PoCoG
Psycho-oncology Co-operative Research Group

<Insert study title>
Study ID: <Insert PoCoG Study ID>

Protocol Deviation/Violation CRF

Site Details:	
Site:	
Name of person completing this form:	

Protocol Deviation/Violation Details:	
Date of Event:	
Subject ID	
Describe the Protocol Deviation/Violation:	
Type of Deviation:	☐ **Incorrect consent procedure** ☐ **Incorrect randomisation** ☐ **Randomisation of ineligible patient** ☐ **Enrolled outside prescribed time periods** ☐ **Incomplete data for enrolled patient** ☐ **Treatment cannot be verified** ☐ **Serious Adverse Event (SAE) not reported** ☐ **Other (specify):**
Classification (see appendix):	☐ **Minor Violation** ☐ **Major Violation**
Action taken:	☐ **Patient withdrawn** ☐ **Data inclusion to be modified** ☐ **Data Safety Monitoring Committee notified** ☐ **Ethics committee notified** ☐ **No action – include in analysis** ☐ **Other (specify):**
Date of action/decision:	

Other comments:

Signed: **Date:**

APPENDIX

Classification of Protocol Violations

Minor Protocol Violation: A protocol violation that does not impact the safety or welfare of study participants, compromise the integrity of study data, or affect participants' willingness to participate in the study. Examples of minor protocol violations include the following (not an all-inclusive list):

- Use of an outdated version of the consent form if risks to participants described in the form do not differ from those described in the current consent form;
- A study procedure conducted out of sequence;
- A study visit conducted outside the required time period;
- Failure to perform a required lab test that, in the opinion of the PI, is unlikely to have a negative impact on participant safety or welfare or the integrity of the data collected; or
- Enrolling more than the HREC-approved number of participants.

Major Protocol Violation: A protocol violation that may impact the safety or welfare of study participants, compromises the integrity of study data, or affects participants' willingness to participate in the study. Examples of major protocol violations include the following (not an all-inclusive list):

- Failure to obtain informed consent, or obtaining informed consent from a participant after initiation of study procedures;
- Using an outdated version of the consent form when risks to participants described differ from those described in the current consent form;
- Performing a study procedure not approved by the HREC;
- Modifying a study without prior HREC approval unless to remove an apparent immediate hazard to one or more study participants;
- Enrolment of a subject who did not meet all inclusion / exclusion criteria;
- Failure to perform a required lab test that, in the opinion of the PI, may affect the safety or welfare of one or more participants or the integrity of the data collected;
- A drug / study medication dispensing or dosing error;
- A study visit conducted outside of the required time period with a potentially adverse effect on the safety or welfare of one or more study participants;
- Failure to follow applicable federal / state regulations or HREC policies and procedures, including those for reporting Breaches and Adverse Events; or
- Failure to follow an HREC-approved safety monitoring plan.

Source: Definitions adapted from "**Protocol_Deviation_Violation_Clinical_Trials"** Clinical Trials Governance, Research Portfolio, University of Sydney.

PoCoG
Psycho-oncology Co-operative Research Group

Protocol Violation/Deviation Log

<Insert study title>

Study ID: <Insert PoCoG Study ID>

	Date of Event (dd/mm/yyyy)	Subject ID	Description of the Deviation	Reason for the Deviation and the corrective Measures taken	HREC Notification (Yes/No/NA)	Investigator Initials and Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Principal Investigator

Name: _____ **Signature:** _____ **Date:** _____

Key Definitions

Protocol Violation: Any deviation, change or departure from the HREC-approved protocol that does not have prior approval by the HREC unless the change is necessary to remove an apparent immediate hazard to one or more study participants.

Minor Protocol Violation: A protocol violation that does not impact the safety or welfare of study participants, compromise the integrity of study data, or affect participants' willingness to participate in the study. Examples of minor protocol violations include the following (not an all-inclusive list):

- Use of an outdated version of the consent form if risks to participants described in the form do not differ from those described in the current consent form;
- A study procedure conducted out of sequence;
- A study visit conducted outside the required time period;
- Failure to perform a required lab test that, in the opinion of the PI, is unlikely to have a negative impact on participant safety or welfare or the integrity of the data collected; or
- Enrolling more than the HREC-approved number of participants.

Major Protocol Violation: A protocol violation that may impact the safety or welfare of study participants, compromises the integrity of study data, or affects participants' willingness to participate in the study. Examples of major protocol violations include the following (not an all-inclusive list):

- Failure to obtain informed consent, or obtaining informed consent from a participant after initiation of study procedures;
- Using an outdated version of the consent form when risks to participants described differ from those described in the current consent form;
- Performing a study procedure not approved by the HREC;
- Modifying a study without prior HREC approval unless to remove an apparent immediate hazard to one or more study participants;
- Enrolment of a subject who did not meet all inclusion / exclusion criteria;
- Failure to perform a required lab test that, in the opinion of the PI, may affect the safety or welfare of one or more participants or the integrity of the data collected;
- A drug / study medication dispensing or dosing error;
- A study visit conducted outside of the required time period with a potentially adverse effect on the safety or welfare of one or more study participants;
- Failure to follow applicable federal / state regulations or HREC policies and procedures, including those for reporting Breaches and Adverse Events; or
- Failure to follow an HREC-approved safety monitoring plan.

Source: Definitions adapted from "**Protocol_Deviation_Violation_Clinical_Trials"** Clinical Trials Governance, Research Portfolio, University of Sydney.