NHS
Greater Glasgow and Clyde

PROTOCOL DEVIATION GUIDANCE

The log 51.008C attached should be used for category 1 and category 2 protocol deviations only.

Sponsors categorisation of deviation

CATEGORY 1:
Issues of non-compliance of an administrative or technical nature are detected that do not compromise patient safety and/or the integrity of the data

CATEGORY 2::
Issues are detected that could affect the conduct of the study but do not constitute a potential serious breach of GCP or the protocol. Category 2 may include issues that have minor impact on patient safety and/or the integrity of the data. However, it is still important to record Category 2 issues as a reasonable volume of the same issue can lead to a Category 3 issue.

The log should be sent monthly to the monitoring email address, RandD.MonitoringGroup@ggc.scot.nhs.uk and please copy in and the trial project manager.

The protocol deviation form 51.008A should only be used for category 3 and 4 deviations described below:

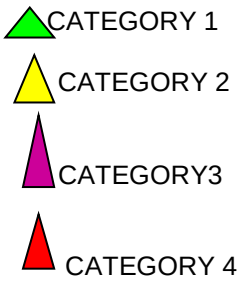
Category 3:
Issues are detected that may have a major impact on patient safety and/or integrity of the data. This may include potential serious breaches of GCP and/or the trial protocol.

Category 4:

Issues are detected that have a significant/critical and/or immediate impact on patient safety and/or integrity of the data. This may include life threatening patient safety issues and potential serious breaches of GCP and/or the trial protocol.

EXAMPLES OF EACH CATEGORY OF DEVIATION (Please note this list is not exhaustive and sites are encouraged to email the monitoring team for guidance.

CATEGORY 1	CATEGORY 2	CATEGORY 3	CATEGORY 4
CT scan out with protocol defined time window	**Visit missed out of trial schedule**	**Affects eligibility out with inclusion/exclusion of the study.**	**Wrong IMP given and causes harm to patient**
Missed blood sample which is not a safety blood and does not determine treatment or affect patient safety.	**CT scan not performed as site not aware of the scan.**	**Incorrect dose of study drug given**	**Numerous patients have not given ICF consent.**
	Witness consent not completed appropriately.	**Consent process not followed.**	**Falsification of Data, data fraud.**
		Continuous primary and secondary data missed.	
		Use of pencil	



Please contact the RandD.MonitoringGroup@ggc.scot.nhs.uk, or Sponsor Trial project manager or any queries regarding deviations. All deviations relating to IMP must be sent to the Sponsor Pharmacy team at R&DIMP@ggc.scot.nhs.uk for assessment. NOTE: Protocol waivers are not permitted under the Clinical Trial Regulations, 2004, as amended

Document Details:

Prepared by: Caroline Watson Signature: Date:

Approved by: Chloe Cowan Signature: Date:

Document History

Version	Details	Date
1.0	First Release	19/04/2022