Obtaining Acceptance of Sponsorship from Bournemouth University: Standard Operating Procedures

1.0 BACKGROUND

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. 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 (SOP).

2.0 PROCEDURE

The Principal Investigator (PI) is responsible for making a request to BU to act as Sponsor. Research Development & Support (RDS) (formerly RKEO), 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.

2.1 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.

2.2 Who should request Sponsorship

It is the responsibility of the PI 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.

2.3 When to request Sponsorship

The PI 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[1].

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

2.4 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.

[1] Research Governance Framework: Resource Pack for Social Care. 2nd Edition. 2010. http://www.researchregister.org.uk/files/RGFGuidancepack2010.pdf.

2.5 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[2];
iii. Signed and dated Principal Investigator Declaration (Appendix A).

Further information and/or documentation may be requested as necessary.
The PI (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 PI to discuss the documentation to gain further clarity.

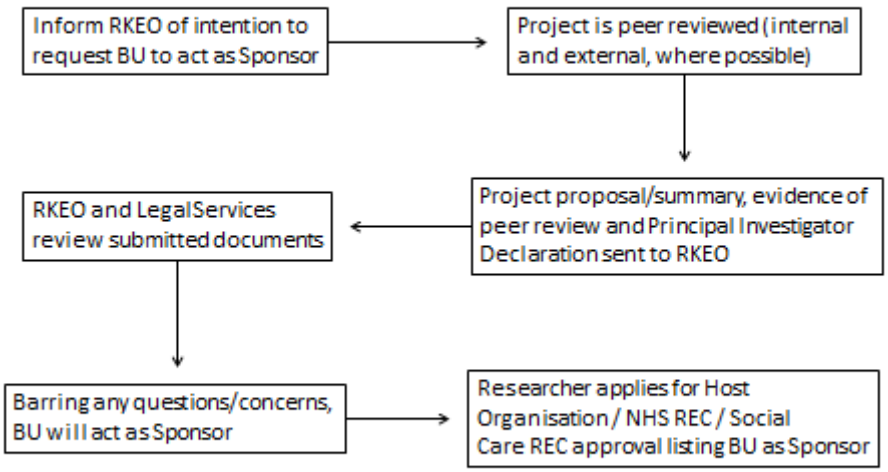
RDS and Legal Services will review the submitted documentation and if no questions or concerns are raised during the review process, Sponsorship approval will be granted within 4 weeks of receipt of all documentation.

Requests should be made by email to researchethics@bournemouth.ac.uk

3.0 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.

FLOW CHART: Process for BU to act as Sponsor



[2] External peer review is expected; if this is not possible, an explanation is required.

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 PI 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 European 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)