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Information and guidance for primary care sites on how to use a research site Signature & Delegation Log

The purpose of this guide is to provide primary care sites with an explanation of what a signature and delegation log is and how to complete and maintain it for a research study.

1. What is a signature and delegation log?

This is a record of all study staff members at a site with the duties and tasks that have been delegated to them by the Principal Investigator (PI). It is usually provided by the sponsor, however if the sponsor has not provided one, see website for the primary care signature and delegation log template and example.

2. Why is the signature and delegation log important?

The log is not just a paper exercise, it is documented evidence of appropriate delegation of the PI's responsibilities. It ensures that everyone knows their role and responsibility for a particular study. The document may also be called the delegation log or delegation of responsibilities log depending on the sponsor.

3. What information is needed on the log?

Signatures and **initials** of staff working on the study. The log can be pre-populated electronically however signatures, initials, PI signature and PI date should be wet ink. The study sponsor will be able to advise whether electronic signatures are acceptable.

Each staff member's study specific **role** in the study. This may be different to their usual job title.

The specific **tasks** each individual member of staff is authorised to carry out. This might be screening for potential participants, taking informed consent, dispensing a study drug. The PI must confirm that each staff member has been appropriately trained to carry out delegated tasks before they carry them out. Some tasks can only be delegated to specific staff groups for example adverse event (AE) and serious adverse event (SAE) assessments can only be conducted by a medical doctor and not by a study nurse. The overall responsibility of the study cannot be delegated by the PI.

The 'from' **date** for an individual should state the date they began working on the study. The 'to' date should not be completed until the individual has left the study team or the study ends at the site.

The **PI** initials and dates each entry for each individual to carry out delegated tasks. Individual staff should not conduct any study activity before their recorded start date on the log.

4. When should the log be completed?

The log should be completed before the site starts the study.

5. Where should the log be kept?

The log should be filed as part of the Investigator Site File (ISF).

6. What do we need to do if staff leave or join the local study team?

The log should be kept up to date throughout the study. New staff need to be added to the log and can only start their study related tasks after the PI has authorised them on the log. If staff stop working on the study the log should be updated with an end date, then signed and dated by the PI.

7. Do support staff need to sign the log?

Members of staff performing tasks as part of their routine job function with no study specific role do not need to be added to the log. An example may be where a health care assistant is collecting routine blood samples.

8. What happens at the end of the study?

At the end of the study all staff should have their end date on the log countersigned and dated by the PI. The PI should also sign the bottom of each page once the study site has closed and the log is complete. The log should then be archived as part of the ISF.

9. Where can I find out more about signature and delegation logs?

Training for delegation of duties in research can be found at:

https://learn.nihr.ac.uk/enrol/index.php?id=833 (accessed 06/02/2023)

IRAS Delegation Log template can be found here:

https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Delegation-Log (accessed 06/02/2023)

10. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk