

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 | | | |