SOP NUMBER (FIFE): SOP42(Fife)
VERSION NUMBER: 1.0
PREVIOUS VERSIONS: N/A
ISSUE DATE: 10th May 2018
EFFECTIVE DATE: 10th May 2018
REVIEW DATE: 10th May 2020
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DATE APPROVED: 10th May 2018

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DOCUMENT HISTORY

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1. PURPOSE

This document describes the procedure used to create and maintain a training record for staff involved in clinical research.

It is the responsibility of all researchers 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 any NHS Fife employee 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, Data Managers and members of the Research & Development Department.

3. POLICY

3.1 All staff will have a job description that sets out the essential/desirable skills, qualifications and knowledge required for their post.

3.2 All staff involved in clinical research must be appropriately qualified and trained (NHS Fife Corporate Induction, R&D Induction (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 Health Board requirements and must be able to produce evidence of any training undertaken in order to verify this.

3.3 It is the Chief Investigator (CI), Principal Investigator (PI) and 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 they do in order to carry out their tasks in a safe and competent manner.

3.4 The CI/PI/Line manager must ensure that staff are informed of the relevant NHS Fife Policies, SOPs and Work Instructions (WI) that are specific to their role.

3.5 It is an individual’s responsibility to document evidence of all relevant and mandatory training undertaken by maintaining an accurate up to date training record.

4. PROCEDURE

4.1 An individual's Line Manager must ensure that a training record is established for each member of staff on the commencement of their appointment and this must be kept in a secure but accessible area.

4.2 The training record will consist of:
   - Training Record Index (Doc Ref 42-01) - R&D staff must use this index in their training record. Other staff may use this in the absence of a department specific template.
   - Current job description along with all previous versions.
   - Current CV (signed and dated within last 2 years) along with all previous versions.
   - Non Study-Specific Training Log (Doc Ref 42-02) - all R&D Department staff must complete this log to document all NHS Fife Core Training and generic research training undertaken. Other staff may use this in the absence of department specific template.
   - Policy/SOP/WI Training Log (Doc Ref 42-03) - All R&D Department staff must complete this log to document that the current version of all relevant SOPs has been read and understood and record if further training was undertaken as a result of an update.
At the time of issue of Local Management Approval all non R&D Department members of the research team listed on the SSI will be sent a copy of this log detailing all mandatory Policy/SOP/WI training to be completed.

Staff will 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.

- Copy of any Study Specific Clinical Training Logs (Doc Ref 42-04) - all R&D Department staff must complete this log to document training undertaken on non-routine clinical procedures. Other staff may use this in the absence of a department specific template. The original log must be retained within the relevant study specific Investigator Site File and a copy filed in the individual’s training record.
- 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

4.3 Training records for 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 will be retained in line with NHS Fife and departmental policies.

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

5. 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 Clinical Training Logs

6. 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
7. REFERENCES

World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.
(http://www.wma.net/en/30publications/10policies/b3/)

Medicines for Human Use (Clinical Trials) Regulations 2004.
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