Glasgow Clinical Trials Unit Guideline

Guideline Number	**57.006A**	Version	**2.0**
Title	**PI Oversight Plan**		

The Principal Investigator (PI) should develop a plan for the conduct and oversight of a research study.

A PI should:

1. Appropriately delegate tasks to research study team and ensure this is documented.
2. Prior to site initiation visit work with the study team to clearly define recruitment plans
3. Document routine meetings with co-investigators and study team to review the progress of the study, recruitment and update them on any changes to the protocol, other procedures and adverse events. The PI or deputy must be available to study team as and when agreed and as required to ensure patient safety.
4. Review delegation of tasks with the study team, to ensure tasks are current and appropriate. In the event study staff are not adequately performing delegated tasks, the PI should escalate to the appropriate GCRF Nurse Manager and QA Lead to assess compliance with protocol.
5. Ensure protocol training is documented with details of who was trained, who provided the training and what information was presented.
6. Ensure study modifications are disseminated to study team and repeat point 5 if training required.
7. To ensure information in source records is accurately captured on data collection forms, case report forms and patient medical records. To be involved in the development of study specific worksheets where these are created by the study team.
8. In the event of a serious breach of GCP or non-compliance with protocol, oversee the resolution of corrective preventative action plans.
9. Make themselves available for regular meetings with study monitors. Ensure data query and monitoring actions provided by local team are complete and accurate,
10. Ensure medical and ethical issues that may arise during the study are addressed in a timely manner.

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	18/04/2018	Creation of Guidance document	No
2.0	10/04/2026	Transfer to updated template Change to author/approver	No

		Minor administrative changes	

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