POLICYI019 MONITORING – PROTOCOL VIOLATIONS

Manual:	Policies	**Document ID:**	PI019	**Date Created:**	May 09
Section:	Investigator	**No. Pages:**	1	**Review Date:**	Sep 13
				Future Review Date:	Sep 15

PURPOSE

To explain the reporting requirements to the HREC in the event of a protocol violation/deviation. National Statement section **3.3.19-22** and Chapter **5.5.**

Protocol Violation is any failure to comply with the final study protocol approved by the HREC, which may affect a participant's rights, safety or well being (or their willingness to stay in the study) and/or may affect the integrity of the data being collected.
Examples of protocol violations include:

- Failure to obtain informed consent, i.e., there is no documentation of informed consent or informed consent was obtained after initiation of study procedures
- Enrolment of a participant who did not meet all inclusion/exclusion criteria
- Performing a study procedure not approved by the HREC
- Failure to report a serious adverse event to the HREC and/or sponsor
- Failure to perform a required laboratory test that, in the opinion of the PI, may affect participant safety or data integrity
- Drug/study medication dispensing or dosing error
- Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect participant safety
- Failure to follow safety monitoring plan

Protocol Deviation is a less serious non-compliance, usually to deal with unforseen circumstances and can be agreed between the sponsor and the investigator either in advance or after the event. Protocol deviations may be considered slightly differently to protocol violations in that they generally do not have a major impact on participant welfare or data integrity. Examples of a protocol deviation may include the scheduling of a required procedure outside the time frame specified in the protocol or the use of a prohibited concomitant medication by a participant. **Deviations are not required to be reported to Bellberry.**

Reporting

Bellberry requires a report of **Protocol Violations** as soon as possible after the matter is discovered and within 14 days of the event.

These should be reported utilising eProtocol and the report include the following information:

- A concise report on the event – what happened, when it happened, where it happened, how it happened and why it happened?
- The affect the event had on the participant
- Any action taken in regard to the event
- Action taken to prevent any future occurrence
- Information on to whom the violation was reported.