Standard Operating Procedure

RESEARCH TRAINING

SETTING Trustwide

AUDIENCE 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.

Standard Operating Procedure (SOP)

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Approved by:	Trust Research Group		
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Date reviewed	Version number	Version Date	Effective Date	Reason for change	Author/Responsible person	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

1. Purpose

The purpose of this standard operating procedure is to describe what types of training are required for staff who are developing, carrying out and supporting the delivery of research, how this should be documented in a standardised and accessible manner, and the requirements for retaining training records.

2. Scope

In scope:

- Staff developing, carrying out and supporting research which falls under the responsibility of UHBristol, according to the Research Governance Framework for Health and Social Care (RGF).
- Staff who deliver research sponsored by UHBristol, whether or not conducted within

UHBristol premises.
- Training relevant to developing, supporting or delivering research.

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

3. Definitions/Abbreviations

RGF	**Research Governance Framework for Health and Social Care**
SOP	**Standard Operating Procedure**
CTIMP	**Clinical Trial of an Investigational Medicinal Product**
CV	**Curriculum Vitae**
CPD	**Continuing Professional Development**
CRF	**Case Record Form**

4. References

"For research in health or social care, the chief investigator is responsible for ensuring the following….Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented." (Research Governance Framework for Health and Social Care, 2nd Edition, 2005, page 31).

"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)

5. 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 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 CI/PI to ensure that this takes place; 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.

5.1 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 CV; other training may be delivered by face to face training courses, on the job training, meetings or self-directed learning, for example. 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 principle investigator should refer to the UHBristol R&I department (research@uhbristol.nhs.uk or 0117 34 **20233**) or to the sponsor of the study.

However 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:

5.1.1 Generic

Research-specific training courses which provide basic or advanced knowledge. Examples include Good Clinical Practice, Valid Informed Consent, Fundamentals of Clinical Research, Monitoring Skills, Disease-specific teaching sessions, Inspection-Readiness, Dry Ice training.
Self-directed training which includes 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.

5.1.2 Study specific

These relate to training which is relevant to a particular study. The training should take place near to the time the study starts/during the study conduct. 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.

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, and this will include sponsor representatives where relevant. It can be captured in a number of different ways, including the following:

- 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
- CPD record: include the topic, how the learning was carried out, the date.
- SOP training record: title of the SOP, how the training was delivered, name

and signature and date.
- Follow-up email: include the topic(s) covered, the personnel present and the date of the meeting

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

5.2.1 Curriculum Vitae (CV)

Educational and vocational training, employment history and publications demonstrate relevant training and experience and may be captured in the form of a 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. To facilitate sponsor oversight, an abridged version of a CV may be more accessible and should be provided if requested.

For research sponsored by UHBristol, a copy of the chief investigator's CV should be provided with the application for sponsorship (please refer to the 'Sponsorship' SOP for further details). As part of the 'capability and capacity' assessment, evidence that staff are trained and qualified appropriately will be requested. A 'short CV' template is appended to this SOP and defines the minimum standards. Use of the template is optional, but the minimum standards must be met.

5.2.2 Continuing Professional Development (CPD)

Continuing professional development relating to the research role should be documented in an ongoing manner, 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 prospectively within annual performance appraisals 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 appended to this SOP and defines the minimum standards. Use of the template is optional, but the minimum standards must be met. If the standard system for recording CPD is electronic, then this can be printed hard copy or printed to file to store in the study file/ISF.

5.3 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.

5.3.1 *With the Study File or Investigator Site File*

A copy of the training record should be filed within the Investigator Site File in the relevant section. Please see the Essential Research Documents SOP for the study file template for UH Bristol 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 using a header/footer); the CPD record should include dates of training attended.

5.3.2 *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.

5.4 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 if that is the case. 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.

5.5 How long to store training records

For Clinical Trials of Investigational Medicinal Products – ie trials falling under the law (SI 1031), CVs and CPD records must be archived with the Trial Master File in accordance with the timelines described in the 'Archiving' SOP. 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' SOP for guidance. There is no legislative requirement for the duration of storage, but the training records should be reconciled with and archived alongside the Trial Master File.

6. Mandated training

UHBristol 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; UHBristol 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, for example. The R&I office will advise the level of training required, according to role.

7. 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, UHBristol 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 monitoring SOP.

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 are not maintained.

8. Dissemination and training in the SOP

8.1 Dissemination of this SOP

8.1.1 **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 "Authorship, review, revision and approval of research procedural documents produced by research & innovation". 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 UHBristol
- Direct email to the Head of Research Governance at the University of Bristol (as relevant)

8.2 Training in this SOP

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

8.2.2 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.

9. Appendices (include flowcharts, work instructions, templates and forms referred to in the body of the SOP.

Appendix 1 – Trustwide Departmental Training Log

Appendix 2 – Personal CPD Folder Template

Appendix 3 – CPD Log Template – NMC revalidation

Appendix 4 – Short CV template

IMPORTANT NOTE:

Depending on the nature of the SOP, it may be necessary to complete an Equality Impact Assessment form for this procedure. This can be found on HR Web under "Equality Impact Assessment"

RELATED DOCUMENTS	UHBristol Research SOPs located at http://www.uhbristol.nhs.uk/research-innovation/our-research/strategy,-policy-sops/
AUTHORISING BODY	Trust Research Group

SAFETY None

QUERIES Contact research@uhbristol.nhs.uk , x20233

Appendix 1 – Trustwide Departmental Training Log

Area of training* **or name of trainee**:_____

Date of training	Type of Training Undertaken (eg trainer, meeting, read document)	Name of trainee **or SOP***	Name of trainer (if applicable)	Signature (trainee)	Signature of trainer (if applicable)

*ensure the version number and date of SOPs, protocols etc are documented.

Personal CPD folder

In order to standardise CPD folders we suggest the following sections are adopted by research staff. This will enable all training records to be maintained in a single location whilst fulfilling the multiple requirements for training records to be kept.
The documents stored may vary and can include:

- Certificate of attendance
- Certificate of completion, notes, learning outcomes
- Copies of publications read, data reviewed, review notes including practice related outcomes
- Evidence of peer review including notes, observations and outcomes
- Evidence of coaching/mentoring undertaken including letters, notes, observations and practice related outcomes

Section Headings

Section 1	**Trust Essential**	Deemed as essential by the trust for all staff
Section 2	**Trust Clinical**	Includes essential and additional clinical training
Section 3	**Research**	
Section 4	**Study Specific**	
Section 5	**Leadership / Management**	
Section 6	**Revalidation info**	Adapt for profession's regulatory requirements
Section 7	**Other e.g. IT training**	

If training could be stored in more than one section, choose which one to file in and add a 'file note' to the alternative section stating where the record is kept.
The first page of each section should list contents in date order. See sample below:

Section No. 4 Section Title: Study Specific

Date	**Course/Subject Title**	**Location of evidence if not in this section**
10 Oct 2014	Generic Handling dry ice –required for AStERIX, TInTIn and NAruTO studies	Section 3

CPD Folder Name _____

Section No. _____ Section Title _____

Contents list

Date	Course/Subject Title	Location of evidence if not in this section

Continuing Professional Development (CPD) Log Template – NMC Revalidation

Please provide the following information for each learning activity until you reach 35 hours of CPD (of which 20 hours must be participatory.)

For examples of the types of CPD activities you could undertake and the types of evidence you could retain please refer to Guidance Sheet 3 in 'How to Revalidate with the NMC'

Date	Method (please describe the types of method you used for the activity)	Topic(s)	Link to Code	No. of hours	No. of participatory hours

Guide to completing CPD record log

Examples of learning method	What was the topic?	Link to Code
• Online learning • Course attendance • Independent learning	Please give a brief outline of the key points of the learning activity, how it linked to your scope of practice, what you learnt, and how you have applied what you have learnt to your practice.	Please identify the part(s) of the Code relevant to the CPD • Prioritise people • Practice effectively • Preserve safety

CURRICULUM VITAE

Name:	
Current appointment:	
Address:	
Telephone number:	**Email address:**
Qualifications:	
Professional registration:	
Previous and other appointments: *(Include previous appointments in the last 5 years)*	
Research experience:	
Research training:	
Relevant publications:	
Signature:	**Date:**