**UAB CFAR HUMAN SUBJECTS STUDY RECORD**

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf> - starting at page 161

[Edit](https://public.era.nih.gov/assist/humanSubjectsClinicalTrials.era?function=editStudy&itemPath=/humanSubjectStudies%5b0%5d)

**Section 1: BASIC INFORMATION**

1.1. Study Title: Click here to enter text.

1.2. Is this Study Exempt from Federal Regulations? Yes No

1.3. Exemption Number  1 2 3 4 5 6

1.4. Clinical Trial Questionnaire: If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial—Contact Mary Thielen (Clinical trials aren’t allowed on CFAR grants!)

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

Click here to enter text.

**Section 2: STUDY POPULATION CHARACTERISTICS**

2.1 Conditions or Focus of Study (255 characters each—can add up to 20 conditions if needed)

Condition 1: Click here to enter text.

Condition 2: Click here to enter text.

2.2. Eligibility Criteria (15,000 characters max)

Click here to enter text.

2.3. Age Limits       Minimum Age       Maximum Age (Can select NA)

2.3.a Inclusion of Individuals Across the Lifespan

Include a separate Word Doc attachment addressing this. [See guidelines on page 165](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

2.4. Inclusion of Women and Minorities

Include a separate Word Doc attachment addressing this. [See guidelines on page 166](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

2.5. Recruitment and Retention Plan

If Section 1.4a above is yes, then this is required. Include a separate Word Doc attachment addressing this. [See guidelines on page 168](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

2.6. Recruitment Status:

If Section 1.4a above is yes, then this is required.

Not Yet Recruiting Active, not recruiting Terminated(Halted Prematurely)

Recruiting Completed Withdrawn(No participants enrolled)

Enrolling by invitation Suspended

2.7. Study Timeline

If Section 1.4a above is yes, then this is required. Include a separate Word Doc attachment addressing this. [See guidelines on page 169](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

2.8. Enrollment of First Participant:

      Date: MM/DD/YYYY Anticipated Actual

**Inclusion Enrollment Report(s): up to 20 reports can be added** [See guidelines on page 170](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

1. Title of Study: Click here to enter text.
2. Using an Existing Dataset or Resource: Yes No
3. Enrollment Location Type: Domestic Foreign
4. Enrollment Country(ies): Only if foreign above Click here to enter text.
5. Enrollment Location(s): (255 characters)

Click here to enter text.

1. Comments: (500 characters)

Click here to enter text.

1. Planned Enrollment Table: **If not using an existing dataset or resource (#1=no)** (If foreign site, then include separate table for domestic and foreign enrollment: don’t mix the two on the same inclusion report)

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

Cumulative (Actual): **If using an existing dataset or resource (#1=yes)**

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

**Section 3: PROTECTION AND MONITORING PLANS**

3.1. Protection of Human Subjects Include a separate Word Doc attachment addressing this. [See guidelines on page 175](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/multi-project-forms-h.pdf).

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

If yes, describe the single IRB plan: Include a separate Word Doc attachment addressing this.

3.3. Data and Safety Monitoring Plan​: (**OPTIONAL**): Include a separate Word Doc attachment addressing this.

3.4. Will a Data and Safety Monitoring Board be appointed for this study? (**OPTIONAL**) Yes No

3.5. Overall Structure of the Study Team​  ​(**OPTIONAL**)

**[Section 4 and Section 5 not required]**

**Section 6: CLINICAL TRIAL MILESTONE PLAN**

6.1. Study Primary Completion Date       Date: MM/DD/YYYY Anticipated Actual

6.2. Study Final Completion Date       Date: MM/DD/YYYY Anticipated Actual

6.3. Enrollment and randomization

Enrollment of the first participant (Study Start Date)       Date: MM/DD/YYYY Anticipated Actual

25% of planned enrollment recruited by       Date: MM/DD/YYYY Anticipated Actual

50% of planned enrollment recruited by       Date: MM/DD/YYYY Anticipated Actual

75% of planned enrollment recruited by       Date: MM/DD/YYYY Anticipated Actual

100% of planned enrollment recruited by       Date: MM/DD/YYYY Anticipated Actual

6.4. Completion of primary endpoint data analyses       Date: MM/DD/YYYY Anticipated Actual

6.5. Reporting of results in ClinicalTrials.gov       Date: MM/DD/YYYY Anticipated Actual

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