

Date: [Insert Date]

To: [Recipient Name/Trial Oversight Committee]

Organization: [Organization Name]

Address: [Street Address, City, State, Zip Code]

RE: FORMAL STATEMENT OF TRIAL PLAN VIOLATION

Trial Reference Number: [Insert Trial ID/Protocol Number]

Trial Title: [Insert Full Title of the Trial]

Dear [Recipient Name],

This document serves as a formal statement regarding a violation of the established Trial Plan (Protocol) identified on [Date of Discovery].

1. Nature of the Violation:

[Provide a clear, factual description of the deviation. Specify which section of the protocol was breached, such as dosage, timeline, eligibility, or safety monitoring.]

2. Date and Location:

The violation occurred on [Date] at [Specific Site or Department].

3. Individuals Involved:

[List the names or roles of the personnel involved in the incident.]

4. Impact Assessment:

[Describe the impact on participant safety, data integrity, or the overall validity of the trial results.]

5. Corrective Actions Taken:

[Detail the immediate steps taken to mitigate the violation and any long-term measures implemented to prevent recurrence.]

Please acknowledge receipt of this statement. We remain committed to maintaining the standards of the Clinical Trial Plan and regulatory requirements.

Sincerely,

[Signature]

[Printed Name]

[Title/Role]

[Contact Information]