

**SAFETY REPORTING AGREEMENT
Cancer Institute NSW Clinical Research Ethics Committee**

Study Title: [INSERT STUDY TITLE]

We hereby agree to submit safety report information to the Cancer Institute NSW Clinical Research Ethics Committee in accordance with the following requirements:

1. SAE occurring at site under Clinical Research Ethics Committee Approval:
 - a. Reported within 72 hours with a comment from Principal / Local Investigator.
 - b. *If Multi-centre trial*, the Principal / Local Investigators must report to the Lead HREC with comments.
 - c. They must also notify the Coordinating / Lead Investigator and the local Research Governance Officer.

2. Australian SUSAR
 - a. Expedite report to the HREC with comment from Principal / Local Investigator.
 - b. *If Multi-centre trial*, the Coordinating / Lead Investigator is to report to the Lead HREC with comments.

3. International SUSAR:
 - a. Quarterly summary reports of all SUSARs relating to the drug/device to be provided to Ethics Committee unless it impacts on research and action is planned(See Quarterly report due dates below)

4. SAE that occurs at site outside of the Clinical Research Ethics Committee Approval:
 - a. Annual summary reports of all SAEs to be provided to the Ethics Committee with annual report unless it impacts on research and action is planned.

5. Quarterly Summary Reports must be provided with comment from the Principal Investigators about the impact on the study. These must be submitted in March, June, September and December.

6. Annual Safety Reports must be submitted with the annual report to the Ethics Committee.

7. Adverse Events – Recorded in case report form (CRF). Only submit to Ethics Committee if it impacts on the research and action is planned.

PLEASE NOTE SAFETY REPORTS WILL NOT BE ACCEPTED IN ANY OTHER FORM.

Signed: (Coordinating Investigator): _____

PRINT: _____

Date: _____

Signed (Sponsor): _____

PRINT: _____

Date: _____