

[Company Name]  
[Department Name/Pharmacovigilance]  
[Address]  
[City, State, Zip Code]

[Date]

To: [All Healthcare Professionals / Clinical Staff / Stakeholders]

**Subject: Standard Operating Procedure for Reporting Adverse Reactions**

Dear [Recipient Name],

The purpose of this letter is to outline the mandatory procedure for reporting any suspected adverse reactions (AR) or adverse events (AE) associated with the use of [Product Name/All Products].

To ensure patient safety and regulatory compliance, please follow these steps immediately upon becoming aware of an event:

**1. Identification:** Identify any untoward medical occurrence in a patient, regardless of whether a causal relationship with the product is suspected.

**2. Information Collection:** Gather the four minimum criteria required for a valid report:

- An identifiable patient (initials, age, or gender).
- An identifiable reporter (your name and contact details).
- A description of the adverse reaction.
- The name of the suspected product.

**3. Reporting Timeline:** All suspected reactions must be reported within [Number, e.g., 24 hours] of initial discovery.

**4. Submission Channels:** Reports should be submitted via one of the following methods:

- **Email:** [Email Address]
- **Online Portal:** [URL]
- **Phone:** [Phone Number]
- **Fax:** [Fax Number]

Attached to this letter is the [Adverse Event Reporting Form]. Please ensure all sections are completed to the best of your ability. Ongoing monitoring and follow-up information should be submitted as it becomes available.

Thank you for your cooperation in maintaining our commitment to patient safety.

Sincerely,

[Signature]

[Name]

[Title/Position]

[Contact Information]