CLICK SAFETY AMEND SUBMISSION

Instructions for amending (modifying) an approved submission (creating a 'Follow-On Submission').

From the APPROVED submission workspace, click Create Amendment/CR button on the left column.

Note: An APPROVED submission can have only one outstanding amendment at a time.
Select the Type of Submission:

- Amendment (Amend current safety protocol)
- Amendment/CR (Amend and submit Annual Continuing Review document)
- Continuing Review (Annual Continuing Review)

Select Amendment Type: check both boxes.

Creating New: Safety Submission

Amendment / Continuing Review

1. *Type of Submission:*
   - Amendment/CR
   - Continuing Review

To change the FI, select "Other parts of the protocol." When changing team members, select both amendment types. If team members must be added or removed as handlers of materials.

2. *Amendment type:*
   - Protocol item member information
   - Other parts of the protocol

Note: select both checkboxes to open the entire submission up for modification (ability to edit all Smart Form pages). If only one checkbox is marked, this will only allow for a subset of the Smart Form pages to be edited and displayed.

Select Amendment Introduction from the Navigation Panel, enter a description of the changes and rationale.

Note: A system-generated unique identifier is assigned to the Amendment

When edits are completed within the various Smart Form pages, click EXIT to display the Amendment workspace again.

Click SUBMIT to submit this amendment to the Safety Office to be reviewed.
Note: The system allows only the Principal Investigator or PI Proxy to submit the Amendment to the Safety Office. When the amendment is approved, the changes are published into the approved (parent) submission.