Type of "Other Grant/Funding Number," "Other Identifier" or "Registry Identifier," is selected, provide the name of the funding organization, clinical trial registry, or organization that issued the identifier. If a Secondary ID Type of "U.S. National Institutes of Health (NIH) Grant/Contract Award Number" or "EudraCT Number" is selected, the Description box can remain blank. **Note that NIH Grant/Contract Award Numbers contain Institute Codes that identify the specific NIH-affiliated funding institute.** For example, in a grant number of R01AI000000, the "AI" identifies the National Institute of Allergy and Infectious Diseases as the funding institute. **Therefore, naming the specific NIH funding institute in the Secondary ID Description is not necessary.** *Limit: 119 characters*

4. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Study Status** module will open. Proceed with the following steps:
    a. Enter the **Record Verification Date** by entering the current month and year. *Update this date every time the record is edited and/or reviewed for accuracy*.
    b. Enter the **Overall Recruitment Status**. During the Record Registration process, this will most likely be "Not Yet Recruiting." Instructions for editing this section once recruitment commences or has completed can be found in the ClinicalTrials.Gov Record Update Guide. Skip "Why Study Stopped." Again, see ClinicalTrials.Gov Record Update Guide for information on when and why this entry may be necessary.
    c. For **Study Start Date**, select "Anticipated" and enter the date you expect recruitment to commence.

d. For **Primary Completion Date**, select "Anticipated" and enter the date you expect data collection for primary measures to be completed. ClinicalTrials.gov considers primary outcome data collection completion to be the date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome. For more information see Protocol Registration Data Element Definitions and/or contact irbqip@case.edu for assistance.
e. For **Study Completion Date**, select "Anticipated" and enter the date you expect data collection for both primary and secondary measures to be completed. ClinicalTrials.gov considers primary and secondary measures data collection completion to be the date that the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures *as well as adverse events* (for example, last participant's last visit). For more information see Protocol Registration Data Element Definitions and/or contact irbqip@case.edu for assistance.

5. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Sponsors/Collaborators** module will open. Proceed with the following steps:
   a. In the **Responsible Party, by Official Title** section, select "Sponsor," "Principal Investigator," or "Sponsor-Investigator." Generally, this selection will be "Sponsor" until the Record has been released and assigned a Record NCT number. Once that process is complete, the CWRU PRS Administrator(s) will change the Responsible Party to the PI. For definitions of these terms, see the Protocol Registration Data Element Definitions. Underneath the **Responsible Party,** by the **Official Title** section is a statement that 'Investigator Information is required only for "Principal Investigator" or "Sponsor-Investigator.' Please ignore this statement and proceed to **Investigator Information**.
   b. Under the **Investigator Information** section, enter the following information.
      i. **Investigator Name**: enter the first and last name of the Principal Investigator.
      ii. **Investigator Official Title**: enter the Principal Investigator's official title at CWRU. *Limit: 254 characters*
      iii. **Investigator Affiliation**: enter the name of the Principal Investigator's primary organizational affiliation, such as Case Western Reserve University, University Hospitals Cleveland Medical Center, etc. *Limit: 160 characters*
      iv. **Name of the Sponsor**: enter Case Western Reserve University. For the purposes of this specific field, "Sponsor" refers to the funding administrators, in this case CWRU, *NOT* the PI's affiliation or source of funding. Exception Note: 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 the sponsor. *Limit: 160 characters*
   c. In the **Collaborators** section enter the organization names of any collaborators providing the study with support, including funding, design, implementation, data analysis or reporting. This includes the funding source and Co-Investigators' organizations. **If your award or contract involves a Non-Disclosure Agreement or**

ARPA funds, please contact the CWRU Office of Research Administration for special instructions. Note that there is an Add Collaborator button for every additional collaborator, and there is no limit on the number of collaborators listed. ***While entering Collaborators is optional, it is a requirement of the International Committee of Medical Journal Editors (ICMJE).*** If you do not plan to publish with an ICMJE Member Journal (list at ICMJE | About ICMJE), or with journals stating that they follow the ICMJE guidelines (list at ICMJE | Journals stating that they follow the ICMJE Recommendations), this field can remain blank. However, it is recommended that this field be completed in an effort to increase publication opportunities. *Limit: 160 characters per collaborator*

6. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Oversight** module will open. Proceed with the following steps:
   a. Select Yes or No for **U.S. FDA-regulated Drug**
   b. Select Yes or No for **U.S. FDA-regulated Device**
   c. Select Yes or No for **U.S. FDA IND/IDE**
   d. In the **Human Subjects Protection Review** section, select from the drop-down list. Note that this will likely be "Submitted, approved," but for any questions please contact irbqip@case.edu
   e. In the **Approval Number** box, enter the assigned CWRU or UH IRB number, e.g., STUDY12345678 (see 2.a).
   f. In the **Board Name** box, enter the appropriate IRB name, either Case Western Reserve University Institutional Review Board or University Hospitals Cleveland Medical Center Institutional Review Board, depending on which IRB reviewed and approved your protocol. For other IRBs, please contact irbqip@case.edu
   g. In the **Board Affiliation** box, enter either Case Western Reserve University or University Hospitals Cleveland Medical Center, depending on which IRB reviewed and approved your protocol. For other IRBs, please contact irbqip@case.edu *Limit: 255 characters*
   h. In the **Board Contact** section, enter the following information, again depending on which IRB reviewed and approved your protocol. For **CWRU**, enter the phone, email, and address as 216-368-6925, cwru-irb@case.edu, 10900 Euclid Avenue, Cleveland, OH, 44106. For **UH** enter the phone, email, and address as 216-844-1529, uhirb@uhhospitals.org, 11100 Euclid Avenue, Cleveland, OH, 44106. For other IRBs, please contact irbqip@case.edu
   i. Select Yes or No for **Data Monitoring Committee**. Note that this should be "Yes" if the IRB-approved protocol specifies the establishment of a data monitoring committee for the study.
   j. Select Yes or No for **FDA Regulated Intervention**.

7. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Study Description** module will open. Proceed with the following steps:
   a. In the **Brief Summary** box, enter a short description of the study hypothesis, written in language understandable to the lay public. This language can be adapted from the

consent form and/or study protocol. Important note: do NOT use personal pronoun language such as "we" or "you." *Limit: 5,000 characters*

b. The **Detailed Description** field is optional and can be left blank. It does not have to be in lay language and can be adapted from the background or aims section of the protocol. However, do not copy and paste the entire protocol. This field cannot contain promotional language. Where applicable, explain uncertainties or exploratory nature of the study. If there are any parts of the trial which the public cannot know about while the study is ongoing without affecting scientific integrity, such as deception research or inclusion/exclusion criteria which could be easily faked in order to join a study, it would be good to explain that here, e.g. "Some inclusion/exclusion criteria are purposely omitted at this time to preserve scientific integrity. They will be included after the trial is complete." *Limit: 32,000 characters*

8. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Conditions** module will open. Proceed with the following steps:
   a. In the **Conditions or Focus of Study** field, enter the names of the diseases or conditions being studied or, if no specific diseases or conditions are being studied, a brief description of the focus of study. Enter only one per line. Select **Add Condition** to add each separate condition/focus of study. Utilize the Search MeSH hyperlink under the field to search for valid condition terms.
   b. In the **Keywords** field, enter words or phrases that best describe the protocol. **Keywords help users find studies in the database, including potential participants.** Be as specific and precise as possible, avoiding acronyms and abbreviations.

9. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Edit Study Design** module will open. Proceed with the following steps for Interventional Study Design:
   a. In the **Primary Purpose** field, select the most appropriate option: Treatment, Prevention, Diagnostic, Supportive Care, Screening, Health Services Research, Basic Science, Device Feasibility, or Other. See Protocol Registration Data Element Definitions for detailed descriptions of these options.
   b. In the **Study Phase** field, select the most appropriate option: N/A, Early Phase 1, Phase 1, Phase 1/Phase 2, Phase 2, Phase 2/Phase 3, Phase 3, or Phase 4. See Protocol Registration Data Element Definitions for detailed descriptions of these options. *Note that if your study is not testing a drug, biological or device, the phase option will be N/A.*
   c. In the **Interventional Study Model** field, select the most appropriate option: Single Group, Parallel, Crossover, Factorial, or Sequential. See Protocol Registration Data Element Definitions for detailed descriptions of these options.
   d. The **Model Description** field is optional. However, you may use this field to enter details regarding the study model. *Limit: 1000 characters*
   e. Enter the maximum number of interventional arms in the **Number of Arms** field. Note that the Arms fields should correlate with how the data is being reported for the study.

f. In the **Masking Roles** section, select the most appropriate option: Participant, Care Provider, Investigator, Outcomes Assessor, or None.
g. The **Masking Description** field is optional. However, you may use this field to enter details regarding masking roles and/or descriptions. *Limit: 1000 characters*
h. In the **Allocation** field, select the most appropriate option: Randomized, Nonrandomized, or N/A (for single-arm studies).
i. In the **Enrollment Type** field select "Anticipated." In the **Number of Participants field**, enter the anticipated number of research participants indicated in the IRB-approved protocol.

10. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Arms, Groups and Interventions** module will open. Proceed with the following steps for Interventional Study Design:
    a. Beginning with Arm 1, select the most appropriate **Arm Type** option: Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No Intervention, or Other.
    b. In the **Arm Title** field, enter a brief descriptive label of the arm name. Use the arm name or label that you will use as a row or column heading in results tables. Do not title your arm as Intervention 1 or Arm 1. *Limit: 100 characters*
    c. In the **Arm Description** field, describe the arm's intervention. If the intervention uses drugs, use the drug's generic name, dosage, dosage form, frequency, and duration. *Limit: 999 characters*
    d. The template provides two arm sections to complete. However, if your study has more than two arms select the "Add Arms" button. This will open a new arm section with each field as described above. Continue until all arms are added.
    e. Moving to the Intervention section, start with Intervention 1 by selecting the most appropriate **Intervention Type**: Drug, Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, or Other.
    f. In the **Intervention Name** field, enter a descriptive name used to refer to the intervention(s) studied in each arm of the clinical study. For a drug, use generic name if established. Use the same name as in the associated Arm/Group Description(s). Limit: 200 characters.
    g. The **Other Intervention Name (if any)** field is optional if there are no other names by which the intervention is known. However, if the intervention is commonly known by another name, such as a brand-name drug, enter it here. Add as many other names as necessary utilizing the **Add Other Name** button.
    h. Add the **Intervention Description** in the supplied field. Without repeating information that was already supplied in the arm description(s), enter details regarding the intervention that can be made public. Do not repeat the Arm Description word-for-word.
    i. Add as many Interventions as necessary utilizing the **Add Intervention** button.
    j. In the **Arm/Interventional Cross-Reference** table, assign all the interventions to each arm by selecting the pre-supplied checkboxes. For example, each arm of a Parallel model will have only one checkbox selected, while each arm of a Crossover model will have all checkboxes selected.

11. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Outcome Measures** module will open. The template is pre-populated with two (2) blank Primary Outcome Measures, two (2) blank Secondary Outcome Measures, and two (2) blank Other Pre-specified Outcome Measures. Additional measures of each type can be added by selecting the "Add Outcome" buttons. Enter them in order of greatest importance. Note that the order can be rearranged if necessary. If you are unsure which measures should be included as *Primary*, vs Secondary or Other, ClinicalTrials.gov defines *Primary* as *"the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation."*

    Be sure to expand acronyms when entering them for the first time in Outcome Measures, e.g., "The Epworth Sleepiness Scale (ESS)." Once expanded, all subsequent references can use the unexpanded acronym.

    Outcome Measures should be formatted in a very specific format: **What** you are measuring and **How**; do not include descriptions or narrations. Only enter ONE measure per outcome. Try to be as numerical as possible.

    PLEASE NOTE: all primary and secondary outcomes listed in the IRB-approved protocol are REQUIRED to be entered in the record. Proceed with the following steps:

    a. Beginning with the **Primary Outcome Measure** section (*Limit: 254 characters*), enter the primary measure **Title**. The title is the name of the specific outcome measure and must include the following:
        i. The metric being used (i.e., scale, score, number, percentage)
        ii. Clear and concise language with the omission of verbs (e.g., Maximum Tolerated Dose of Drug A in patients with breast cancer)
        iii. A separate accounting for each measure UNLESS the measure is a composite score
    b. The **Description** field is optional IF the metric used to characterize the measure is not included in the Primary Outcome Measure title. However, most Primary Outcome Measures utilizing scale or survey instruments cannot comprehensively describe the instruments' components or metrics within the confines of the Title field. Therefore, the description should include a thorough description of the instrument (e.g., "The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression."). *Limit: 999 characters*
    c. In the **Time Frame** field, enter the time point(s) at which the measurement is assessed. Be specific with time, such as minutes, days, weeks, and/or months. Examples: "Baseline and 12 Months," "5 Days Post-Hospitalization," "4 Weeks Pre-Intervention and 4 Weeks Post-Intervention." *Limit: 254 characters.*
    d. Proceed with the **Secondary Outcome Measure** fields, if applicable, following the same steps and instructions above in 11a., 11b., and 11.c. Secondary Outcome Measures are defined by ClinicalTrials.gov as outcome measures that are "of lesser

importance than a primary outcome measure, but part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical study, and is not specified as an exploratory or other measure."

e. Proceed with the **Other Pre-specified Outcome Measure** fields, if applicable, following the same steps and instructions above in 11a., 11b., and 11.c. Other Pre-specified Outcome Measures are defined by ClinicalTrials.gov as "any other measurements, excluding post-hoc measures, that will be used to evaluate the intervention(s)."

12. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **Eligibility** module will open. Proceed with the following steps:
    a. Enter the **Sex** of the participants eligible to participate in the clinical study. Select one from the drop-down menu: "All," "Female," or "Male." *Note that here Sex refers to biological distinctions. Gender distinctions are entered in item b. below.*
    b. Select "Yes" or "No" in the **Gender Based** field, depending on if participant eligibility is based on self-representation of gender identity. If "Yes," you will also need to enter a **Gender Eligibility Description**, describing the gender criteria used to assess eligibility. *Limit: 1000 characters*
    c. In the **Age Limits** section, enter Minimum and Maximum eligibility age limits. For unit of time, you can select from Years, Months, Weeks, Days, Hours, Minutes, or N/A (No limit). Note that if you select N/A (No limit) the number field will remain blank.
    d. Select "Yes" or "No" in the **Accepts Healthy Volunteers** field.
    e. In the **Eligibility Criteria** section, create two headers labeled "Inclusion Criteria:" and "Exclusion Criteria:" Under each header, use a bulleted list to describe each element of eligibility or ineligibility. *Limit 20,000 characters*

13. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. A **Contacts, Locations, and Investigator Information** module will open. Proceed with the following steps:
    a. In the **Central Contact Person** fields, enter the name, phone number, and email for the person who should be contacted regarding enrollment at any/all study sites, as well as a point of contact for ClinicalTrials.gov record issues. This can be the Principal Investigator, Project Manager, or another study team member with comprehensive knowledge of the study's protocol. Additionally, this person should be listed on the record's Access List.
    b. In the **Central Contact Backup** fields, enter the name, phone number, and email for the person who should be contacted if the Central Contact Person is not available. Note: these fields should be updated if and when a contact person leaves the study team, i.e., are removed from the IRB Protocol's Study Team Member list.
    c. The **Overall Study Official** section is listed as optional on the template BUT, as this is a requirement of the WHO, Case Western Reserve University requires that it be completed. The role, name, and Organizational Affiliation (CWRU) of the Principal Investigator should be entered.

d. In **Facility Information**, enter the name and address of all participating study sites. Examples include Case Western Reserve University, University Hospitals Cleveland Medical Center, MetroHealth Medical Center, etc.
e. Enter the **Site Recruitment Status**. During the Record Registration process, this will most likely be "Not Yet Recruiting." Instructions for editing this section once recruitment commences or has been completed can be found in the ClinicalTrials.Gov Record Update Guide.
f. Enter the **Facility Contact** and **Facility Contact Backup**. If each facility does not have a separate contact for recruiting, the individual listed as Central Contact or Study Official can be entered here.
g. If Investigators at each facility differ from the Principal Investigator listed in the record, select the "Add Investigator" button, and enter their information.

14. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. An **IPD Sharing Statement** module will open. Note that this section regarding Individual Participant Data is optional. However, it is recommended that it be completed. Additionally, this field is *specifically* for individual participant level data, *NOT* for aggregate data sets. Proceed with the following steps:
    a. In the **Plan to Share IPD** field, select "Yes," "No," or "Undecided." *Note that ICMJE only accepts "Yes" or "No."*
    b. If you selected "No" or "Undecided," use the **IPD Sharing Plan Description** field to describe why you are not sharing data or why you are undecided about sharing data, then skip to item 15 below. If you selected "Yes," **IPD Sharing Plan Description** field should include information regarding what specific individual participant data sets are to be shared, and how they will be shared, and with whom. You may use language from the IRB-approved protocol and/or consent form to complete this field. *Limit: 1,000 characters*
    c. In the IPD Sharing Supporting Information Type field, select all that apply: "Study Protocol," "Statistical Analysis Plan," "Informed Consent Form," "Clinical Study Report," and/or "Analytic Code."
    d. Describe when the data will become available and for how long in the **IPD Sharing Time Frame field**. You can enter absolute dates, such as a month and year, or a relative date, such as 6 months after publication. *Limit: 1,000 characters*
    e. In the **IPD Sharing Access Criteria** field, describe how researchers can request data, what will or will not be shared, and other circumstances or requirements for accessing the data. *Limit: 1,000 characters*
    f. In the **IPD Sharing URL**, enter the web address, if any, where additional information about the IPD sharing plan can be found. If none, leave blank. Limit: *3,999 characters*

15. Select **Continue**. A dialogue box will open with an overview of the protocol modules. Select **OK**. A **References** module will open. The References module collects information about references to other information about the study. This includes citations for journal articles and publications, links to websites related to the study, and links to available individual participant data (IPD) sets and supporting information. Note that this section is optional. However, it is recommended that it be completed *if relevant to your study*. For

more information see the PRS Entering References Guide here - Entering References Information (clinicaltrials.gov). Note that the **Citations** section will likely remain blank until there is a publication related to this study (post results). However, if your study is related to a previous pilot or feasibility study with published results, you can enter any of those citations here. Proceed with the following steps:

a. In the **Citations** section, select the "Add Citation" button. Enter the PubMed ID or, if no PubMed ID, select "Enter Citation Text" to input a bibliographic reference.
    i. Enter the PubMed ID or the PubMed Central ID including the letters "PMC" before the search (e.g., PMC3066456) and click on the "Lookup" button to locate the citation information. If the PubMed ID or PubMed Central ID exists, the PRS will automatically fill in the citation. If you do not know the PubMed ID, you can search for it by clicking on the PubMed Citation Matcher link under the "Lookup" button. Copy and paste the result in the PubMed ID field.
    ii. To add a citation that is not on PubMed, click on the "Enter Citation Text" button. Enter manually, formatting according to the example in the PRS Entering References Tutorial - Entering References Information (clinicaltrials.gov). After manually entering the citation, PRS attempts to find the citation in PubMed. If a returned result matches, click the "Select" button next to the correct citation. If no or incorrect matches are returned, you can select "Edit Citation" to clarify the search or select "Submit for Review" to have the ClinicalTrials.gov staff review the citation.
    iii. Select "Yes" or "No" from the dropdown menu in the **Results Reference** section, depending on whether the citation provides reports from results.
    iv. Repeat until all citations are entered.
b. In the **Links** section, if your study has any URLs for citation, select the "Add Link" button. Enter the URL preceded by http:// and provide a description of the website. Repeat until all links are entered.
c. If your study has any references to other supporting information to share, select the "Add Data/Information" button. In the **Available IPD and Supporting Information** field, enter the name or title of any de-identified IPD sets or other information. From the dropdown menu in **Available IPD/Information Type**, select the type of supporting information: "Individual Participant Data Set," "Study Protocol," "Statistical Analysis Plan," "Informed Consent Form," "Clinical Study Report," "Analytic Code," or "Other." If "Other" is chosen, enter the type in the text box next to the dropdown menu.
d. In the **Available IPD/Information URL** field, enter the web address used to request or access the data set or supporting information. *Limit: 3,999 characters*
e. In the **Available IPD/Information Identifier** field, enter the unique identifier used by a data repository for the data set or supporting information if applicable. *Limit 30 characters*
f. In the **Available IPD/Information Comments** field, enter any additional information, including the name of the data repository or the location where the data set or supporting information is available. Provide any additional explanations about the data set or supporting information and instructions for obtaining access, particularly if a URL is not provided. *Limit: 1,000 characters*

16. The **Documents** section can remain blank until the time of enrollment completion, when the most recent versions of the study consent form and protocol will need to be uploaded.

17. The **Results** sections can remain blank until the 1-year deadline of post study completion.

18. Once the template is complete, the page will display a **Record Summary** box. Each section will show a green checkmark if completed correctly. A checkmark will be missing from a section if it has not been completed or if there are errors present. Errors and required information will be displayed in red text. Errors are serious issues that must be addressed before releasing the record. Warnings indicate potentially serious issues that should be reviewed and addressed expediently. Notes indicate other potential issues that should be addressed as needed. Once the Errors, Warnings and Notes have been corrected or addressed, select the "Spelling" link at the top left of the page to review spelling errors and unexpanded acronyms. Correct as needed.

19. When the Record Summary is complete and free from error, enter the record's **User Information**. Make sure that the Record Owner is the study's PI. If not, alert CWRU's PRS administrators by emailing irbqip@case.edu; only a CWRU PRS administrator can change the Record Owner. In **Access List**, add any study team members or department administrators who should have access to and editing privileges for the record. ***Adding study team members to the Access List is highly recommended.*** These should be team members who are familiar with the study and can make necessary, accurate edits when needed, similar to a PI Proxy in SpartaIRB. If you cannot find a ClinicalTrials.gov username for individuals you wish to add to the Access List, please email irbqip@case.edu. An account will be created for them by a CWRU PRS administrator.

20. Review all entries for accurate information. Once you are satisfied that all information is complete and correct, select the "Entry Complete" button. The Responsible Party will be notified that the record is ready for approval and release. Until the record is assigned an NCT number, the Responsible Party should be CWRU (Sponsor). If, however, you are the Responsible Party, select "Approve," then select "Release."

21. Once the record is released, ClinicalTrials.gov conducts a manual review. If major issues are identified, the record owner and Responsible Party will receive notification from ClinicalTrials.gov with comments. The study will be reset to In Progress; issues must be corrected, and the record re-released **within 15 calendar days**. If no major issues are identified, the study is assigned an NCT number and published on the public side of the database (clinicaltrials.gov). This process takes about 3-5 business days.

22. Once created and released for public viewing, the record will need to be periodically updated. See the ClinicalTrials.Gov Record Update Guide for information on when and how to update the record.