STANDARD OPERATING PROCEDURE FOR CREATING AND MAINTAINING A TRAINING RECORD FOR RESEARCH STAFF

SOP NUMBER:	**Fife R&D SOP 42**
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process that must be followed to create and maintain a training record for staff involved in research sponsored by or hosted in NHS Fife.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Department via fife-uhb.randd@nhs.net).

2. APPLICABILITY

This SOP applies to all staff involved with clinical research hosted at or sponsored by NHS Fife including, Department Heads, Chief Investigators (CI), Principal Investigators (PI), Consultants, Clinicians, Clinical Trial Pharmacists, Research Managers, Statisticians, Research Nurses, Health Care Support Workers, Allied Health Professionals, Trial Coordinators and Data Managers.

3. RESPONSIBILITIES

3.1 It is an individual's Line Manager's responsibility to ensure that each member of staff has the appropriate qualifications, skills, knowledge and training for the type of work for which they are employed.

3.2 For staff employed in the NHS Fife R&D Department each individual's Line Manager has a responsibility to ensure that each member of staff is aware of the relevant NHS Fife Policies, SOPs and Work Instructions (WI) that are specific to their role.

3.3 It is the responsibility of the Chief Investigator (CI)/Principal Investigator for a particular study to ensure that each member of staff working on that study has the appropriate qualifications, skills, knowledge and training in order to follow the protocol and carry out the tasks they have been delegated in a safe and competent manner.

3.4 The CI/PI for a particular study must ensure that staff working on that study are informed of the NHS Fife Policies, SOPs and Work Instructions (WI) that are relevant to their role on that study.

3.5 It is an individual's responsibility to identify any training needs and to document evidence of all relevant and mandatory training undertaken by maintaining an accurate up to date training record and to keep this in a secure but accessible area.

4. POLICY

4.1 All staff involved in clinical research must be appropriately qualified and trained (NHS Fife Corporate Induction (NHS Fife staff only), R&D Induction (NHS Fife R&D Department staff only), UK Policy Framework for Health and Social Care Research, Good Clinical Practice (GCP) and relevant NHS Fife R&D Department SOPs) in order to meet research governance, regulatory and local requirements and must be able to produce evidence of any training undertaken in order to verify this.

5. PROCEDURE

5.1 For all NHS Fife R&D Department staff members the individual's Line Manager must ensure that a training record is established for them on the commencement of their appointment. This training record must consist of:

- Training Record Index (Doc Ref 42-01).
- Current job description along with all previous versions.
- Current CV (signed and dated within last 2 years) along with all previous versions.
- A list of all mandatory training for R&D staff (Doc Ref 42-05).

  All R&D Staff must record completion of this training in the Core Training Record in S:\Research\HOW TO\TRAINING\R&D Team Training.
- Non Study-Specific Training Log (Doc Ref 42-02) - all R&D Department staff must complete this log to document all generic research and clinical training undertaken.
- GCP certificate(s) if applicable - GCP training and re-certification every 2 years is mandatory for staff working on a Clinical Trial of Investigational Medicinal Product (CTIMP) – see FWP-GCPT-01 - NHS Fife Procedure on GCP Training.
- Other training certificates or evidence of training attended.

5.2 Research staff not directly employed by the NHS Fife R&D Department must follow their individual department requirements for the contents of their training record. However, they may use the documents detailed in section 5.1 to create and maintain a training record to meet research governance, regulatory and local requirements.

5.3 Details of all relevant new and revised R&D Policies, SOPs and WIs must be distributed to NHS Fife R&D Department Research staff via Q-Pulse. Staff will receive an email notification alerting them to the new or revised document and must read and acknowledge receipt via Q-Pulse.

5.4 All non NHS Fife R&D Department staff must be notified of all new/updated versions of R&D SOPs, Policies, WIs and associated documents via the R&D 'Need to Know' email communications.

5.5 At the time of issue of NHS Fife Sponsor Approval/NHS Fife Local Management Approval the R&D Approvals Team must send the CI/PI for each study a list of all mandatory NHS Fife R&D Policies, SOPs and WIs relevant to their role.

5.6 For studies Sponsored by NHS Fife the CI/PI must ensure that where appropriate all non NHS Fife R&D Department staff involved in the study complete the Policy/SOP/WI Training Log (Doc Ref 42-03) to document that the current version of all SOPs relevant to their role has been read and understood and any further training undertaken as a result of an update has been recorded.

5.7 Where deemed appropriate by the CI, staff involved in research studies Sponsored by NHS Fife must complete a Study Specific Training Log (Doc Ref 42-04) to document study specific training undertaken, including training on any non-routine clinical procedures. Staff working on studies hosted by NHS Fife may use this log in the absence of a study specific log provided by the Sponsor.

The original Study Specific Training Log must be retained within the Study Master File/Investigator Site File.

5.8 Training records for NHS Fife R&D Department staff must be archived for 25 years (either in hard copy or electronic form) after a member of staff leaves their post.

Training records for all other research staff must be retained in line with NHS Fife and local departmental policies.

5.9 Study specific training records must be filed within the Study Master File/Investigator Site File and retained for the appropriate duration in line with the study specific archiving requirements (See SOP35 (Fife)).

6. ASSOCIATED DOCUMENTS

Doc Ref 42-01 - Training Record Index
Doc Ref 42-02 - Non Study Specific Training Log
Doc Ref 42-03 - Policy/SOP/WI Training Log
Doc Ref 42-04 - Study Specific Training Log
Doc Ref 42-05 - Mandatory Training for R&D Staff

7. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
CV	Curriculum vitae
GCP	Good Clinical Practice
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure
WI	Work Instruction

8. REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

UK Policy Framework for Health and Social Care Research
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

9. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	10 May 2018	N/A – new SOP
2	Julie Aitken R&D Quality & Performance Lead	07 Sept 2020	Reformatted in line with current SOP template. Section 2 updated to clarify that this SOP applies to all research staff involved in studies hosted or Sponsored by NHS Fife. Section 3 added to clarify responsibilities. Section 5 updated to clarify process for recording training in NHS Fife R&D Policies, SOPs and WIs. Doc Ref 42-01 updated in line with revisions to this version of this SOP. Doc Ref 42-02 updated to enable details of clinical training to also be recorded. Doc Ref 42-04 updated and renamed to enable non-clinical training to also be recorded. Doc Ref 42-05 added to specify mandatory training for NHS Fife R&D Department staff.

10. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	07 Sept 2020