STANDARD OPERATING PROCEDURE FOR TRAINING RECORDS

SOP NUMBER:	TASC SOP054 v8
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the Training Record requirements for staff delegated tasks within a clinical research project that is sponsored and/or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST).

This is to ensure that there is documented evidence that they are qualified by education, training, and experience to carry out their respective tasks in accordance with the UK Policy Framework for Health and Social Care Research.

2. SCOPE

This SOP applies to all UoD and NHST staff delegated a study task within clinical research. It is mandatory for Clinical Trials of Investigational Medicinal Products (CTIMPs) and advisory for all others.

3. RESPONSIBILITIES

UoD/NHST researchers:

- Ensure they maintain an up-to-date Training Record.

Chief Investigators (CI):

- Ensure only appropriately trained individuals are delegated tasks.
- Supervision of staff to ensure they carry out their tasks as delegated.

Principal Investigator (PI)

- Ensure only appropriately trained and competent individuals are delegated study tasks at their site.
- Ensure appropriate supervision of delegated study staff.

Clinical Trials Monitors:

- Monitoring of research team training records to ensure appropriate delegation.

4. PROCEDURE

Each individual delegated tasks within a clinical research project must ensure they have a Training Record that evidences they are trained and competent in the tasks they are delegated.

This can be a hard copy folder or an electronic version which following prior notification of a monitoring visit, must be readily available to monitors for review on the agreed day. This includes if the record is retained electronically.

4.1 Minimum required:

- **Curriculum Vitae (CV)** This should specify the previous work experiences and evidence of suitability for the delegated tasks.
- **Job Description**
- **Training Log**

The Training Log (Doc Ref 077) must be an ongoing, cumulative list of all internal and external training.
Information recorded should cover all training relevant to the individual's ability to carry out their delegated tasks.

It must include:

- a record of having read and understood the Sponsor SOPs and policies
- Evidence of competency in the use of study specific equipment
- Evidence of competency to carry out study specific procedures such as randomisation processes and Investigational Medicinal Product (IMP) management and handling.

4.2 On staff departure

Training records should be taken with an individual on leaving their current role, but copies of the essential training records (e.g. CV, Good Clinical Practice [GCP] training certificate, study specific training etc) must be retained by the CI.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CV	Curriculum Vitae
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
NHST	NHS Tayside
PI	Principal Investigator
SOP	Standard Operating Procedure

TASC Tayside Medical Science Centre
UoD University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 077: Training Log

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
5	Patricia Burns (Senior Research Governance Manager)	28/10/2022	Updated to provide further clarity on requirements. Removal of Policy/SOP/WI Log (Doc Ref 119).
6	Patricia Burns (Senior Research Governance Manager)	28/10/2024	Scheduled review no changes required.
7	Patricia Burns (Senior Research Governance Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. Requirement for printed certificates has been removed to align with current practices, where certificates may be issued electronically, if at all.
8	Patricia Burns (Senior Research Governance Manager)	28/10/2026	Updated to reflect current MHRA guidance. Changed “and/or” to “and” in the wording on education, training and experience. Added a separate PI responsibility.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	21 Oct 2026
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	21 Oct 2026