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Information and guidance for primary care sites on protocol deviations, violations and serious breaches

The purpose of this guide is to provide primary care sites with guidance on the difference between protocol deviations, violations and breaches and how research staff in primary care should act on each.

1. What is a protocol deviation?

An unintended (non-serious) departure from the approved protocol would be considered a 'protocol deviation'. Protocol deviations tend not to have a significant impact on the participants safety or the trial's scientific value. An example of a protocol deviation is - a study visit date being outside the window defined in the protocol.

Protocol deviations need to be documented on a protocol deviation log. A Note to File (NTF) should be completed to outline future measures to prevent multiple repeat deviations.

See the website for the templates: Protocol deviation log and Note to file.

2. What is a protocol violation?

A protocol violation is a significant occurrence or event which may affect study participant's rights, wellbeing and/or safety, or the integrity of the research. Violations are also documented and along with any preventative measures. Examples of protocol violations

include – failure to obtain informed consent, enrolment of participants that do not meet the inclusion/exclusion criteria.

3. What is a serious breach of the protocol?

A 'serious breach' is defined as a breach likely to effect to a significant degree the safety or physical or mental integrity of the subjects of the trial or the scientific value of the trial. They are reported in Clinical Trials of Investigational Medicinal Products (CTIMPs) and the process will be specified in the protocol.

4. Who should I report deviations/violations/serious breach to?

Staff at a GP practice should report these to the Principal Investigator (PI). If you are the PI you should refer to the protocol for study sponsor reporting requirements.

5. Where can I find out more about protocol deviations/violations/serious breach?

Each study protocol will contain information about these and how to report them.

6. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk