Federal Regulations 21CFR 56.108(b) states “Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

**Use this form to record protocol violations occurring at your site that adversely affect the rights, safety or welfare of subjects, or significantly impact the integrity of research data. If your IRB does not have their own Protocol Violation Form, this form may be used and submitted per IRB reporting guidelines.**

Principal Investigator Name: Dr. White

**Institution Name:**

Protocol Name/Number: SRC-AI-Example-2020-12345

|  |
| --- |
| **Date of Occurrence:** |
| **Description of Violation:** |
| **Impact on the participant(s):** |
| **Reason for Violation:** |
| **Action to Prevent Recurrence:** |

Name of Person Completing Form:

Signature of Principal Investigator: Date: