Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

* Always Required field	Expir	ation Date: 02/28/202
Section 1 - Basic Information		
.1 * Study Title (each study title must be unique)		
.2 * Is this Study Exempt from Federal Regulations?		
.3 Exemption Number		
.4 *Clinical Trial Questionnaire		
If the answers to all four questions 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 effectiveness 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
.5 Provide the Clinical Trials.gov Identifier (eg. NCT87654321) for this trial, if applicable		
Section 2 - Study Population Characteristics		
2.2 Eligibility Criteria 2.3 Age Limits Minimum Age Maximim Age		
2.3.a. Inclusion of Individuals Across the Lifespan Add Attachment Delete Attachment	hment	View Attachment
2.4 Inclusion of Women and Minorities Add Attachment Delete Attachment	hment	View Attachment
.5 Recruitment and Retention Plan Add Attachment Delete Attachment	hment	View Attachment
.6. Recruitment Status		
.7. Study Timeline Add Attachment Delete Attac	hment	View Attachment
.8. Enrollment of First Participant		
.9. Inclusion Enrollment Report(s) Add Inclusion Enrollment Report		
Inclusion Enrollment Report		3 Number: 0925-XXX ation Date: 02/28/202
. * Inclusion Enrollment Report Title		
2. * Using an Existing Dataset or Resource		
2 * Enrollment Location Type		

Racial Categories	Not Hispanic	or Latino	Hispanic o	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)

					Ethnic	Categories				
Racial Categories	No	t Hispan	ic or Latino	His	spanic o	r Latino	Not F	Unkno	wn/ d 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

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 \square No □ N/A Single IRB plan attachment Add Attachment Delete Attachment View Attachment 3.3. Data and Safety Monitoring Plan Add Attachment **Delete Attachment** View Attachment

. Overall structure of the St	tudy Team			Add Attachment	t [Delete Attachment	View Attachment
ction 4 - Protocol Synop	sis						
. Study Design							
4.1.a. Detailed Description							
b. Primary Purpose							•
.c. Interventions							
χ Intervention Type						•	
Name							
Description							
Add New Intervention							
d. Study Phase						•	
ls this an NIH-	defined Phase III	clinical trial?	□Yes	□No			
Is this an NIH-	defined Phase III (clinical trial?	□Yes	□No			
	defined Phase III (clinical trial?	□Yes	□No		▼	
e. Intervention Model	defined Phase III d	clinical trial?	Yes	□No			
.e. Intervention Model				□ No	□ Out		
e. Intervention Model f. Masking	□Yes	□No			□ Out	▼	
e. Intervention Model f. Masking	□Yes	□No			□ Out	▼	
e. Intervention Model f. Masking l.g. Allocation	□Yes	□No			□ Out	comes Assessor	
e. Intervention Model f. Masking l.g. Allocation 2. Outcome Measures X Name	□Yes	□No			Out	comes Assessor	
e. Intervention Model f. Masking I.g. Allocation C. Outcome Measures X Name Type	□Yes	□No			Out	comes Assessor	
i.e. Intervention Model if. Masking i.g. Allocation c. Outcome Measures X Name Type Timeframe	□Yes	□No			Out	comes Assessor	
i.e. Intervention Model i.f. Masking i.g. Allocation 2. Outcome Measures X Name Type Timeframe Brief Description	□Yes	□No			Out	comes Assessor	
i.e. Intervention Model i.f. Masking i.g. Allocation c. Outcome Measures X Name Type Timeframe	□Yes	□No			Out	comes Assessor	
a.e. Intervention Model a.f. Masking a.g. Allocation b.c. Outcome Measures b.c. Name b.c. Type b.c. Timeframe b.c. Brief Description b.c. Add New Outcome	☐ Yes ☐ Participant	□No	der (comes Assessor	View Attachment
a.e. Intervention Model a.f. Masking a.g. Allocation b.c. Outcome Measures b.c. Name b.c. Type b.c. Timeframe b.c. Brief Description b.c. Add New Outcome	☐ Yes ☐ Participant	□No	der (□ Investigator		comes Assessor	View Attachment
.e. Intervention Model .f. Masking 1.g. Allocation 2. Outcome Measures X Name Type Timeframe Brief Description	☐ Yes ☐ Participant ☐ wer	□No	der (□ Investigator		comes Assessor	View Attachment
i.e. Intervention Model i.f. Masking i.g. Allocation c. Outcome Measures X Name Type Timeframe Brief Description Add New Outcome 3. Statistical Design and Po	☐ Yes ☐ Participant ☐ Partici	□ No □ Care Provid	der (☐ Investigator		comes Assessor	View Attachment
i.e. Intervention Model i.f. Masking i.g. Allocation i.g. Outcome Measures X Name Type Timeframe Brief Description Add New Outcome i. Statistical Design and Po	☐ Yes ☐ Participant ☐ Partici	□ No □ Care Provid	ler (Add Attachment		comes Assessor • • • • • • • • • • • • •	View Attachment
i.e. Intervention Model i.f. Masking i.g. Allocation c. Outcome Measures X Name Type Timeframe Brief Description Add New Outcome 3. Statistical Design and Po	☐ Yes☐ Participant☐ ☐ Participant☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	□ No □ Care Provid	ler (Add Attachment		comes Assessor • • • • • • • • • • • • •	View Attachment

4.7. Dissemination Plan			Add Attachment	Delete Attachment	View Attachment
ection 5 - Other Clinical Tria	I-related Attac	hments			
ection 5 - Other Clinical Tria	I-related Attac	hments			

SECTION 6 - Clinical Trial Milestone Plan 6.1. Study Primary O Anticipated O Actual **Completion Date** 6.2. Study Final Completion O Anticipated O Actual 6.3. Enrollment and randomization Enrollment of the O Anticipated O Actual first subject (Study Start Date) 25% of planned O Anticipated O Actual enrollment recruited by 50% of planned O Anticipated O Actual enrollment recruited by 75% of planned O Anticipated O Actual enrollment recruited by 100% of planned O Anticipated O Actual enrollment recruited by 6.4. Completion of primary O Anticipated O Actual endpoint data analyses 6.5. Reporting of results in O Anticipated O Actual ClinicalTrials.gov 6.6. Is this an applicable clinical trial under FDAAA? O Yes O No