**Glasgow Clinical Trials Unit Form**

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

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| **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.
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