

STANDARD OPERATING PROCEDURE 3

Research Sponsorship

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Revision Chronology:	Effective date:	Reason for change:
Version 2.0	21 February 2018	Reference to new sponsorship policy. Web links updated and change of format.
Version 1.4	4 December 2013	Addition of new process to obtain sponsorship from the University of Warwick. Web links updated.
Version 1.3	4 January 2011	Bi-annual review, addition of responsibilities for dealing with protocol deviations or breaches.
Version 1.2	22 Dec 2008	Bi-annual review, minor text changes, no significant change to context.
Version 1.1	20 th December 2006	Co-sponsorship information added.
Version 1.0	January 2006	

Research Sponsorship

Purpose

The purpose of this Standard Operating Procedure (SOP) is to inform University staff and students when University research sponsorship will be required, how to apply and how sponsor responsibilities are delegated.

Background

All research carried out within the NHS or social care within England will require a research sponsor in accordance with the UK Policy Framework for Health and Social Care Research.

In addition, all trials involving an Investigation Medicinal Product (IMP) will require a research sponsor under the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031).

The UK Policy Framework for Health and Social Care Research states that research sponsors are responsible for 'ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project'.

The sponsor is responsible for ensuring that arrangements are in place for the research team to access the 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 also 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 study design.

Procedure

3.1 Who?

The Chief Investigator (CI) is responsible for ensuring sponsorship arrangements are in place as they are the individual with responsibility for the day-to-day running of a study, and for the safety of the study participants. This includes, but is not limited to, responsibility for the study budget, overseeing the work of the study staff, ensuring that the study is conducted rigorously and on time, that the results are made available and that all necessary regulations are complied with at all times.

In the case of a study that is being undertaken by a student as part of an academic qualification, the application for sponsorship should be made in the name of the student's University substantively employed supervisor, with the supervisor taking on the responsibility for and being named as the CI.

3.2 When?

An application for research sponsorship should be made as early as possible during the study set up phase. Studies involving NHS patients, their tissue or data will require Health Research Authority (HRA) approval which may take some time and sponsorship must be confirmed prior to applying to the HRA.

If your study requires a research sponsor, work should not commence until sponsorship has been approved by the University Sponsorship Committee and confirmed in writing by the Research Governance Team in Research and Impact Services (R&IS). All relevant regulatory and ethical

approvals must also be in place prior to the start of a study (see SOP 6, Ethics Approvals and Communications and SOP 5, Regulatory Approvals and Communications).

Certain funding bodies will require an 'intention to sponsor' or 'sponsorship in principle' letter or signature from the sponsor at grant application stage. For details of this process, see section 3.4 below.

3.3 How?

The Sponsorship Committee operates to the principles of the Institutional Oversight and Sponsorship Policy, which is also available on the Research Sponsorship webpages.

The Committee will assess each sponsorship application on its merits, making a sponsorship decision based on a risk-assessment and the detailed study information submitted as part of the application.

If you are unsure whether your study requires University sponsorship please refer to the Research Sponsorship webpages for further information:

http://www2.warwick.ac.uk/services/ris/research_integrity/sponsorship/

3.3.1 Step 1

The Research Governance Team in R&IS should be contacted at the earliest opportunity via the research sponsorship email address sponsorship@warwick.ac.uk for advice and guidance regarding whether University sponsorship is required, how to apply, the timescales involved and any insurance considerations. Information can also be found on the Research Sponsorship webpages by following the above link.

3.3.2 Step 2

Once the Research Governance Team have confirmed that sponsorship is required, the CI or student (in the case of research carried out as part of an academic qualification) should complete the Sponsorship Application Form available on the Research Sponsorship webpage https://warwick.ac.uk/services/ris/research_integrity/sponsorship and prepare/ collate study documentation to be submitted for Committee consideration and approval, including all participant facing documents and study information including:

- Study protocol
- Participant/ patient Information sheets or leaflets
- Consent forms
- Completed IRAS (Integrated Research Application System) form (exported as a pdf via the 'print tab')
- Statement of Activities (SoA) and Schedule of Events (SoE) (not required for Committee review but for sponsor IRAS authorisation, see <http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/>)
- Evidence of sufficient funding
- Evidence of appropriate peer review
- Questionnaire(s)
- Interview Schedule(s)
- Study advertisement(s)/poster(s)/leaflet(s)
- Any other participant facing documents

The completed application form and supporting documents will need to be provided to the Research Governance Team via the research sponsorship email address above at least two weeks before the Sponsorship Committee meeting date to allow for your application to be included in papers to be

circulated to attendees in advance of the meeting. The Committee meets on a monthly basis and meeting dates can be found on the Research Sponsorship webpages via the link below:

http://www2.warwick.ac.uk/services/ris/research_integrity/sponsorship/scmeetingdates/

The Research Support & Contracts Team in R&IS (and the relevant Research & Development contact in the lead NHS Trust in which the work is to be undertaken where a co-sponsorship agreement is to be implemented) should be contacted as early as possible in the study set-up phase to discuss the contracts required.

3.3.3 Step 3

The study will be risk assessed by the Research Governance Team using set criteria resulting in the allocation of an overall risk score. This will be considered by the Committee alongside the details submitted as part of the sponsorship application and will inform the level of sponsorship oversight, and where applicable quality assurance required for the study.

The Committee may:

- approve the sponsorship application at the meeting
- issue conditional approval
- reject the application
- request further information, clarification or amendment for consideration at a future Committee meeting, or to be reviewed by the Chair or Research Governance Team.

Once the Committee has made a decision regarding sponsorship, the result will be communicated in writing to the applicant within 5 working days. If the Committee approves sponsorship, a sponsorship approval letter will be issued setting out the conditions of University sponsorship.

3.3.4 Step 4

For sole sponsored studies, the CI will be required to meet with the Research Governance and Quality Assurance Manager (or their delegate) in R&IS to discuss and clarify respective study responsibilities, which will be formally documented. The document will be signed to confirm the agreed responsibilities detailed therein.

A signed copy of this document will be retained in the sponsor's file for the trial. The CI should file a signed copy of the document in the Trial Master File (TMF)/ study file.

For co-sponsored studies, these responsibilities will be documented within the co-sponsorship agreement, which should also be signed by the CI and retained in the sponsor's file and TMF.

3.3.5 Step 5

Key study details such as proposed start and end dates, status, study type and Chief Investigator details will be recorded by the Research Governance Team. Researchers are responsible for notifying the Research Governance Team of any changes to these details via sponsorship@warwick.ac.uk throughout the lifecycle of the study.

3.4 Intention to Sponsor

Some funding bodies will require an intention to sponsor or 'sponsorship in principle' to be confirmed at grant application stage. In order for an application to be considered on this basis an application should be submitted to the Research Governance Team for review. It is recognised that study documentation such as a final protocol, participant facing documents and study full details will not be available at grant application stage and so the full list of documents set out in 3.3.2 above will not be required. The applicant should submit as a minimum requirement a Sponsorship Application Form completed with as much information as possible, a study proposal including costings and a draft protocol, where available. Any draft versions of participant facing documentation already developed should also be submitted for consideration. Applications should be submitted to sponsorship@warwick.ac.uk

The application for intention to sponsor will be reviewed by a panel consisting of The Head of Research Governance or their delegate and at least one other member of the Research Governance Team. The applicant will be notified of the outcome by the Research Governance Team and if applicable, the grant application will be signed by the sponsor's representative indicating intention to sponsor and/or an intention to sponsor letter may be issued, depending on the requirements of the funder.

3.5 Chief Investigators of Sponsored Studies who leave the University of Warwick

Where a CI of a Warwick Sponsored Study or studies is to terminate their substantive employment with the University, either the CI will need to be changed to an alternative academic holding a substantive employment contract with the University, or transfer of sponsorship of the study will need to be agreed with another institution. In both cases, the Research Governance Team should be contacted for advice on how to proceed. Once agreement has been reached it is likely that a substantial amendment will need to be submitted to the HRA and MHRA as applicable (see SOP 5 Regulatory Approvals and Communications and SOP 6 Ethics Approvals and Communications for details of how to submit a substantial amendment).

List of Abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
REC	Research Ethics Committee
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
TMF	Trial Master File

Templates

Sponsorship Application Form