

Date: [Insert Date]

To: [Recipient Name]

From: [Your Name]

Subject: Notification of Protocol Changes for Regulatory Compliance

Dear [Recipient Name],

I am writing to inform you of changes to our study protocol as necessary to ensure compliance with the latest regulatory requirements. These modifications were implemented in accordance with [specific regulations or guidelines, e.g., FDA regulations, ICH guidelines].

Key changes include:

- Change 1: [Brief description of change]
- Change 2: [Brief description of change]
- Change 3: [Brief description of change]

We believe these adjustments will enhance the integrity of the study and safeguard participant welfare. Detailed documentation of these changes will be submitted to the relevant authorities and is available upon request.

Please feel free to reach out if you have any questions or require further information regarding these changes.

Thank you for your attention to this matter.

Sincerely,

[Your Name]

[Your Position]

[Your Institution/Organization]

[Your Contact Information]