

<b>Title: Obtaining Acceptance of Sponsorship from Bournemouth University and Applying for Approvals</b>	
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Approver: University Research Ethics Committee	

## 1. Scope

This Standard Operating Procedure (SOP) outlines the requirement for the timely request should a Researcher require Bournemouth University to act as the research Sponsor for a given project. In addition this SOP outlines the procedures and processes for applying for external approvals alongside (Integrated Research Application System) IRAS guidance.

## 2. Responsibilities

The *Sponsor*, usually delegated by the *Chief Investigator (CI)* is responsible for setting up a study by gaining the necessary approvals, prior to inviting sites to undertake the research project.

The *Researcher* is responsible for obtaining sponsorship from BU prior to making an application for external approvals and in most cases will make the applications for external approvals, on behalf of the CI.

The *Clinical Governance Advisor (CGA)* is responsible for liaising with the CI/ Researcher in identifying contacts at suitable sites to undertake the research study. They are also responsible for advising as to which approval bodies need to be contacted and how to gain the necessary approvals from each party. The CGA will ensure that staff applying for BU sponsorship have undertaken Good Clinical Practice (GCP) training, and can likewise assist with IRAS applications.

The *Head of Research Development & Support (RDS)* is responsible for signing off IRAS applications prior to submitting for HRA<sup>1</sup> and REC approvals.

The *National Institute for Health Clinical Research Network (NIHR CRN)* is responsible for offering study support via the designated mailbox, and for offering support regarding study adoption on the NIHR research portfolio (see BU RDS SOP 018). Applicants may apply for inclusion via the IRAS application form.

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<sup>1</sup> Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

### 3. Purpose

The [UK Policy Framework for Health & Social Care Research](#) (Nov 2017) sets out the broad principles of good research governance in the research areas of health and social care. The framework applies to all research that relates to the responsibilities of the Secretary of State for Health. That is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and nonclinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. Research which falls within the scope of this requires a research sponsor; the Sponsor is a company, institution or organisation which takes responsibility for the quality and governance of the project. More specifically:

*'for assessment of the quality of the research as proposed, the quality of the research environment within which the research will be undertaken and the experience and expertise of the principal investigator and other key researchers involved. They are responsible for ensuring that arrangements are in place for the research team to access resources and support to deliver the research as proposed and that agreements are in place which specify responsibilities for the management and monitoring of research. They are responsible for ensuring that arrangements are in place to review significant developments as the research proceeds, particularly those that put the safety of individuals at risk, and to approve modifications to the design' (Research Governance Framework, Section 3.8)*

Formal confirmation from the designated Sponsor must be obtained prior to an application for HRA Approval or Research Ethics Committee (REC) approval via IRAS. To obtain approval for BU to act as the Sponsor for a project falling within the scope of the UK Policy Framework, this document outlines the Standard Operating Procedures.

The MHRA Good Clinical Practice Guide (2012) define a Sponsor as taking responsibility for the initiation, management and financing (or arranging the finance) of a trial. They set out the legal requirements for Sponsors of Clinical Trials of Investigational Medicinal Products (CTIMPs), in that they must be established in the European Economic Area (EEA), and a legal entity. Clinical trial Sponsors in the UK include commercial companies such as pharmaceutical, and non-commercial bodies such as research councils, charities, universities and NHS Trusts.

The Sponsor should identify whether the planned research falls within clinical trial legislation. If the research does, then the Sponsor should categorise the trial as such:

- Type A = No higher than the risk of standard medical care;
  - Type B = Somewhat higher than the risk of standard medical care;
  - Type C = Markedly higher than the risk of standard medical care.
- (Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products, 2011)

**The Sponsor should ideally undertake this risk assessment at the protocol development stage so as to make an informed decision as to whether to proceed with sponsorship.**

### **3.1 PROCEDURE**

Following submission of the Bournemouth University (BU) ethics checklist, which highlights the risk of a given research project, and the applicant's requirement for external review, the Chief Investigator/Researcher is responsible for making a request to BU to act as Sponsor. Research Development & Support (RRDS), Legal Services and the University's Insurance and Financial Accounting Officer are responsible for liaising with the BU insurers and accepting Sponsorship on behalf of the University.

#### **3.1.1 How to determine whether BU is the likely Sponsor**

For each project RDS and Legal Services will liaise with the BU insurers to assess whether BU can accept the Sponsor responsibilities for the project. BU will review Sponsorship requests for research projects where:

- The NHS partner will not act as Sponsor;
- The third party partner will not act as Sponsor;
- The research project does not have a NHS or third party partner.

#### **3.1.2 Who should request Sponsorship**

It is the responsibility of the Researcher or Chief Investigator on a project to request Sponsorship. However it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity.

If research is being conducted as part of a degree course the Academic Supervisor should request sponsorship on behalf of the individual undertaking the course. For student projects BU MUST act as Sponsor.

#### **3.1.3 When to request Sponsorship**

The Researcher must liaise with RDS as early as possible to discuss Sponsor responsibilities and is expected to request Sponsorship once funding for a research project has been confirmed, or in the case of student research projects when the Academic Supervisor has approved the study. Sponsorship should be confirmed ('in principle' as a minimum) before an ethical approval application to any of the following:

- Host organisation (NHS Trust, Local Health Board, Primary Care Trust, etc.);
- NHS REC or Social Care REC (HRA, 2010).

In circumstances where the funding body requires confirmation of Sponsorship prior to submission of the funding application, the Researcher should contact RDS.

### **3.1.4 Information to be provided for insurance consideration**

All projects involving BU must be covered by BU's insurance. When BU acts as a sponsor, this involves a greater level of risk, and must therefore be notified to insurers on a case by case basis, in order for them to confirm that the project is covered by the University's insurance policy. Each project needs to be looked at on a case by case basis, and sufficient information regarding the nature of the project must be provided. Projects involving clinical trials in particular must be identified early. Where the clinical trials are potentially high risk, the University's exposure may be such that the insurers will not extend current policies to cover the risk. However where the clinical trials are in lower risk areas, sponsorship may not be a problem.

### **3.1.5 Requesting BU to act as Sponsor**

As a minimum, the following documentation is required by RDS and Legal Services before Sponsor assessment may be made:

- i. Project protocol/summary;
- ii. Evidence of internal and external (where possible) peer review and confirmation of changes related to the peer reviewers comments<sup>2</sup>;
- iii. Signed and dated Chief Investigator Declaration (Appendix A).

Further information and/or documentation may be requested as necessary.

The CI (or nominated individual) will need to be available to answer any additional questions raised and RDS and Legal Services may need to meet with the CI to discuss the documentation to gain further clarity.

RDS and Legal Services will review the submitted documentation and if no questions or concerns are raised during the review process, Sponsorship approval will be granted within 4 weeks of receipt of all documentation.

Requests should be made by email to [researchethics@bournemouth.ac.uk](mailto:researchethics@bournemouth.ac.uk) and during this process; the CGA will verify whether the applicant holds GCP certification.

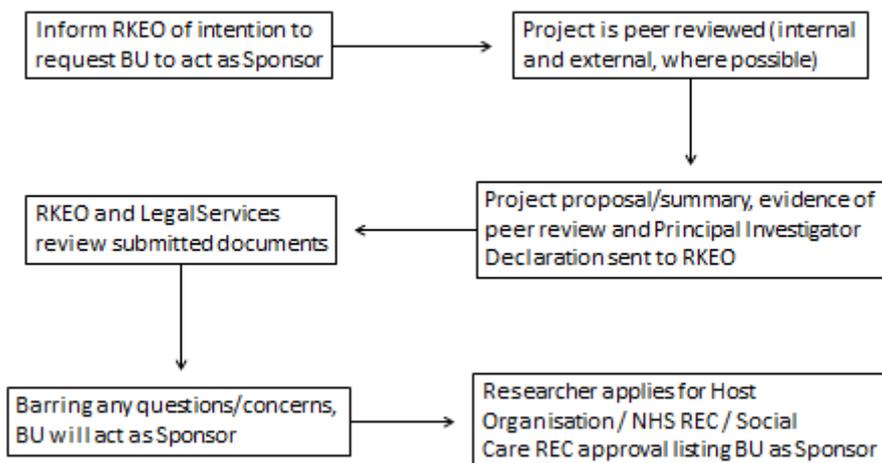
## **3.2 FLOW CHART**

Below is a flow chart indicating the process for BU to act as Sponsor. If the project is funded, the process begins at bid stage to ensure BU is aware of the potential requirement to act as Sponsor.

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<sup>2</sup> External peer review is expected; if this is not possible, an explanation is required.

### FLOW CHART: Process for BU to act as Sponsor



### 3.3 Applying for HRA and REC approvals

3.3.1 Research involving the NHS, including patients, carers or data *may* require ethical approval from an NHS REC. Guidance on whether a project requires REC approval can be found here by completion of the [decision tool](http://www.hra-decisiontools.org.uk/ethics/) (<http://www.hra-decisiontools.org.uk/ethics/>).

3.3.2 HRA and REC approvals are sought via completion and submission of the IRAS application form, created on [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk). Through this form, the applicant attaches key study documentation for approval and outlines the processes and requirements of the study. It is expected that a Sponsor will have decided which sites (initially) are to take part in the project, and they should complete Part C of the IRAS form identifying these.

3.3.3 The CGA can assist applicants with their IRAS submission and offer guidance on any queries relating to documentation and the content of the application form. The CGA or equivalent colleagues should have final review of the content of the form, before sign-off by the Head of RDS. Please note, for studies requiring HRA review, there are two additional documents that the applicant is required to complete and submit alongside their other documents (Organisation Information Document and Schedule of Events).

Within IRAS there is a validation process which will identify whether there are any documents or information missing. The HRA will send an email entailing which documents are missing, and which are required for assessment or REC review, thus making the application quicker and easier. Please note, currently under this validation process, should any part of the application be incomplete, the authorisations obtained for the form, will become invalid.

3.3.4 HRA approval is a requirement for all project-based research that involves NHS organisations in England where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. If a study does not involve NHS

patients as the participant group, but recruits staff members by virtue of their professional role, then only HRA approval is required (not NHS REC). There are some circumstances where you will need NHS REC, for example, if it is likely that there may be a breach of confidentiality. Research that involves midwives requires REC approval in addition to HRA; despite participants being classed as staff members.

The HRA have provided a [decision tool](http://www.hra-decisiontools.org.uk/research/) (http://www.hra-decisiontools.org.uk/research/) which aids applicants in determining whether their project is classed as research.

3.3.5 If conducting social care research not involving NHS patients, then you will not need REC approval, but *will* need BU ethical approval. If your social care research involves NHS patients then you will need to apply for NHS REC and HRA approvals. It is important to note that REC approval is always required if the research will alter or have an effect on a patient's care.

3.3.6 Sites undertaking projects that have received HRA approval will then be required to undertake an assessment of their capacity and capability to run the study. In order for this assessment to be triggered, the Sponsor is required to send the site R&D and study team, a set of key documentation, as outlined on the HRA website - <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/>. Also, see BU RDS SOP009.

3.3.7 For projects requiring HRA approval only, the HRA may assess these as not requiring a capacity and capability review by NHS sites. In this instance, projects are sent to the generic Trust R&D email (for sites listed in Part C of the IRAS form). Within this email the Sponsor will confirm on behalf of the HRA whether the research can be implemented immediately at site or whether a 35 day review for 'no objection' is required. If the NHS site does not respond, then you may assume that the project will go ahead at site.

3.3.8 NHS REC approval *only* is required, if a researcher is creating a research database. A research database is a structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research project with defined endpoints. Research purposes, in this context, refer to analysis of data to answer research questions in multiple projects. The Researcher will also need to make an application to the Confidentiality Advisory Group under Section 251 of the NHS Act 2006, to set aside the common law duty of confidentiality owed by care professionals to their patients or clients.

3.3.9 If creating a research tissue bank or biobank (stored for potential research use beyond the life of a specific project) then NHS REC, a Human Tissue Authority (HTA) licence and registration in the UKCRC Tissue Directory is required.

3.3.10 Under the [HTA Research Code of Practice](#), when extracting human DNA from acellular materials, NHS REC approval is required.

#### **4. Abbreviations and definitions**

BU	Bournemouth University
CGA	Clinical Governance Advisor

CI	Chief Investigator
HRA	Health Research Authority
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
NIHR CRN	National Institute for Health Research Clinical Research Network
PI	Principal Investigator
RDS	Research Development & Support
REC	Research Ethics Committee

## 5. Related documentation and references

BU RDS SOP 009 – NHS Site Set-up and Amendment Procedures

[Good Clinical Practice Guide. \(2012\). London: Medicines and Healthcare products Regulatory Agency](#)

[Health Research Authority. \(2010\). \[online\] Available at:   
https://www.hra.nhs.uk/documents/379/research-governance-framework-resourc.pdf \[Accessed 9 Jul. 2018\].](#)

[hta.gov.uk. \(2018\). \[online\] Available at:   
https://www.hta.gov.uk/sites/default/files/Code%20E.pdf \[Accessed 8 Oct. 2018\].](#)

Integrated Research Application System – [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

UK Policy Framework for Health and Social Care Research. (2017). Health Research Authority

## APPENDIX A: Chief Investigator Declaration

As Chief Investigator, I agree to abide by the following:

- ✓ The dignity, rights, safety and well-being of participants must be the primary consideration in any research study, in addition to reliable and accurate research data;
- ✓ I am familiar with my responsibilities as Chief Investigator under the [UK Policy Framework for Health and Social Care and should I vacate the role, will organise a suitable replacement and gain the necessary approvals for this change](#);
- ✓ I will undertake the project in accordance with the [UK Policy Framework for Health and Social Care, Good Clinical Practice \(GCP\) regulations](#), and, where applicable, the [Medicines for Human Use \(Clinical Trials\) Regulations and RDS SOPs](#);
- ✓ The project will not commence until approval has been received from the Sponsor, the appropriate Research Ethics Committee, Health Research Authority, the Host Organisation (and, for Clinical Trials, the [MHRA](#));
- ✓ Any amendments to the protocol or Trial design, including changes to start / end dates must be notified to the Sponsor, the appropriate Research Ethics Committee, Health Research Authority, and the Host Organisation;
- ✓ Each member of the research team is suitably qualified by education, training and experience to undertake the research;
- ✓ Each member of the research team will have access to adequate support, supervision and training;
- ✓ Any serious adverse events that occur during the research will be reported immediately to RDS. As CI I understand that I will be responsible for reporting such events to other appropriate bodies (Research Ethics Committees, Health Research Authority, Host Organisation, [MHRA](#)).
- ✓ Data will be processed and stored in accordance with the [General Data Protection Regulation and the Data Protection Act 2018](#);
- ✓ An adequate project master file will be maintained and made available for audit inspection;
- ✓ Full, accurate and legible records will be maintained in accordance with GCP guidelines and will be made available for audit inspection;
- ✓ Any adverse events or reactions as identified through GCP guidelines will be reported within the required timelines and a full record kept in the project master file;

- ✓ Make every reasonable effort to ensure that a peer-reviewed publication results from the research;

Project Title:

Signed: .....

**(Must be signed by the Chief Investigator or in the case of student projects, by the project supervisor)**

Name: (PLEASE PRINT) .....

Date: ...../...../..... (dd/mm/yy)