Standard Operating Procedure

RESEARCH TRAINING

SETTING Trustwide

FOR STAFF Staff working under research protocols

ISSUE Staff should be appropriately and adequately trained to develop, carry out and support the delivery of research, and that training should be documented in a training record.

QUERIES Contact Research Operations Manager on Ext 29873. Alternatively e-mail: research@uhbw.nhs.uk.

Document History

Review date	Version Number	Version Date	Effective Date	Reason for change	Author/Reviewer	Authorised by
-	V1.0	27/10/15	03/11/15	N/A - original	Diana Benton	Trust Research Group
02/12/15	V1.1	02/12/15	23/12/15	Minor updates	Jess Bisset	Diana Benton
05/12/16	V1.2	04/04/17	04/04/17	Annual review resulting in typo correction, update to the footer and 'date for review'	Paula Tacchi/Jess Bisset	Jake Harley
21/12/18	V1.3	18/01/19	18/JAN/19	Minor updates	Diana Benton	Diana Benton
17/AUG/20	V1.4	17/AUG/20	21/SEP/20	Minor updates to reflect change of Trust name	Karen Morgan	Jess Bisset
23/NOV/20	V1.5	23/NOV/20	23/NOV/20	Minor updates including additions to abbreviation table	Becky Lambert	Jess Bisset
03/NOV/21	V1.6	03/NOV/21	05/NOV/21	Minor update – correction to review date	Amelia Lowe	Jess Bisset

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Definitions/Abbreviations	
CI	Chief Investigator
CPD	Continuing Professional Development
CRF	Case Record Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
CV	Curriculum Vitae

HRA	Health Research Authority
ISF	Investigator Site File
MDT	Multidisciplinary team
PI	Principal Investigator
R&I	Research & Innovation
SOP	Standard Operating Procedure

1. Purpose

The purpose of this standard operating procedure (SOP) is to define the level of competence required by members of the multidisciplinary team (MDT) that are developing, delivering and supporting research across University Hospitals Bristol and Weston NHS Foundation Trust (UHBW). This SOP will describe how training records should be recorded, documented and stored. Training records should be easily accessible and available on request.

2. Scope

In scope:

- Staff developing, carrying out and supporting research which falls under the responsibility of UHBW, according to the UK policy framework for health and social care research (v3.3, 2017).
- Staff who deliver research sponsored by UHBW, whether or not conducted within UHBW premises.
- Training relevant to developing, supporting or delivering research.

Out of scope: Staff carrying out duties unrelated to research within UHBW.

3. References

"For research in health or social care, the chief investigator is responsible for the overall conduct of the research project including: … satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project".

Training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards (see www.hra.nhs.uk/planning-and-improving-research/best-practice/researcher-suitability-and-training/; UK policy framework for health and social care research v3.3, 2017, page 16)

"Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s)." (Medicines for Human Use (Clinical Trials) Regulations 2004: http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf part 2, point 8, page 31)

4. Procedure

All staff involved in research should be trained appropriately for the role which they are carrying out, and should document that training in a way which demonstrates to external reviewers that the training and experience are adequate. All research training within the scope of this SOP should meet the minimum standards defined in this SOP.

It is recognised that staff join and leave research teams. New staff – both permanent and temporary - must be trained in all relevant systems and procedures so that they can meet the requirements of the

research.

It is the responsibility of the Chief Investigator/Principal Investigator (CI/PI) to ensure that this takes place (see Investigator Oversight SOP_008); this activity may be delegated to another member of the team. Good practice is to have a handover period between leavers and joiners, although this may not always be possible. Proportionate research training is advocated for any members of the clinical team supporting the clinical research team in the delivery of the study. This will include Good Clinical Practice (GCP) training tailored to the study requirements. However, unless directly involved with obtaining consent and / or signing eligibility criteria (e.g. for CTIMPs – see Extended Roles of non-medical clinicians SOP_022) the minimum training required will be GCP.

4.1 What training, education and skills should be documented?

Research can be a complex process, and as a result there are wide ranging types and levels of skills and knowledge in which research teams must demonstrate their competence. Some of these are generic and others are study specific. There are areas of expertise which may be developed over many years through education and experience, and this will be captured using a Curriculum Vitae (CV) or employment record (see SOP_008 Investigator Oversight of Research); other training may be delivered by face to face training courses, on the job training, meetings or self-directed (including e-learning). Individuals should agree with their line or professional manager what training is required on an ongoing basis. Future training needs should be agreed and planned following annual appraisal.

In order to make best use of staff time and ensure that learning is appropriate to the role staff are carrying out, targeted, modular or refresher training can be undertaken. The person delivering the training must be able to demonstrate their competence in the subject matter; if in doubt, the chief or principal investigator should refer to the UHBW R&I department (research@uhbw.nhs.uk or 0117 34 **20233**) or to the sponsor of the study.

Regardless of how the training is recorded, it is important, particularly for clinical trials of investigational medicinal products (CTIMPs), that the relevant training records can be easily located.

The different types of training, experience and skills required can be categorised in two ways outlined below:

4.1.1 Generic

Research-specific training courses which provide basic or advanced knowledge. Examples include Good Clinical Practice, Valid Informed Consent, and Next Steps in Delivering Clinical Research, monitoring skills, disease-specific teaching sessions, inspection-readiness and dry ice training. Examples of self-directed training, include familiarisation with corporate research standard operating procedures, refreshers in the latest legislation and guidance, shadowing or on the job training with staff who have more experience in specific areas. This type of training should be captured as part of CPD records.

4.1.2 Study specific

This relates to training which is relevant to a particular study. The training should take place either near to the time the study starts or during the study conduct depending on what is appropriate. It includes training in the protocol and all

amendments to the protocol, training in study-specific standard operating procedures, study drug or intervention procedures, unblinding procedures, use of CRFs, use of databases, etc.

Where particular duties are delegated to a member of the research team, the delegation of the duty must be captured on the delegation log, and any training required to carry out those delegated duties must be recorded, for example, protocol training or study-specific SOP training.

For type A and type B Clinical Trials of Investigational Medicinal Products (CTIMPs) the clinician signing the eligibility criteria must complete the risk assessment in Appendix 1 of SOP_022 extended roles of non-medical clinicians' v1.0 25.07.18 if applicable.

Training may be self-directed or be conducted by means of formal training sessions, meetings or small group discussions, but it is important that it is documented. Training must be delivered by the most appropriate person, which may include sponsor representatives where relevant. Evidence can be documented as follows:

- Notes from meetings: include the topic(s) covered, copies of presentations given, the personnel present and the date of the meeting
- Signed record of attendance: include the topic/title, the method of training (and who delivered it if relevant), name and signature and date of attendance
- CPD record: include the topic, how the learning was carried out, date of attendance
- SOP training record: title of the SOP, how the training was delivered, name and signature and date of attendance
- Follow-up email: include the topic(s) covered, the personnel present and the date of the meeting

4.2 Where to document personal/individual training, qualifications and skills

4.2.1 Curriculum Vitae (CV)

Educational and vocational training, employment history and publications demonstrate relevant training and experience and may be captured in the form of curriculum vitae. Staff should review and update their CV at least every 3 years, to include all relevant information and provide a copy to research sponsors or hosts as required. In order to ensure the latest version of the CV is made available, the document should be dated and signed. To facilitate sponsor oversight, an abridged version of a CV may be more accessible and should be provided if requested.

For research sponsored by UHBW, a copy of the chief investigator's CV should be provided with the application for sponsorship (please refer to Research Sponsorship at UHBW_SOP_002 for further details). As part of the 'capacity and capability' assessment, evidence that staff are trained and qualified appropriately will be requested as applicable. There is an expectation that all research units should ensure all research active members of the multidisciplinary team are GCP compliant (e.g. have completed GCP training in the previous three years) and have provided evidence of a CV or employment history (see SOP_008 Investigator Oversight of Research). A 'short CV' template is available as a separate document on the Research and Innovation website and provides the minimum standard

accepted. Use of the template is optional, but the minimum standards must be met.

4.2.2 Continuing Professional Development (CPD)

Continuing professional development relating to the research role should be documented along with evidence of the training (where available), such as certificates or other documentation. The title of the course, conference or other method of personal development should be recorded, along with the date it took place. Training may have been identified at the annual appraisal or undertaken in an *ad hoc* manner to support specific research requirements.

For staff carrying out mixed roles, for example part clinical and part research, CPD records may be kept together. However, to facilitate sponsor oversight, CPD relating to research should be clearly identified or stored as a separate section within the CPD record. A CPD template is available on the Research and Innovation website and defines the minimum standards. Use of the template is optional, but the minimum standards must be met.

4.3 Where to store individual training records

It is recognised that staff often take part in multiple research projects, and that storing several copies of the same document can be inefficient. In addition to an individual's own personal training record, for every project there should be a copy of the training record for relevant staff within the study/site file, or a file note stating where they are located.

4.3.1 *With the Study File or Investigator Site File*

A copy of the training record should be filed within the Investigator Site File (ISF) in the relevant section. Please see the Essential Research Documents SOP for the study file template for UHBW Sponsored research. The CV should have been updated within the last 3 years and be signed and dated as evidence of this (by hand or electronically); the CPD record should include dates of training attended.

4.3.2 *In a central location*

For studies which are conducted by a trials unit/research unit or where a research team is conducting multiple different studies, it is acceptable to store CV/CPD records in a central file and refer to them. All training records must be current, CVs should be dated (by hand or using a header/footer) and the CPD record should include dates of training attended. A file note must be placed in the relevant section of each study file/ISF referring to the specific location of the relevant training records so that they can be easily located.

4.4 Where to store group training records

These are most likely to be study specific and should be stored within the ISF within the training section. Where study-specific training is carried out as part of a broader meeting, for example, it is important that a record of that training can be identified easily at a later date, in order to provide evidence of that training. This is particularly important for CTIMPs. Research teams should consider either duplicating relevant sections of meeting notes or cross referring from the training section in these cases.

4.5 How long to store training records

For Clinical Trials of Investigational Medicinal Products – i.e. trials falling under the clinical trial regulations (SI 1031), CVs and CPD records must be archived with the ISF in accordance with the timelines described in the Archiving of Research SOP_015. The Principal Investigator must ensure that copies of leavers' CVs and CPD records are obtained and placed in the ISF when staff leave the organisation or the research team.

For other research, please also refer to the Archiving of Research SOP_015for guidance. There is no legislative requirement for the duration of storage of non-CTIMPs but the training records should be reconciled with and archived alongside the ISF.

5. Mandated training

UHBW mandates Good Clinical Practice training for all staff involved in research at a level commensurate with their involvement. Whilst staff remain research active, GCP should be updated every three years. Other sponsors may require GCP training more frequently than every three years; UHBW does not have the authority to over-rule a requirement by another sponsor to do GCP training more frequently. However, please refer to the R&I department for questions in relation to this requirement, as negotiation may be possible. The manner in which each individual is trained should be proportionate to the involvement in the research. It may be appropriate for a small section of the whole GCP training course to be tailored to a particular staff group. The R&I office will advise the level of training required, according to role. It is expected that all PIs providing oversight to CTIMPs will be compliant with PI Oversight training as per SOP_008 Investigator oversight. Training will be recorded and uploaded to the research management database and compliance will be monitored.

6. Compliance

It remains the responsibility of the chief investigator to ensure that his/her team is suitably qualified and trained to conduct the research. To support the chief investigator and in its role as sponsor, UHBW R&I team will review training records as part of the programme of monitoring carried out within the trust. Further details can be found in the SOP_010 monitoring and oversight of research.

This SOP should be used as a minimum standard. If a sponsor requires a research team to work to its own training SOP which meets or exceeds these standards, that is an acceptable approach; however, the research team must still demonstrate familiarity with this SOP.

It is at the discretion of the Director of Research (or delegated representative) to temporarily suspend a study if evidence of appropriate training and qualifications is not available for inspection or monitoring purposes.

7. Dissemination and training in the SOP

7.1 Dissemination of this SOP

7.1.1 **New SOPs and new versions of existing SOPs:** The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the SOP 001 Production and management of research procedural documents developed by R&I. Internal Trust Staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates; as communicated in the Training SOP.

Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly)

- Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade
- Direct email to Chief Investigators of CTIMPs sponsored by UHBW
- Direct email to the Head of Research Governance at the University of Bristol (as relevant)

7.2 Training in this SOP

7.2.1 All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

7.2.2 The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.

8. Additional Documents (include flowcharts, work instructions, templates and forms referred to in the body of the SOP.

1. Trustwide Departmental Training Log
2. Personal CPD Folder Template
3. CPD Log Template – NMC revalidation
4. Short CV template

REFERENCES	N/A
RELATED DOCUMENTS AND PAGES	UHBW Research SOPs located at http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Contact the Research & Innovation Department on 0117 342 9873 or research@uhbw.nhs.uk