Common IRB amendment pre-review comments and how to respond

Common issue: ***The amendment is returned indicating not all changes in the amendment are discussed in the amendment summary.***

The amendment summary is the first snapshot of the amendment the IRB reviewers and staff will view. It is a component of the amendment that the IRB relies on heavily. The amendment summary can be found in **View 1.2 question 3** of the amendment submission form in AURA.

Please note that when IRB reviewers consider an amendment (or when an approved amendment is accessed at a future time), the summary is generally the starting point. It presents a snapshot of the amendment and its impact on the whole study.

Common issue: ***The amendment is returned indicating the changes described in the amendment form are not reflected in the modified AURA SmartForm.***

Amendments in AURA have two components.

- One component is the AURA amendment submission form where questions about the specifics of the amendment are listed (**View 1.1** through **View 1.4**).
- The other component is the main AURA SmartForm that should be modified to reflect the amendment changes. **Views 1.0 through 8.1** include detailed information for the ongoing approved study, together with all documents (consent forms, protocol, surveys, etc.) The AURA form is updated by clicking "Edit Smartform" on the left side of the amendment page.

Common issue: ***The amendment is returned indicating too much material or too little information is listed in the amendment summary.***

The amendment summary should be a **summary of the proposed changes**:

- Avoid providing too little information (for example, a brief list of items without explanation of purpose and how they impact the study). This will likely prompt further questions by the IRB, especially if certain items appear too vague or veiled.
- Avoid providing too much information (for example, a comprehensive list of revisions to all sections of a multi-site protocol with references to specific sub-sections of the protocol and minor changes). Please do not copy-paste the detailed, bulleted, section-specific list of changes section from a revised protocol or Investigator's Brochure.

Common issue: ***The amendment is returned noting the study team did not respond to all pre-review items or all reviewer comments.***

When responding to amendment comments, please address each item and/or provide a memo or explanation in the amendment summary about why any items were not addressed. For auditing purposes, the IRB needs to be able to demonstrate how each item was addressed.

Common issue: ***The amendment is returned requesting clarification on the connection between new funding being added, and the context and contents of the current protocol.***

For amendments that involve addition of funding source(s), please include within the amendment summary a statement on *HOW* the research described in the funding source being added is within the scope of work for the current study. We recommend including the title and source of the grant in the amendment summary.

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Common issue: ***The amendment is returned requesting clarification on the source of changes.***

If an amendment is being submitted to address **stipulations** issued during IRB review, or an amendment is being submitted in connection with comments received during a recent **Continuing Review** for a protocol, please include brief discussion on this in the amendment submission form, and especially the amendment summary.

If an amendment is introducing changes in risks without the submission of an accompanying revised protocol or Investigator's Brochure (IB), IRB staff will request the study team to clarify the source of these risk changes. Please provide adequate information in the amendment summary regarding the source of these risk changes.

Example: The study team is making corrections to the study risks in the consent form that are already included in the most recent protocol or IB.

Common issue: ***The study team is asking for a stamped consent form when the study is closed to enrollment.***

If the study is closed to enrollment and the study team requests to have any consent form(s) remain "active" or "stamped," please include the rationale for this request in the amendment summary.

Common issue: ***The study team notes they do not have stamped (or active) consent forms anymore, or the updated consent form was not stamped with the amendment approval.***

Please pay close attention to the question regarding study enrollment (**View 1.2 question 4**) in the amendment form, "**Is the study open to enrollment?**".

- Please note that a "No" response under **View 1.2 question 4** will prompt the IRB administrator to remove all stamped material for the study, as this option indicates the study is permanently closed to accrual.
- For studies that are temporarily halted, or are awaiting site re-activation, please select "Yes" and provide discussion on this in the amendment summary.

In **View 1.2 question 1**, please ensure all applicable boxes are checked and harmonized with changes being made in the amendment. Please note, if revised consent form(s) are being submitted with the amendment, and "Change in Consent Form" is not checked, the updated forms approved with the amendment may not be stamped.

Common issue: ***The amendment is returned inquiring about translated documents.***

For amendments requesting to add Non-English speaking participants, please provide translated versions of all subject-facing materials (such as recruitment documents, surveys, and consent documents). The IRB Policies and Procedures Manual and the IRB FAQ webpage (https://biologicalsciences.uchicago.edu/irb/irb-faqs-and-guidance) also have additional guidance on including the Non-English speaking subject population in a study .

For amendments requesting to add a Short form consent, please provide a brief comment in the amendment summary regarding how any surveys or other subject-facing materials will be presented to the new subject.

Common IRB amendment pre-review comments and how to respond

Common issue: ***The amendment is returned inquiring about why there are no revisions to the consent form.***

When submitting a new Investigator's Brochure (IB) for a study without any accompanying changes to the consent form, please respond to appropriate sections in the amendment submission form on why no changes are being made to the consent form.

Common issue: ***The amendment is returned inquiring about dates for retrospective chart reviews and waiver of consent/authorization.***

For retrospective chart/specimen review protocols initially approved with a waiver of consent/authorization, when requesting an extension to the date range, please consider the following and address in a memo and in the amendment summary:

- Why could the study not be done (or completed) with the originally proposed dates?
- As the initial waiver of consent/authorization approved for the study applies only to the data in the original date range, not to the revised date range, please provide an updated justification request for a waiver.
- Generally, all subsequent requests to move dates forward should indicate either 1) consent will be obtained from participants, or 2) fully de-identified data will be provided by the Center for Research Informatics (CRI) to the study team.

Common issue: ***The study team is asking why there has been no action on an amendment.***

When preparing an amendment, please ensure the amendment is endorsed by the PI to be considered "submitted." After submission, the status of the submitted amendment in AURA should be "**Pre-review**" or "**IRB Assignment**."

The states "**Pending PI Endorsement**" and "**Changes Requested by IRB Administrator**" mean that the amendment has not been submitted or submitted back to the IRB. The current state can be located in the dark blue box in the upper left corner of the submission screen.

After initial submission of an amendment, when resubmitting an amendment back to the IRB, any study team member can make the resubmission and re-endorsement by the PI is not needed. However, the PI should re-endorse the amendment if responding to a deferral motion after IRB Committee review.

Common issue: ***An amendment to add a relying site includes other non-reliance changes.***

The IRB has asked that reliance amendments only include changes directly related to the addition of relying site(s). Other changes should be removed and submitted with a separate amendment. For additional guidance regarding reliance, please see the reliance materials on the IRB website at **https://biologicalsciences.uchicago.edu/irb/irb-reliance**

Common issue: ***The study team is asking to add or remove study team members, but the change is not fully documented in AURA.***

IRB personnel amendments and non-personnel change amendments are two separate types of amendments that can be submitted and reviewed concurrently in AURA. Personnel changes to add or remove study team members cannot be made via a non-personnel change amendment, unless it is the study PI that needs to be changed.

Common IRB amendment pre-review comments and how to respond

The IRB recommends ensuring personnel listed in study consent forms and study protocols are harmonized with the current and up-to-date list of co-investigators in the AURA SmartForm.

If study personnel are removed with a personnel change, consider whether the consent form requires updating, for example, to remove external relationship information that is no longer relevant. Similarly, if personnel are added, consider whether the consent form requires updating with an amendment. A separate amendment (non-personnel change amendment) may be needed.

Common issue: ***The study team is asking to change the PI, but the change is not fully documented in AURA.***

PI change amendments should be submitted as an amendment (not a personnel change amendment). In this amendment:

- PI change amendments should also include a memo from the incoming PI confirming they agree to take over study responsibilities.
- The new PI should be identified in the modified AURA SmartForm **View 1.0 question 3** and under any other views where the PI is named.
- Please also consider whether the consent form and/or protocol document require updating, with the name and contact information of the new study PI.
- Please consider whether the new PI has an external relationship that may require disclosure in the consent form.