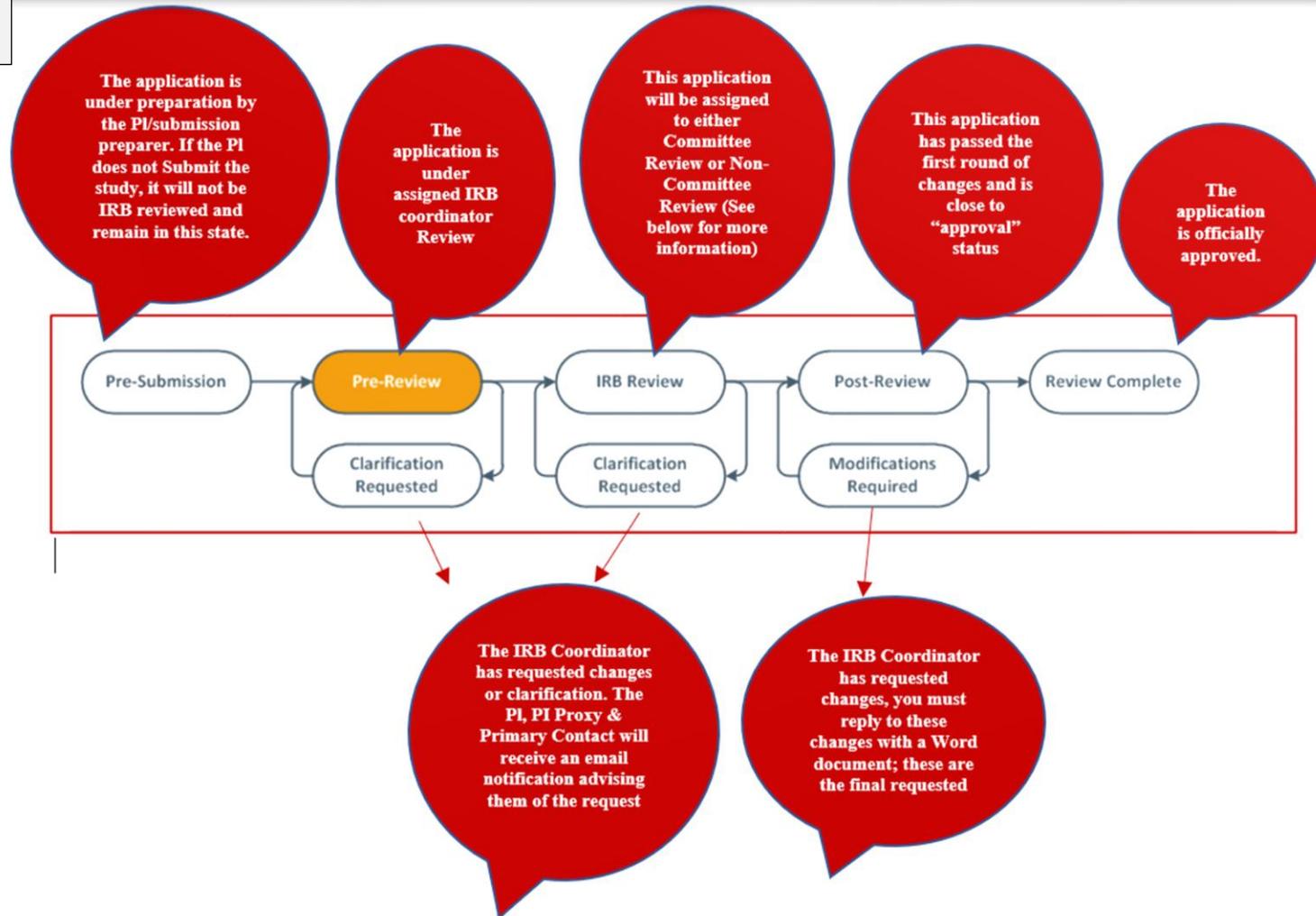


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## Helpful Hints/FAQ's for Navigating ICON

### Study Status Diagram



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<b><u>Study/ Modification Possible Statuses</u></b>	<b><u>Description/ Meaning of Status</u></b>
<ul style="list-style-type: none"> <li>• <b>Pre-Submission</b></li> </ul>	The application is under preparation by the PI/submission preparer. If the PI does not Submit the study, it will not be IRB reviewed and remain in this state.
<ul style="list-style-type: none"> <li>• <b>Pre-Review (Clarification Requested)</b></li> </ul>	The IRB Coordinator has requested changes or clarification. The PI and Primary Contact will receive an email notification advising them of the request.
<ul style="list-style-type: none"> <li>• <b>Pre-Review Completed (Convened Review)</b></li> </ul>	The submission awaits assignment to an IRB panel for review.
<ul style="list-style-type: none"> <li>• <b>Pre-Review Completed (Expedited or Exempt Review)</b></li> </ul>	The submission awaits assignment to a designated IRB member for review.
<ul style="list-style-type: none"> <li>• <b>Non-Committee Review</b></li> </ul>	The submission is currently is being reviewed by an IRB member.
<ul style="list-style-type: none"> <li>• <b>Committee Review</b></li> </ul>	The submission awaits assignment to an IRB panel for review, or the submission has been assigned to a panel meeting and is being reviewed by IRB panel members.
<ul style="list-style-type: none"> <li>• <b>Clarification Requested (Designated Review)</b></li> </ul>	The IRB member has requested changes or clarifications regarding the submission under review.
<ul style="list-style-type: none"> <li>• <b>Clarifications Requestion (Committee Review)</b></li> </ul>	The IRB panel has requested changes or clarifications. The PI and Primary contact will receive an email notification advising them of the request.

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## Helpful Hints/FAQ's for Navigating ICON

### Next Steps

Edit Study

Printer Version

View Differences

 Submit

 Assign Primary Contact

 Assign PI Proxy

 Manage Ancillary Reviews

 Manage Guest List

 Add Related Grant

 Add Comment

 Copy Submission

 Discard

\*\*Please note the “Withdraw” button sends the submission back to you (so edits can be made) and takes it out of “IRB review”

 Withdraw

### Understanding the “Controls” within ICON

<u>Controls Name</u>	<u>Description</u>
• <b>Edit Study</b>	This button allows you to modify the study/modification
• <b>Printer Version</b>	Shows you the “print view” of your study/modification
• <b>View Differences</b>	Shows you the changes that are occurring in a modification
• <b>Submit</b>	This button put the study/modification in the “IRB review status”
• <b>Assign Primary Contact</b>	When you assign an individual as primary contact, they get all the study notifications
• <b>Assign PI Proxy</b>	Allows selected study team member to be given the “submit” button (see below for more information).
• <b>Manage Ancillary Review</b>	Assign a Departmental, Committee Reviewer for a modification/ continuing review (see below for more information)
• <b>Manage Guest List</b>	Assigning a guest allows an individual to view this study who id not listed on the study team.
• <b>Add Related Grant</b>	Use this button to add grant information
• <b>Add Comment</b>	Use this button to add a comment to your study/modification
• <b>Copy Submission</b>	This button will copy the entire study/ modification submission
• <b>Discard</b>	Use this button to completely remove a study/ modification

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## Helpful Hints/FAQ's for Navigating ICON

### 1. Understanding how to Assign PI proxy and What it Means

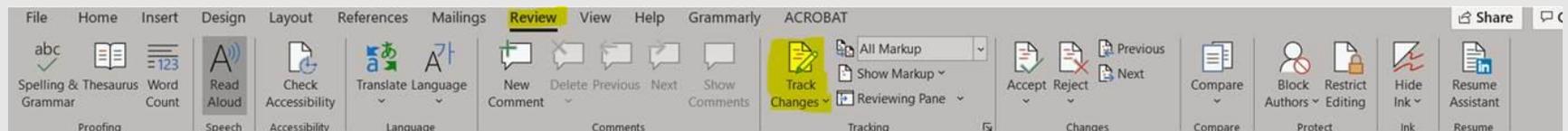
- Only the Principal Investigator has the “Submit” button/ option within their view with ICON.
  - The submit button allows the ICON submission (new study submission, Modification, or continuing Review) to be moved into “IRB review” status.
- No one listed on the study team has the permissions to use the “Submit” button unless the PI assigns a study team member as “PI Proxy.”
- A proxy must be a study team member listed on the study team within ICON.

### 2. When Making a Modification Submission

- Within the modification summary (in lay terms), summarize the key changes proposed.
- Summarize the reason for the changes.
- List the documents included in the submission
- **Please note:** anything you put in the “Modification Summary” will appear on the approval letter.
- Please ensure that any revised documents are in track-changes mode (setting within Word) or otherwise highlighted so that changes are apparent.
- Any time the protocol, consent or any other supporting Word document, “Tracked Chagnes” in Word needs to be utilized.
  - To use the "Tracked Changes" setting within Word, please click the "Review" tab at the screen's top.
  - Then click "Track Changes."
  - I've provided a screenshot of the buttons you will use highlighted below, along with an example of what tracked changes will look like below:

#### **Tracked Changes Explained:**

##### 1. Buttons to press:



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### 2. Example of Tracked Changes

This is an example of a text with track changes. ~~Some text has been deleted.~~ Other text has been inserted.

Track changes can be displayed in a number of ways in Word. You can change the display settings whenever you want without removing the tracked changes.

In this example, inserted text is in red and underlined whereas ~~deleted text is in blue and strikethrough~~