

To submit an amendment or modification request to NCI Institutional Review Board (IRB), the following documents are required:

1. Cover Letter for Amendment Request Form

- A formal request detailing the proposed amendments or modifications, including a summary of changes and the rationale.

2. Cover Letter for modification Request Form

- A formal request detailing the proposed modifications, including a summary of changes and the rationale.

3. Study Protocol

- An updated version of the study protocol with highlighted or tracked changes to identify modifications from the original or previously approved version.

4. Revised Informed Consent Form(s)

- Updated consent forms with tracked changes should be provided.

5. Revised Patient Information Sheet (if applicable)

- Any updates to information provided to participants should be highlighted for easy identification.

6. Summary of Changes Document

- A document listing all changes made to the study protocol, consent forms, or other study materials, explaining the reasons for each change.

7. Current IRB Approval Letter for the Study

- A copy of the most recent IRB approval letter to verify the study's active approval status.

8. Proof of Payment:

Documents for Amendments

	Document Name	Hard Copy	Soft Copy	Version Date
1	Submission Letter			
2	IRB Application Form			
3	Study Protocol			
5	Proof of Payment for Amendment			

Documents for Modified Version

	Document Name	Hard Copy	Soft Copy	Version Date
1	Submission Letter			
2	IRB Application Form			
3	Study Protocol			
4	Table of Changes			
6	Proof of Payment for modified version of the study protocol			