Sponsorship Arrangements and Responsibilities

What is a sponsor?
A sponsor is the individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

Any research requiring sponsorship must have an organisation willing and able to take on the responsibilities of the research sponsor. The responsibilities of sponsors are set out in more detail in the Department of Health’s (DoH) Research Governance Framework (RGF) for Health and Social Care (2005)¹ and by the Health Research Authority² (HRA).

The sponsor must be satisfied that the project meets the standards prescribed by the DoH RGF (2005) and makes sure arrangements are established and kept in place for governance, monitoring, reporting and audit.

The following national bodies require a sponsor to conduct a study or project due to the nature of the intended research (this list is not exhaustive):

- NHS (National Research Ethics Service) [http://www.hra.nhs.uk/resources/applying-to-recs/]
- Social Care Institute for Excellence (Social Care Research Ethics Committee) [http://www.scie.org.uk/research/ethics-committee/]
- Human Tissue Authority [http://www.hta.gov.uk/]
- Health Research Authority [http://www.hra.nhs.uk/]

The University as Sponsor
The University of Sussex (UoS) is registered with the DoH to act as a Sponsor under the RGF. Although the University is registered with the DoH as a Sponsoring institution, this does not constitute blanket acceptance of Sponsor for all University-led research projects. The risks attached to assuming the Sponsor role vary from

² In 2013/14 the Health Research Authority undertook a public consultation on the responsibilities of a sponsor due to concerns that the expectations of Sponsors were not being met, particularly in the context of Higher Education [http://www.hra.nhs.uk/about-the-hra/consultations-calls/]
financial to legal risks and also damage to reputation and the University will have to assess each case on its merits.

Where a project or trial is led by a member of the University staff, the University will consider acting as Sponsor, in principle, for all research under the Research Governance Framework and Clinical Trial Regulations.

The University has worldwide cover for research projects, with the exception of those classed as Clinical Research where there is no cover for research provided within the USA or Canada and any territory within their jurisdictions. The limit of indemnity is £2m. Clinical trials and clinical research are different and covered under different sections of the policy. The above clause relates to Clinical Research and is covered under the Public Liability section. Clinical trials are currently covered by an endorsement on the Professional Negligence section.

The Policies can be found at the following webpage http://www.sussex.ac.uk/finance/services/corporateaccounting/insurance. For further information, please contact the Insurance Office: insurance@sussex.ac.uk

Requests for the University to take on the Sponsor role should be made by the Chief/Principal Investigator (PI/CI), for student projects the request must be made by their supervisor(s).

When will UoS consider sponsoring
- UoS staff\(^3\) or student registered at UoS (including BSMS)

When will UoS not consider sponsoring
- PI/CI/Supervisor not substantively employed by UoS
- Student not registered at UoS
- It has been agreed that the relevant NHS Trust are more appropriate to sponsor
- Any reason (be it legal, financial, liability, insurance, risk or governance reasons) for why the study could not proceed or be considered for sponsored by UoS.

Applying for University Sponsorship
Applications for the University to undertake the role of Sponsor should be made:
- After funding has been confirmed, however, determining if the University can sponsor a study/project, in principle, can be undertaken beforehand with the Research Governance Officer; and
- After the protocol has been subjected to scientific critique and peer review commensurate with the nature of the research.

The Role of the Sponsor in accordance with the Health Research Authority
The Research Governance Framework issued by the Department of Health (including all health care research where NHS patients are involved) requires that all research in healthcare that involves NHS patients, their tissues, data or information, (and some other NHS resources) to have a formal Sponsor.

\(^3\) Regulatory bodies like the HRA and National Institute for Health Research recommend that the default sponsor is the employer of the PI/CI or supervisor.
The Sponsor plays the major role in assuring the quality of the research project. According to the Research Governance Framework it is the Sponsor’s responsibility to be satisfied that:

- The research proposal respects the dignity, rights, safety and wellbeing of participants and the relationship with care professionals
- An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money
- An appropriate research ethics committee or independent ethics reviewer has given a favourable opinion
- The CI/PI, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully
- The resources are adequate to allow the collection, analysis and protection of high quality research data
- The arrangements and resources proposed will allow the collection of high quality, accurate data, and the systems and resources proposed are those required to allow appropriate data analysis and data protection
- Arrangements proposed for the work are consistent with this research governance framework
- Organisations and individuals involved in the research agree the division of responsibilities between them
- Proper arrangements are in place for the initiation, management and monitoring and financing of the research
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or to scientific direction
- Appropriate indemnity or insurance arrangements are in place for compensation in the event of harm to the participants of the related research, and that these are known to the participants and subjects
- There are suitable arrangements in place for the dissemination of the research findings
- Intellectual property rights are addressed in any contract or terms of grants
- Assistance is provided to any enquiry, audit or investigation related to the funded work.