Standard Operating Procedure

4.2.4 Delegation of Duties

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Introduction / Background

It is a requirement of Good Clinical Practice that personnel employed to work on clinical research studies are qualified to do so by education, training, and experience.

While maintaining responsibility for the conduct of the clinical trial, the Principal Investigator may delegate significant clinical study related tasks and duties to appropriately qualified and trained staff.

It is the responsibility of the Principal Investigator to ensure that all study staff at the site understand and undertake their delegated tasks/duties in accordance with the study protocol and regulatory requirements to ensure the protection of the rights, safety, and well-being of participants.

The Principal Investigator is responsible for supervising any individual or party to whom they have delegated tasks/duties at the trial site. This responsibility also extends to any external individual or party whose services are contracted and retained by the Principal Investigator/Institution to perform trial related duties and functions.

For a clinical study to be conducted appropriately, it is essential that all involved personnel are aware of the anticipated extent of their involvement, their responsibilities relating to the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) and the limits to their authority.

Objective

This SOP describes the process of delegating tasks and duties related to the clinical trial.

Scope

This SOP applies to all staff directly involved in the conduct of the study including (but not limited to):

- Sub-Investigators/Co-Investigators
- Research Nurses
- Study Co-ordinators
- Clinical Trial Assistants
- Clinical Trial Pharmacists

This SOP also applies to staff associated with, but not directly involved in the research including (but not limited to):

- Clinicians
- Specialist nurses
- Laboratory staff
- Radiologists
- Support staff

Some research will involve participants who are inpatients at the time, and where the nursing staff on the ward are required to collect data for the safety or primary outcome of the study. It

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is not feasible to require each rostered nurse to be delegated tasks on the Staff Signature and Delegation Log (Template 1), taking into account roster and rotation. It is acceptable to consider ward nursing staff in the description above, and to require the unit nurse manager (or equivalent) to sign the Staff Signature and Delegation Log. It is appropriate to complete a Staff Training Log (Template 3) for all staff within the inpatient unit to demonstrate that while individual ward nursing staff are not listed on the Staff Signature and Delegation Log, the staff are appropriately trained to complete their study related duties according to the protocol.

Ownership and Responsibility

The Principal Investigator is responsible for delegating significant trial-related tasks/duties and for supervising any individual or party to whom they have delegated activities. Delegation of tasks/duties will be dependent on the qualifications and experience of team members.

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Procedure

Individual study related tasks and duties are defined, established, and allocated prior to the initiation of a study as per the Staff Signature and Delegation Log.

The Principal Investigator may delegate key tasks and duties to other individuals based on their skill level, qualifications and the tasks required. These delegations are recorded on the Staff Signature and Delegation Log.

It is important for the Principal Investigator to note that although tasks/duties may be delegated, responsibility for the clinical trial cannot be delegated (*refer* SOP 4.0 Investigator responsibilities). Therefore, it is important that the Principal Investigator ensures all tasks/duties are delegated to appropriately trained personnel.

The Staff Signature and Delegation Log must be completed at each site and held in the Investigator Site File for that site (*refer* SOP 8.0 Essential Documents). New personnel or new delegation of tasks/duties must be updated on this Log as appropriate and at the time of delegation.

The Principal Investigator must assess each person for their qualification and experience to determine if each task/duty is appropriate for that person. This may include a review of the person's CV and other relevant documentation/qualifications.

The Principal Investigator must undertake a detailed discussion of each task/duty being delegated to that person in the context of the study and must ensure that the person fully understands the tasks/duties being delegated to them.

The person who accepts those tasks/duties must fully understand the study, their role and the specific scope and limitations of the tasks/duties delegated to them.

Joint signatures on the Staff Signature and Delegation Log are a confirmation that this discussion takes place and that both parties fully understand the tasks/duties to be undertaken by each party.

All required protocol and other relevant study training including Good Clinical Practice training must be completed before adding the staff member to the Staff Signature and Delegation Log. The start date listed for the staff member must be on or after the date that all training requirements have been met.

Only one Staff Signature and Delegation Log will be maintained for each study, and this must be filed in the study specific Investigator Site File at all times. **All personnel delegated tasks/duties will be listed on the one log i.e., there will be no second log or copy of the log maintained elsewhere.**

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The Staff Signature and Delegation Log will:

- state names and roles of staff members delegated to complete specific trial related tasks/duties. **Only staff members who are appropriately qualified, and who have received the relevant protocol training (documented), should be listed on the log.**
- have at least one member of staff from each department involved in the study, including pharmacy, radiology, and pathology (where appropriate) and including both internal departments and external provider staff (where appropriate). It is also acceptable for one member of staff to sign the log as the person responsible for that department and the staff within it. However, the Staff Training Log (Template 3) must be completed for all staff within the department to demonstrate that while individual staff are not listed on the Staff Signature and Delegation Log, the staff are appropriately trained to complete their study related duties according to the protocol.
- be signed and dated by the Principal Investigator (PI), as staff are added. PI's signature must never be added retrospectively i.e., the date of the PI's signature must be the same or prior to the start date listed for the staff member.
- be made available to the Sponsor, where applicable.
- be updated when new members join or leave the study team, and as otherwise required.
- be filed in the appropriate section of the Investigator Site File.
- be retained with the archiving, including a copy of each version, for audit purposes.

The Principal Investigator must ensure regular supervision and oversight of all staff on the Staff Signature and Delegation Log. Ongoing training and communication are core activities of supervision. All supervision and communication by the Principal Investigator to site staff should be documented and retained. Several different approaches can be used appropriate to the site and to the study.

In order to demonstrate ongoing supervision, training and communication, the Principal Investigator can make use of:

- group email with return acknowledgements
- Staff Meeting Log (Template 2)
- Staff Training Log (Template 3)

These documents must be retained in the Investigator Site File.

If a third-party provider is required for any aspect of trial management (such as pharmacy, radiology and/or pathology providers), a policy must be developed that is specific to the site and the third party, to ensure that the Principal Investigator is able to comply with their responsibilities and the study requirements are met. The policy must be followed at all times. A copy of the policy must be retained in the Investigator Site File.

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Related SOPs

4.0 Investigator Responsibilities

8.0 Essential Documents

Related documents

Template 1: Staff Signature and Delegation Log

Template 2: Staff Meeting Log

Template 3: Staff Training Log

Template 3a: Individual Training Record

Template 3b: Group Training Record

Template 4: Short CV

References

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017)

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

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History			
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1.0	28/02/2018	B Fazekas, S Kochovska	New procedure
1.1	16/03/2020	C Strauss	Periodic review
1.2	06/01/2022	C Strauss	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.2	Meera Agar	

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