Glasgow Clinical Trials Unit Guideline

Guideline number	GUI 56.001A	Version	1.0
Title	Green for Go: Completion of the Delegation Log		

1. Preparation of the study specific delegation log

A delegation log is an essential document and must be completed and maintained by all participating locations as part of the set up process.

Form 56.002D should be used as a template to create a study specific delegation log. All 'core tasks' such as consent, eligibility, SAE reporting etc. must be retained. Other tasks should be removed as relevant e.g. any related to pharmacy can be removed if the study is a non-CTIMP or any related to samples and processing removed if not applicable.

Any additional tasks must also be added under other i.e. any study specific tasks not otherwise listed.

The delegation log should be agreed with the relevant Sponsor stakeholders (if applicable) and version controlled before sending to participating locations as part of the Local Information Pack (LIP).

2. Receipt of the completed delegation log

Prior to signing off the Green for Go checklist, the delegation log must be reviewed and meet the following conditions:

- PI has all delegated tasks assigned including 'overall responsibility at location'.
- Only the PI can have 'overall responsibility at location'.
- At least one co-investigator included and has been delegated tasks in relation to SAE reporting (in addition to the PI).
- All staff have tasks delegated that are relevant to their role/training
- Ensure everyone is trained on the study prior to being added to the delegation log (i.e. date of SIV / training on or before delegation date).
- All names are legible
- All tasks have been assigned
- The delegation log has been completed in full (each entry has included their initials, signature, study involvement start date and been signed off by the PI).
- Tasks are only assigned to those that are trained and qualified to complete those tasks.

Additional considerations for CTIMPs:

- Only medics are delegated the responsibility of assessing eligibility (unless otherwise agreed with the Sponsor team)
- A Pharmacist must be included on the delegation log with responsibility for all pharmacy related tasks at the participating location.

3. Changes to the delegated tasks

If any original member of staff is later delegated additional responsibilities (e.g. a co-investigator takes over as PI or a nurse adds sample processing tasks) this should be added as a new line with a new start date in order to show the contemporaneous nature of the addition rather than amending the original entry.

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4. Guideline Signatories

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5. **Document history**

Version	Date	Description	Retrospective Implementation
1.0	03/12/2025	First Release	No

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