THIS FORM IS A NON-INTERACTIVE PDF FOR PLANNING PURPOSES ONLY

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 09/30/2024

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☒ No **Note: Selecting Yes prompts filling in 1.3 Exemption Number**

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?	☒ Yes ☐ No
1.4.b. Are the participants prospectively assigned to an intervention?	☐ Yes ☐ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	☐ Yes ☐ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable (fillable field)

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

(fillable field, can add more than one condition; list the name(s) of the condition(s) you are studying or the focus of the study)

2.2. Eligibility Criteria

(fillable field: list the study's inclusion/exclusion criteria, see FOA and agency specific instructions)

2.3. Age Limits **Minimum Age** (fillable field) (pull down for years, months, etc) **Maximum Age** (fillable field) (pull down for years, months, etc)

2.3.a. Inclusion of Individuals Across the Lifespan		Add Attachment	Delete Attachment	View Attachment
2.4. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
2.5. Recruitment and Retention Plan		Add Attachment	Delete Attachment	View Attachment
2.6. Recruitment Status	(pull down options) not yet recruiting, recruiting, enrolling by invitation, active not recruiting, completed, suspended, terminated, withdrawn			
2.7. Study Timeline		Add Attachment	Delete Attachment	View Attachment

2.8. Enrollment of First Participant MM/DD/YYYY (pull down: anticipated, actual, blank)

2.9. Inclusion Enrollment Report(s) **Clicking the "Add Inclusion Enrollment Report" Button Opens the Next 3 Pages***

Add Inclusion Enrollment Report

OMB Number: 0925-0770
Expiration Date: 09/30/2024

Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Note: Inclusion Enrollment Report is required for all human subjects studies unless, on Question 1.3 "Exemption Number" you selected only 4 and no other exemptions. Entry is limited to 600 characters. There is a maximum of 20 IERs per Study Record.

2. * Using an Existing Dataset or Resource ☐ Yes ☐ No

3. * Enrollment Location Type ☐ Domestic ☐ Foreign

Participants at US and Non-US sites must be reported separately even if for the same study.

4. Enrollment Country(ies)

USA: UNITED STATES **(Pull down menu of countries, can add multiple with button on interactive PDF)**

5. Enrollment Location(s)

(fillable field: where participants will be enrolled (e.g. hospital, university, research center)

6. Comments **Maximum 500 characters**

Planned **Total is automatically calculated from numbers filled in for each category.**

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		**Total**
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual) **Totals are automatically calculated from numbers filled in for each category.**

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	Female	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects Add Attachment | Delete Attachment | View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

NOTE: UVM is not equipped to serve as the institutional lead for a multi-site IRB Clinical Trial; Requires hiring an outside company as a consultant on a study needing this capability.

Single IRB plan attachment Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan Add Attachment | Delete Attachment | View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No

3.5. Overall Structure of the Study Team Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

(fillable field)

4.1.b. Primary Purpose (pull down: treatment, prevention, diagnostics, supportive care, screening, health services research, basic science, device feasibility)

4.1.c. Interventions Note: can add additional interventions

Intervention Type	(pull down: drug (including placebo), device (including sham), biological/vaccine, procedure/surgery, radiation, behavioral (e.g. psychotherapy, lifestyle counseling), genetic (incl. gene transfer, stem cell and recombinant DNA), dietary supplement (e.g. vitamins, minerals)
Name	(fillable field, name of intervention)
Description	(fillable field, description)

4.1.d. Study Phase (pull down, Phases 0-5 including half-phases, e.g. 2/3)

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

4.1.e. Intervention Model (pull down: single group, parallel, cross-over, factorial, sequential, other)

4.1.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.1.g. Allocation {pull down: N/A, randomized, non-randomized)

4.2. Outcome Measures **Note: can add additional outcome measures**

Name	**(fillable field: enter the name of the individual outcome or measure)**
Type	**(pull down: primary, secondary, other)**
Time Frame	**(fillable field: indicate when a measure will be collected for analysis)**
Brief Description	**(fillable field: brief description of the measure)**

4.3. Statistical Design and Power Add Attachment | Delete Attachment | View Attachment

4.4. Subject Participation Duration **(fillable field: enter the time it will take for each individual participant to complete all study visits)**

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Add Attachment | Delete Attachment | View Attachment

4.6. Is this an applicable clinical trial under FDAAA? ☐ Yes ☐ No

4.7. Dissemination Plan Add Attachment | Delete Attachment | View Attachment

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Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments Add Attachments | Delete Attachments | View Attachments