**Glasgow Clinical Trials Unit Form**

|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **56.002L** | Version | **2.0** |
| Title | **Laboratory Master Research File** | | |

|  |  |
| --- | --- |
| **Section** | **Documents to File** |
| 1. Laboratory Organogram | * Organisation details of the laboratory |
| 1. Treatment of Routine Samples | * UKCRC Document and File Note |
| 1. Staff Records and Training | * Staff Training Log (Form 53.005I) and Certificates |
| 1. Contract (s) and Service Level Agreement(s) | * Contract and/or SLA between Lab and NHS GG&C R&I |
| 1. Meeting Minutes | * Minutes of meetings between study teams and labs |
| 1. Quality Assurance and Quality Control Checks | * QC checks of processes |
| 1. Deviations and violations | * Record of any shipping, storage or other deviation should be filed here. |
| 1. Correspondence | * All key correspondence should be printed and filed |
| 1. Approvals | * R&I Permission for each trial |
| 1. Laboratory Manuals for non-routine trial samples and processing | * Each research trial may have a laboratory manual * The manual will include shipping information, sample storage, method and analytical plan, stock and solution prep and analytical records |
| 1. Equipment Maintenance | * Calibration Certificates for equipment used in trials |
| 1. Shipping Documentation | * File all receipts from couriers * Multiple tear-offs slips can be fixed on an A4 sheet and filed |
| 1. Archiving | * Archiving process |
| 1. File Note(s) | * File Note template (Form 53.005J) * Completed File Notes must be filed in relevant section. General File Notes can be filed here. |