brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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Contract Negotiation and Review

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Version	Date	Reason for Change
1.0		

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for staff involved in the preparation and / or review of contracts or written agreements in relation to clinical trials or research projects. This document sets out the procedures to be followed by all Brighton & Sussex University Hospitals NHS Trust (BSUH NHS Trust) employees entering into a research related agreement.

2.0 INTRODUCTION

This document defines the Trust's research procedures for preparing and reviewing contracts pertaining to research studies and clinical trials run at or sponsored by Brighton & Sussex University Hospitals NHS Trust.

The document clarifies the requirements for the establishment of a contract between two or more parties so as to comply with the relevant national and international clinical trial legislation, regulations and conditions set out by research sponsors and funders. For any research falling within the following category, then contracts and agreements need to be in place prior to trial start.

These include:

- Clinical trials of medicines, devices or other novel interventions
- Supply of the medical device or equipment for the use in a research project
- Research project funding, including educational or non restricted grants
- Procurement of laboratory, clinical, emergency medical cover and/or pharmacy services to support research on other sites
- Transfer of tissue, human material or data for research
- Participation of other sites in research sponsored by the Trust

The document aims to provide clear guidance on who should contribute to, review and approve research contracts and agreements on behalf of Brighton & Sussex University Hospitals NHS Trust. The management of Research Finance post contract is outside the scope of this SOP and therefore will not be discussed in this document.

3.0 DEFINITIONS

The following list sets out some of the more common definitions of the contracts used for NHS research.

mNCA - The Model Agreement for Non-Commercial Research is a template endorsed by the UK Clinical Research Collaborative and the NIHR, for documenting the relationship between and the responsibilities of the non-commercial sponsor of a research study and the Health Service organisation where the study takes place.

mCTA - model Clinical Trial Agreement is designed to be used without modification for industry sponsored trials in patients in hospitals throughout the UK Health Service.

mCIA - model Clinical Investigation Agreement (mCIA) is designed to be used without modification for company sponsored commercial research involving medical devices in patients in hospitals throughout the UK Health Service.

MTA - Material Transfer Agreement is a sponsor specific template that is put in place to cover the transfer of tissue from one site to another.

CRO mCTA - The Contract Research Organisation model Clinical Trial Agreement (CRO mCTA) is a tripartite agreement between: the pharmaceutical company

sponsoring a trial, the contract research organisation (CRO) managing the trial and the NHS organisation where the trial takes place.

CRO mCIA -The Contract Research Organisation model Clinical Investigation Agreement (CRO mCIA) is a tripartite agreement between: the company sponsoring commercial research involving medical device(s), the contract research organisation (CRO) managing the research and the NHS organisation where the research takes place.

Grant and Funding Agreements – These are specific to the awarding body and will set out the conditions for receipt and use of funding awarded, along with any specific restrictions or reporting requirements.

Collaboration Agreements – These are specific agreements co-signed by recipients of a funding award that ensure all parties of the award are in agreement with the terms and conditions of the funding agreement that the award holder has entered into with the funding body.

For the purposes of this SOP the generic term research contract will be used to cover all types set out above.

The Trust prefers for the NIHR Model Clinical Trial Agreements to be used, where possible. It does recognise that some research organisations that reside outside of the UK will require different agreements. These will be accepted where appropriate and legal.

4.0 RESPONSIBILITIES & SIGNATORIES

4.1 Legal Body

The legal body with which all must be made is Brighton & Sussex University Hospitals NHS Trust. Irrespective of the site where the research is taking place, the following address should be used on the contract:

Brighton & Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
BN2 5BE

4.2 Signatories

The Head of Research and Development is the responsible officer within the organisation for all matters relating to the review, negotiation and eventual signing and approval of research contracts.

Delegated authorisation extends to the following personnel in order:

1st Deputy Head of Research- Delivery

2nd Deputy Head of Research – CTU Operational Manager
3rd (Medical) Director of Research

In some instances a contract may specifically require the signature of the Chief Finance Officer or Chief Executive may be required to sign. In such a case the responsible officer should first review the agreement before requesting the relevant signature.

The Head of Research & Development is also the responsible officer, known as the Legal Entity Appointed Representative (LEAR), for European Commission research contractual matters.

Contracts must not be entered into by individuals. Principal Investigators must not enter into agreements with third parties or sign contracts on behalf of the Trust.

5.0 PROCEDURE

5.1 Hosted Research

Once research and governance teams are aware that their research proposal requires a contract, a draft should be submitted to the Head of Research & Development or designated deputy for review as soon as possible.

The Trust commits to conduct an initial review of all model agreements, as detailed in section 3.0 within 2 working weeks. If a non-model contract template is required, or suggested by the sponsor, then the review may take up to 3 working weeks.

The review process should ensure that the agreement defines the following:

- Scope of work including recruitment expectations and site obligations
- Reporting arrangements
- Acceptable payment arrangements
- Publication and intellectual property rights
- Protection of confidential information
- Indemnification of parties
- Supply and shipments details
- Is applicable to English Law

Changes to the contract should be made in mark-up and returned to the sponsor/funder for review. If a sponsor/funder is unable to accept changes to aspects of the contract that result in some ambiguity around the Trust's legal liabilities, contract negotiations and research set up will be suspended whilst formal legal advice is sought from the Trust's lawyer. Advice form the Trust lawyer will be final and binding. If a sponsor/funder is unable to accept this, then the project will be abandoned.

Once a final version of the contract has been agreed the sponsor/ funder should initiate signatures first and send copies to the relevant research governance officer to arrange for Trust sign off.

5.2 Sponsored Research

For research sponsored by the Trust the default will be to use the mNCA. Trial Managers will be responsible for populating the contract with project specific details and sending to the study sites for review. The contract should include any project specific details in relation to:

- Recruitment expectations and site obligations
- Reporting arrangements
- Payment arrangements
- Publication and intellectual property rights
- Supply and shipments details

Any changes proposed by the study sits must be entered into the document in mark-up. The Head of R&D or designated deputy will review changes and accept or enter into direct negotiation with the sites contract officer if required. If the Trust is unable to accept changes to aspects of the contract that result in some ambiguity around the Trust's legal liabilities, and the site is unwilling to accept the default mNCA contract negotiations and research set up will be suspended whilst formal legal advice is sought from the Trust's lawyer. Advice form the Trust lawyer will be final and binding. If a site is unable to accept this, then the project will be abandoned.

Once a final version of the contract has been agreed the site the Trust will initiate signatures first and send copies to the relevant site to arrange sign off.

5.3 Final Sign Off

The Trust undertakes to ensure that all finalised contracts are fully executed within 10 working days of receipt.

6.0 Cross Referenced SOPs

No cross referenced SOPs

7.0 References

No references