AURA-IRB SmartForm Version 1 (shows as SmartForm Version *blank*)

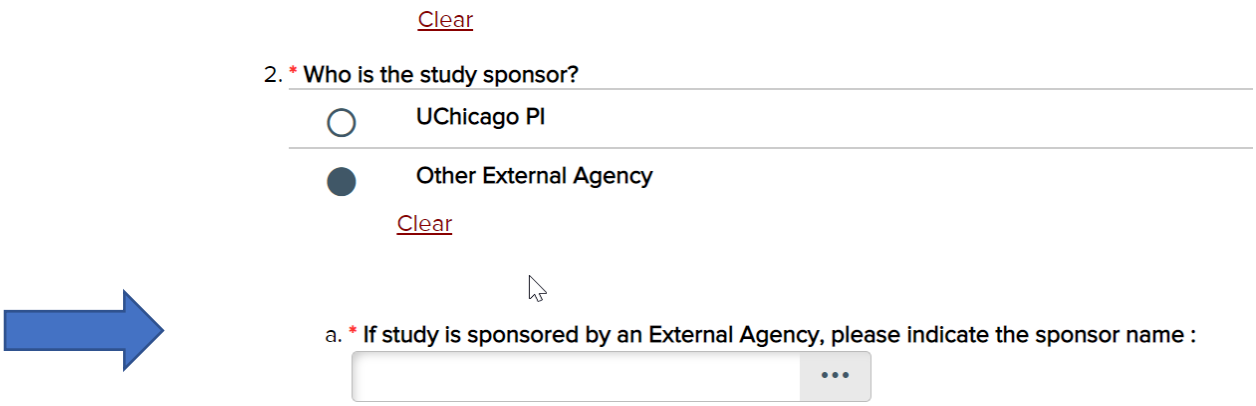
As part of any amendment submission, the protocol smart form is edited to reflect the amendment changes. Once the amendment form is complete, you are required to "Edit Modified Study" before submitting an amendment. After the AURA Upgrade on April 8, you will now be asked to answer questions that have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

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



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

Go to forms menu | Print | Help

5. Is another site asking the UChicago to be the IRB of record?
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 Questions 2, 6, 8 and 10

3.11 Specimen Collection and/or Analysis

1. * What type of specimens will be involved in this study? (Check all that apply)
   - [ ] Existing (already sitting on the shelf at the time of initial IRB submission)
   - [x] Prospective (will be collected)

   a. What type of specimens will be prospectively collected? (check all that apply)
   - [x] Leftover specimens that were obtained for clinical purposes (no additional research procedures required)
   - [x] Specimens obtained specifically for research purposes-additional taken during a clinical procedure
   - [x] Specimens obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study
   - [ ] Commercial (for profit) specimens

2. * What type of specimens will be analyzed? (Check all that apply)
   - [ ] Blood
   - [ ] Tissue
   - [ ] Bone Marrow
   - [ ] Cells from Swabs
   - [ ] Urine
   - [ ] Other

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

7. * Will this study involve banking of specimens (storing for future research use)?
   - ○ Yes ● No Clear

8. * With whom will you share specimens? (Check all that apply) Note, if specimens will be shared outside UChicago, a contract, grant, or material transfer agreement (MTA) should be place outlining sharing of specimens.
   - [ ] Other UChicago Investigators
   - [ ] Investigators outside of UChicago
   - [ ] Sponsor
   - [ ] NIH
   - [ ] N/A - no specimens will ever be shared

10. What will happen to specimens at the end of the study? If specimens will not be destroyed, where and how will they be stored? What will happen to identifiers associated with those specimens (i.e. will samples be de-identified and links to identifiers removed)?

6. 3.12 – Data Collection - New Question 2

2. * **What is the source(s) of the data that will be collected and/or used during the study (as opposed to during screening or for feasibility)?**

- ☐ **UCM Medical records (Manual viewing/abstraction)**
- ☐ **Ingalls Medical records (manual viewing/abstraction)**
- ☐ **EPIC Downloads (i.e. Slicer Dicer, Reporting Workbench, etc.)**
- ☐ **Medical images**
- ☐ **CRI (Clinical Research Data Warehouse)**
- ☐ **Commercial (for profit) entity**
- ☐ **Data collected under a different research study**
- ☐ **Publically available records**
- ☐ **From subject self-report**
- ☐ **Federal dataset, e.g. dbGap, Framingham dataset, etc.**
- ☐ **Other**

7. 3.13 – Costs and Compensation – New Question 1

3.13 Costs and Compensation

1. * Does this study involve clinical care expenses that are either billed to the patient, their insurance, or to research?

○ Yes ○ No Clear

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

4.1 Study Population

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

○ Yes ○ No Clear

9. 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?

10. 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.**

11. 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