SOP Research Contracts & Vendors

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1. Purpose

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
This SOP is to be used for contractual arrangements and the process for selection of third party vendors to conduct research activities for research sponsored by SBU HB.

2. Background

The purpose of this document is to describe the type of contracts SBU HB 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.

This SOP will be used for SBU HB sponsored research or where SBU HB holds the funding.

3. Roles and Responsibilities

R&D are responsible for identifying and selecting suitable vendors to carry out research related activities on behalf of SBU HB.
R&D are responsible for ensuring that appropriate contractual arrangements are put in place with other organisations as required.
This SOP is to be used by Research & Development staff involved in setting up and conducting research sponsored by Swansea Bay UHB.

4. Procedure

4.1Contractual Arrangements (other than funding agreements)

- For all research Co/sponsored by SBU HB an assessment will be made in R&D 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 SBU HB 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 addition to the use of the model templates for host sites, R&D have in place a template SLA and MTA for use when research is being conducted within JCRF and other facilities within SU.
- In instances where a template for a particular agreement does not exist or the other party to the agreement is unwilling to use the proposed model template, SBU HB may review a template provided by another organisation.
- Any amendments requested from other organisations to national or local templates will be reviewed and agreed within R&D, with a further legal review on behalf of SBU HB if appropriate. R&D will request this further legal review using either the Welsh Health Legal Services or appropriate personnel contracted to SBU HB to carry out this activity.

- Where existing overarching research agreements exist between SBU HB and its partner organisations, study specific research contracts may not be required. These will be assessed on a case by case basis.
- SBU HB existing overarching agreements are listed below; a process of regular review of these documents is in place:
    - Co-Sponsorship Framework – SBU HB/SU (under review)
    - Joint Working Protocol – SBU HB/ SU (under review)
    - Service Level Agreement, SU, original dated 2019 (reviewed annually)
    - Service Level Agreement , Velindre NHS Trust

- All research contracts and agreements will receive internal review by the R&D Manager, Assistant R&D Manager, R&D Finance Manager and HTA Governance Officer as appropriate.

- All research agreements and contracts will be signed by appropriate personnel in R&D on behalf of SBU HB in accordance with SBU HB standing financial instructions, delegation of authority and budget managers responsibilities.

4.2 Vendor selection

- As sponsor SBU HB may be required to delegate certain research related

activities to other organisations.

- R&D 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 usually apply to academic/NHS collaborations unless the R&D team consider there to be specific reasons to undertake a vendor assessment of an academic partner.
- 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 SBU HB 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 SBU HB procurement processes where applicable. The process of assessment and selection decision will be clearly documented.
- Some services may already be provided for SBU HB 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&D department. Accompanying this will be a list of vendors who have met the defined assessment criteria. These lists will be used by SBU HB for future vendor selection. Full Re-assessment will not be required unless the vendor is offering different services or has changed its SOPs significantly. New vendors may also be approached.

4.3 Funding agreements

- In many cases SBU HB co/ 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 SBU HB can accept.
- R&D will lead on agreeing the funding contracts and terms and conditions, with appropriate legal or specialist input, for example around exploitation terms.
- All research grants will require sign off by R&D as described in 6.1 above,
- Usually a Brunswick agreement will be executed with any Academic Partner collaborating on the bid.

5. References

- Medicines and Healthcare products Regulatory Authority (MHRA), 2015. Good Clinical Practice Guide. 4th impression. TSO (The Stationary Office).
- SOP Research Sponsorship at SBU HB
- Co-Sponsorship Framework – SBU HB/SU (under review)
- Joint Working Protocol – SBU HB/ SU (under review)
- Service Level Agreement, SU, original dated 2019 (reviewed annually)
- Service Level Agreement , Velindre NHS Trust
- SBU HB Research Operational Framework

6. Definitions

Abbreviations	
HCRW	Health and Care Research Wales
JCRF	Joint Clinical Research Facility
MTA	Material Transfer Agreement
mNCA	Model non-commercial agreement
NIHR	National Institute for Health Research
R&D	Research & Development department
SBU HB	Swansea Bay University Health Board
SLA	Service Level Agreement
SU	Swansea University

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
Co-Sponsor	Study is sponsored collaboratively between two organisations. For the purpose of this SOP, Co-Sponsored refers to studies which are co-sponsored between SBU HB and SU, in line with the Co-Sponsorship Framework and Joint Working Protocol.
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.