Standard Operating Procedure

RESEARCH CONTRACTS AND VENDOR SELECTION

SETTING Trustwide for research sponsored by UHBristol

AUDIENCE 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.

Standard Operating Procedure (SOP)

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Date for review:	November2017		

Review date	Version number	Version Date	Effective Date	Reason for change	Author/Responsible person	Authorised by
-	1.0	19/10/15	03/11/15	N/A-original	Jake Harley	Diana Benton
November 2016	1.1	25/11/16	12/12/16	Minor updates and clarifications	Jess Bisset	Diana Benton

1. Purpose

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

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.

2. Scope

In scope: UH Bristol sponsored research.

Out of scope: Research sponsored by organisations other than UH Bristol.

3. Definitions/Abbreviations

MTA	Material Transfer Agreement
mNCA	The model agreement for non-commercial research
NBT	North Bristol NHS Trust
R&I	Research & Innovation department (leading on ensuring sponsor responsibilities are met, where UHBristol is the sponsor).
SLA	Service Level Agreement
UH Bristol	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol
Vendor	An organisation to which research-related activities have been contracted, other than other NHS Trusts recruiting patients which should be considered research sites.

4. Procedure

4.1 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

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 (see appendices). 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 and delegation of authority.

4.2 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.

5. Dissemination and training in the SOP

5.1 Dissemination of this SOP

5.1.1 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).

5.2 Training in this SOP

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

5.2.2 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.

6. Appendices

Appendix 1 - UH Bristol Service Level Agreement Template

Appendix 2 – UH Bristol Material Transfer Agreement Template

Appendix 3 – UH Bristol Amendment to Contract Template

Appendix 4 – UH Bristol Confidential Disclosure Agreement Template

7. References

Medicines and Healthcare products Regulatory Authority (MHRA), 2015. Good Clinical Practice Guide. 4th impression. TSO (The Stationary Office).

RELATED DOCUMENTS	Sponsorship SOP
AUTHORISING BODY	Trust Research Group
QUERIES	Research Operations Manager or Research Management Facilitators - Research & Innovation Department via 0117 342 0233

Appendix 1 UH Bristol Template Service Level Agreement

Service Level Agreement for Services provided by NHS Organisations

This Agreement dated [Insert DATE] is entered into between:

(1) [Insert name of Organisation and registered address] ("the Customer");

(2) [Insert name of Organisation and registered address] ("the Provider").

which may be referred to individually as a "Party" or collectively as "the Parties."

Background

(A) The Customer is taking part in a clinical trial entitled *"[Insert details of the Trial]"* ("the Trial").

(B) The Customer wishes to enter into an agreement with the Provider to provide [insert type of services] services for the Trial.

It is agreed as follows:

1. Service Description

1.1. The Provider agrees to [insert details of the services to take place]

("the Services").

2. Commencement & Duration

2.1. This Agreement will commence on the date of the final signature ("Commencement Date") and shall terminate on [Insert Date] /or on the date that the Service(s) under this Agreement are deemed to have been completed as advised by the Customer in writing or unless the Agreement is terminated by either Party in accordance with Clause 7.

3. Payment

3.1. The sum of [insert amount] shall be paid to the Provider by the Customer within thirty (30) days after receipt of an invoice from the Provider in accordance with Schedule One (1) OR
The Provider agrees to provide the Services at its own cost and shall make the necessary arrangements with the relevant [insert department] department for reimbursement of any costs incurred under this Agreement.

3.2. If the Customer terminates this Agreement in accordance with Clause 7, otherwise than in accordance with Clause 7.1.1, the Customer shall pay, upon receipt of a valid invoice, the Provider any outstanding monies due to the Provider as at the date of termination.

4. Quality Standards & Performance Monitoring

4.1. In addition to the Provider's local policies and procedures, the Service(s) will be provided in accordance with the Protocol and Good Clinical Practice and in line with applicable legislation and quality assurance standards including, but not limited to:

4.1.1 Human Rights Act 1998
4.1.2 Data Protection Act 1998
4.1.3 Medicines Act 1968
4.1.4 Medicines for Human Use (Clinical Trials) Regulations 2004
4.1.5 ICH Good Clinical Practice (GCP) Guidelines (E6 (R1), Step 5, 2002)
4.1.6 World Medical Association (WMA) Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects (1996)
4.1.7 Department of Health Research Governance Framework for Health & Social Care (2nd Ed., April 2005)
4.1.8 Human Tissue Act 2004

4.2. The Customer shall monitor the performance of the Provider against good clinical practice and the standards set out in this Agreement on an ongoing basis. In the event of the Provider failing to provide the Service(s) to the reasonable satisfaction of the Customer, the Party Representatives named in clause 9 will discuss such issue(s) and agree any corrective and remedial actions to be taken within an appropriate timescale.

4.3. Any concerns relating to the quality or safety of clinical services of the Provider shall be raised with the Provider's Representative who shall investigate such concerns in accordance with the Provider's policy and procedures. The Provider shall at all times keep the Customer updated on the progress of the investigation.

5. Confidentiality & Data Protection

5.1. Any and all information relating to the Trial and its participants that may become available to the Provider or that the Provider may have access to, for the purposes of performing the Service(s) required, shall be held in confidence and not divulged to any third party without the express written consent of the Customer in accordance with the Data Protection Act 1998.

6. Warranty & Indemnity

6.1. While the Provider will use all reasonable endeavours to ensure the quality and accuracy of the Service(s) provided under this Agreement, the Provider makes no warranty, express or implied, as to quality and accuracy and will not be held responsible for any consequence arising out of any inaccuracies or omissions unless such inaccuracies or omissions are the result of negligence or wilful misconduct by the Provider.

6.2. Nothing in this clause shall operate so as to restrict or exclude the liability of the Provider in relation to death or personal injury caused by the negligence of the Provider, its employees, students, consultants and subcontractors, including researchers, or to restrict or exclude any other liability of the Provider which cannot be so restricted in law.

6.3. Subject to clauses 6.4 and 6.5, the Provider shall indemnify and keep the Customer indemnified against any claims, proceedings, related costs, expenses, losses, damages and demands to the extent that they arise or result from the Provider in performing the Services.

6.4. The liability of the Provider to the Customer in respect of any contractual liability the Customer may or does incur to a third party arising or resulting from this Agreement shall be limited to the fees payable in aggregate by the Customer to the Provider.

6.5. In no circumstances shall either Party be liable to another in contract, tort, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

7. Termination

7.1 Either Party may terminate this Agreement by notice in writing to the other Party if:

7.1.1 the other Party is in material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of 30 days after written notice has been served by the non-breaching Party.

7.2 The Customer may terminate this Agreement should the Funder terminate the Study. In the event that this should occur the Customer shall inform the Provider immediately by notice in writing.

7.3 This Agreement may be terminated by thirty (30) days notice in writing by either Party.

8. General

8.1. Any amendments to this Agreement shall be valid only if agreed in writing by the Parties. No Party shall novate, assign or subcontract all or any part of their rights or obligations under this Agreement without the prior written consent of the other Parties.

8.2. The Provider shall not be liable for any delay in performance or failure to perform its obligations under this Agreement if such delay or failure is due to an occurrence beyond its reasonable control. If the circumstances causing the delay or failure continue for longer than thirty (30) days, the Customer shall be entitled to terminate this Agreement in writing immediately.

8.3. No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.

8.4. Nothing in this Agreement shall confer on any third party any benefit or right to enforce any term of this Agreement.

8.5. If any clause or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be effective without, as far as possible, modifying any other clause or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.

8.6. This Agreement is deemed made and shall be interpreted in accordance with the laws of England and Wales and the parties submit to the exclusive jurisdiction of the English and Welsh Courts.

9. Party Representatives

9.1 Any correspondence relating to the performance of the Service(s) under this Agreement shall be made directly between the Party Representatives:

For the Provider:	**For the Customer:**
[Insert Name and contact details]	[Insert name and contact details]

10. Notices

10.1 Any notice to the Parties concerning this Agreement shall be in writing, signed by the relevant Party to the Agreement and delivered personally, by courier, by recorded delivery post, or by facsimile.

For the Provider:	**For the Customer:**
[Insert Name and Address]	[Insert name and Address]

SIGN OFF

Signed by the duly authorized representatives of the Parties on the dated stated at the beginning of this Agreement

For the Provider:	**For the Customer:**
Signed:	Signed:
[Insert Name]	[Insert Name]
[Insert Date]	[Insert Date]

Schedule One

Payment Schedule

Appendix 2 UH Bristol Template Material Transfer Agreement

Material Transfer Agreement

This Agreement is dated [Insert Date] between

[Insert details of the organisation and the address]

(referred to as the "**Recipient**")

and

University Hospitals Bristol NHS Foundation Trust of Trust Headquarters, Marlborough Street, Bristol, BS1 3NU

(referred to as the "**Provider**")

WHERAS the Provider is recruiting Study Participants to a Study entitled "[Insert Study Title]." Hereafter referred to as the "Study".

WHEREAS the Recipient shall be [insert activity the samples will be used for] in accordance with the Study Protocol which is attached at Schedule One.

Material(s) shall mean [Insert Details], in accordance with this Agreement.

1.1 The Provider agrees to transfer Material(s) from the [Insert Hospital details] (the **"Provider"**) to [Insert Recipients Details including address] (the **"Recipient"**) by [insert transport details]. The Material(s) shall be transferred for the purposes of the Study as specified within the Protocol attached at Schedule One (1).

1.2 The Recipient shall keep the Material(s) secure at the Recipient's laboratory and ensure that access to the Material(s) is restricted to the Recipient, authorised co-workers and agents who have entered into legally binding obligations with the Recipient on terms equivalent to those set out in this Agreement.

1.3 The Provider confirms that Material(s) have been collected and handled in accordance with the Human Tissue Act 2004 and any amendments thereto and in accordance with the Study Participants consent;

1.4 The Recipient also agrees that Material(s) will be handled, stored, used and disposed of in accordance with the Human Tissue Act 2004 and any amendments thereto.

1.5 The Recipient agrees that the Material(s) must be used and disposed of in accordance with the Study Participants consent and as set out in the Patient information sheet.

1.6 The Recipient agrees that the Material(s) shall only be used for research purposes in relation to this Study as specified in the Protocol, attached at Schedule One (1). The Recipient agrees not to transfer or dispose of any part of the Material(s) to any third party without the prior approval in writing of the Provider and the relevant ethics committee.

1.7 All documents and information provided with the Material(s) including patient data shall be considered Confidential Information and must not be disclosed to any other person other than to fulfil the obligations under this Agreement. Such information shall be dealt with in accordance with the Data Protection Act.

1.8 The Material(s) shall at all times remain the 'property' of the Provider and the Recipient shall be returned immediately return the Material(s) on the written request of the Provider.

1.9 The Recipient or the Recipient's agents shall use the Material(s) in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Material(s).

1.10 The Provider makes no representation and gives no warranty or undertaking, in relation to the samples. As examples, but without limiting the foregoing, the Provider gives no warranty:

1.10.1 that it owns all necessary property and other rights in the Material(s); or

1.10.2 that the Material(s) are of merchantable or satisfactory quality or fit for any particular purpose.

1.11 In supplying the Material(s) the Provider warrants that the original supply from the donor complied with all legal and ethical requirements and guidelines and that it has obtained the donor's express informed consent to the use of such Materials for academic research and that such express informed consent:

1.11.1 Permits the Recipient to use the Material(s), in accordance with the provisions of this Agreement.

1.12 The Recipient shall ensure it complies with all applicable laws and any relevant guidance issued by the Department of Health, the Human Tissue Authority and all ethical guidelines relating to the use, storage, transportation and disposal of Material(s) for research purposes as laid down by the competent body or authority.

1.13 The Recipient shall hold harmless the Provider from any and all claims, proceedings, losses, damages, demands and liabilities arising from the use by the Recipient of the Material(s).

1.14 It is agreed by the parties that the custodianship of the Material(s) detailed within this Agreement will pass to the Recipient from the point of physical delivery of the Material(s) to the Recipient's site as referenced in Clause 1.1 of this Agreement. The Recipient will then be responsible for the use, storage, transfer and disposal of the Material(s).

The Authorised Representatives of both the Recipient and the Provider acknowledge that they have read and understood this agreement and agree to be bound by its terms

Signed on behalf of the Recipient

Signature:

Name:

Position:

Date:

Signed on behalf of the Provider

Signed:

Name:

Position:

Date:

Schedule 1

Protocol

[nb. This should only be attached if the Confidentiality Agreement allows disclosure to the other Party or you have obtained written consent to disclose the Protocol for the purpose of the MTA.]

Appendix 3 UH Bristol template Amendment to Contract

RESEARCH AGREEMENT - AMENDMENT NO. [insert number]

THIS AMENDMENT dated **[insert date]** is made

BETWEEN:

University Hospitals Bristol NHS Foundation Trust which has its administration offices at Trust Headquarters, Marlborough Street, Bristol BS1 3NU.

AND

[insert organisation who the contract you are changes is with] which has its administrative offices at [insert address].

Collectively referred to as "Parties" and individually referred to as "Party"

WHEREAS

The Parties have entered into an Agreement dated [date to be inserted] to carry out a clinical research Study entitled " [insert Study title] and the Parties now wish to amend the Agreement as it appears below.

Amendment No: [insert amendment number as above]

The contract shall be varied as follows:

- Schedule [ ] shall be revised and replaced with the Schedule [ ] attached to this amendment.
-

STATUS OF AGREEMENT:

This Amendment No [insert number] is supplemental to the current Agreement. Except as expressly amended by this Amendment No [insert number], the current Agreement shall remain in full force and effect. Terms defined in the Current Agreement shall have the same meaning in this Amending Agreement, unless otherwise provided by this Amending Agreement.

SCHEDULE [ ]

AGREED by the parties through their authorised signatories:

Signed for and on behalf of
University Hospitals Bristol NHS Foundation Trust:

……

DATE: ……..

PRINT NAME: ……..

POSITION: ……..

Signed for and on behalf of
[insert organisation] :

……..

DATE: ……..

PRINT NAME: ……..

POSITION: ……..

Appendix 4 UH Bristol Template Confidential Disclosure Agreement

CONFIDENTALITY AGREEMENT

This agreement is made on [Insert Date]

Between

University Hospitals Bristol NHS Foundation Trust of Trust Headquarters, Marlborough Street, Bristol. BS1 3NU.

(referred to as UHBristol)

And

[INSERT NAME OF PARTY] of [ADDRESS]

(referred to as [Insert name])

Which are collectively referred to as the "Parties" or individually as a "Party"

WHEREAS The Parties are about to enter into discussions concerning a clinical trial and contemplate that in the course of these discussions each may make available to the other Confidential Information.

WHEREAS a pre-condition of entering into formal discussions each party requires that the other should enter into this Agreement.

The Parties agree to the following:

1.1 In this Agreement "Confidential Information" of a party means any confidential information of that party or concerning it and without prejudice to the generality of the foregoing includes:-

1.1.1 Any information in relation to the Clinical Trial, this shall include the Protocol, the Study Agreement and the Parties involved.

1.1.2 Intellectual Property Rights of either Party.

1.1.3 Trade secrets, technology and technical and other information relating to the development of the Study and the Products of [Insert Name]. This includes but is not limited to all verbal and written information, documents, specifications, drawings and formulae.

1.1.4 Information concerning the business affairs of either Party.

1.2 The provision of clause 1.1 shall not apply to any confidential information which is:

1.2.1 Information which is at the relevant time, in the public domain (other than as a result of a breach of clause 3)

1.2.2 Information which the other party can establish to have been known to it at the relevant time and not have been acquired directly or indirectly from the other Party.

2.1 This Agreement is entered into in good faith by both Parties. Each Party acknowledges that it acquires confidential information of the other Party on the basis of the other Party's trust that it will carry out its duties of confidentiality in relation to the confidential information.

3.1 The Parties duties of Confidentiality:

3.1.1 Except when authorised by the other Party or by a Court Order the Parties must not disclose to any person, or make use of any Confidential Information of the other Party.

3.1.2 The Parties will ensure that any employee or agent are aware of the obligations of this Agreement and that they agree to be bound by it before any Confidential Information of the other Party is discussed or provided to them.

3.1.3 The Parties will use all reasonable endeavours to prevent unauthorised publication or disclosure by any person any Confidential Information of the other Party, this shall include publication or disclosure by any employer, employee or agent of the other Party.

3.1.4 Unless the Parties agree in writing, on ceasing to do work for the other Party or at any other time when requested to do so, the other Party agrees to return all confidential information to the other Party.

3.1.5 The Confidential information is made available solely to enable to the Parties to assess their interest in the Study and for their employees in performing the obligations of such a Study.

4.1 The obligations undertaken by each Party under this Agreement are in addition to and do not derogate from any other obligation, express or implied on the part of that Party.

5.1 This Agreement shall remain binding on both Parties in the event that either Party should change their organisations name, to take over another organisation.

6.1 This Agreement is deemed made and shall be interpreted in accordance with the laws of England and Wales and the Parties submit to the exclusive jurisdiction of the English and Welsh Courts.

7.1 Any provision in this Agreement found to be void, voidable or unenforceable shall not affect the validity en enforceability of any other provision in this Agreement.

8.1 This Agreement shall continue in force for a period of 10 years from the date stated at the beginning of this Agreement.

IN WITNESS THEREOF the parties hereto have executed this Agreement on the date stated at the beginning of this document.

Signed for and behalf of the **University Hospitals BRISTOL NHS Foundation Trust**

Name: .....

Position:.....

Signature:.....

Date: .....

Signed for and behalf of the [INSERT NAME]

Name: .....

Position:.....

Signature:.....

Date: .....