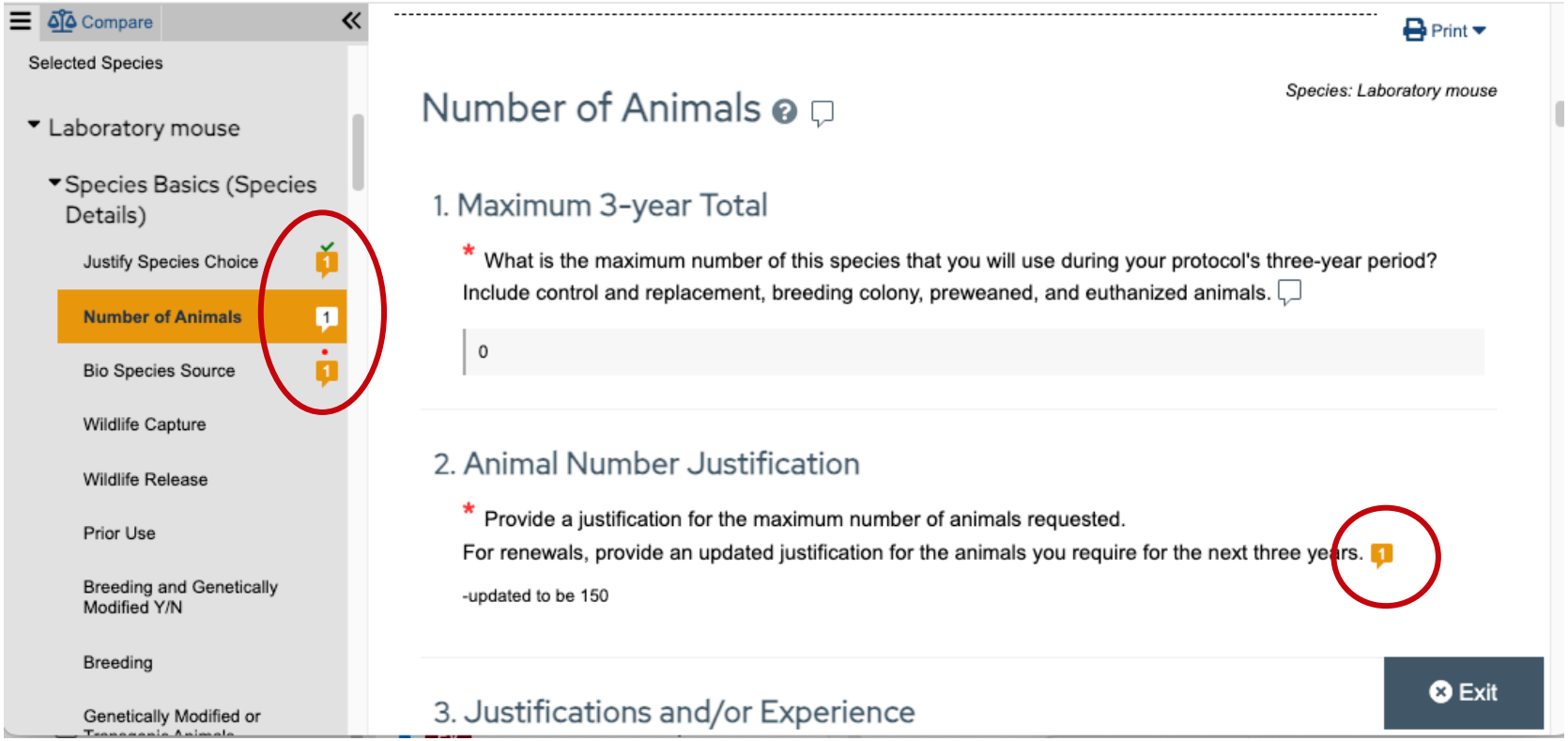
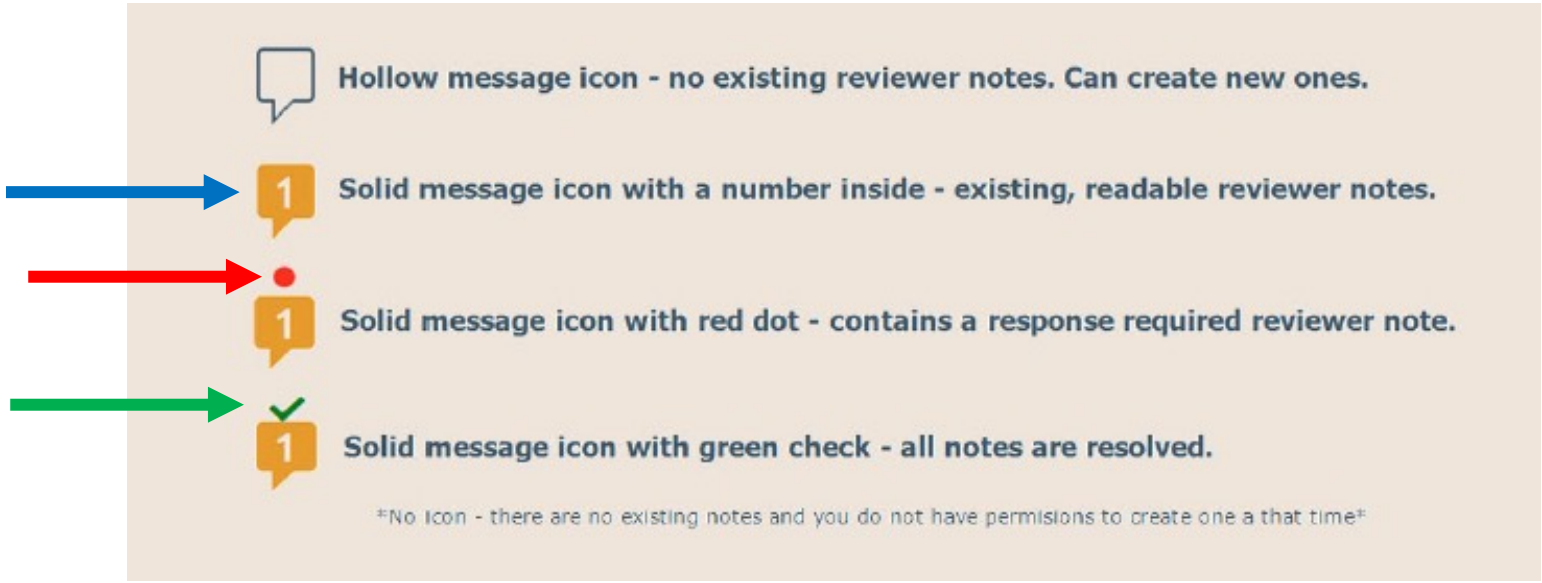
Reviewer Notes

Reviewer notes are now represented by clickable chat bubbles both on the navigation menu and the application pages.



The color of the bubble as well as other features tell you

1. How many notes on page
2. Whether there is a required response
3. If you have effectively addressed the note



Editing: 2024-0024

Print

Drug and Device Documents 1

Reviewer notes can be page level notes

1. Drug or Biological Product Documentation

1. For investigational (i.e., unapproved) drugs or biological products, upload the Investigator's Brochure(s).
2. If an IB is unavailable, upload a summary document detailing the agent's pharmacological and toxicological effects, safety and effectiveness in humans, and potential risks and side effects, if any.
3. For approved drugs or biological products, upload the most recent version of the package insert(s).

If drugs or biological products will be used in this study, upload any documents that apply (reference the above list for descriptions of applicable document types). 1

OR question level notes

+ Add

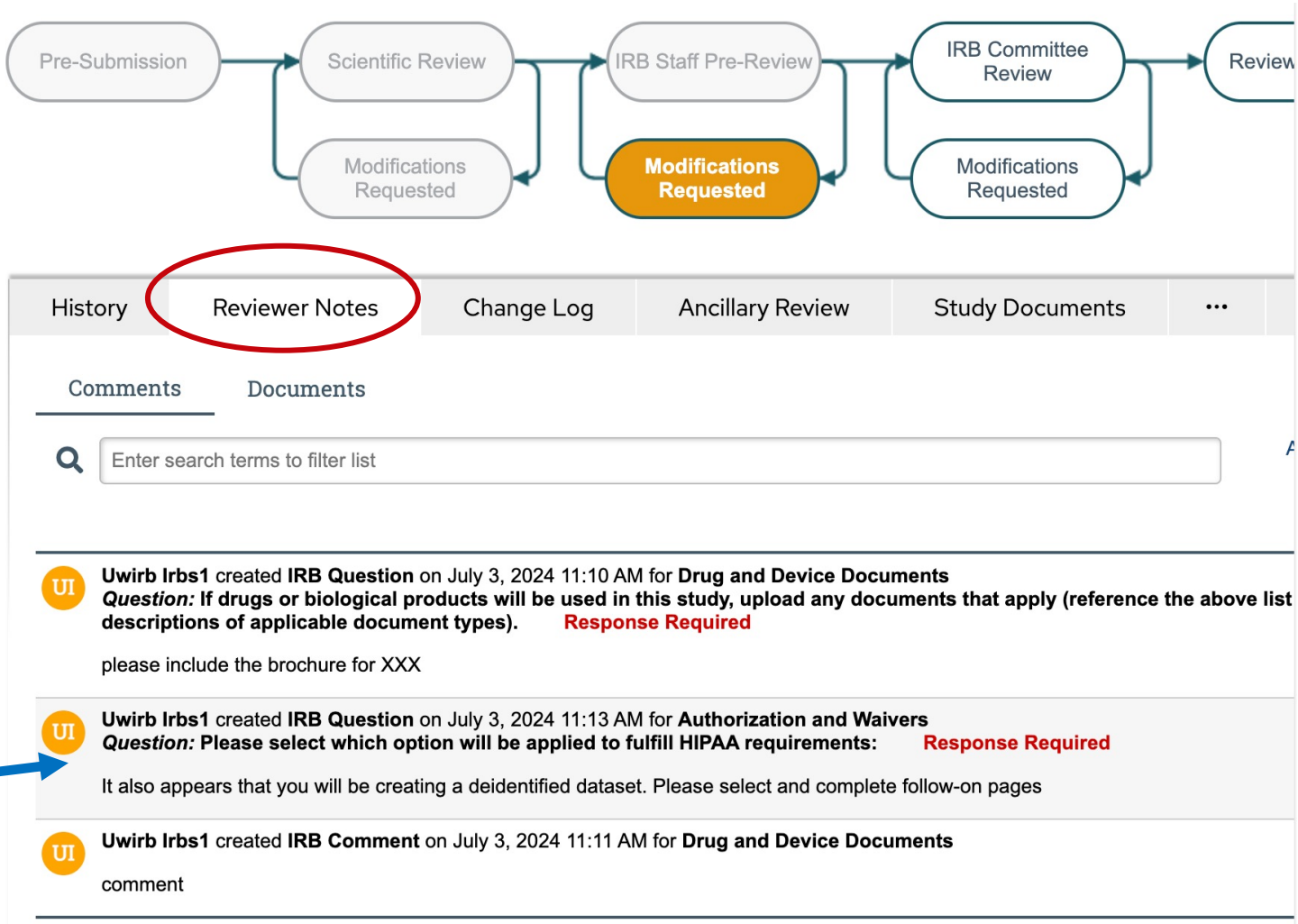
There are no items to display

The easiest way to see all the notes is to click on **Reviewer Notes** tab in the study workspace.

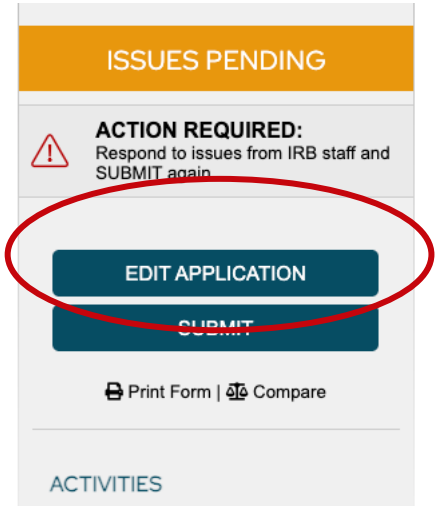
All reviewer notes are listed.

Clicking on the "Question" takes you to that page.

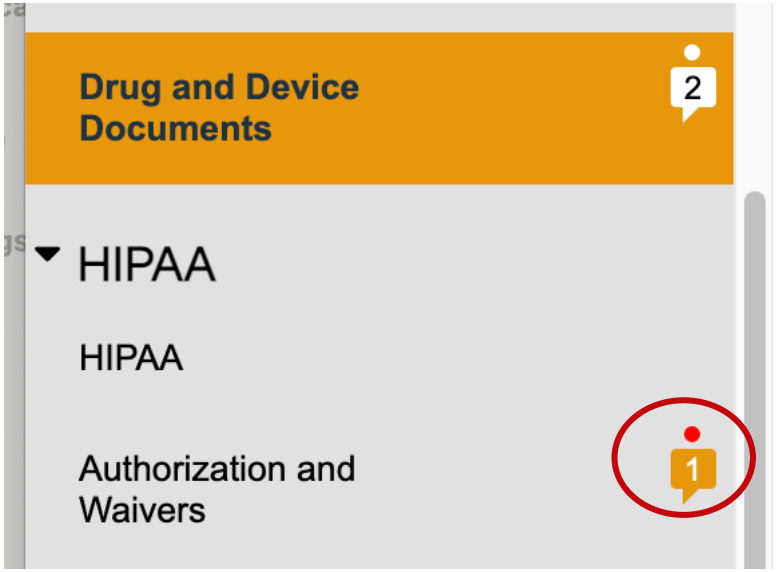
You must respond to the note in the application itself.



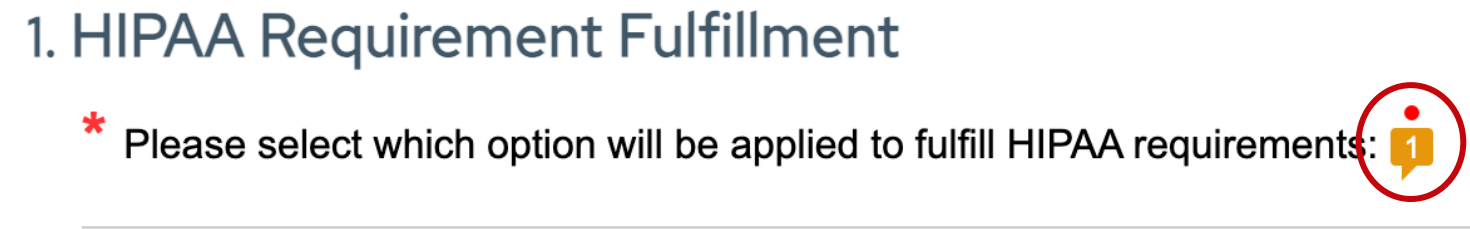
Alternatively, you can begin to Edit the application



And then use the navigation menu to identify pages with notes that require a response

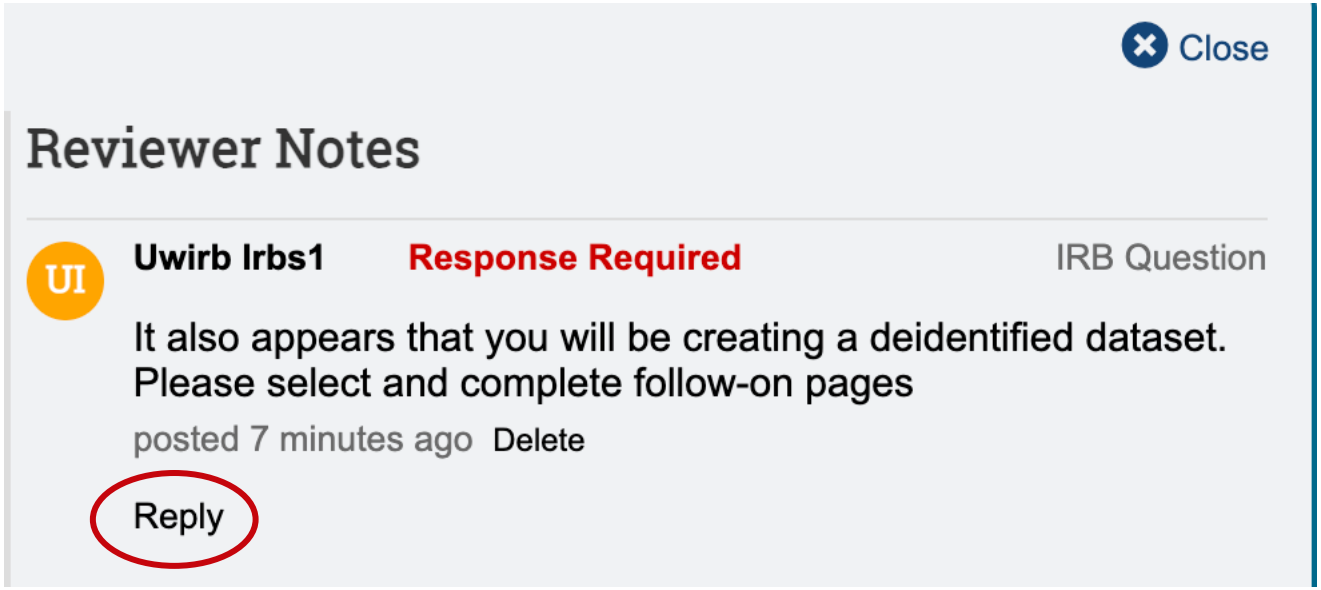


To respond to a reviewer's note, click on the note bubble



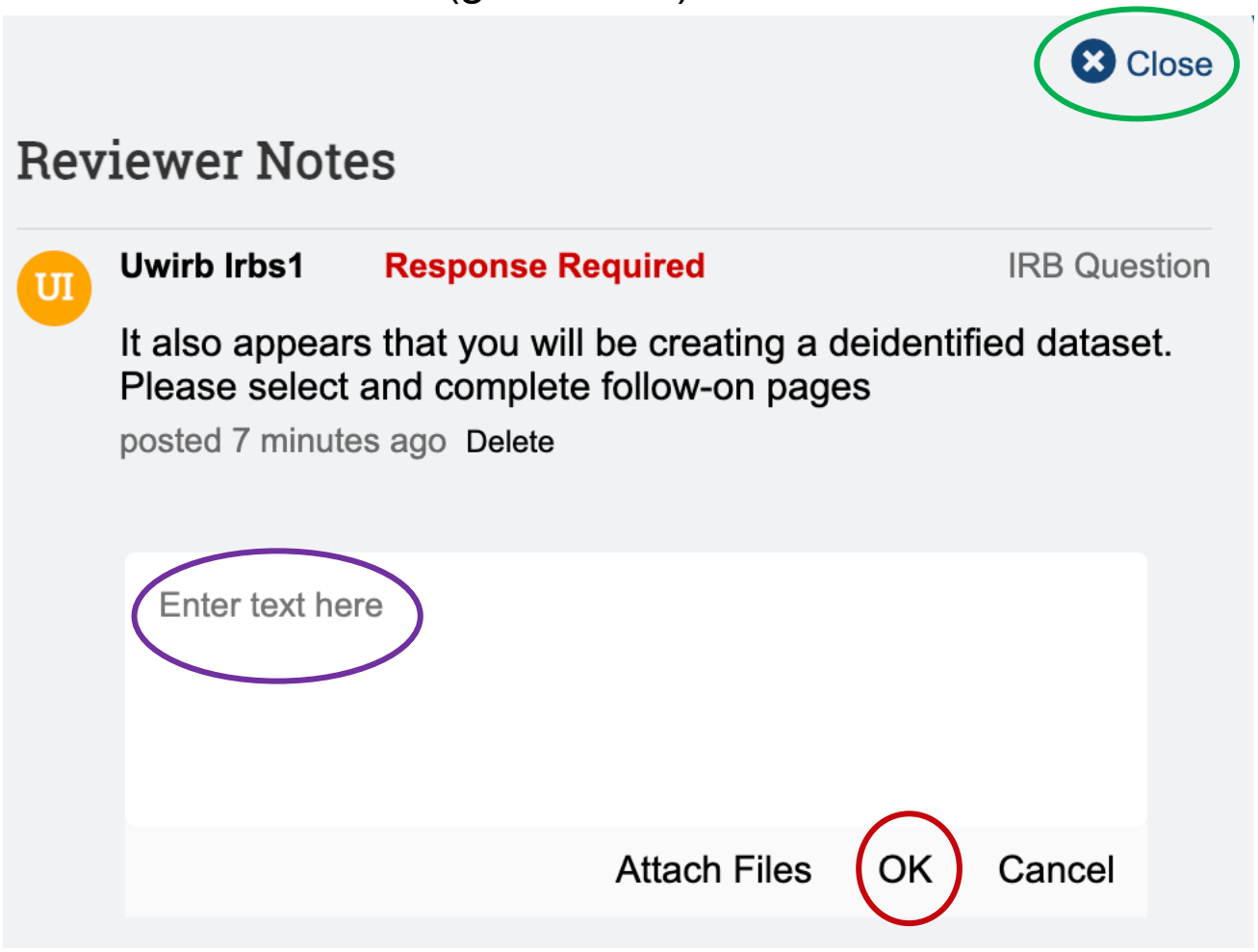
Which opens the review notes pop-up.

Then click on the REPLY button



Which opens the response screen.

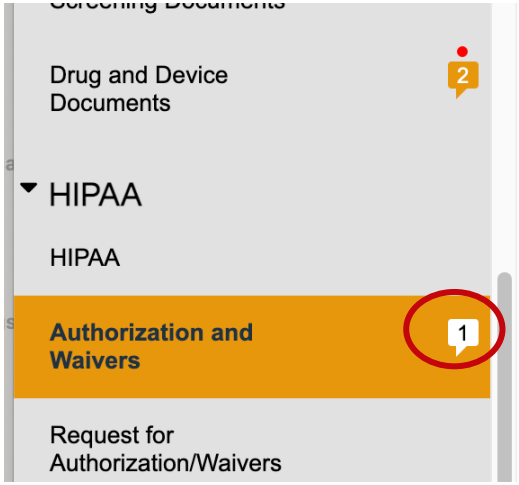
1. Type your response in open text box (purple oval)
2. Click OK (red circle)
3. And THEN close (green oval)

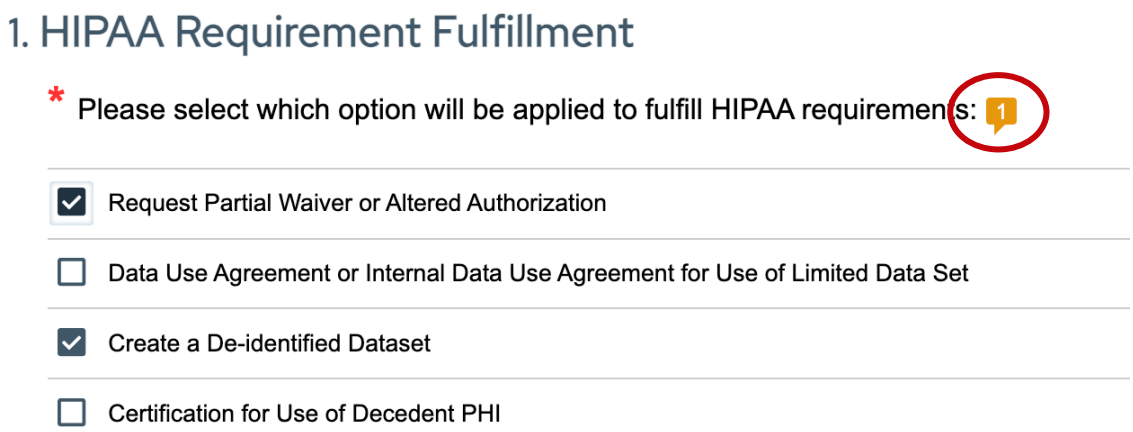


If you close before hitting OK, your response will not be saved.

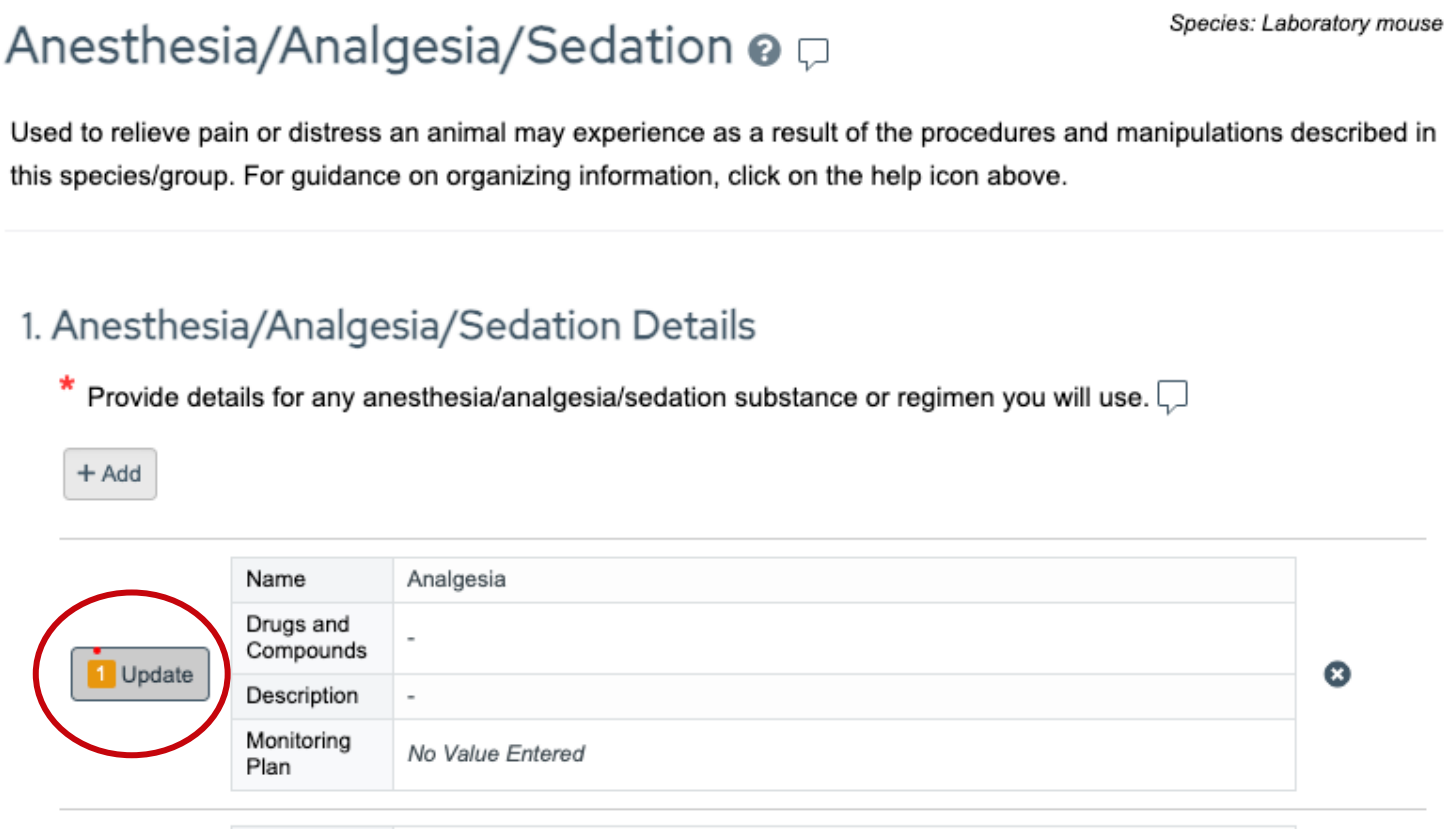
When you respond to a review note, the reviewer note bubble no longer has the red dot above it and will not trigger an error message when you submit

As now, **BE SURE TO update the text in your protocol to address the question raised by the reviewer.**



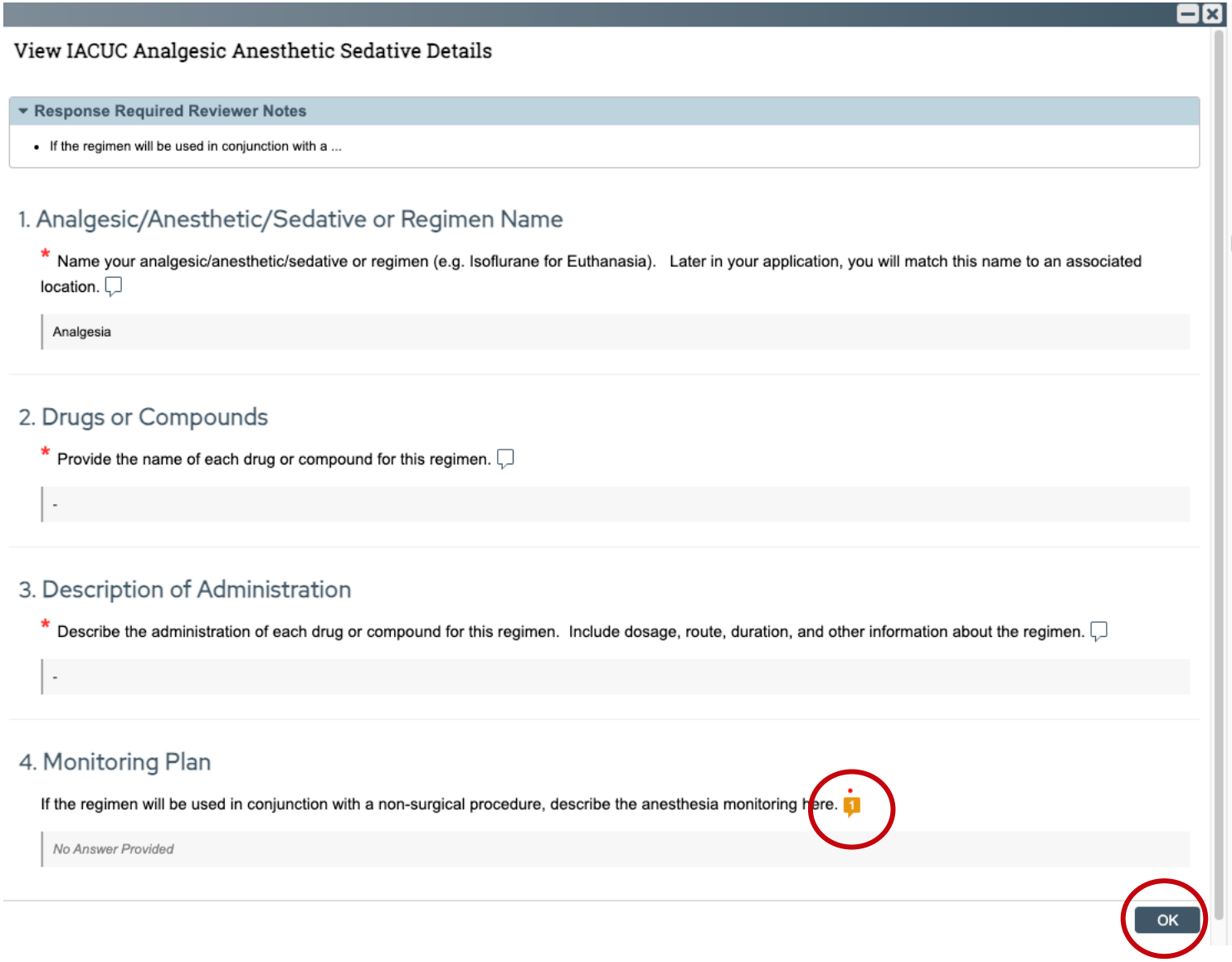


When the note is about information in a table, you must OPEN the table (click the update button) to see the reviewer note.



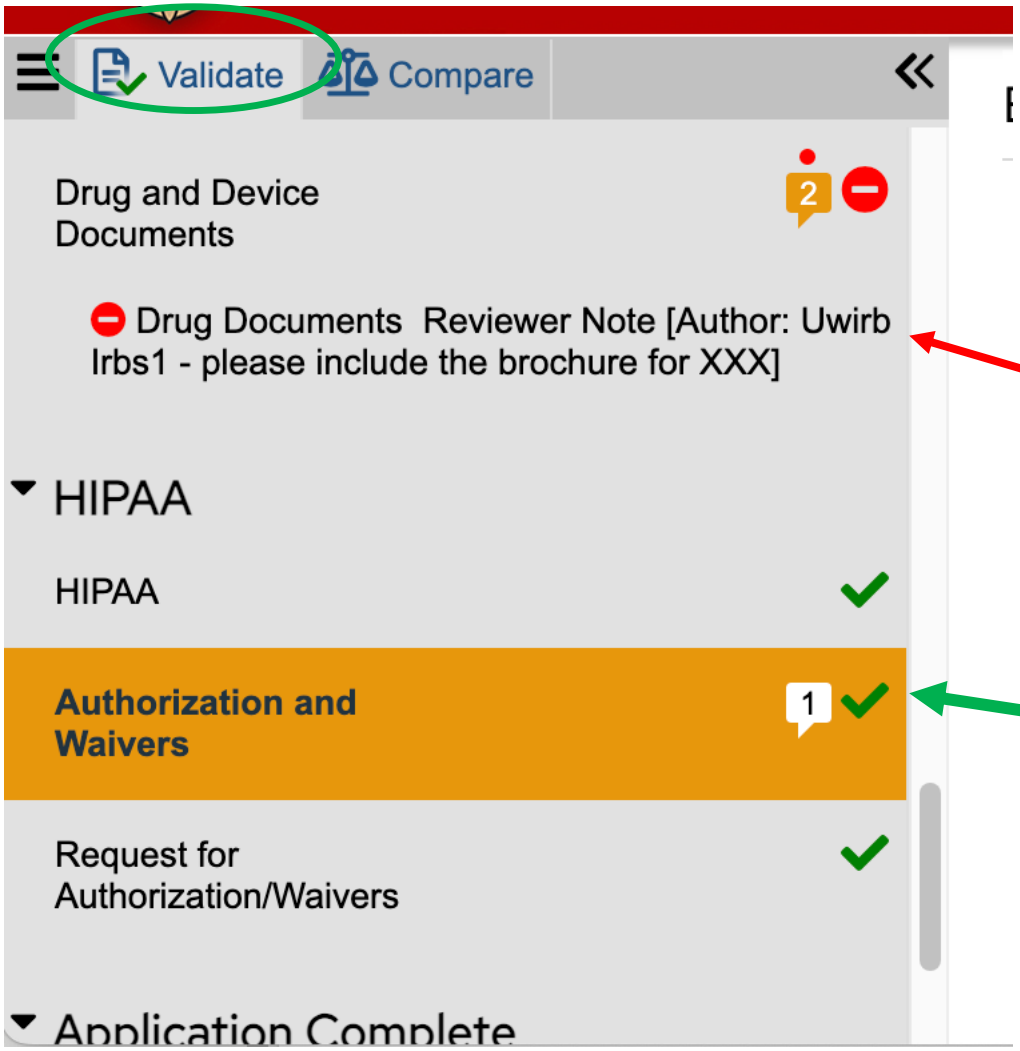
The number in the note bubble by a table indicates the total number of notes in that table

The table slides in from the right.
As with all notes, click on the note bubble to respond.
Click OK to close table



Validate – Response to Notes

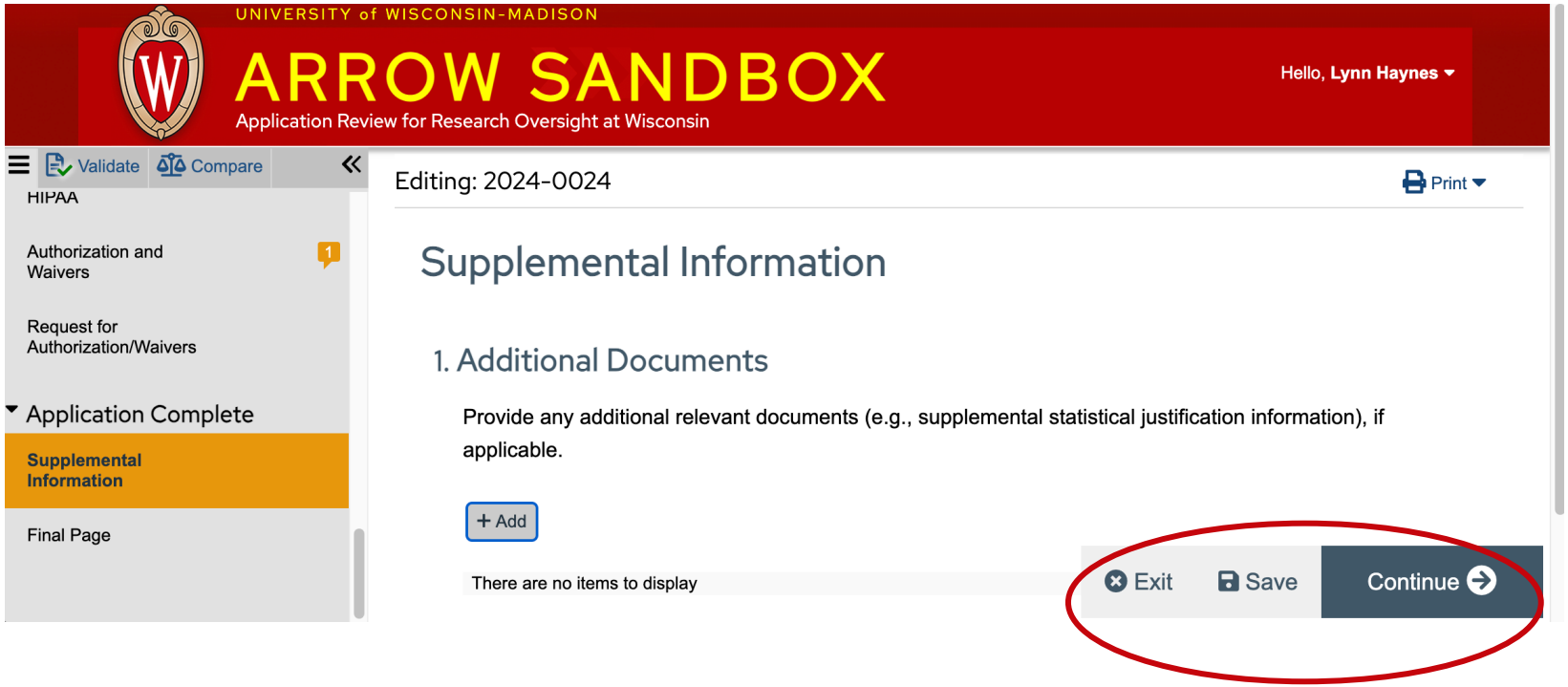
Ensure that you have addressed all the required reviewer notes.



Red error message includes details about outstanding issues

Green checks = page is complete – no outstanding reviewer notes

- To exit application, click the SAVE, then EXIT button in bottom right



Click submit to send the protocol back to reviewers