Protocol Deviations on Study Level[1,2]

Site Investigator name:	**Site name / number:**
Study Title (short name): ULTRA	
ABR number / Protocol ID: NL39577.018.12	

Description of deviation	Date deviation occurred	Reason for deviation	Corrective action taken to resolve this occurrence[3]	Preventive action taken to prevent future occurrence[3]
	|__|__| |__|__|__| |__|__|__|__| d d m m m y y y y			
	|__|__| |__|__|__| |__|__|__|__| d d m m m y y y y			
	|__|__| |__|__|__| |__|__|__|__| d d m m m y y y y			

[1]: Repeat this page if more deviations need to be reported; [2]: To report protocol deviations on individual subject level, please use the Form MET F03: Protocol Deviations on Subject Level or the appropriate (e)-CRF page; [3]: If applicable; If not, please state NA

Signature Principal Investigator: _____

Date: |__|__| |__|__|__| |__|__|__|__| d d m m m y y y y

Guidance notes to Protocol Deviations on Study Level

Definition of a protocol deviation:

A protocol deviation is a failure to conduct all aspects of the study as described in the approved study protocol and GCP/ISO14155 (when applicable). These may be the result of human error when the deviation is investigator or trial management related or they could be subject related, where subjects misunderstand or ignore guidance given to them whilst they are on study.

Examples of protocol deviations on study level include but are not limited to the following*:

- Inadequate or improper informed consent procedure, e.g. unapproved version implemented;
- Inadequate or improper Serious Adverse Event reporting; e.g. not according to mandatory timelines
- Inadvertent loss of samples or data;
- Repeated or continued negligence in performance of study procedures;
- Loss of laptop/computer/data stick containing identifiable, private information about subjects;
- Accidental distribution of incorrect study medication or dose;
- Performance of research at an unapproved site;
- Use of expired study medication;
- Over-enrolment to a protocol;

*: Please note that if the examples mentioned above occur more than once or if no adequate corrective and/or preventive action is undertaken, they are considered serious breaches of the GCP principle and should therefore be reported as such on form Serious Breach of GCP or Study Protocol (See AMC-CRU site, MET F02 Serious Breach of GCP or Study Protocol Form).

Reporting of protocol deviations

The Principal Investigator is responsible for the reporting of protocol deviations. Site staff or a study monitor may prepare a protocol deviation form, but this form should be signed by the PI. This form should be kept in the Trial Master File.

Protocol deviations are summarized for Data Safety Monitoring Boards (DSMBs), if applicable, and are reported to the accredited METC in the annual progress report.