Standard Operating Procedure

RESEARCH CONTRACTS AND VENDOR SELECTION

SETTING Trustwide

AUDIENCE Research & Innovation (R&I) staff involved in setting up and conducting research sponsored by UH Bristol. Research staff to note.

ISSUE Contractual arrangements and the process for selection of third party vendors to conduct research activities for research sponsored by UH Bristol.

QUERIES Contact R&I department : Ext 20233 or research@uhbristol.nhs.uk

Document History

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-	1.0	19/OCT/15	03/NOV/15	Jake Harley	Diana Benton
November 2016	1.1	25/NOV/16	12/DEC/16	Jess Bisset	Diana Benton
December 2017	1.2	22/DEC/17	20/FEB/18	Elinor Griffiths	Jess Bisset

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Original V1.0	N/A-original
1.1	Minor updates and clarifications
1.2	Annual review. Funding agreements section added.

1. Introduction

Research may require different contractual arrangements to be put in place between the organisations involved in the sponsorship, funding, management and delivery of a study, depending on the study type and the research activities being undertaken.

2. Purpose

The purpose of this document is to describe the type of contracts UH Bristol will use when acting as sponsor for research and the process by which third party vendors will be selected to undertake any contracted research related activities.

3. Scope

In Scope: UH Bristol sponsored research or where UH Bristol holds the funding.
Out scope: Research sponsored by organisations other than UH Bristol.

4. Responsibilities

R&I are responsible for identifying and selecting suitable vendors to carry out research related activities on behalf of UH Bristol.
R&I are responsible for ensuring that appropriate contractual arrangements are put in place with other organisations as required.

5. Abbreviations and Definitions

Abbreviations	
MTA	Material Transfer Agreement
mNCA	Model non-commercial agreement
NBT	North Bristol NHS Trust
NIHR	National Institute for Health Research
R&I	Research & Innovation department
SLA	Service Level Agreement
UH Bristol	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol

Definitions	
Collaborator	An institution (e.g hospital or university) whose employees are collaborating on a project and/or are co-applicant on a grant application
Vendor	An organisation to which research-related activities have been contracted or sub-contracted, other than other NHS Trusts recruiting patients which should be considered research sites.

6. Procedure

6.1 Contractual Arrangements (other than funding agreements)

- For all research sponsored by UH Bristol an assessment will be made in R&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
    - Supplier contracts

- Where possible UH Bristol 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.
- Where national templates do not exist, UH Bristol has developed a suite of template agreements which will be used and adapted as required:
    - TMPL_049- UH Bristol Service Level Agreement Template
    - TMPL_050 UH Bristol Material Transfer Agreement Template

- TMPL_051 UH Bristol Amendment to Contract Template
- TMPL_052 UH Bristol Confidential Disclosure Agreement Template
- TMPL_053 UH Bristol template for research collaboration agreements where funding has been provided by NIHR or partner charity.

- 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 UH Bristol template, UH Bristol may review a template provided by another organisation.
- Any amendments requested from other organisations to national or UH Bristol templates will be reviewed and agreed within R&I, with a further legal review on behalf of UH Bristol if appropriate. R&I will request this further legal review using either the UHBristol legal department or appropriate personnel contracted to UHBristol to carry out this activity.

- Where existing overarching research agreements exist between UH Bristol and its partner organisations, study specific research contracts may not be required. These will be assessed on a case by case basis.
- UH Bristol's existing overarching agreements are listed below; a process of regular review of these documents is in place:
    - Framework Agreement, NBT, original dated 7th August 2013 (reviewed annually)
    - Service Level Agreement, UoB, original dated 24th July 2012 (reviewed annually)
    - Framework Agreement for Collaborative Research, UoB, original dated 14th October 2014 (reviewed every 5 years or sooner if required)

- All research agreements and contracts will be signed by appropriate personnel in R&I on behalf of UH Bristol in accordance with UH Bristol's standing financial instructions, delegation of authority and budget managers responsibilities.

6.2 Vendor selection

- As sponsor UH Bristol may be required to delegate certain research related activities to other organisations.
- R&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.
- 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 (in accordance with UHBristol's Procurement processes)
    - Obtaining appropriate references where applicable
    - Assessment of the vendor's quality system and/or written procedures
    - Cost/budget
- The type of assessment undertaken will be determined on a case by case basis and will follow UH Bristol procurement processes where applicable. The process of assessment and selection decision will be clearly documented.
- Some services may already be provided for UH Bristol 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.
- A list of vendors who have previously provided research services will be maintained by the R&I department. Accompanying this will be a list of vendors who have met the defined assessment criteria. These lists will be used by UH Bristol for future vendor selection. Full

reassessment will not be required unless the vendor is offering different services or has changed its SOPs significantly. New vendors may also be approached.

6.3 Funding agreements

- In many cases UH Bristol sponsored research will be the result of a grant application to an external funder, usually the NIHR or a partner charity.
- The funder will have either a contract or terms and conditions that need to be adhered to or in some cases negotiated before UH Bristol can accept.
- R&I will lead on agreeing the funding contracts and terms and conditions, with appropriate legal or specialist input, for example around exploitation terms.
- NIHR grants will require sign off by R&I as described in 4.1 above, or for non-NIHR grants by an appropriate Divisional representative.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training*.

8. Related documents

- Medicines and Healthcare products Regulatory Authority (MHRA), 2015. Good Clinical Practice Guide. 4th impression. TSO (The Stationary Office).
- SOP_002 Research Sponsorship at UH Bristol
- SOP_007 Research Training
- TMPL_049 UH Bristol Service Level Agreement Template
- TMPL_050 UH Bristol Material Transfer Agreement Template
- TMPL_051 UH Bristol Amendment to Contract Template
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