ClinicalTrials.gov

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Interventional Study Protocol Registration Template

For more information, see How to Register Your Study at https://clinicaltrials.gov/ct2/manage-recs/how-register.

* Required
*§ Required if Study Start Date is on or after January 18, 2017
[*] Conditionally Required

1. STUDY IDENTIFICATION

*Unique Protocol Identification Number:	*Brief Title:
IRB STUDY ID (i.e., STUDY12345678)	**Study title written in lay language. DO NOT use acronyms here.**

*§Official Title:	[*]Acronym (if any):
Study title as identified in the grant application and/or funding agreement	**Study acronym, if applicable**

*Study Type (select one): (•) Interventional ( ) Observational ( ) Observational—Patient Registry ( ) Expanded Access **Must select one**

More than one Secondary ID can be entered. If more than two are needed, more space is available in the PRS.

[*]Secondary ID 1 (if any): **Grant/contract award number**

[*]Secondary ID 1 Type (select one): **Must select one** ( ) U.S. National Institutes of Health (NIH) Grant/Contract Award Number ( ) Other Grant/Funding Number ( ) Registry Identifier ( ) EudraCT Number ( ) Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*]Description 1: **Only complete if anything other than "U.S. National Institutes of Health (NIH) Grant/Contract Award Number" selected**

[*]Secondary ID 2 (if any): **Additional grant or funding #s or registry identifier numbers. DO NOT REPEAT SECONDARY ID 1 HERE.**

[*]Secondary ID 2 Type (select one): ( ) U.S. National Institutes of Health (NIH) Grant/Contract Award Number ( ) Other Grant/Funding Number ( ) Registry Identifier ( ) EudraCT Number ( ) Other Identifier

If "Other Grant/Funding Number", "Registry Identifier", or "Other Identifier" is selected for Secondary ID Type, provide the name of the funding organization, trial registry, or organization that issued the ID.

[*]Description 2: **Only complete if anything other than "U.S. National Institutes of Health (NIH) Grant/Contract Award Number" selected**

2. STUDY STATUS

*Record Verification Date: Month: **Current Month** Year: **Current Year**

*Overall Recruitment Status (select one): **Must select one** ( ) Not yet recruiting ( ) Recruiting ( ) Enrolling by invitation ( ) Active, not recruiting ( ) Completed ( ) Suspended (halted prematurely but may resume) ( ) Terminated (halted prematurely) ( ) Withdrawn (no participants enrolled)

If the Overall Recruitment Status is "Suspended," "Terminated," or "Withdrawn," provide the reason why the study was stopped.

*§Why Study Stopped: **Only complete if "Suspended," "Terminated," or "Withdrawn" selected above**

Day is not required for Anticipated dates. **See Data Element Definitions for Study Start, Primary, and Study Completion Dates**

*§Study Start Date:	*Type (select one):	( ) Anticipated	( ) Actual	[*]Day:		*Month:		*Year:
*Primary Completion Date:	*Type (select one):	( ) Anticipated	( ) Actual	[*]Day:		*Month:		*Year:
*§Study Completion Date:	*Type (select one):	( ) Anticipated	( ) Actual	[*]Day:		*Month:		*Year:

3. SPONSORS/COLLABORATORS

*Responsible Party, by Official Title (select one): ◯ Sponsor ☒ Principal Investigator ◯ Sponsor-Investigator **Must select one (will usually be PI)**

Investigator Information is required only for "Principal Investigator" or "Sponsor-Investigator."

[*]Investigator Information:

Investigator Name:

Name of PI

Investigator Official Title:	Investigator Affiliation:
Institutional Title (i.e., Assistant Professor, etc.)	**CWRU or Other Institution Name**

*Name of the Sponsor

Case Western Reserve University

Enter as many Collaborators as needed. Additional fields are available in the PRS.

Collaborators (if any): **Enter below the name(s) of any organizations providing funding, design, implementation, or other functional support**

Name of Collaborator 1:	Name of Collaborator 2:

4. OVERSIGHT

For more information, see the ACT checklist: http://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf.

*§Studies a U.S. FDA-regulated Drug Product (select one): ◯ Yes ◯ No **Must select Yes or No**

*§Studies a U.S. FDA-regulated Device Product (select one): ◯ Yes ◯ No **Must select Yes or No**

If Yes, provide information below:

*§Device Product Not Approved or Cleared by U.S. FDA (select one): ◯ Yes ◯ No **Must select Yes or No**

If Yes, indicate whether NIH is authorized to post publicly clinical trial registration information.

Post Prior U.S. FDA Approval or Clearance (select one): ◯ Yes ◯ No

[*]Pediatric Postmarket Surveillance of a Device Product (select one): ◯ Yes ◯ No

Investigational New Drug Application(IND)/Investigational Device Exemption (IDE) Information:

*U.S. Food and Drug Administration IND or IDE (select one): ◯ Yes ◯ No **Must select Yes or No**

If Yes, provide information below:

[*]FDA Center (select one): ◯ CDER ◯ CBER ◯ CDRH	[*]IND/IDE Number:	[*]IND Serial Number:

[*]Availability of Expanded Access (select one): ◯ Yes ◯ No ◯ Unknown	[*]Expanded Access Record NCT Number:

[*]Product Manufactured in and Exported from the U.S. (select one): ◯ Yes ◯ No

*Human Subjects Review: **Must select one of the options below; update once IRB approval or determination obtained or denied**

*Human Subjects Protection Review Board Status (select one): ◯ Request not yet submitted ◯ Submitted, pending ◯ Submitted, approved ◯ Exempt ◯ Submitted, denied ◯ Submission not required

If the study is not required to be registered under 42 CFR Part 11, is not funded in whole or in part by the U.S. Government, and is not conducted under an IND or IDE, the following information is required.

[*]Board Approval Number:	[*]Board Name:
IRB STUDY ID (i.e., STUDY12345678)	**e.g., Case Western Reserve University Institutional Review Board, etc.**

[*]Board Affiliation: **e.g., Case Western Reserve University, University Hospitals Cleveland Medical Center, etc.**

[*]Board Contact:					
See your IRB for this info; CWRU included here	Phone:	**216-368-6925**	Ext.:	Email:	**cwru-irb@case.edu**
	Address:	**10900 Euclid Avenue, Cleveland, OH, 44106**			

Data Monitoring Committee (select one): ◯ Yes ◯ No

FDA Regulated Intervention (select one): ◯ Yes ◯ No

If Yes, indicate whether this is an applicable clinical trial as defined in U.S. Public Law 110-85, Title VIII, Section 801.

Section 801 Clinical Trial (select one): ◯ Yes ◯ No **Only select if FDA Regulated Intervention above is "Yes"**

5. STUDY DESCRIPTION

*Brief Summary (using lay language):

Enter here 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."

Detailed Description:

This field does not have to be in lay language and can be adapted from the protocol's background or aims section. Do not copy and paste the entire protocol. Cannot contain promotional language. Where applicable, explain uncertainties or exploratory nature of the study. For 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, 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."

6. CONDITIONS AND KEYWORDS

Enter as many Conditions as needed. Additional fields are available in the PRS.

*Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study:

1. **Names of conditions/diseases being studies or focus of study, e.g., "Diabetes," "Asthma," "Food Insecurity." Enter one per line.**
2.

Enter as many Keywords as needed. Additional fields are available in the PRS.

Keywords:

1. **Terms that will help users find studies, e.g., "Autoimmune," "Lung Diseases," "Nutritional Deficiency." Enter one per line.**
2.

7. STUDY DESIGN (INTERVENTIONAL)

*§Primary Purpose (select one): ◯ Treatment ◯ Prevention ◯ Diagnostic ◯ Supportive Care ◯ Screening ◯ Health Services Research ◯ Basic Science ◯ Device Feasibility ◯ Other
Must select one

*Study Phase (select one): ◯ N/A ◯ Early Phase 1 ◯ Phase 1 ◯ Phase 1/Phase 2 ◯ Phase 2 ◯ Phase 2/Phase 3 ◯ Phase 3 ◯ Phase 4
Must select one

*§Interventional Study Model (select one): ◯ Single Group ◯ Parallel ◯ Crossover ◯ Factorial ◯ Sequential **Must select one**

Model Description:

Optional field; can be used to provide details regarding the interventional study model

*§Number of Arms: **The maximum number of arms or groups; note that this number must correlate with how the data is reported**

*§Masking Roles, if Masking (select all that apply): ☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor ☐ None (open label) **Must select one**

Masking Description:

Optional field; can be used to provide details regarding masking roles or other parties who may be masked in the trial

*§Allocation (select one): ◯ Randomized ◯ Nonrandomized ◯ N/A (not applicable) **Must select one here and one below (Enrollment Type)**

*§Enrollment Type (select one): ◯ Anticipated ◯ Actual | Number of Subjects: **Enter # of anticipated or actual enrolled participants**

8. ARMS, GROUPS, AND INTERVENTIONS

Enter as many Arms as needed. Additional fields are available in the PRS. **Must select one type below**

Arm 1: *Arm Type (select one): ◯ Experimental ◯ Active Comparator ◯ Placebo Comparator ◯ Sham Comparator ◯ No Intervention ◯ Other

*Arm Title:	[*]Arm Description:
Arm name/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.	**Describe the arm's intervention including any drug or device name, dosage, frequency, and duration; if placebo, describe**

Arm 2: *Arm Type (select one): ◯ Experimental ◯ Active Comparator ◯ Placebo Comparator ◯ Sham Comparator ◯ No Intervention ◯ Other

*Arm Title:	[*]Arm Description:
Arm name/label that you will use as a row or column heading in results tables. Do not title your arm as Intervention 2 or Arm 2.	**Describe the arm's intervention including any drug or device name, dosage, frequency, and duration; if placebo, describe**

8. ARMS, GROUPS, AND INTERVENTIONS (CONTINUED)

Enter as many Interventions as needed. Additional fields are available in the PRS. **Must select one type below**

Intervention 1: *Intervention Type (select one): ◯ Drug ◯ Device ◯ Biological/Vaccine ◯ Procedure/Surgery ◯ Radiation ◯ Behavioral ◯ Genetic ◯ Dietary Supplement ◯ Combination Product ◯ Diagnostic Test ◯ Other

*Intervention Name:

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).

[*]Other Intervention Name 1 (if any):

If commonly known by another name, such as a brand-name drug, enter it here. If not, leave blank.

[*]Other Intervention Name 2 (if any):

If commonly known by another name, such as a brand-name drug, enter it here. If not, leave blank.

*§Intervention Description:

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.

Intervention 2: *Intervention Type (select one): ◯ Drug ◯ Device ◯ Biological/Vaccine ◯ Procedure/Surgery ◯ Radiation ◯ Behavioral ◯ Genetic ◯ Dietary Supplement ◯ Combination Product ◯ Diagnostic Test ◯ Other

*Intervention Name:

See above

[*]Other Intervention Name 1 (if any):

See above

[*]Other Intervention Name 2 (if any):

See above

*§Intervention Description:

See above

*Arm/Interventional Cross-Reference:
Assign all the interventions to each arm by selecting the pre-supplied checkboxes.

	Intervention 1	Intervention 2
Arm 1	☐	☐
Arm 2	☐	☐

Parallel models will have only one box selected, Crossover models will have all boxes selected

9. OUTCOME MEASURES

Enter as many Outcome Measures as needed. Additional fields are available in the PRS.

Outcome 1: *Primary Outcome Measure: **NOTE: enter each measure separately UNLESS the measure is a composite score**

*Title:
Name of the specific primary outcome measure including the metric used (scale, score, percentage, etc.). DO NOT USE ACRONYMS

*Time Frame:
Point(s) of assessment (Baseline & 12 Months, 4 Weeks Post-Intervention, etc.)

[*]Description:

Optional IF the metric used to characterize the measure is not included in the Primary Outcome Measure title. Otherwise, enter here a thorough description that includes the full instrument name with any acronyms in parentheses and the scale/score descriptions, e.g., "The Hamilton Depression Rating Scale (HDRS) is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression."

Outcome 2: *Primary Outcome Measure:

*Title:

See above

*Time Frame:

See above

[*]Description:

See above

Outcome 3: [*]Secondary Outcome Measure:

*Title:
Name of the specific secondary outcome measure including the metric used (scale, score, percentage, etc.). DO NOT USE ACRONYMS

*Time Frame:
Point(s) of assessment (Baseline & 12 Months, 4 Weeks Post-Intervention, etc.)

9. OUTCOME MEASURES (CONTINUED)

[*]Description:

Optional IF the metric used to characterize the measure is not included in the Primary Outcome Measure title. Otherwise, enter here a thorough description that includes the full instrument name with any acronyms in parentheses and the scale/score descriptions, e.g., "The Hamilton Depression Rating Scale (HDRS) is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression."

Outcome 4: [*]Secondary Outcome Measure:

*Title:	*Time Frame:
See above	**See above**

[*]Description:

See above

Outcome 5: Other Pre-specified Outcome Measure: **Other measures that will be used to evaluate the intervention**

*Title:	*Time Frame:
See above	**See above**

[*]Description:

See above

Outcome 6: Other Pre-specified Outcome Measure:

*Title:	*Time Frame:
See above	**See above**

[*]Description:

See above

10. ELIGIBILITY

*Sex/Gender:

*Sex (select one): ◯ All ◯ Female ◯ Male **Must select one**

[*]Gender-Based (if any): ◯ Yes ◯ No **Optional**

If Yes, provide descriptive information about the Gender Based criteria.

Gender Eligibility Description:

If Gender-Based "Yes" selected above, describe the gender criteria used to assess eligibility

*Age Limits:	*Minimum Age:	*Unit of Time:	*Maximum Age:	*Unit of Time:	
	Number	**Days, weeks, years**	**Number**	**Days, weeks, years**	**If no age limits, mark N/A for both units of time and leave min and max ages blank**

*§Accepts Healthy Volunteers (select one): ◯ Yes ◯ No **Must select one**

Provide bulleted lists (one criterion per bullet) below the headers "Inclusion Criteria" and "Exclusion Criteria."

*Eligibility Criteria:

Create two headers labeled "Inclusion Criteria:" and "Exclusion Criteria:" Under each header, use a bulleted list to describe each element of eligibility or ineligibility.

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

*Central Contact Person:	First Name:	Middle Initial:	*Last Name or Official Title:

Degree: **Name and contact info of the person who should be contacted regarding enrollment at any/all study sites**

*Phone:	Ext.:	*Email:

Central Contact Backup:	First Name:	Middle Initial:	Last Name or Official Title:

Degree: **Name and contact of backup for the person who should be contacted regarding enrollment at any/all study sites**

Phone:	Ext.:	Email:

Enter as many Overall Study Officials as needed. Additional fields are available in the PRS. **STUDY OFFICIAL MUST BE COMPLETED FOR CaseWestern ORG**

Overall Study Official 1:	First Name:	Middle Initial:	Last Name:
Enter PI's info	**Enter PI's info**		**Enter PI's info**

Degree:	Organizational Affiliation:
Enter PI's info	**Enter PI's info**

Official's Role (select one): ◯ Study Chair ◯ Study Director ◯ Study Principal Investigator **This should be the PI**

Overall Study Official 2:	First Name:	Middle Initial:	Last Name:
Leave blank			

Degree:	Organizational Affiliation:

Official's Role (select one): ◯ Study Chair ◯ Study Director ◯ Study Principal Investigator

*Facility Information:	*§Facility Name:	*City:	*State/Province:	*§ZIP/Postal Code:	*Country:
Info for study sites CWRU here as example	**Case Western Reserve University**	**Cleveland**	**OH**	**44106**	**USA**

*Individual Site Status (select one): **Must select one**

◯ Not yet recruiting ◯ Recruiting ◯ Enrolling by invitation ◯ Active, not recruiting
◯ Completed ◯ Suspended (halted prematurely but may resume) ◯ Terminated (halted prematurely) ◯ Withdrawn (no participants enrolled)

*Facility Contact:	First Name:	Middle Initial:	*Last Name or Official Title:

Degree: **Can use the identified Central Contact here or the names/contact info of individual site staff for multi-site studies**

*Phone:	Ext.:	*Email:

Facility Contact Backup:	First Name:	Middle Initial:	Last Name:

Degree:

Phone:	Ext.:	Email:

Enter as many Investigators as needed. Additional fields are available in the PRS.

Investigators:	First Name:	Middle Initial:	Last Name:

Degree: **Complete this section if Investigators at each site differ from Principal Investigator; will likely only apply for multi-site studies**

Role (select one): ◯ Site Principal Investigator ◯ Site Sub-Investigator

12. IPD SHARING STATEMENT

Indicate whether there is a plan to make individual participant data (IPD) available to other researchers.

Plan to Share IPD (select one): ◯ Yes ◯ No ◯ Undecided **Must select one**

Describe the IPD sharing plan, including which IPD will be shared with other researchers.

IPD Sharing Plan Description:

If you selected "Yes," this 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. If you selected "No" or "Undecided," use this field to describe why you are not sharing data or why you are undecided about sharing data, then skip to 13. References.

IPD Sharing Supporting Information Type (select all that apply):

☐ Study Protocol ☐ Statistical Analysis Plan ☐ Informed Consent Form ☐ Clinical Study Report ☐ Analytic Code **Complete if plan to share is "Yes"**

Describe when the data will become available and for how long.

IPD Sharing Time Frame:

Describe when the data will become available and for how long. Can use absolute dates, such as a month and year, or a relative date, such as 6 months after publication

IPD Sharing Access Criteria:

Describe how researchers can request data, what will or will not be shared, and other circumstances or requirements for accessing the data

Web address (if any) with additional information about the plan to share IPD.

IPD Sharing URL:	**Web address where additional information about the IPD sharing plan can be found. If none, leave blank.**

13. REFERENCES

Enter as many Citations, Links, and Available IPD and Supporting Information items as needed. Additional fields are available in the PRS.

Citations:	PubMed Identifier:	Citation:
	Results Reference (select one): ◯ Yes ◯ No	
Links:	URL:	

Description:

For information on how to complete this optional section, see https://prsinfo.clinicaltrials.gov/tutorial/content/index.html#/lessons/GE_igGejMjFu9WtErAxXw9-qdeUggVBX

Available IPD and Supporting Information:

Available IPD/Information Type (select one): ◯ Individual Participant Data Set ◯ Study Protocol ◯ Statistical Analysis Plan ◯ Informed Consent Form ◯ Clinical Study Report ◯ Analytic Code ◯ Other (specify)

Available IPD/Information URL:

Available IPD/Information Identifier:

Available IPD/Information Comments: