BU RDS SOP 013 V1

Title: Staffing and Delegation	
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1. Scope

The purpose of this Standard Operating Procedure (SOP) is to emphasise the importance of ensuring that all staff working on a given research project possess the necessary contracts and permissions prior to undertaking their role. This SOP also highlights the necessity for a complete and fully supported delegation log prior to any sites undertaking study-related procedures or tasks, as per Good Clinical Practice (GCP) guidelines.

2. Responsibilities

The *Sponsor,* usually delegated by the *Chief Investigator (CI)* is responsible for keeping a copy of all delegation logs for all sites in the Trial Master File (TMF) as well as ensuring that they are complete and accurate. In the case of Postgraduate Researcher (PGR) projects, the PGR will be responsible for these tasks, with the support of the Clinical Governance Advisor.

The study team at the participating site is responsible for completing the study delegation log with the full name, date of entry, study role, signature, initials and designated study tasks. They should keep the delegation log in the Investigator Site File (ISF).
This team comprises the *Research Nurses, Data Managers and/or Clinical Trial Assistants* as well as the *Principal Investigator (PI), any Co-Investigators* and *support staff* such as *pharmacy.* They are also responsible for documenting any changes in staffing on the log and seeking approval from the Principal Investigator for these additions or cessations.

Some duties and roles may differ at each organisation.

The *Principal Investigator* is responsible for ensuring that their entire site staff are fully trained and have the adequate skills and experience to undertake the tasks allocated to them on the delegation log, prior to signing off the entry. The PI has overall responsibility at each site and may delegate any task apart from *responsibility.* If a PI changes at a given site, then they (or a delegate) are responsible for notifying the Sponsor, so that an amendment may be submitted to the appropriate bodies.

The *Clinical Governance Advisor (CGA)* is responsible for maintaining a record of, and ensuring that all staff with an active role in clinical studies have GCP certification. It may be that their role also requires additional training, such as training in obtaining informed consent. This is assessed on a case-by-case basis.

3. Procedure

3.1 Every study that requires a full capacity and capability assessment will require a fully signed delegation log, outlining all study staff at the given site, and the duties delegated to them. All staff involved must be qualified to carry out their responsibilities and duties by education, training and experience. Further guidance may be found on the NIHR website.

3.2 A member of staff's entry on the delegation log is only valid once it has been reviewed and signed off by the PI. If a member of staff decides to add a duty once they have been signed off at the beginning of their involvement, then this is to be added as a new line which will then require the PI's signature.

3.3 If a site's PI changes then this may need to be submitted to the appropriate approval bodies as a Non-Substantial/Substantial Amendment. See BU RDS SOP 002.

3.4 When a member of staff is no longer working on the study in question, then an end date must be added to their entry. Similarly, when a member of site staff takes on a new duty, then they must complete another line of the log (in addition to their existing entry), and request signature from the PI. This then shows the exact date that they were delegated this new responsibility.

3.5 For staff who are employed elsewhere, but wish to work on a given research study, the NIHR have produced the document entitled *Research in the NHS – HR Good Practice Resource Pack.* This document outlines the required checks and permissions required for any external staff visiting NHS Trusts in order to undertake research-related activities.

For example, if a Postgraduate Researcher without an NHS honorary contract wishes to visit an NHS Trust in order to carry out their research study, then they will need a *research passport.* This is then sent to all sites, in order for them to issue a *letter of access*. See appendix figure 1 for a useful table.

Students conducting research as part of their healthcare placements do not need to complete a Research Passport Form and do not require an honorary research contract or Letter of Access.

The CGA can offer advice on how to proceed with gaining these permissions and documents.

Principal Investigator

3.6 The PI is the individual with the overall responsibility for trial conduct at a *single site* and for oversight of the site trial team. Whilst they may delegate duties to their site staff (e.g. obtaining informed consent, ISF management), they cannot delegate their responsibility.

Within the European Medicines Agency ICH GCP E6 R2 guidelines (EMA, 2016) (which were recently updated), the PI has additional/redefined responsibilities. These are covered in NIHR GCP training and include:

- The oversight of an individual or party to which the investigator has delegated study tasks at the trial site, in addition to ensuring that any third-party organisation, to which tasks have been delegated, is appropriately qualified. The PI should ensure

that this third-party organisation performs study tasks in a way that maintains the integrity of the study and the data generated;
- Maintenance of records of the documents use for critical processes, whilst clearly documenting evidence of their oversight and involvement in the trial (this also applies to studies not involving medicinal products);
- Ensuring that clinical investigations are carried out in accordance with the protocol, the investigational plan and applicable regulations;
- Establishing good communication in order to adequately monitor all study activities (in addition to permitting monitoring and auditing by the Sponsor, and inspection by the relevant regulatory authorities).

3.7 If any study activities are outsourced (e.g. MRI scans to a neighbouring Trust with the facility), then there should be the following measures in place:

- Sponsor awareness and approval;
- An agreement in place which specifies the duties delegated and the requirement to perform the trial in accordance with the protocol and applicable regulations;
- Training requirements;
- Source data retention requirements and data flows to the PI;
- If applicable, then safety reporting will likewise need to be considered.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
GCP	Good Clinical Practice
ISF	Investigator Site File
NIHR	National Institute for Health Research
PGR	Postgraduate Researcher
PI	Principal Investigator
TMF	Trial Master File

5. Related documentation and references

BU RDS SOP 002 - Amendments

Ema.europa.eu. (2016). [online] Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf [Accessed 3 May 2018].

NIHR Delegation and Training Decision Aid. [online] Available at: https://sites.google.com/a/nihr.ac.uk/dandtda/ [Accessed 3 May 2018].

Research in the NHS – HR Good Practice Resource Pack, HR Good Practice: Information for researchers, R&D and HR staff in Higher Education Institutions and the NHS, (version 2.1 – September 2012), National Institute for Health Research

UK Policy Framework for Health and Social Care Research. (2017). Health Research Authority.

Appendix

Figure 1

Version 2.1, September 2012

Table 1: Summary of forms of contractual arrangement available for individuals undertaking research in the NHS

Forms of contractual arrangement that can be issued to cover research activity	Substantive Employer							
	(1) HE Substantive Employee	(2) Substantive HE with Honorary Clinical NHS Contract (Clinical Academic)	(3) HE Student on a formal healthcare placement	(4) HE Student NOT on a formal healthcare placement	(5) NHS Substantive Employee	(6) Independent Contractor e.g. GP (providing NHS services under contract))	(7) Commercial Researcher	(8) Commercial Researcher under contract to HE (non-commercial research)[5]
HRC	YES[6]	NO	NO	YES[6]	NO	NO	NO	YES[6]
LoA accepting an HRC	YES[7]	NO	NO	YES[7]	NO	NO	NO	YES[7]
LoA (no HRC required)	YES[8]	NO	NO	YES[8]	NO	NO	NO	YES[8]
NHS to NHS LoA	NO	YES[9]	NO	NO	YES[9]	NO	NO	NO
Service Level Agreement	NO	NO	NO	NO	NO	NO	YES[10]	NO
Healthcare Placement Agreement	NO	NO	YES	NO	NO	NO	NO	NO
Is a Research Passport needed?	YES[11]	NO[12]	NO	YES[11]	NO[12]	NO	NO	MAYBE[13]

5 Applies only to HEs contracting researchers to undertake research funded and sponsored by non-commercial bodies
6 Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care.
7 Appropriate where the Trust owes a duty of care to research participants and the researcher's activity will have a direct impact on patient care and the researcher already holds an HRC with another NHS organisation.
8 Appropriate where the Trust owes a duty of care in respect of the research activity and the researcher's activity has no direct impact on care but involves access to NHS patients, data or facilities.
9 Covers all types of research activity i.e. direct and indirect impact on patient care, where the researcher has a contractual relationship with the NHS.
10 HR issues should be addressed in a service level agreement unless covered by Trial Agreement e.g. Data Monitors
11 Yes, where evidence of pre-engagement checks are required
12 NHS to NHS proforma confirmation of pre-engagement checks should be used for those with an existing substantive or honorary clinical NHS contract.
13 Yes, to facilitate sharing of pre-engagement checks

RP001 - Good Practice: Information for researchers, R&D and HR staff in HEIs and the NHS
Research in the NHS: HR Good Practice Resource Pack