APPENDIX 3

**Version control Document – keep at front of Trial Site File**

**THE MOST UP-TO-DATE VERSION OF EACH DOCUMENT MUST BE PLACED UPPERMOST IN THE FILE – Retain all earlier versions for audit purposes and mark: ‘Superseded by Version (No) on (date)’ to avoid accidental use of wrong version.**

**protocol**

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| **VERSION No.** | **DATE** | **DATE APPROVED BY ETHICS**  | **DATE APPROVED BY MHRA** | **DATE C&C issued BY R&I** | **DATE IMPLEMENTED**  | **COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc** |
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**PARTICIPANT INFORMATION SHEET**

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