**BSMS Checklist for University Sponsorship**

**For applicants:** Before starting, please use the documentation checklist in Annex A to ensure the Committee has the appropriate documentation to consider your study for sponsorship.

**For the Committee:** Complete the checklist when determining if the University can sponsor a project. Please use this checklist when reviewing a sponsorship request.

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| **Checklist** | **Helptext** | **Notes** | **Y/N/?** |
| **Pre-study** |
| Who is the Applicant: student or staff? Are there any comments about the applicant such as experience, track record, qualifications.  | If the applicant is a student who lacks experience, is the supervision sufficient (e.g. clinical supervision agreed upon if the student and principal supervisor do not have a clinical background). The Applicant, and other key researchers, including those at collaborating sites and their supervisor(s) if they are a student, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.This is covered by the scientific review process, internal HR appointment and management processes – if evidence e.g. qualification certificates, are required these should be made available either via the researcher(s) or through HR if they have copies. |  |  |
| Does this application include all relevant documentation as listed on the document checklist (see Annex A)?  |  |  |  |
| Has risk assessment been undertaken by the Research Governance Officer?  |  |  |  |
| Legal & Regulatory (Any legal reasons why the study cannot proceed and what further approvals need to be gained, for sponsorship and approvals (incl. NRES approval and R&D) |  |  |  |
| Financial (Any financial issues that may impact on the delivery of the project, incur cost to the University, partners if applicable or participants) |  |  |  |
| Liability and Insurance (Any issues that may pose an organisational risk and leave the sponsor liable to a claim or complaint. Any insurance reasons why the study cannot proceed.  | The Insurance Officer can be contacted directly if there are queries, on a case by case basis. 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. |  |  |
| Methodology, Sampling & Recruitment Plan  | Any concerns with the design of the project and make suggestions where necessary on how it might be improved. |  |  |
| The research proposal respects the dignity, rights, safety and wellbeing of participants and researchers involved | This should be informed by the ethics approval process. With the application is there a Participant Information Sheet (PIS) (or equivalent if needing to use an alternative consent method) and Consent Form (or equivalent if needing to use an alternative consent method). Are there any anticipated risks to the safety or wellbeing of the researcher(s) and have steps been taken to resolve or minimise those risks?  |  |  |
| The research proposal is considered 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 or intend to seek approval |  |  |  |
| Organisations and individuals involved in the research agree the division of responsibilities between them  | How this is clarified will depend on the nature of the study e.g. collaborative research will have agreements in place; if Sussex only, then individual roles are clarified in the application/protocol if applicable and in any HR appointment letters. |  |  |
| Proper arrangements are in place for the initiation, management and monitoring and financing of the research  | These arrangements are covered by Sussex internal governance arrangements, e.g. Research Finance, Funder reporting requirements, supervisor oversight (if PG project) etc.  |  |  |
| **During research activity** |
| Arrangements are in place for the sponsor to be alerted to significant developments during the study (whether in relation to the safety of individuals or to scientific direction), adverse events and breach of care, GCP or any other issues relating to research conduct | An explicit reporting process must be in place in the event of serious or unexpected side effects (beyond adverse events) to report to the sponsor and relevant stakeholders (particularly in accordance with the funders terms and conditions if applicable). In the instance where developments amend scientific direction significantly, additional ethics review must be sought and the sponsor must be informed. If this is a student project then the supervisor is the key person with whom the student should liaise with unless they are unavailable in which case the student can contact the research governance officer or ethics committee chair.  |  |  |
| There is written agreement about the arrangements for the management and monitoring of the study. | If externally funded, the arrangements will be covered by agreements between the funder and the University, and possibly addressed by the ethics committee. For own-funded research, the agreement is within the research proposal agreed by appropriate ethics committee, CI/PI and other key researchers. Monitoring will be determined by the risk assessment process undertaken by the Research Governance Officer.  |  |  |
| 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. | This is part of UoS’ internal costing and governance processes. |  |  |
| Assistance is provided to any enquiry, audit or investigation related to the funded work  | Assistance is provided depending on the nature of the enquiry/investigation (allegations of research misconduct procedure is supported by the Governance Officer and audit and/or investigation can be supported by the School and RGO).  |  |  |
| **Post-study** |
| There are arrangements for the conclusion of the study including appropriate plans for the dissemination of the research findings  | This depends on the nature of the study and the status of the applicant e.g. thesis for a student or academic publication, conferences and colloquia for staff.BSMS RGEC need to be notified at the end of a study and sufficient arrangements must be in place for archiving of study documentation for a period of 5 years |  |  |

**Annex A: Pre-Study Document checklist**

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| **Document (answer if applicable)** | **Version** | **Dated** | **Notes** |
| Proof of registration of trial  |  |  |  |
| RGEC application form  |  |  |  |
| Research Protocol or sufficient detail provided in RGEC application |  |  |  |
| Summary CV for Chief/Principal Investigator and/or GCP certificates of research team (e.g. for Clinical Trials or medical device studies) |  |  |  |
| Participant Information Sheet  |  |  |  |
| Invitation Letter or email text copy to participant/s and volunteers  |  |  |  |
| Letter to Gatekeeper  |  |  |  |
| Participant Consent form |  |  |  |
| Interview schedules, topic guide, interview questions or questionnaire  |  |  |  |
| Validated questionnaire  |  |  |  |
| Non-validated questionnaire  |  |  |  |
| Recruitment materials for research participants  |  |  |  |
| Overseas Travel Safety and Security Risk Assessment form  |  |  |  |
| Evidence of sufficient funding arrangements and resource |  |  |  |
| For student projects: Evidence of adequate supervision in place – the lead supervisor should be employed by University of Sussex, if a lead supervisor lacks appropriate clinical experience a 2nd supervisor with appropriate experience will need to be available to the student.  |  |  |  |
| For student projects overseas: Evidence of adequate local field supervision in place |  |  |  |