

## AURA-IRB SmartForm Version 2 (studies created 11/2016 – 4/2018)

As part of any amendment submission, the protocol smart form is edited to reflect the amendment changes. Once the amendment form is complete, you are required to “Edit Modified Study” before submitting an amendment. After the AURA Upgrade on April 8, you will now be asked to answer questions that have been added to the SmartForm since the protocol was approved.

This document highlights the new questions that may be required (dependent upon the type of study) when you edit the SmartForm. Please remember to include all changes proposed in your amendment as well as any to provide responses to all required questions.

In the event that you attempt to submit an amendment without all required questions, you will receive a system error that you will notify you of the questions that require a response.

### 1. Funding Section (1.4) – New Question #1A (IF EXTERNALLY FUNDED/SUPPORTED) is checked!

#### 1.4 Funding Source

1. \* Funding source(s):

(Please check all that apply) ?

- Internally Funded
- Externally Funded/Supported

a. \* Check all external funding sources that apply:

- United States Federal government agency/department
- State or local government agency/department
- Private foundation
- Subcontract/subaward from another institution
- Pharmaceutical company
- Other funding source



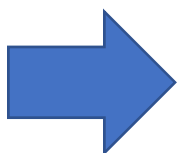
### 2. Funding Section (1.4) – New Question #2A (IF EXTERNAL AGENCY) is checked as study sponsor!

2. \* Who is the study sponsor?

- UChicago PI
- Other External Agency

[Clear](#)

a. \* If study is sponsored by an External Agency, please indicate the sponsor name :



### 3. 1.5 Study Locations – New questions if another site is requesting UChicago to be IRB of record

5. Is another site asking the UChicago to be the IRB of record?

[Go to forms menu](#)  Print  Help

Yes  No [Clear](#)


a. What site(s) are requesting that UChicago relies upon our IRB?

Full Name	External Key	Agency Abbreviation	Org Class
There are no items to display			

b. Please describe research activities being conducted at all sites. If the activities are the same as those conducted at the UChicago, please simply state that fact. If activities will differ, please specify how they will differ for each site.


c. Please attach request from other site(s) and/or describe existing authorization agreement between UChicago and the other site(s).

### 4. 3.1 Recruitment and Screening – New Question 1D

 d. \* Please confirm that the use of identifying information during screening is no more than minimal risk to the individuals' privacy.


Yes  No [Clear](#)

### 5. 3.11 Specimen Collection and/or Analysis – New Question 6

 6. \* Are there plans for, or could the research involve, whole genome sequencing (i.e., sequencing of a human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen)?

Yes  No [Clear](#)

### 6. 4.1 – Study Population – New Question 6 (effective 8/2022)

 6. \* In order to enroll this number of subjects, will you be screening 50 or more patient records?

Yes  No [Clear](#)

7. 5.2 Data Confidentiality and Privacy – New Questions 1, 3 and 4

5.2 Data Confidentiality and Privacy

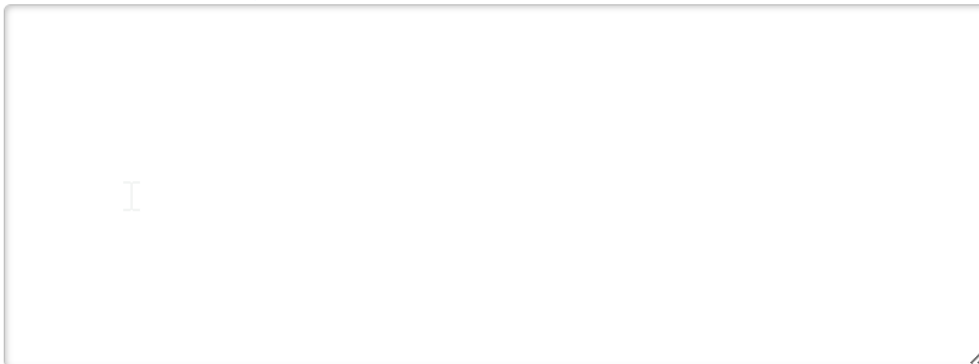
1. \* How will research data be collected and stored?

- Paper
- Electronic (see BSD Information Security Policy)
- Audio/Video recording
- Other

3. \* Will data be shared with other UChicago investigators or with investigators outside of UChicago?

- UChicago Investigators
- Investigators outside of UChicago
- Funder
- Sponsor
- N/A-data won't be shared

4. \* If you are aware of a data incident , what is your process for reporting the event to the IRB? What is the process for reporting to others, as applicable?



## 8. 6.3 Results – new view

1. Will clinically relevant research results, including individual research results, be disclosed to subjects?

Yes  No [Clear](#)

a. Please specify what information would be disclosed and under what conditions.

*Please ensure to describe this disclosure in the consent.*

2. If the study is NIH funded, please clarify which groups, including dbGap, would have access to the data resulting from this study. Please specify the conditions in which this data will be shared.

## 9. 7.3 HIPAA Authorization – New Question 1 and New Questions E and F

### 7.3 HIPAA Authorization

1. \* Please indicate how authorization for use/disclosure of PHI will be documented (check all that apply).

Authorization forms and/or consent/authorization forms should be uploaded in the following section.

- Signed HIPAA authorization (combined with consent form)
- Signed HIPAA authorization (separate from consent form)
- Request for waiver of HIPAA authorization
- Request for a Limited Data Set (Only dates and/or zip codes will be utilized)
- HIPAA does not apply - no PHI will be used or disclosed
- Does not apply - data will be sourced from an existing IRB approved research registry/database
- Does not apply - all data will be sourced from CRDW

e. \* Please provide written assurance that you will not re-use Protected Health Information. For example, please state the following: "I will not re-use PHI collected or used during the study for other purposes."

f. \* Please confirm that the use of identifying information is no more than minimal risk to the individuals' privacy.

- Yes, confirm
- No, cannot confirm

[Clear](#)