

**Amendment smart form:**

- Are all questions in the amendment form completed and accurate, including all checkboxes in view 1.2?
- Have changes been summarized rather than listed line by line in question 2 in view 1.2?
- Have re-consenting procedures (if applicable) been described or an appropriate explanation provided as to why re-consent is not needed? (view 1.3)
- Are changes reflected in a revised protocol document, as needed?
- Have ALL corresponding changes been made to the Modified Study smart form?
- Have ALL changes to the Modified Study smart form been described in the amendment form?

**Type of change:**

Yes No N/A

**PI Change**

- View 1.1/1.0 updated
- All other views where PI name is mentioned have been updated, as applicable
- Consent form(s), advertisement(s), protocol updated, as applicable
- Memo from new PI uploaded

**Funding**

- View 1.4.1/1.4 updated in AURA with FP # in correct question (primary vs second funding)

**IRB of Record**

- If adding a new request, all documents have been uploaded in view 2.2
- If adding personnel from an outside site, training certificate(s) were uploaded

**Adding/Revised advertisement(s)**

- If adding new ads, description of where/how ads will be posted provided in 8.1/3.1
- Revised document(s) uploaded in AURA view 8.1/3.1
- Ads reviewed for lay language, no emphasis on compensation, etc.

**Adding/revised IB**

- Documents(s) uploaded in view 4.1/3.4
- Any change in risk is also described in amendment form and in view 10.1/5.1

**Adding/ Revised surveys/questionnaire(s)**

- Revised document(s) uploaded in AURA view 5.1/3.7
- Changes to surveys were reviewed for pertinence to study, lay language, reporting obligations, etc.

**Increase number of subjects**

- 7.1/4.1 updated
- Consent form and protocol updated, if applicable

**Non-English speakers**

- Consent process for Non-English speaker(s) described? (if amend is for 1 subject (confirm it will only be used for one subject), can be described in amend form. If not, add to 16.2/7.1)

**Adding/removing risks**

- View 10.1/5.1 updated
- Has been the consent form been modified? (*if there is no consent form, consult Director*)
- Re-consent of existing subjects described

**Requesting Additional Collection or Sharing of Data/Samples**

- Will consent be obtained or has consent been obtained?
- If not, has justification for a waiver of consent been provided?
- If identifiable info will be shared, has IRB approval from outside site been submitted?

**Revising consent form**

- Two copies uploaded (1 clean, 1 changes marked) and all changes highlighted? (spot check)
- Are the requested changes appropriate?

**Revising consent process**

- If requesting a change in the process, documented in AURA view 16.1 and 16.2 /7.1,7.2
- If requesting a waiver of consent for a retrospective portion or additional dates for a waiver, has a waiver of consent been noted on amendment submission form and justified in 16.4/7.1?
- If adding a new population, appropriate portions of form completed (e.g. request for assent/assent waiver)
- If requesting oral consent, has this been noted and oral consent script been uploaded?

**Revised protocol document**

- Have the protocol changes been described in the amendment form?
- Revised protocol uploaded in 17.1/8.1 and description of changes or tracked version provided

**IRB requested changes (e.g. CR)**

- Have changes requested by the IRB been incorporated (e.g. the consent form contains all changes)?

**Other Change (describe)**

**COMMENTS:**