Site Specific Continuing review for affiliate sites relying upon the University of Chicago IRB.

**This form should only be used by Affiliate Sites where the University of Chicago PI is also the PI of the site, such as Advent Health and Ingalls.**

University of Chicago Protocol #: Click or tap here to enter text.

Protocol Title: Click or tap here to enter text.

Relying Site Name: Click or tap here to enter text.

1. **Study Status**
2. Enrollment Status at Site:

Enrollment Open

Enrollment Permanently Closed

Enrollment Temporarily Halted or Suspended

No direct subject interaction - Study approved only for collection of data/samples (ongoing)

No direct subject interaction – collection of data/samples complete

1. If applicable, please explain why enrollment is halted or suspended. Please attach any documentation regarding the halting or suspending of enrollment.

Click or tap here to enter text.

1. Current Study Status at Site:

Same as the University of Chicago ***OR*** Choose from an option below:

Research has not begun/no subjects have been enrolled and/or no records or data analyzed

Research related interventions/activities on-going

Long-term Follow-up only - (all subjects have completed all research related interventions/activities)

Chart review/specimen analysis on-going

Data Analysis Only (no further subject interaction and no further data collection)

Closed - Awaiting Closeout or Other (Answer only for Request for Continuing Review)

Closed - All study activities are completed and thus requesting protocol termination (Please note: If this is option is selected, the IRB will terminate approval for research at this site).

II.  **Number of Subjects**

1. What is the total number of subjects enrolled/studied at this site?

(total):

Please separate the total number by age range.

0-6 years Click or tap here to enter text.

7-17 years Click or tap here to enter text.

18+ years Click or tap here to enter text.

1. How many subjects were enrolled/studied at this site since the last review?

(total):

Please separate the total number by age range.

0-6 years Click or tap here to enter text.

7-17 years Click or tap here to enter text.

18+ years Click or tap here to enter text.

1. What is the total number of subjects taken through the consent process to date at this site? (This number should include screen failures and withdraws and anyone else who signed the consent form or otherwise agreed to participate)

(total):

Please separate the total number by age range.

0-6 years Click or tap here to enter text.

7-17 years Click or tap here to enter text.

18+ years Click or tap here to enter text.

1. Enrollment Summary: Please describe enrollment activities to date at this site as well as status of current subjects. Please be sure to include the following information, if applicable.

* Describe types of subject enrolled, especially vulnerable populations.
* If enrollment was permanently closed within the last approval period, include the date enrollment was closed.
* If the clinical research remains open only for long-term follow-up of subjects, describe the status of these subjects and the nature of the follow up. (Please clearly state if these long-term follow-up activities are standard of care or research related)

Click or tap here to enter text.

1. If the study enrolls children, have any minors who will continue their participation in the study reached the age of majority in the past year (continued participation includes additional interventions, interactions, study visits, identifiable data collection, continued data availability in a registry)

Click or tap here to enter text.

If yes, please provide a description of the process by which minors that have been consented for their continued participation. If subjects have not been consented justification for not doing so should be provided including clarification as to whether or not their participation in the study continues.

Click or tap here to enter text.

1. **Subject Withdrawals**
2. Number of subject initiated withdrawal(s) since last IRB review:

Click or tap here to enter text.

1. Please provide the reason(s) for the subject initiated withdrawal(s). (Please provide a description of any changes to the research protocol, informed consent process and/or consent document(s) that were necessary as a result of the withdrawal):

Click or tap here to enter text.

1. **Subject Complaints**
2. Number of subject complaints since last IRB review:

Click or tap here to enter text.

1. Please provide the reason for the subject complaint(s). (Please provide a description of each complaint and explain how each complaint was handled.)

Click or tap here to enter text.

**IV. Unanticipated Problems**

1. Have any Unanticipated problems been noted sine the last IRB approval?

Click or tap here to enter text.

1. If yes, please provide a summary of the unanticipated problem (s).

Click or tap here to enter text.

**V. Minor Protocol Deviations/Violations & Other Safety Concerns**

1. Minor Protocol Deviations/Violations: Please summarize any minor protocol deviations or violations that occurred in the past year at this site. If applicable, please describe any corrective action plans implemented or to be implemented to address these issues.

Click or tap here to enter text.

1. Other Reporting: Please summarize other problems, adverse events or safety concerns that occurred in the past year at this site.

Click or tap here to enter text.

**VI. Other Information**

1. If applicable, please provide any other information that would be helpful in the IRBs review of this continuing review. Please ensure to attach any additional documentation to the continuing review, as needed.

Click or tap here to enter text.

Inclusion of this form with the study continuing review certifies that the information contained within this form and submitted within the AURA IRB Continuing Review is complete and accurate.