**Log of Deviations, Violations, Potential Serious Breaches, Serious Breaches, Urgent safety measures**

* Record all protocol or GCP deviations / violations / potential serious breaches / serious breaches / urgent safety measures in this log
* The JRO must be informed of all violations / potential serious breaches / serious breaches / urgent safety measures
* See JRO/SPONS15 ‘SOP for the recording and reporting of Deviations, Violations, Potential serious breaches, Serious breaches and Urgent safety measures’ for more information (<https://www.ucl.ac.uk/joint-research-office/sops-and-templates/jro-sponsor-sops-and-templates-ucl-and-uclh>)

**Definitions**

**Deviation**: A deviation is usually an un-intended departure from the expected conduct of the trial (approved trial protocol, trial documents, SOPs or GCP).

*It is recognised that minor deviations from approved clinical trial protocols and GCP occur commonly in CTIMPs. The majority of these deviations are technical deviations that do not result in harm to the trial participants or significantly affect the scientific value of the reported results of the trial.*

**Violation**: A violation can occur when there is a departure from the expected conduct of the trial (approved trial protocol, trial documents, SOPs or GCP) and which may result in harm to the trial participants or significantly affect the scientific value of the reported results of the trial.

*A violation could constitute a serious breach of the protocol and/or GCP or an urgent safety measure, see below for further definitions.*

**Serious Breach:** *according to Regulation 29A (SI 2006/1928)*

“For the purposes of this regulation, a “**serious breach**” is a breach which is **likely** to effect to a significant degree –

(a) the safety or physical or mental integrity of the subjects of the trial; or

(b) the scientific value of the trial.”

**Potential Serious Breach:**A breach which is investigated as a breach potentially meeting the definition of “serious breach” above.

**Urgent safety measures:** *according to Regulation 30 (SI 2004/1031), amended by (SI 2009/1164):*

“The sponsor and investigator may take appropriate **urgent safety measures** to protect clinical trial subjects from any immediate hazard to their health and safety.”

This allows an Investigator to implement a deviation from, or a change of the protocol to eliminate an immediate hazard(s) to trial subjects without prior approval from the REC / MHRA, however a notification must be submitted within 3 days of the urgent safety measure having taken place.

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| **Trial Short Title:**  | **Principal Investigator:** |
| **Sponsor No:**  | **Site name:**  |

| **Type of Event***Deviation**Violation**Potential Serious breach**Serious breach**Urgent Safety measure**(according to definitions)* | **Nature of Event***Include full description of the event**Date event took place**Date the PI became aware of the event* | **Corrective and Preventative****Actions***Describe what preventative and corrective actions have been implemented following the event* | **If Violation or Breach***Date event was notified to JRO**and**Signature of PI* | **If Urgent Safety Measure***Date USM was reported to the MHRA, REC, JRO**and**Signature of PI* |
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