University Hospitals Plymouth NHS Trust

STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Research agreements, contracts and vendor selection

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APPROVED BY

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Date: 18th Jan 2019

1 Purpose and Scope

The RD&I Office is responsible for negotiating and authorising all contracts which facilitate research. These include sponsored research agreements, the exchange of confidential information, datasets, research tools or materials. The purpose of this SOP is to describe the general procedures relating to the management and maintenance of agreements and contracts within the Research, Development and Innovation (RD&I) Dept. of University Hospitals Plymouth NHS Trust (UHPNT).

The RD&I Dept. acts on behalf of UHPNT in managing research carried out by the Trust in order to ensure it complies with scientific, ethical, regulatory and financial standards.

The Management and maintenance of UHPNT Research contracts is the responsibility of the research office team made up of the RD&I Manager and Deputy, RD&I Finance Co-ordinator, RD&I Deputy Finance Co-ordinator and the Chief Investigator or Principal Investigator. The signing of contracts is the responsibility of a Trust board member.

In scope: All research hosted by, and/or sponsored by UHPNT.

Definitions

CDA	Confidentiality Agreement – also known as a non-disclosure agreement (NDA) is a legal contract between at least two parties to enable the exchange of secret information and which outlines confidential materials or knowledge the parties wish to share with one another for certain purposes, but wish to restrict from general use.
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
Force Majeure	The literal interpretation from French is “greater force”. However, the expression “force majeure” has acquired a commercial usage which is widely recognised by businessmen and lawyers. The general principle is that a party to an agreement should not be liable for the non-performance of its obligations due to an unexpected event outside its control.
GCP	Good Clinical Practice
HRA	Health Research Authority
LoI	Letters of Intent – a document used as a preliminary agreement between UHPNT RD&I Dept and the third party to enable preliminary/preparatory activities to begin prior to a formal final contract being signed.
MHRA	Medicines and Healthcare products Regulatory Agency
MSA	Master Service Agreement or similar – usually provided if UHPNT RD&I Dept intends to use the service provider on a regular basis. This document routinely defines general responsibilities of UHPNT and the third party.

MTA	Material Transfer Agreement - is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for either their own research purposes or they are conducting analysis of specimens for the researcher at the donating site. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.
NIHR	National Institute for Health Research
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigator
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SLA	Service Level Agreement - is a contract between a service provider (either internal or external) and the end user that defines the level of service expected from the service provider. SLAs are output-based in that their purpose is specifically to define what the customer will receive.
SoA	Statement of Activities
SOP	Standard Operating Procedure
TA	Technical Agreements – defining technical requirements and roles and responsibilities of UHPNT RD&I Dept and the third party with regard to the manufacture and analysis of Investigational Medicinal Product(s) (IMPs) for use in clinical research.
WO	Works Order or similar – defining specific roles and responsibilities of UHPNT RD&I Dept. and the third party for an individual trial or study.

2 Who should read this document?

The Associate Director of Finance and all RD&I Office staff involved in negotiating and authorising all contracts which facilitate research in the Trust. Including when appropriate the Chief Investigator (CI) and Principal Investigator (PI).

3 Procedure to Follow

3.1 Contractual Arrangements (other than funding agreements)

For all research sponsored by UHPNT an assessment will be made in RD&I as to what type of contracts and agreements will be required with the other organisations involved in the study, including but not limited to:

Site agreements, with other NHS organisations recruiting patients into the study

Collaboration Agreements

Material Transfer Agreements

Data sharing agreements

Service Level Agreements

Confidentiality Agreements

Where possible UHPNT will utilise national templates and guidance for contractual arrangements for research (http://www.ukcrc.org/regulation-governance/model-agreements/), for example the model non-commercial agreement (mNCA) developed by the UK Clinical Research Collaboration.

In instances where a template for a particular agreement does not exist or the other party to the agreement is unwilling to accept the relevant template, UHPNT may review a template provided by another organisation.

Any amendments requested from other organisations to national templates will be reviewed and agreed by RD&I.

3.2 Statement of Activities (SoA)

The SoA is part of the application document set for non-commercial studies submitted for Health Research Authority (HRA) Approval. The Statement has three main functions:

1. The template completed by the sponsor provides key information to facilitate the HRA assessment component of HRA Approval;
2. The information that is confirmed as part of HRA initial assessment, and provided by the sponsor to participating NHS organisations in England as part of the local document package, is intended to facilitate the assessing and arranging of capacity and capability (where applicable) to undertake the study;
3. In certain cases, the completed and localised SoA forms the agreement between the sponsor and participating organisation in England, through which the organisation confirms that it is ready to commence the study (i.e. in place of any other form of site agreement/contract). Where this is the case, it is made clear in the HRA Initial Assessment letter and in the HRA Approval letter. In all other cases, other agreements are to be put in place between sponsor and participating organisation, e.g. the model non-commercial agreement (mNCA).

The HRA encourages use of the SoA as the agreement for studies that are not clinical trials or clinical interventions. For clinical trials and clinical interventions, the HRA encourages use of the appropriate model agreement (e.g. mNCA). The SoA should not be used as an agreement with participating organisations in Northern Ireland, Scotland or Wales.

3.3 RD&I Support

The RD&I Dept. provides support in the following areas:

- specialist advice and assistance with grant funding opportunities,
- project costing

- funding terms and conditions,
- authorisation of applications and awards,
- support for contracts and tenders for sale of research related activity subject to commercial conditions of contract,
- contract management including provision of contract negotiation expertise, reviewing contract conditions and drafting contract terms,
- specialist advice and assistance with research policy and compliance such as ethics and insurance,
- legal reviews of funder terms and conditions of contract,
- maintenance of agreements and contracts, including contract renewal and extension,
- protection and exploitation of intellectual property,
- confidentiality agreements,
- support for consultancy contracts.

3.4 Responsibility for signing research contracts lies with the Trust Board of UHPNT

The Associate Director of Finance for the Trust signs all research contracts and agreements on behalf of the Trust.

3.5 Content of Research Contracts: Clinical Trials

National template Agreements/Contracts have been created by the National Institute for Health Research (NIHR) and in most cases these will be utilised (see Appendix 1). The Agreements/Contracts templates should include the sections for/reference to the following:

- Duration of trial
- Indemnity and Insurance
- Reference to requirement of UHPNT to undertake services in accordance with all applicable laws, enactments, orders, regulations and other similar instruments including, but not limited to, Good Clinical Practice and Data Protection
- Reference to requirement of UHPNT to report any perceived or suspected fraud or significant non-compliance to company/client or regulatory authority if applicable.
- Company's obligations including reference to requirement for company/client to obtain and maintain in force all necessary approvals including, but not limited to, ethics and regulatory approvals and to provide copies to UHPNT on request.
- UHPNT's responsibility for Serious Adverse Event Reconciliation (indicating either 'requirement' or 'no requirement').
- Intellectual property

- Confidentiality
- Publication rights
- Warranties
- Termination of contract
- Force Majeure
- Notices
- General items including requirements with respect to sub-contracting
- Applicable law
- Inclusion of final protocol
- Statement of work including tasks and responsibilities to be undertaken by UHPNT
- Archival arrangements including items to be archived by UHPNT, length of time to be archived and clause covering requested retrievals by company/sponsor
- Financial and supply provisions

In circumstances where the draft contract is provided by the company/client/external party, the RD&I Dept. will ensure that all of the above items are included in it.

3.6 Review of contract against final protocol and in response to protocol revisions

The RD&I Dept. prepares all costings in accordance with the study protocol or other relevant documents or discussions. The draft or version of the protocol and/or details of any other relevant documents or discussions against which the costing is prepared will be included in the costing proposal. The final version of the protocol will be included in the contract. The RD&I Dept. will check that the initial contract has been reviewed against the final protocol, with the date and version of protocol being specified. Any amendment to the protocol will trigger a review of the contract against the amendment, with any required changes to the contract documented and implemented. If it is considered that an update to the contract is required, this will be notified by the Finance Co-ordinator to the RD&I Manager.

3.7 Sub-Contracting / Vendor Selection

As sponsor UHPNT may be required to delegate certain research related activities to other organisations. RD&I will assess the suitability of a vendor, to ensure that the vendor can perform the services to applicable standards and regulations prior to signing the research contract. This does not apply to academic / NHS collaborations.

Sub-contracting will be carried out in accordance with the UHPNTs standing financial instructions for sub-contracting. Selection of appropriate sub-contractors must include consideration of the appropriateness of any company to comply with relevant GXP, data protection and other relevant standards. The Trust's RD&I Dept. is responsible for the

production of all UHPNT sub-contracts with external parties. UHPNT's contract template for sub-contracting of clinical trial services is managed by the RD&I office and each contract will be prepared in accordance with any obligations relating to compliance as required on the part of the sub-contractor.

Prior to selection of any sub-contractor, consideration will be given to the appropriateness of the selection based on perceived competency with respect to task in question and their ability to comply with any necessary regulations. For some suppliers, this may be limited to an obligation of confidentiality, security of information and competency to carry out particular sub-contracted task. If considered appropriate, the proposed sub-contractor may be audited on behalf of UHPNT prior to final selection.

A variety of assessment methods will be used when assessing the suitability of a vendor, including but not limited to:

Assessment of expertise
Prior experience of working with the vendor
Pre-qualification questionnaires
Review of marketing material
Demonstration of product
Experience and qualifications of staff
Company history and stability
CE marking (if applicable)
GMP, GLP or ISO certification (if applicable)
Capability to deliver within specified time frame
After sales service including training
Obtaining appropriate references where applicable
Assessment of the vendor's quality system and/or written procedures
Cost/budget

Some services may already be provided for UHPNT by external organisations in the clinical setting. Where this is the case, a separate assessment of suitability may not be required for the same organisation to provide the same services for research purposes.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

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

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

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

5 Reference material

International Conference on Harmonisation of Good Clinical Practice 1996
http://www.ich.org/about/history.html

Department of Health Research Governance Framework for Health and Social Care 2005
http://www.nihr.ac.uk/about/nihr-publications.htm

Medicines for Human Use (Clinical Trials) Regulations 2004
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Model Commercial Agreements
http://www.nihr.ac.uk/industry/industry-tools.htm

National model non-commercial Sponsorship Agreement
http://www.nihr.ac.uk/industry/industry-tools.htm

Statement of Activities & Schedule of Events
http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/

Model Brunswick collaboration agreement
https://www.arma.ac.uk/resources-1/research-contracts/research-collaboration-agreements

Appendix: Template contracts — Appendix 1

National template Agreements/Contracts have been created for the following scenarios and the Trust has fully adopted the use of these template Agreements. The Research Office will propose the use of the appropriate template if an appropriate Agreement has not been proposed by the Sponsor. Up-to-date versions of these templates can be found on http://www.nihr.ac.uk/industry/industry-tools.htm

1. Commercially Sponsored Clinical Trials for Pharmaceutical Research -bipartite arrangement between Sponsor and Trust. The ABPI DOH mCTA (October 2006) will be used unmodified.
2. Commercially Sponsored Clinical Trials for Pharmaceutical Research - tripartite arrangement between Sponsor, Clinical Research Organisation (CRO) and Trust. The CRO mCTA (CRO Template) October 2007 will be used unmodified.
3. The model Clinical Investigation Agreement (mCIA) for medical technology industry sponsored research carried out in NHS hospitals - NHS ABHI mCIA (England) 2008 will be used unmodified.
4. The model Clinical Investigation Agreement (mCIA) for medical technology industry sponsored research carried out in NHS hospitals - tripartite arrangements between Sponsor, Clinical Research Organisation (CRO) and the Trust. CRO mCIA (England) 2008 will be used unmodified.
5. Non-Commercial Sponsored studies. The model Non-Commercial Sponsor Agreement (mNCA) will be used with appropriate modifications negotiated between Sponsor and NHS Trust as required.
6. Model Brunswick collaboration agreement. Is an academic research collaboration agreement which comes in two forms: short and long. The two agreements have been designed to be suitable for the majority of cases where two or more universities or NHS Trusts receive a joint grant from a research council or charity.

   It is intended that both the Short-Form Letter of Agreement and the Long Collaboration Agreement will govern collaborations which are funded by research councils and charities where:

   (i) the award is made for a research project (not a Centre) under standard terms;

   (ii) the collaborators are academic or non-profit making institutions;

   (iii) the collaborating institutions are named in the application as undertaking a specific and significant proportion of the project; and

   (iv) the terms of the award do not restrict the universities' ownership or publication of research results or include warranties of any kind.

   See: https://www.arma.ac.uk/resources-1/research-contracts/research-collaboration-agreements

Appendix: Contract and costing – review process — Appendix 2

Draft contract and protocol received by RD&I Office

The study team and the RD&I Office review costings / resources required to conduct the study (*for commercial studies – the industry costing template should be used*).

RD&I Office (Finance) review the contract wording against information provided by the study team or Sponsor in the study protocol

RD&I Office (Feasibility & Finance) to ensure the following is uploaded to EDGE:

Study number, IRAs form, Protocol Timelines, Local Recruitment Target, PI Name, Details of Approved Costs and Sponsor Details.

RD&I Office (Finance) to feedback to the Sponsor and copy the RD&I Office in e-mail correspondence

The final contracts and costs approved by the RD&I Manager (or deputy in their absence) should then be communicated to the sponsor.

On acceptance by the Sponsor, contracts / agreements are then signed off on the same day or very close to the date that UHPNT RD&I confirms Capacity & Capability by the Associate Director of Finance.

The RD&I Office (Finance) will then populate the EDGE Database Contracts Attributes and Workflows.

Fully executed Contracts / Agreements are filed and retained appropriately in the RD&I Office, and a copy of a fully executed document sent to the research team for filing in the Investigator Site File.

6 Amendment History

Version Number:	3.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name; Reduce signature requirement to single senior RD&I Manager.

Version Number:	3.0
Date Of Amendment:	Jul 2017
Details Of Amendment:	Review SOP, update SOP template and numbering system, updated SOP content.

Version Number:	2.0
Date Of Amendment:	Mar 2014
Details Of Amendment:	Updated to make clear this SOP is a general overview.

Version Number:	1.1 (minor amendment)
Date Of Amendment:	Mar 2012
Details Of Amendment:	Cover page - Change of SOP location address.