

AURA-IRB SmartForm Version 3 (studies created on or after 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. 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](#)



2. 7.3 HIPAA Authorization – New Questions e and f

- 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](#)