

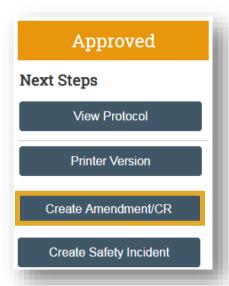
Create and Submit a Follow-On Submission

If you need to make changes to an approved protocol or review it, you can create the following submissions:

- Amendment: Created to submit a change to an approved protocol. Users can submit multiple
 amendments for review at any given time, including protocol team member changes, providing there is
 no existing open amendment of the same type. Minor changes, such as the addition or removal of
 personnel, do not require full committee review. Changes in material and scope will be reviewed by full
 committee.
- Continuing Review (CR): Created to request renewal of the approval period for 3 years.
- Amendment/CR: Created to request changes to an approved protocol and extension of the approval period in a single submission. Amendment/CR can only be submitted if there is no existing open CR and / or an existing amendment of the same type. The submission follows the same review process as the original protocol submission.

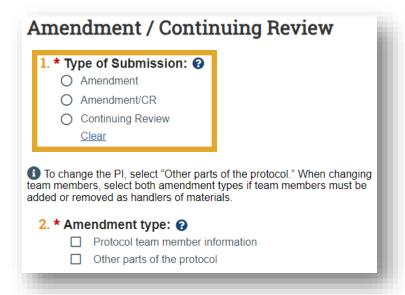
To create an amendment/continuing review submission

- 1. From the Top Navigator, click **Safety.**
- 2. On the **Active** tab, select the name of the approved protocol.
- 3. On the left of the workspace, click the **Create Amendment/CR** button.



- 4. Select whether the submission is an Amendment, CR, or a combination of both.
- 5. If your submission is an Amendment or Amendment /CR, select an appropriate amendment type.





- 6. Complete the SmartForms associated with the selected submission type. Click **Continue** to move to the next page.
- 7. When done, save changes and click **Exit** or click **Finish** on the final page. The submission workspace appears.

Tips:

- You can continue to edit the submission until you submit it for review.
- You can convert a follow-on submission to another submission type before it is approved. See Convert an Amendment or CR.

Submit a Follow-on Submission

- 1. Read the statement and select the check box at the bottom in agreement.
- 2. Click **OK** to submit the protocol.

