Advance-CTR
Human Subjects and Clinical Trial Information Form

This form reflects the content that must be provided to NIH and Other PHS Agencies. Word Document "Comments" are interspersed throughout this document to provide clarity on terms or instructions related to specific questions. Please be sure to click the 🗨 symbol when it appears. For further clarity on any section, please reference the NIH G.500 instructions, where this section starts on page 54.

ALL projects (including non-human subjects projects) need to complete sections i.- iii. of the Advance-CTR Human Subjects and Clinical Trial Information Form.

i. Are Human Subjects Involved?.....Yes ○ No ◉

ii. Is the project Exempt from Federal Regulations?.....Yes ○ No ◉

If yes, list the Exemption number (1-5):..... [ ]

iii. If No to Human Subjects Involved:
Does the proposed research involve human specimens and/or data?..... Yes ◉ No ○

If yes, provide an explanation of why the application does not involve human subjects research, and then skip the rest of the form.

Enter up to 1500 characters

Skip the Rest of the Human Subjects and Clinical Trial Information Form and Study Record.

iv. If Yes to Human Subjects Involved:

Complete a Study Record for each proposed Human Subject Study.

Advance-CTR Study Record:
Human Subjects and Clinical Trial Information Form

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1.1 Study Title:

1.2 Is this study exempt from federal regulations?.....Yes ○ No ◉

1.3 If Yes- Exemption number?

1.4.a* Does this 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 ◉

***If the answers to 1.4.a-1.4.d are all yes- this study qualifies as a clinical trial**.

Is this study a clinical trial?.....Yes ○ No ◉

1.5 Provide the ClinicalTrials.gov Identifier if applicable:

ALL Human Subjects projects (including non-clinical trials) need to complete sections 2.1 to 2.8 and 3.1 to 3.2

2.1 Conditions or Focus of Study: Enter up to 1500 characters

2.2 Eligibility Criteria Enter up to 1500 characters

2.3 Age limits- minimum age: maximum age:

2.3.a Inclusion of individuals across the lifespan: Enter up to 5000 characters

2.4 Inclusion of women and minorities: Enter up to 5000 characters

2.5 Recruitment and Retention Plan Enter up to 5000 characters

2.6 Recruitment Status (Not yet recruiting, recruiting, enrolling by invitation, active but not recruiting, completed, suspended, terminated, withdrawn): Withdrawn

2.7 Study Timeline:

2.8 Enrollment of first subject (anticipated or actual) date:

3.1 Protection of human subjects: Enter up to 5000 characters

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 ( )

Sections 3.3 to 4.7 are for clinical trials only

3.3 Data safety monitoring plan: Enter up to 3000 characters

3.4 Will a data safety monitoring board be appointed for this study?.....Yes (●) No ( )

3.5 Overall structure of the study team? (optional) Enter up to 3000 characters

4.1 Study Design
4.1.a. Detailed Description Enter up to 32000 characters

Continue in next block on the next page if neccessary

Continued from previous page if necessary

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

4.1.c Interventions (For each intervention fill out the following; up to 50)

Intervention Type	Name	Description

Intervention Types: Drug (including placebo), Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic (including gene transfer, stem cell, and recombinant DNA), Dietary Supplement, Combination Product, Diagnostic Test, Other

4.1.d Study Phase: Early Phase 1 or 0

4.1.e Intervention model (single group, parallel, cross-over, factorial, sequential, other): Single Group

If Other, please specify:

4.1.f Masking: Yes ◯ No ◯

If yes mark all that apply: Participant..... ☐
Care Provider..... ☐
Investigator..... ☐
Outcomes Assessor... ☐

4.1.g Allocation..... Non-randomized

4.2 Outcome measures (for each please describe):

TYPE	NAME	TIME FRAME	BRIEF DESCRIPTION

Outcome Types: Primary, Secondary, Other

4.3 Statistical design and power Enter up to 3000 characters

4.4 Subject Participation Duration:

4.5 Will the study use an FDA-regulated intervention? Yes ◉ No ○

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status: Enter up to 5000 characters

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

4.7 Dissemination Plan Enter up to 5000 characters

Clinical Trial Milestone Plan

6.1 Study Primary Completion Date:.....

6.2 Study Final Completion Date:.....

6.3 Enrollment and randomization

25% of planned enrollment recruited by:....

50% of planned enrollment recruited by:....

75% of planned enrollment recruited by:....

100% of planned enrollment recruited by:..

6.4 Completion of primary endpoint data analyses

6.5 Reporting of results in ClinicalTrials.gov