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/research-sops

Clinical Trial Agreements (CTA) for Non-Commercially Sponsored Trials

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APPROVED BY

Name: Chris Rollinson

Job Title: Research Governance Manager

Signature: .....

Date: 18th Jan 2019

1 Purpose and Scope

This SOP outlines the procedures involved in the agreement and signature of the Clinical Trial Agreement (CTA) for hosted non-commercially sponsored research studies conducted within University Hospitals Plymouth NHS Trust (UHPNT).

All non-commercially sponsored research involving an investigational medicinal product or a device carried out at UHPNT must have a fully executed non-commercial clinical trial agreement and sponsorship agreement in place before the study starts. Both the study Sponsor and the Participating Site must sign a written agreement that formalises the responsibilities between the Parties for the conduct of the trial. This agreement must define the scope of work, establish acceptable payment arrangements, and address important issues such as the right to publish research results, protection of confidential information, and indemnification of third parties and/or case injury.

Non-commercial sponsors may propose to the Health Research Authority (HRA) that the Statement of Activities (SOA) is used with participating organisations as a form of site agreement; in line with the criteria and standards published by the HRA (this would be unlikely for research involving an IMP or device).

The UKCRC (UK Clinical Research Collaboration) has developed a Model Agreement for Non-Commercial Research in the NHS (the mNCA) in 2008. This is a standard contractual framework for non-commercial trials involving NHS patients (see section 5 Reference material). The mNCA is the preferred contract of choice in UHPNT to be used for non-commercially sponsored studies conducted within the Trust. Some NHS Trust and Universities may have developed their own template agreement for use in non-commercial trials which they sponsor. Such templates are acceptable to UHPNT if they follow the same principles as the mNCA and clearly define the roles and responsibilities of each Party to the agreement.

The Model Agreement for Non-Commercial Research in the NHS (mNCA) is a document to outline the contractual responsibilities between 2 or more persons/institutions for the conduct of a clinical trial or research study.

The RD&I Finance Coordinators in the Research Department are responsible for negotiating and executing mNCAs at UHPNT; individual investigators are not permitted to enter into contractual agreements on behalf of the Trust.

In scope: Non-Commercial Research hosted by UHPNT.

Definitions

CI	Chief Investigator
CTA	Clinical Trial Agreement
CTIMP	Clinical Trial of an Investigational Medicinal Product

GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
mNCA	Model Agreement for Non-Commercial Research
UHPNT	University Hospitals Plymouth NHS Trust
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOA	Statement of Activities
SOP	Standard Operating Procedure
UKCRC	UK Clinical Research Collaboration

2 Who should read this document?

Trust RD&I Manager, Deputy RD&I Manager, Principal Investigator (PI), RD&I Finance Coordinator, RD&I Deputy Finance Coordinator and RD&I Finance Administrator.

3 Procedure to Follow

3.1. Receipt & Initial review

The Principal Investigator (PI) registers the project with the Research Department and forwards the Protocol, draft mNCA received from the study Sponsor to the RD&I Deputy Finance Coordinator.

The RD&I Coordinator will review the mNCA for content.

> If the non-commercial sponsor is providing payment to UHPNT for its involvement in a trial, the mNCA will be forwarded to the UHPNT Clinical Trials Finance Co-ordinator their review and approval.

The RD&I Deputy Finance Coordinator reviews the mNCA and corresponds with the Sponsor to gain agreement on the content of the mNCA with the assistance of the UHPNT RD&I Manager, the Trust Legal team where required.

The RD&I Finance Coordinator will request the use of the mNCA where possible in particular if there is not a Sponsor agreement available or if this is unsuitable.

3.2 Principal investigators who are UHPNT Trust substantive contract holders

The RD&I Deputy Finance Coordinator establishes whether the trial has been adopted on the NIHR portfolio of research and is eligible for obtaining support costs from the local Comprehensive Local Research Network.

The RD&I Coordinator informs the UHPNT Clinical Trials Finance Co-ordinator of the portfolio status of the trial and whether any funds are being paid directly from the Sponsor to UHPNT.

The Clinical Trials Finance Co-ordinator with assistance from the RD&I Deputy Finance Coordinator contacts the PI and UHPNT support departments to confirm that all costs associated with the protocol are covered. The costs will include appropriate Trust overheads and Research Governance charges (if applicable), UHPNT support department costs (service support costs if portfolio adopted), excess treatment costs and PI/research nurse time.

Where UHPNT is a participating site, the Clinical Trials Finance Co-ordinator agrees the study service support costs with the local CLRN for portfolio adopted trials and with the Sponsor if funds are being paid to UHPNT directly.

For non-portfolio trials, the Clinical Trials Finance Co-ordinator will agree costs with the study Sponsor only.

The Clinical Trials Finance Co-ordinator reviews the Financial Schedule of the agreement to include all Trust costs (as agreed above), details of payment terms, Trust Bank Account, Trust research account reference and Trust contact and address for invoicing if applicable.

Principal investigators who are University of Plymouth substantive contract holders

The RD&I Deputy Finance Coordinator establishes whether the trial has been adopted on the NIHR portfolio of research and is eligible for obtaining support costs from the local Comprehensive Local Research Network.

The RD&I Deputy Finance Coordinator informs the UHPNT of the portfolio status of the trial and whether any funds are being paid directly from the Sponsor to UHPNT or whether funds are to be paid to and managed by the University of Plymouth.

The RD&I Deputy Finance Coordinator contacts the PI, UHPNT support departments and the University Research Governance Manager to arrange a set up meeting(s) or telecon(s) to confirm that all costs associated with the protocol are covered. The costs will include appropriate Trust and University overheads and Research Governance charges (if applicable), PI time/Research Nurse time, UHPNT support department costs (service support costs if portfolio adopted), excess treatment costs.

The Clinical Trials Finance Co-ordinator agrees the study costs with the CLRN for portfolio adopted trials and with the Sponsor if funds are being paid to UHPNT directly.

For non-portfolio trials, the Clinical Trials Finance Co-ordinator will agree costs with the study Sponsor and PI employer.

The PI completes, with the help of the University Research Governance Manager any University approvals that are required.

The Clinical Trials Finance Co-ordinator revises the Financial Schedule in the trial agreement to include all Trust and University of Plymouth costs (as agreed), details of payment terms, Trust Bank account, Trust research account reference and Trust contact and address for invoicing if applicable; if funds are to be paid to and managed by the University of Plymouth, the appropriate details are provided.

The Clinical Trials Finance Co-ordinator informs the RD&I Deputy Finance Coordinator that the financial arrangements are agreed and confirms the University fee.

The Clinical Trials Finance Co-ordinator approves the applicable financial arrangements confirming that costs and mNCA Financial Schedule are agreed.

On agreement of the mNCA wording and financial arrangements, the RD&I Deputy Finance Coordinator requests three signed copies of the mNCA from the Sponsor contact and arranges signature of the mNCA by the Trust approved signatory.

The RD&I Deputy Finance Co-ordinator returns one copy of the fully executed mNCA to the Sponsor, a second copy to the PI for the Investigator Site File and a final copy is retained in the RD&I Project Master File. The RD&I Deputy Finance Co-ordinator ensures a copy of the fully signed agreement along with the final finance form and signed RD&I authorisation letter are uploaded onto EDGE.

Where the Trust is collaborating with a University

The RD&I Deputy Finance Co-ordinator completes a specific Collaboration Agreement (Model Brunswick Collaboration Agreement). The RD&I Deputy Finance Co-ordinator arranges Trust and University sign off of two copies of this document, ensuring the University Contracts Manager have a final approved copy. The RD&I Deputy Finance Co-ordinator sends a photocopy of the signed study specific Collaboration Agreement to the PI for the Investigator Site File. Where funds are being managed by the University and are to be transferred from the University to UHPNT, the Contracts Manager at the University sends a Collaboration Agreement signed by the University to the RD&I Deputy Finance Co-ordinator who will obtain the Trust signature. The final approved Collaboration Agreement is placed on the EDGE with the wet ink copy filed in the RD&I Project Master file.

On final project RD&I authorisation, the RD&I Deputy Finance Co-ordinator updates the RD&I records with the final agreed funds coming to UHPNT.

The Clinical Trials Finance Co-ordinator and RD&I Manager review the RD&I Finance Records on a regular basis to ensure that all authorised projects have invoicing arrangements in place and are receiving funding as agreed.

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

Model Agreement for Non Commercial Research in the Health Service National template http://www.ukcrc.org/regulation-governance/model-agreements/mnca/

Appendix: Aide memoir – Checklist for study agreements — Appendix 1

Clause	Issues	Yes	No	Comments / Actions
Front page: Study title	Check that the short title of the study is given and is correct.			
Front page: Reference number	Check that EudraCT or other reference number is inserted.			
Front page: date	Check the date of the agreement – they can't be post-dated.			
Front page: Name and Address of NHS Body	Research Office, University Hospitals Plymouth NHS Trust, Level 2 MSCP, Bircham Park Offices, 1 Roscoff Rise, Derriford, Plymouth PL6 5FP			
Front page: Sponsor Name and Address	Check that the Sponsor name and address are correct. If there are co-sponsors, check that their details are correct.			
Front page: Declaration	Ensure that the long title of the study is given and is correct.			
1. Definitions	Additional clauses can be added to this section for clarity. These should be tracked changes and need to be agreed.			
2. Study Governance	Parties agree to comply with all relevant laws e.g. The Parties shall comply with all relevant laws of the EU if directly applicable or of direct effect and all relevant laws and statutes of the UK country in which the Trial Site is located including but not limited to, the Human Rights Act 1998, the Data Protection Act 2018, the Medicines Act 1968, the Medicines for Human Use (Clinical Trial) Regulations 2004, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version), the UK Policy Framework for Health and Social Care Research (2017). In addition, where the Clinical Trial is conducted as part of an IND, the Trust will comply with any other relevant requirements notified by the Sponsor to the Trust. Ensure a statement that reads along the lines of: "Should there be any inconsistency between the Protocol and the other terms of this Agreement, or any other document incorporated therein, including the Sponsor's Standard Operating Procedures, the terms of the Protocol shall prevail" is included.			

Clause	Issues	Yes	No	Comments / Actions
3. Obligations of the Parties	Check that RD&I permission is referred to.			
4. Liabilities and Indemnity	Ensure that all clauses are Present:			
	The Sponsor should indemnify the Trust against losses arising from following the protocol.			
	The indemnity does not apply if negligence is involved.			
	If all parties are NHS bodies, they must rely on the NHS Litigation Authority.			
	The liability of the Trust to the Sponsor is limited to all fees payable by the Sponsor to the Trust.			
	Employers should have arrangements for compensation for negligent harm. For NHS Trusts this is covered by CNST membership, and individual insurance is not necessary.			
	NHS organisations cannot make pre-emptive arrangements for compensation for non-negligent harm.			
5. Confidentiality, data protection and freedom of information	Check clauses for regulatory compliance including data transfer procedures.			
6. Publicity	Content and timing of any publicity must be agreed by all parties.			
7. Publication	Publication policy to be agreed by parties.			
8. Property Rights	Background IP and know-how remain the property of the party that introduced them.			
	IP rights arising directly from the study are normally the property of the Sponsor. For studies involving PUPSMD, IP matters will be subject to the Framework Agreement PUPSMD and UHPNT have in place.			
9. Financial and Supplies Arrangements				
10. Term				
11. Suspension or early termination				
12. Agreement and Modification				

Clause	Issues	Yes	No	Comments / Actions
13. Force Majeure				
14. Notices				
15. Assignment and Subletting	The prior consent of all parties is required before parties can assign or subcontract any part of their obligations.			
16. Dispute Resolution	Dispute resolution should be through mediation. No timescales are stipulated.			
17. General				
18. Survival of Clauses				
19. Governing Law	The Agreement is made and shall be interpreted in accordance with the Laws of England and Wales.			
	The Parties hereby submit to the exclusive jurisdiction of the English and Welsh Courts.			
Signatures	The agreement should be signed on behalf of the Trust by a nominated Board Member. Check that all signatures are the originals and are the signature of the person listed – pp is not acceptable. The Trust should sign last.			
Schedule 1: Protocol	The protocol is unlikely to be included here, but should be referred to. There should be a summary of management responsibilities and a list of key milestones.			
Schedule 2: Division of responsibility	Check that the division and delegation of responsibility is appropriate.			
Schedule 3: Financial Arrangements	Check that the financial arrangements are appropriate and have been agreed. Names and addresses for submitting invoices should be included here. The Trust's bank details are: <*Insert details*>			

6 Amendment History

Version Number:	1.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name. Reduce signature requirement to single senior RD&I Manager. Updated references to the Data Protection Act 2018 and the UK Policy Framework for Health and Social Care Research (2017).