BU RDS SOP 017 V1

Title: Sponsorship Role (including Chief Investigator)	
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1. Scope

This Standard Operating Procedure (SOP) outlines the roles and responsibilities of the Sponsor and Chief Investigator for a given research study as laid out in the Health Research Authority's (HRA) UK Policy Framework for Health and Social Care Research and by the Medicines and Healthcare products Regulatory Agency (MHRA).

2. Responsibilities

The *Clinical Governance Advisor* (CGA) is responsible for obtaining agreement from Bournemouth University Legal and Finance departments regarding sponsorship of a given research project. They are also responsible for ensuring that the Researcher and Chief Investigator have up to date Good Clinical Practice (GCP) training, and that they are aware of the required approvals and NHS permissions, prior to the initiation of their study.

For National Institute of Health Research (NIHR) portfolio studies, the CGA is also responsible for uploading recruitment for sponsored studies or aiding researchers to upload recruitment, to the Central Portfolio Management System (CPMS). This ensures transparency on the NIHR Open Data Platform (ODP).

The *Chief Investigator* (CI)/*Principal Investigator* (PI) is responsible for ensuring that their study recruitment is reported to the NIHR for portfolio adopted projects. They are also responsible for the overall conduct of the research project, which will be highlighted in the next section.

Research Development & Support (RDS) and the BU Legal and *Finance departments* are responsible for ensuring that the research project can be properly insured, and staff indemnified, through provision of the study protocol, evidence of peer review, and signed CI declaration. The CGA confirms BU sponsorship to the researcher by provision of a confirmation letter and BU insurance certificates.

3. Procedure

<u>Chief Investigators at Higher Education Institutions (HEIs)</u>

3.1 The UK Policy Framework for Health and Social Care Research discourages students from undertaking the role of CI, at any level of study, stipulating that this should be accepted by a supervisor or course leader. The exception to this would be when the student is an experienced care practitioner or manager that is undertaking an educational

qualification for the purposes of professional development, or doctoral-level study whilst they are employed by a health or social care provider or university, or when the Researcher is undertaking doctoral-level study in acceptance of a fellowship.

3.2 If students on courses that are not necessarily linked to health and social care wish to conduct research involving patients and service users, their data or tissue, or with the public in a health or social care setting, then they should have a co-supervisor that possesses the relevant experience to enhance their understanding of the care context and corresponding research processes.

3.3 The UK Policy Framework stipulates that universities should accept the role of Sponsor for all education research conducted by its own students, with the exception of a student being employed by a health or social care provider that would prefer to undertake the role.
In sponsoring educational research, the framework emphasises the importance of the Sponsor ensuring that supervisors have the capacity and expertise to fulfil their role, and can adequately oversee the project in terms of location. Should the Sponsor not be satisfied, then it may agree co-supervision with a local care practitioner.

3.4 The UK Policy Framework sets out the following duties of the *Chief Investigator*, in addition to assuming the role of lead researcher and the overall responsibility for the conduct of the study:

- Ensuring that the research proposal or protocol considers any relevant systematic reviews, other research evidence, and any research which may be in progress, so that it is scientifically sound and safe and will make effective use patient, service user and public involvement where suitable. The CI must also ensure that the proposal or protocol is ethical, legal and feasible and continues to be so for the duration of the research, being aware of any developments whilst the research is ongoing;

- Submitting the research proposal or protocol for appropriate independent (peer) review, and making any revisions following that review;

- Submitting the research proposal for review by and approval from a research ethics committee (when required), and any other relevant regulatory bodies;

- Ensuring that everyone involved in the conduct of the research is qualified by education, training and experience, satisfying themselves that the staff member is competent to undertake their study role;

- Ensuring that participant-facing documentation and any information provided to potential participants is in a suitable format and is clear and relevant to their participation. Where consent is required the CI should ensure that the information given adequately and clearly addresses their decision-making about taking part in the project;

- In accordance with applicable agreements, for making information about the research publicly available before it starts (unless the research ethics committee have agreed

a deferral, or this has been agreed on their behalf);

- In accordance with applicable agreements, for making data and tissue accessible in a timely manner after the research has finished, in accordance with adequate consent and privacy safeguards;

- Initiating the research only once given the green light by the Sponsor;

- Adhering to agreed procedures and arrangements for reporting (progress reports, safety reports etc.), and for monitoring the research. The CI should ensure that the study is being conducted correctly and that the participants' safety and well-being is protected, in addition to assessing the ongoing suitability of the proposal or protocol following adverse events or any other developments; and

- Ensuring that information about the findings of the research are made available, to participants if appropriate, and in accordance with the agreements in place.

In the case of Postgraduate Researcher (PGR) projects, the PGR will be responsible for some of these tasks, with the support of the Clinical Governance Advisor.

3.5 The Sponsor is the individual, organisation or a partnership that takes on overall responsibility for the research, and for proportionate, effective arrangements being in place to set up run and report a research project. (UK Policy Framework for Health and Social Care Research, 2017). It is expected that the Sponsor be the employer of the CI in non-commercial research (the Funder in commercial research).

The UK Policy Framework sets out the following duties of the *Sponsor*:

- Identifying and managing poorly designed or planned research, and poor-quality research proposals, protocols and applications, by ensuring that research proposals and protocols:
    - consider systematic reviews of any relevant existing research evidence or relevant research in progress,
    - make appropriate use of patient, service user and public involvement, and
    - are scientifically sound (following peer review for example), and are safe, ethical, legal and feasible, and continue to be so during the research project's life-cycle, accounting for any developments whilst the research is ongoing;

- Ensuring that the investigators, research team and research sites are suitable to undertake the research project;

- Ensuring that roles and responsibilities of the parties involved in the research, and any delegation by the Sponsor of its tasks, are agreed and documented;

- Ensuring that there are adequate arrangements in place with regard to insurance and indemnity, in order to cover liabilities which may arise during the design,

management or conduct of the research project;

- In accordance with applicable agreements, for making information about the research publicly available before it starts (unless the research ethics committee have agreed a deferral, or this has been agreed on their behalf);

- In accordance with applicable agreements, for making data and tissue accessible in a timely manner after the research has finished, in accordance with adequate consent and privacy safeguards;

- Ensuring that information about the findings of the research are made available to participants if appropriate, and in accordance with the agreements in place;

- Ensuring that the research proposal has been submitted for review by and approval from a research ethics committee (when required), and any other relevant regulatory bodies;

- Ensuring that regulatory and practical arrangements are in place, prior to giving the green light for the research to begin, ensuring safety;

- Arranging and maintaining adequate finance management of the research project, including its competent risk management and data management;

- Adhering to agreed procedures and arrangements for reporting (progress reports, safety reports etc.), and for monitoring the research. The CI should ensure that the study is being conducted correctly and that the participants' safety and well-being is protected, in addition to assessing the ongoing suitability of the proposal or protocol following adverse events or any other developments.

<u>CI and Sponsor responsibilities for Clinical Trials of Investigational Medicinal Products (CTIMPs)</u>

3.6 The MHRA 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 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.

3.7 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. By assessing the risk of the given trial earlier in the process, the Sponsor may also identify areas of higher risk and plan for the mitigation of these, in addition to the early planning of logistical and practical arrangements pertaining to the execution and oversight of the trial.

3.8 The Sponsor has specific legal responsibilities, concerning CTIMPs, as laid out in Statutory Instrument 2004/1031 and covers the authorisation for clinical trials, research ethics committee (REC) opinion, GCP and conduct, pharmacovigilance, and the manufacturing and labelling of IMPs (see footnote for link).

Joint/co (-) sponsorship

3.9 Joint sponsorship (or co-sponsorship) may be adopted in the case of CTIMPs, for example where a non-commercial organisation (such as BU) is sponsoring the trial, but a group of partners may make collaborative arrangements to initiate, manage and fund the trial. In this case, the persons or organisation can take joint responsibility for the duties of the Sponsor outlined in the Regulations, or they can allocate the responsibility for carrying out said duties amongst themselves.

3.10 If the partners/organisations choose to take joint responsibility then they will both accept joint liability for all of the Sponsor's responsibilities. Each organisation is then expected to have suitably trained and qualified staff to perform such duties, and clear documentation evidencing decisions and oversight, including insurance arrangements, must be in place.

3.11 Prior to deciding whether sponsorship will be a joint or allocated responsibility, formal assessment should be carried out, assessing each co-sponsor's capabilities, ensuring that duties may be allocated and undertaken appropriately (e.g. audit, CV review etc.).

3.12 There must be adequate oversight by each party in monitoring the tasks executed by the other party. For example, regular meetings, progress reports, documentation and monitoring etc.

3.13 When sponsoring a CTIMP, the MHRA may carry out a routine, requested or triggered inspection at the sponsoring organisation and participating sites. See BU RDS SOP 016.

Archiving

3.14 It is a legal requirement to retain the documents held within the TMF (Sponsor File and Investigator Site File), alongside the medical records of trial participants. The Sponsor and PI must ensure that there are adequate arrangements in place for the archiving and storage of documents and source data held for the duration of the study.
Depending on the nature of the study, there are differing retention periods – see BU RDS SOP 001.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
CPMS	Central Portfolio Management System
CTIMPs	Clinical Trial of an Investigational Medicinal Product
EEA	European Economic Area
GCP	Good Clinical Practice
HRA[1]	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
ODP	Open Data Platform
PGR	Postgraduate Researcher
PI	Principal Investigator
REC	Research Ethics Committee

5. Related documentation and references

BU RDS SOP 001 - Archiving clinical research records

BU RDS SOP 016 – MHRA Inspection

Good Clinical Practice Guide (2012), Medicines and Healthcare products Regulatory Agency

Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products. (2011). MHRA - MRC/DH/MHRA Joint Project

The Medicines for Human Use (Clinical Trials) Regulations 2004 - Statutory Instrument 2004/1031. (2004) http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf [accessed 13th April 2018] – pages 10-11

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

[1] Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval