STANDARD OPERATING PROCEDURE 3
Research Sponsorship

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Author:	Mathew Gane, Research Governance and Quality Assurance (QA) Manager, Research & Impact Services (R&IS)		
WCTU Reviewers:	Claire Daffern, QA Manager, Warwick Clinical Trials Unit (WCTU)		
Sponsor Reviewers:	Deborah Owen, Research Support Manager, R&IS		
WCTU approval:	Natalie Strickland, Head of Operations, WCTU		
Sponsor approval:	Carole Harris, Assistant Director, R&IS (Systems & Strategic Projects) & Head of Research Governance		
Review Lead:	Research Governance Team, R&IS		

Contents

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Revision Chronology:	Effective date:	Reason for change:
Version 4.0	08 November 2023	Biennial review: Details on providing NHS REC Annual Progress/ End of Study/ Annual Reports to Sponsor's Office
Version 3.0	18 February 2021	Biennial review: Change to new format. Minor amends to text.
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	Biennial review, addition of responsibilities for dealing with protocol deviations or breaches.
Version 1.2	22 Dec 2008	Biennial review, minor text changes, no significant change to context.
Version 1.1	20th December 2006	Co-sponsorship information added.
Version 1.0	January 2006	

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Research Sponsorship

1. Purpose and Scope

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

It is applicable to all research staff working on UoW sponsored studies. Staff working on non-Warwick sponsored studies must liaise with and agree responsibilities with the relevant external sponsor.

2. Definitions

Sponsor	An individual, company, institution, or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

3. 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 (2017).

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).

University sponsorship approval will also be required for clinical trials conducted outside the UK to ensure the appropriate sponsor oversight on behalf of the University, ensuring compliance with sponsor responsibilities and other applicable legislative requirements.

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.'

Good Clinical Practice (GCP) guidelines state that 'before initiating a study, the sponsor should define, establish, and allocate all trial-related duties and functions'. Sponsors can formally delegate one or more of the elements of sponsorship for example, to the Chief Investigator, Clinical Trial Unit or another third party, but the sponsor remains accountable for all aspects of sponsorship whether delegated or not. The sponsor must implement procedures to ensure appropriate oversight of all delegated functions.

4. Procedure

4.1 Responsibilities

Sponsor	• Ensuring that arrangements are in place for research teams to access the resources and support to deliver the research as proposed

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	• Ensuring that agreements are in place which specify responsibilities for the management and monitoring of research • Ensuring that arrangements are in place for the oversight of study conduct and to review significant developments as the research proceeds • Approval of modifications to study design/documentation
Chief Investigator (CI)	• Ensuring sponsorship application is made in a timely fashion • Ensuring all appropriate arrangements are in place to ensure participant safety • Ensuring study budget is controlled • Oversight of the study team • Ensuring the study is conducted rigorously and on time • Ensuring study results are published within required timelines • Compliance with all relevant regulations/legislation

4.2 When?

An application for research sponsorship should be made as early as possible once the scope of the study has been agreed. 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's Sponsorship & Oversight Committee (SOC) and confirmed in writing by the Research Governance Team in R&IS. All relevant regulatory and ethical approvals must also be in place prior to the start of a study (see SOP 5 part 1; Gaining Initial Ethical Approval and SOP 5 part 2; Gaining Initial Regulatory Approval).

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 4.4 below.

4.3 How?

The Sponsorship & Oversight Committee (SOC) operates to the principles of the Institutional Oversight and Sponsorship Policy, which is available on the Research Sponsorship webpages: http://www2.warwick.ac.uk/services/ris/research_integrity/sponsorship/

The SOC 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 (link above) for further information.

N.B. 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.

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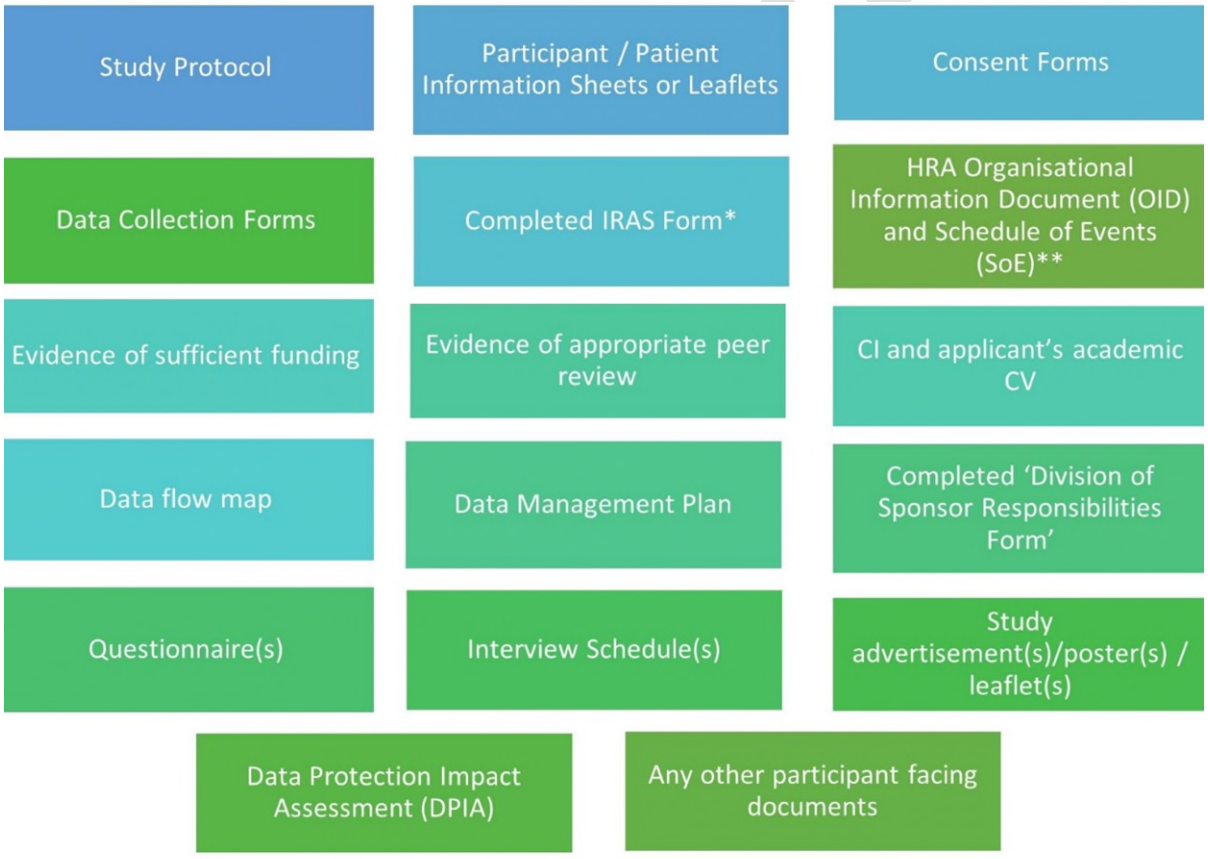
In the case of studies that involve joint responsibilities for the management and monitoring of a study, for example with an NHS Trust, then co-sponsorship may be considered and should be discussed with the Sponsor's Office and the relevant contact at the collaborating organisation prior to submitting an application for research sponsorship (see section 4.3.3).

4.3.1 Step 1 Contact the Research Governance Team

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.

4.3.2 Step 2 Application Submission and Review

The SOC reviews all applications for research sponsorship. 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 SOC consideration and approval, including all participant facing documents and study information:



* exported as a pdf via the 'print tab'
** not required for SOC review but for sponsor IRAS authorisation, see http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/

In the case of applications prepared by a student, the student's University substantively employed supervisor should review the application and sign the Sponsorship Application Form to confirm that they are willing and able to act as CI of the study.

Sponsorship applications must be received by the Sponsor's Office in R&IS via sponsorship@warwick.ac.uk **FOUR** weeks ahead of the meeting date, to be considered by the SOC at that meeting. SOC 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/

Once received the application will be risk assessed by the Sponsor's Office and an initial review will be completed to check for completeness, following which initial feedback will be issued.

Applications will be considered and reviewed at either a full meeting of the SOC or at the Sponsor's Office sub-committee. Applications assessed as medium, high risk or interventional in nature will be subject to review at a full SOC meeting, which are held once every two months. Applications assessed to be low risk and non-interventional in nature will be suitable for review by the Sponsor's Office sub-committee which meets on a monthly basis.

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 which contracts are required. The Research Support & Contracts Team in R&IS will draft and negotiate the agreements which are required to be in place for your study.

4.3.3 Step 3 Division of Responsibilities

Once a sponsorship application has been received, the Division of Sponsor Responsibilities Form (Template T01 which can be found: https://warwick.ac.uk/fac/sci/med/research/ctu/qa/templates/) will be completed by the Sponsor's Office and provided to the applicant, CI and WCTU (for WCTU managed studies) for review and to put forward any amendments if required. Once all parties are content to approve the document all parties will sign the document, and this will then be included in papers for review by the SOC or Sponsor's Office sub-committee.

For co-sponsored studies, a 'Division of Sponsor Responsibilities Schedule - Co-sponsored Studies' will be completed by the Sponsor's Office instead of the Division of Sponsor Responsibilities Form. Once approved the delegated responsibilities will be transposed into the co-sponsorship agreement, which will be put in place by the Research Support and Contracts Team in R&IS.

The final division of responsibilities document will be retained in the sponsor's file for the study. The CI (or delegate) should file a copy of the document in the Trial/Study Master File (T/SMF).

4.3.4 Step 4 Risk Assessment and Outcome of Review

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 SOC 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.

There are 4 potential review outcomes from the SOC:

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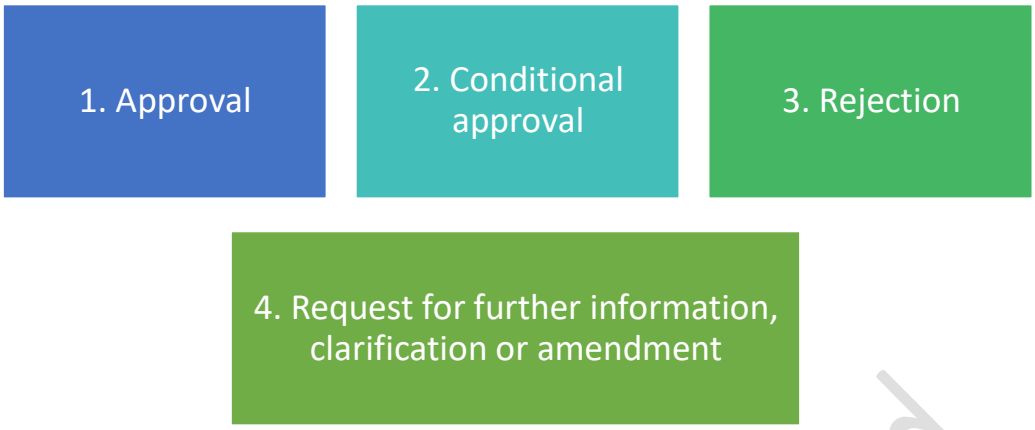

Once the Committee has made a decision regarding sponsorship, the result will be communicated in writing to the applicant within 10 working days.

If a request is made for further information, this will be reviewed by for consideration at a future SOC meeting or reviewed by the Chair or by Research Governance Team.

If the SOC approves sponsorship, a sponsorship approval letter will be issued setting out the conditions of University sponsorship.

4.3.5 Step 5 Recording Study Details

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. Annual Progress Reports and End of Study Reports send to the appropriate NHS REC should also be copied to the Sponsor's Office via sponsorship@warwick.ac.uk. For Warwick sponsored studies with University REC (BSREC or HSSREC) or non-NHS REC ethical approval the Annual Report to Sponsor Form should be completed and submitted to the Sponsor's Office via sponsorship@warwick.ac.uk within one month of the anniversary of their University sponsorship approval.

4.4 Intention to Sponsor

Some funding bodies will require an intention to sponsor or 'sponsorship in principle' to be confirmed at grant application stage. For this to be considered, 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 4.3.2 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. Should the study subsequently be awarded funding then a full application for research sponsorship should be submitted for approval as set out in this SOP.

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4.5 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 6 Amendments to Approved Study Documents for details of how to submit a substantial amendment).

List of abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
QA	Quality Assurance
R&IS	Research & Impact Services
SOC	Sponsorship & Oversight Committee
SOP	Standard Operating Procedure
T/SMF	Trial/Study Master File
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

Template Documents

Division of Sponsor Responsibilities Form (T01)

Annual Report to Sponsor Form

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