

Clinical Trial Protocol Amendment Request

Date: [Insert Date]

[Sponsor's Name]

[Sponsor's Address]

[City, State, Zip Code]

[Email Address]

To: [Regulatory Authority/Institution Name]

[Recipient's Address]

[City, State, Zip Code]

Subject: Request for Protocol Amendment - [Trial Protocol Title or ID]

Dear [Recipient's Name],

We are writing to formally request an amendment to the clinical trial protocol for [Trial Protocol Title or ID]. The amendment is necessary due to [brief explanation of the reason for amendment].

Details of the Proposed Amendment

1. Section Affected: [Specify section of the protocol]
2. Current Text: [Insert current text]
3. Proposed Text: [Insert proposed text]
4. Rationale for Change: [Insert rationale]

Impact of Amendment

[Discuss any potential impacts on the study, participants, timelines, etc.]

We appreciate your consideration of this request and look forward to your approval of the proposed amendments. Please let us know if you require any additional information.

Thank you for your attention to this matter.

Sincerely,

[Your Name]

[Your Position]

[Organization Name]

[Contact Information]