**Protocol Non-Compliance Form**

**Supports: SOP 050: Handling of Protocol and Regulatory non-compliance**

Study title:

R&D reference number:

REC reference number:

Protocol version number and date:

Site name:

Name of person completing form:

Date of completion of this form:

Detail of non-compliance:

*(Please include study subject ID, date of randomisation (if applicable), the date the non-compliance occurred and the reason why the non-compliance occurred)*

Deemed to be: Protocol non-compliance

 Serious breach

If Protocol non-compliance ticked, please justify this categorisation:

If Serious breach ticked, please justify this categorisation:

Date Sponsor notified: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI Name and Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_