



## Safety Protocol Work Flow

### PROTOCOL STATES:

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The diagram located in the Safety workspace will show the state of your protocol within the Safety workflow.

**Pre-Submission:** During Pre-Submission, the PI will create the Safety protocol.



**Specialist Review:** In the Specialist Review state, the protocol has been submitted and is reviewed by the Safety Specialist.



**Specialist Review / Clarification Requested:** The Safety Specialist can send the protocol back to the protocol team for more information or clarifications if needed, which lets the protocol team change the protocol.



**Committee Review:** In Committee Review, the Safety committee members will review the protocol for completeness.





**Committee Review / Clarification Requested:** The Safety committee can send the protocol back to the protocol team for more information or clarifications if needed, which lets the protocol team change the protocol.



**Post-Review / Modifications Required:** The Post-Review state gives the Safety staff the opportunity to:

- Approve documents that were attached to a protocol
- Prepare a letter to inform the protocol team about the decision
- Send the determination letter
- Request modifications



**Review Complete:** When the protocol team submits modifications that are acceptable, the submission returns to the Post-Review state. The submission will reach its final determination, Review Complete, after the approval letter is sent.

