Amendment SmartForm changes – December 2023

The format of the Amendment (AME) SmartForm has been revised with new questions and sections. Additionally, a feature called View Differences will be implemented that allows research teams and IRB reviewers to easily identify what changes have been made to the SmartForm. These changes will remove the need for research teams to list each change being made to the PRO SmartForm and simplify the description of the impact of the changes being introduced with the Amendment.

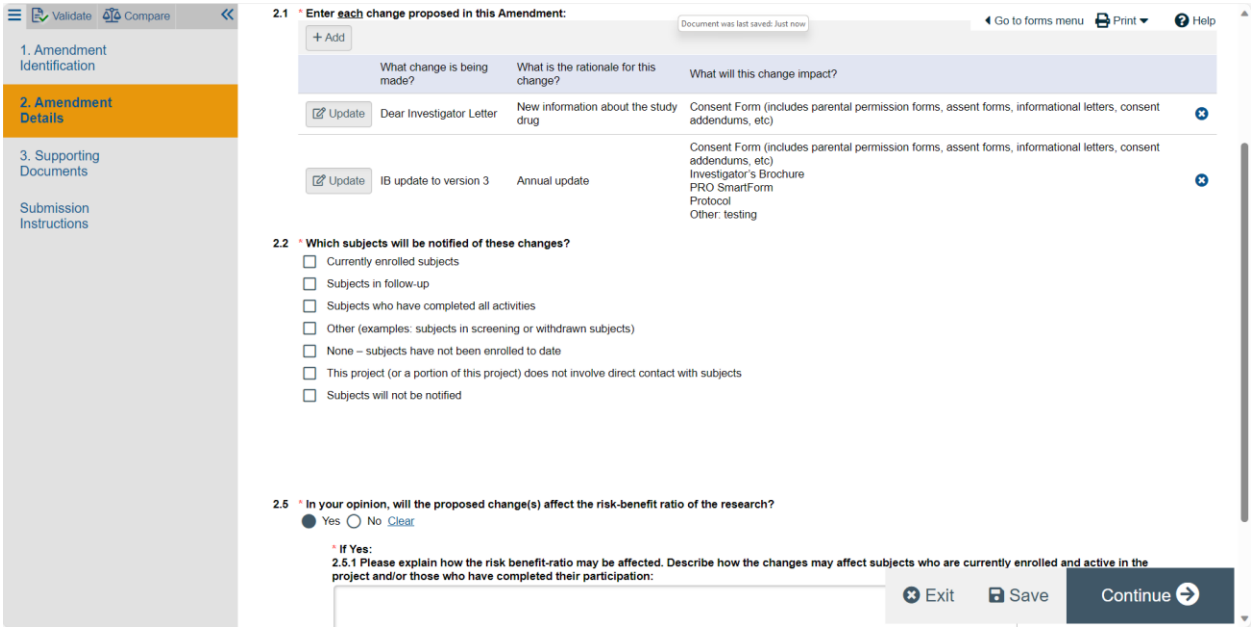
These changes to the layout and functionality of the Amendment SmartForm are being implemented on 12/16/23. These changes will be automatically applied to every Amendment that is open and not yet submitted for review. These changes will cause the loss of some information in certain sections of the Amendment SmartForm. Please either submit the Amendment, withdraw the Amendment, or save a pdf copy of the Amendment SmartForm before 12/16/23.

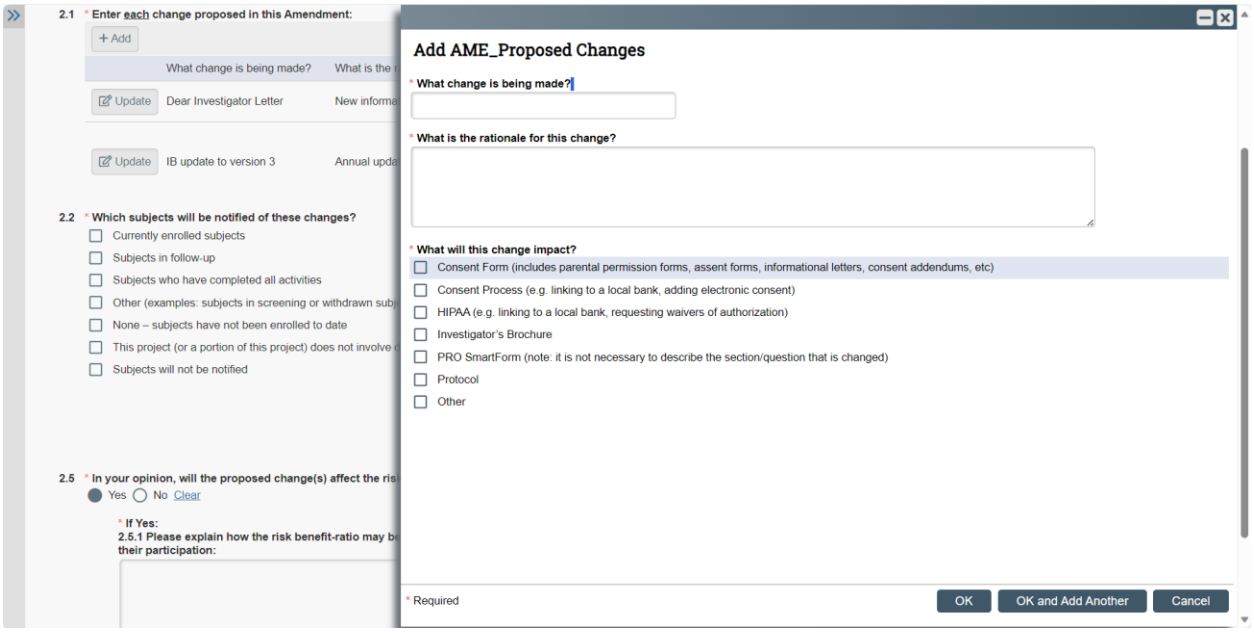
If you have questions or need assistance completing the AME SmartForm, please contact the IRB Coordinator for your project.

Changes to the AME SmartForm

A new question was added, "1.3 **Who initiated this Amendment:"** to differentiate between Investigator-Initiated and Sponsor-Initiated amendments and a new sub-question was added to indicate when the amendment was received.

Section 2 was reformatted to combine several existing sections and uses a table to identify the changes being made and the processes and documents that the changes affect.



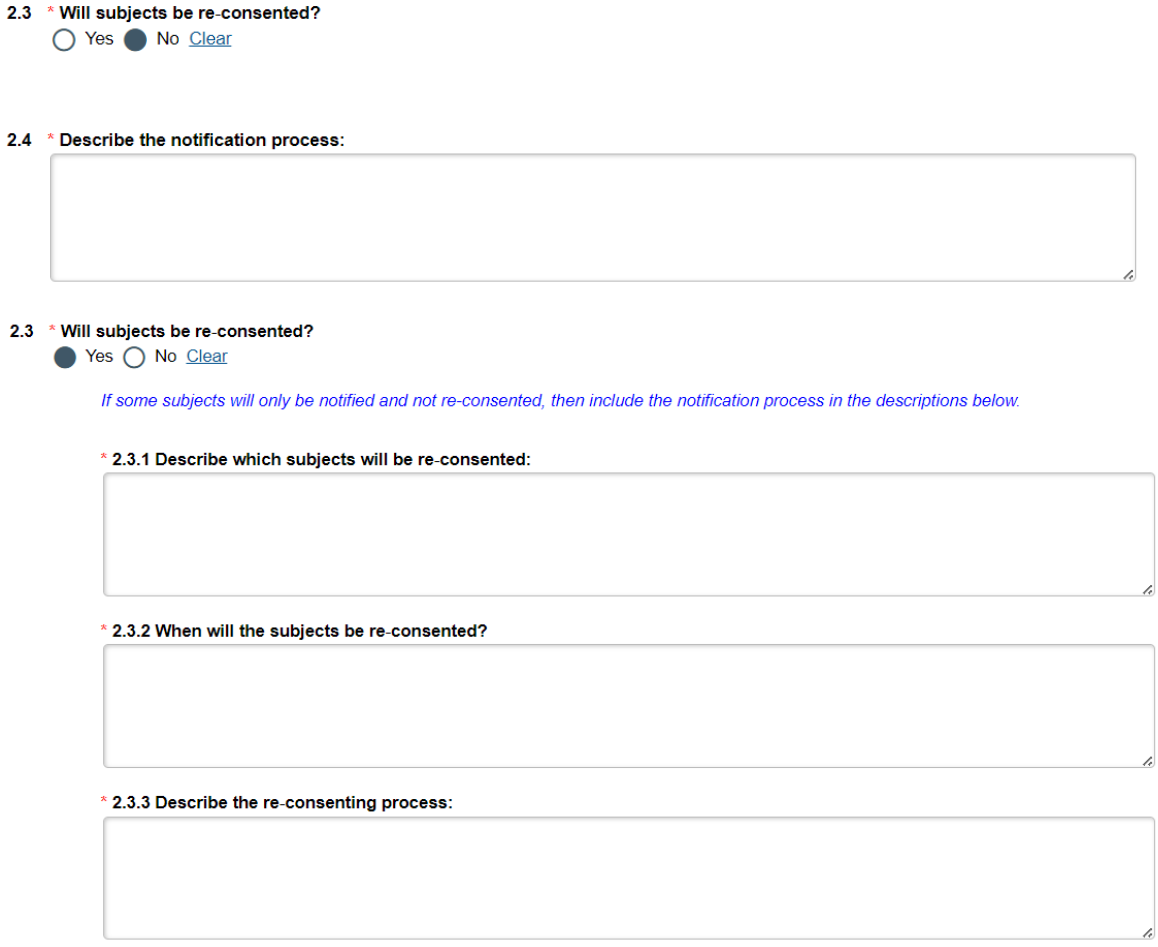


Question 2.2 was added to differentiate between notifying subjects and re-consenting subjects. It also provides flexibility for different research project designs and stages. Subsequent questions will display based upon the selections.

2.2 * Which subjects will be notified of these changes?

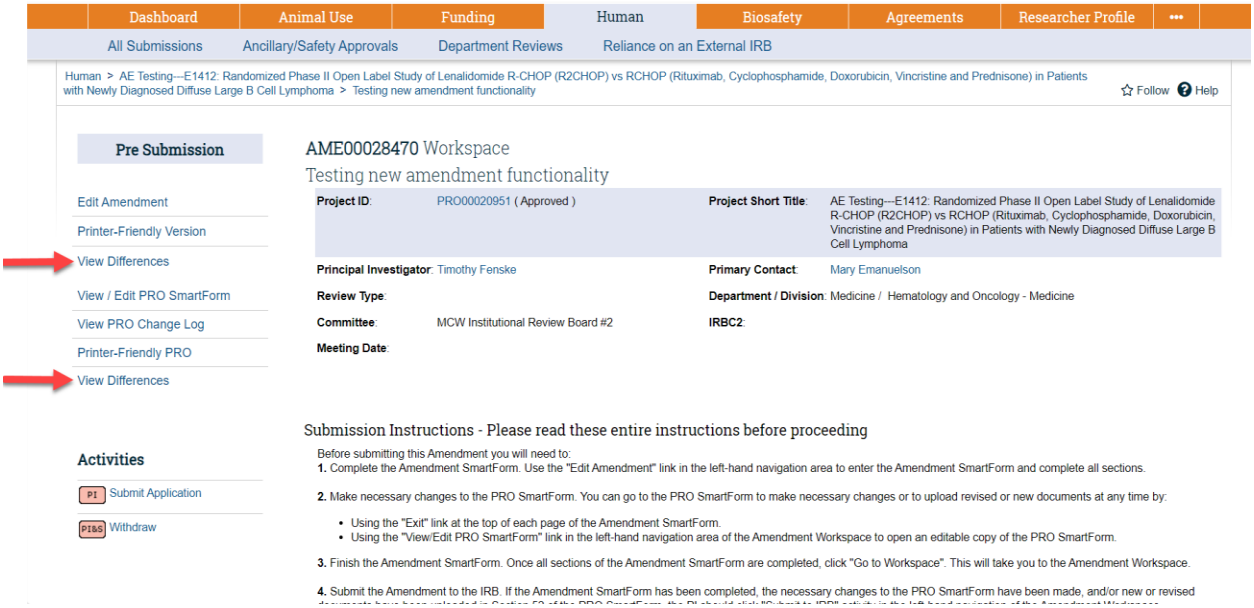
- ☐ Currently enrolled subjects
- ☐ Subjects in follow-up
- ☐ Subjects who have completed all activities
- ☐ Other (examples: subjects in screening or withdrawn subjects)
- ☐ None – subjects have not been enrolled to date
- ☐ This project (or a portion of this project) does not involve direct contact with subjects
- ☐ Subjects will not be notified

Question 2.3 was added to identify if subjects will be re-consented.

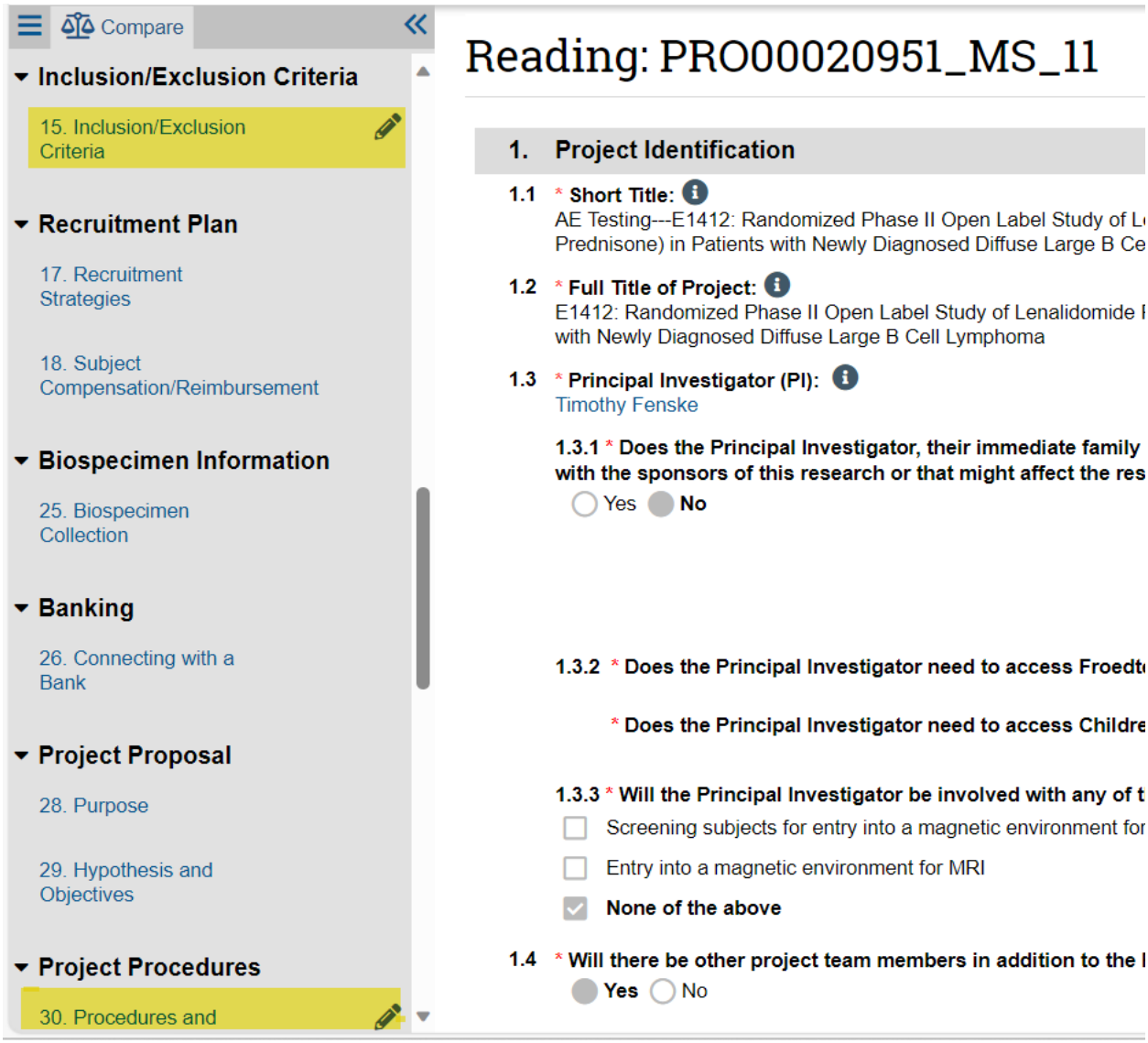


Section 3, The directions in this section have been changed to reflect that documents that were revised or new documents being added no longer need to be identified in this section. New and revised documents should be added in Section 52.1.2 of the PRO SmartForm.

View differences will show changes made to the AME SmartForm and the PRO SmartForm. These changes can be viewed by selecting, “View Differences” in the AME Workspace.



The sections with the pencil icon in the left navigation pane will indicate which sections have been changed.



Newly added information will be highlighted in green and deleted information will be highlighted in red.