Annual Adverse Event Summary Report (Clinical Research)

1. Study Identification

Study Title

Protocol Number

Principal Investigator

Study Sponsor

Report Period

2. Study Summary

Total Number of Participants Enrolled

Study Duration (Dates)

3. Summary of Adverse Events (AEs)

Participant ID	AE Description	Date of Onset	Severity	Outcome	Relationship to Study Drug/Intervention

Total Number of AEs Reported

4. Summary of Serious Adverse Events (SAEs)

Participant ID	SAE Description	Date of Onset	Outcome	Relation to Study Drug/Intervention	Reported to Authority

Total Number of SAEs Reported

5. Actions Taken

Actions in Response to AEs/SAEs

6. Safety Assessment

Investigator Assessment of Study Drug/Intervention Safety

7. Other Relevant Information

Additional Comments

8. Signatures

Principal Investigator Name

Signature

Date