STANDARD OPERATING PROCEDURE FOR TRAINING RECORDS

SOP NUMBER:	TASC SOP054 v5
AUTHOR:	Patricia Burns
ISSUE DATE:	28 Oct 2022
EFFECTIVE DATE:	28 Oct 2022
REVIEW DATE:	28 Oct 2024

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/or 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 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

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 current job description and evidence of suitability for the delegated tasks.
This must be updated when new competencies are added.

- **Certificates/Evidence of Training**

If a certificate does not detail the content of the training course/conference, copies of handouts or an agenda from the course/conference may be retained within the training record if these have been made available to delegates.

- **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 documents (e.g. CV, Good Clinical Practice [GCP] training certificate 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
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

Version Number:	Reviewed By Job Title)	Effective Date:	Details of editions made:
1	Lorna Talbot (TASC R&D Manager)	14/12/2016	New.
2	Lorna Talbot (TASC R&D Manager)	27/02/2018	Updated to reflect current practice. Implementation of a Policy/SOP/WI Log. New TASC SOP template format.
3	Patricia Burns (Senior Research Governance Manager)	29/10/2018	Bring in line with TASC GCP Policy and update as required.
4	Patricia Burns (Senior Research Governance Manager)	29/10/2020	Biennial review no changes required. New TASC website added to footer.
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).

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	25th October 2022
Signature	Graeme Boyle Senior R&D Manager on behalf of Professor Petty	
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature	Valerie Godfrey	24 Oct 2022