|  |
| --- |
| **Study Details** |
| Study Title |  |
| Study Type |  | REC Reference |  |
| Site |  | Lothian R&D Reference |  |

|  |
| --- |
| **Verifications** |
| **(✓)** *if ‘N/A’ specify reason* | Yes | No | N/A | Comment  |
| **Approvals** | Regulatory checks completed by Sponsor and authorisation to start trial received |  |  |  |  |
| Local approval in place at site |  |  |  |  |
| **Facilities** | Adequate facilities at site for product/device storage |  |  |  |  |
| Accountability approved by Sponsor and in place at site (GS010-T02) |  |  |  |  |
| Prescription approved by Sponsor (GS010-T03) |  |  |  |  |
| Product/device handling instructions and/or pharmacy manual approved by Sponsor and in place at site (GS010-T04) |  |  |  |  |
| Product/device labels accurate and consistent with regulatory approval |  |  |  |  |
| Pharmacy/site training completed and pharmacy ready to receive product/device |  |  |  |  |
| Pharmacy/site advised that recruitment cannot begin prior to SATO |  |  |  |  |

|  |
| --- |
| *I confirm that all boxes in the above checklist are ticked yes (or justified as N/A) and therefore IMP can be released to the site.* |
| **Report Signatures** |
| **Authorisation Completion**  |
| Completed by |  | Role |  |
| Signature |  | Date |  |
| *This Document confirms authorisation from the study sponsor or designee to transfer the Investigational Medicinal Product/Device to the above trial site. This does* ***not*** *permit any study activities, screening or dosing upon receipt of IMP at the trial site.* |

*Where this form is completed on behalf of ACCORD by a designee please send a copy of the completed form to the lead clinical trials monitor for the Sponsor’s records and ensure the original is filed in the TMF*