**Glasgow Clinical Trial Unit Form**

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| Form number | **57.010B** | Version  | **2.0** |
| Title | **GCR Site Initiation Visit Checklist** |

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| **Study Title** |  | **R&I Reference** |  |
| **PI** |  | **Sponsor** |  |
| **SIV Date** |  | **Target Date First Subject In (UK Site)** |  |
| **In Attendance** |  |

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| **APPROVALS RECEIVED** | **Comments** |
| REC Favourable Opinion  | Y [ ]  Outstanding [ ]   |  |
| R&I Approval | Y [ ]  Outstanding [ ]   |  |
| **ESSENTIAL DOCUMENTS RECEIVED** | **Comments** |
| Investigator Site File  | Y [ ]  Outstanding [ ]   |  |
| Current GCP Certificates available (within 2 years of study start) | Y [ ]  Outstanding [ ]   |  |
| Current signed and dated CV available (within 2 years of study start) | Y [ ]  Outstanding [ ]   |  |
| Study Worksheets Developed and Approved by Sponsor | Y [ ]  Outstanding [ ]  Not applicable [ ]   |  |
| Lab Manual | Y [ ]  Outstanding [ ]  Not applicable [ ]   |  |
| Lab consumables provided  | Y [ ]  Outstanding [ ]   |  |
| **TRAINING AND DELEGATION** | **Comments** |
| Delegation log complete | Y [ ]  Outstanding [ ]   |  |
| Access to eCRF | Y [ ]  Outstanding [ ]  Not applicable [ ]   |  |
| eCRF Training Complete | Y [ ]  Outstanding [ ]  Not applicable [ ]   |  |
| **SCHEDULES** | **Comments** |
| Monitoring/Audit Plan Agreed | Y [ ]  Outstanding [ ]  Not applicable [ ]   |  |
| Source Data Plan Agreed including physical location  | Y [ ]  Outstanding [ ]   |  |
| **ESCALATION ROUTES** |  | **Comments** |
| Sponsor Escalation | *CRA**CRA Line Manager* *QA Manager*  |  |
| GCRF Escalation | *Nurse Manager**QA Lead*  |  |
| **OUTSTANDING ACTIONS** |
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