Protocols - Adding Action Items

Reviewing a Protocol

Once an investigator has submitted a protocol for review the Protocol Administrator, assigned Reviewers can review all information and make necessary Action Items. The protocols can be accessed from the Manage Protocols option in the menu by clicking on the linked Title of the protocol. The Status of the protocol will indicate to the protocol administrator which protocols require review.

Upon opening the protocol you will have a number of review options to make assignments, add Action Items, set determinations, return to PI, etc. to process the protocol appropriately.

Action Items

When you are assigned as a designated reviewer, you will be able to add comments to a specific field via the "Action Item" links available throughout the submitted protocol form.   This allows a back and forth conversation between the Administrators/Reviewers and the researchers preparing the protocol.

Once clicked it will open up a sidebar panel where you can enter your text and mark who has access to view the specific comment.

"Visibility section" allows you to select (highlight) the appropriate users that should have access to view the added Action Item. If the user type is not added (highlighted) for a given comment it will not be visible to the user. By default, the Administrator can see all action items unless they are also added as a researcher in the protocol. A little more information on the visibility groups available:

- Assigned Reviewers - Any reviewer assigned to the protocol will be able to see the Action Item.
- Researchers - Any users with Researcher roles in the protocol will be able to view the Action Item.
- Meeting Summary – (Full Board) Defines whether Action Item will appear on a meeting agenda/minutes when you use the Agenda Summary option. The action item is nested under that view for the protocol that can be expanded.

NOTE: Only Admins will have visibility options; Committee Members that are assigned for review their comments will automatically default to 'admins only' and if the visibility settings need to be adjusted it would have to be done by an Admin after the review has been submitted.

You can also add a general review comments for the entire protocol via the Add "General Action Items" button located on the upper right side bar.

When the protocol is returned to the researcher they can reply to the comment and you'll notice that the reviewer that made the original comment is marked as Anonymous; only Administrators can see the actual user that made the action item.
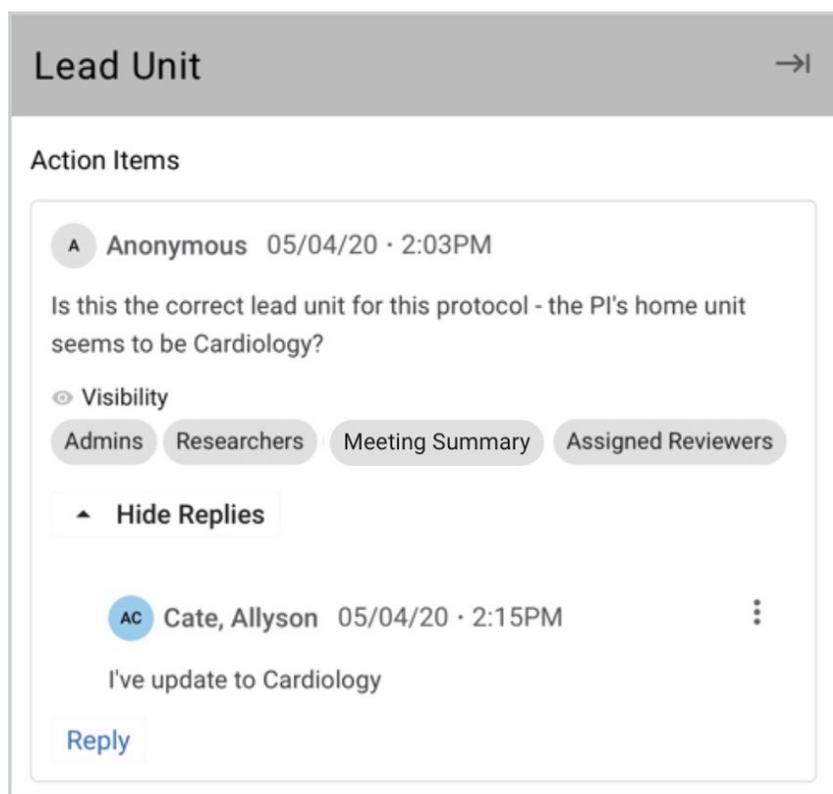
The back and forth conversation for a given Action Item can be expanded using the hide/show options so you can see the entire history. Once an admin feels the issue has been addressed they can use the 'Mark as Resolved' option.

This will set the Action Item to Resolved but it can always be unchecked if further action is required.

NOTE: If a researcher replies to the "Action Item" via the "Reply" button, the designated reviewer will not be able to comment on their reply. A new Action Item will have to be created if you wish to reply to their comment.

Track Changes – Compare Versions

When the "Compare Versions" checkbox is selected it will display all changes to the protocol since the last version. This button is located at the very top of the protocol screen.

This feature allows Administrators/Reviewers a quick way to review what was changed by the investigator since the last review. Items in red are removed text and green are added text.

Review Prior History or Activity

You can also use the Version dropdown to go back to see prior versions of the protocol if you wish to see the record in its entirety.

Version: 2 | New | Resubmitted ▾

Also, the Activity Log allows you to view the history of actions that have occurred on this protocol since its inception, and can be accessed via the top bar of the protocol.

ACTIVITY LOG

Review Actions

Designated Reviewers will have the following action button available on the right-hand corner of the screen.

💬 Action Items Summary

Displays a window allowing you to review all action item comments and replies for this protocol.

📎 Admin Notes & Files

Notes and Files that can be added to the protocol by administrators that stay with the life of the protocol (and can be added at any point).

💬 General Action Items

You can also add a general review comments for the entire protocol via the Add "General Action Items" button located on the upper right-side bar.

◀ Withdraw

The Withdraw button is reserved for the initiator so they can pull their protocol back for edit. If Action Items had been added and made visible to the researcher they could see those after withdraw.

Return to Researcher

Send the protocol back to the PI if it is incomplete and not ready for review; this opens up the entire protocol for edit like it's back in initiated status.

Require Revisions

Review has been completed but further edits are required before it can be approved. This action allows you to record a decision date, and a deadline for the requested revisions. Action items are also required before it can be returned so something specific is pointed out to the user for action/change.

Review Assignments

Review Assignments are designated by the IRB Manager. This button will add the protocol to a committee, schedule, and mark the Review Type.

✕ Close

The Close button is reserved for the IRB Manager. On a close request the Close button will be available and can be used to formally close out the protocol.

Print

Allows you to view the entire protocol in PDF or print hardcopies if desired.