Date: [Insert Date]

To: [Pharmacovigilance Department / Regulatory Affairs]
Organization: [Insert Name of Institution/Company]
Address: [Insert Address]

Subject: Formal Notification of Adverse Event (AE) - Case ID: [Insert ID if applicable]

Dear [Recipient Name or Safety Officer],

This letter serves as formal clinical documentation for an Adverse Event (AE) identified during the course of [Clinical Trial Name / Patient Treatment].

1. Patient Information:

- Patient Initials/ID: [Insert ID]
- Date of Birth: [Insert DOB]
- Gender: [Insert Gender]

2. Adverse Event Details:

- Description of Event: [Insert Clinical Description]
- Onset Date and Time: [Insert Date/Time]
- Severity: [Mild / Moderate / Severe / Life-Threatening]
- Seriousness: [Serious / Non-Serious]

3. Investigational Product (IP) / Medication Info:

- Product Name: [Insert Name]
- Dosage Administered: [Insert Dose]
- Date of Last Dose: [Insert Date]
- Action Taken with Product: [Drug Withdrawn / Dose Reduced / No Change]

4. Clinical Outcome and Assessment:

Current Status: [Recovered / Recovering / Not Recovered / Fatal]

Causality Assessment: [Not Related / Possibly Related / Probably Related / Definitely Related]

5. Reporter Information:

Name: [Insert Name]
Title: [Insert Title]
Contact Information: [Insert Phone/Email]

The attached clinical notes and lab reports provide further context regarding this event. Please acknowledge receipt of this report.

Sincerely,

[Signature]
[Printed Name]
[Clinical Site/Department]