

University of Warwick
Institutional Sponsorship and Oversight Policy

Version control:

Version	Effective date	Reason for change
1.0	1 March 2017	First publication
1.1	29 November 2018	Changes to Sponsorship & Oversight Committee & application review process

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1. Definitions

Within this policy, the following definitions apply:

Term	Definition
Chief Investigator (CI)	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.
CTIMP	<p>Clinical Trial of an Investigational Medicinal Product</p> <p>A clinical trial that tests, or uses as a reference, a pharmaceutical form of an active ingredient or placebo.</p> <p>This can include a product with a marketing authorisation when used or assembled in a way different from the approved form, or for an unapproved indication, or to gain further information about an approved use.</p> <p>All CTIMPs are legally required to comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 and associated amendments and fall under the regulation and inspection of the MHRA.</p>
DSUR	Development Safety Update Report. A common standard for annual safety reporting for clinical trials across the ICH regions. The DSUR replaces the annual safety report as the mechanism for periodic safety reporting in clinical trials.

GCP	Good Clinical Practice: an international ethical and scientific quality standard provided by the International Council for Harmonisation for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials. It also serves to protect the rights, integrity and confidentiality of trial subjects.
IMP	<p>Investigational Medicinal Product. A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial:</p> <ul style="list-style-type: none"> (a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation; (b) used for an indication not included in the summary of product characteristics under the authorisation for that product; or (c) used to gain further information about the form of that product as authorised under the authorisation.
Interventional study	A clinical study in which participants are assigned to receive one or more interventions (or no interventions) so that researchers can evaluate the effects of the intervention on biomedical or health related outcomes. Participants may receive diagnostic, therapeutic or other types of interventions. Randomised controlled trials or studies that are non-CTIMPs may also be interventional studies.
Non-interventional study	A study that does not involve a clinical intervention. Any medicinal product(s) must be prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study.

MHRA	The Medicines and Healthcare Products Regulatory Agency. An executive agency, sponsored by the Department of Health which is the competent authority for the regulation of CTIMPs in the UK.
QMS	A Quality Management System used by a clinical trials unit to provide management and oversight of research studies, and encompassing Standard Operating Procedures that are regularly updated to reflect the required standards for the development, initiation, delivery, management, monitoring, quality assurance, statistical support and closure of the trial or study.
Sponsor	<p>For non CTIMPs, the sponsor is defined by the UK Policy Framework for Health and Social Care Research (2017) as the individual, organisation or group taking responsibility for securing the arrangements to initiate, manage, and finance the trial or study.</p> <p>For CTIMPs, the sponsor is defined by The Medicines for Human Use (Clinical Trials) Regulations 2004 as the individual or organisation that takes responsibility for the initiation, management and financing (or arranging financing) of a CTIMP, encompassing responsibility in four main areas:</p> <ul style="list-style-type: none"> • Authorisation for clinical trials and research ethics committee opinion • GCP and the conduct of clinical trial • Pharmacovigilance • Manufacture and labelling of investigational medicinal products. <p>Sole sponsorship refers to the arrangement by which one individual or organisation assumes full and sole responsibility for sponsorship of the study.</p> <p>Co-sponsorship refers to the arrangement by which the sponsor responsibilities are distributed between two organisations, generally an NHS Trust and a university. In such cases, the responsibility of each sponsor should be clearly outlined in a co-sponsorship agreement.</p>

Sponsor's Office	The team within Research & Impact Services responsible for the administration of the University's sponsorship function as required by the UK Policy Framework for Health and Social Care Research 2017 and Medicines for Human Use Clinical Trials Regulations 2004.
SUSAR	Suspected unexpected serious adverse reaction.
SAE	<p>Serious adverse event. Any untoward medical occurrence in a subject to whom a medicinal product has been administered, (including occurrences which are not necessarily apparently caused by or related to that product) which:</p> <ul style="list-style-type: none"> • Results in death • Is life threatening • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity • Consists of a congenital abnormality or birth defect. <p>'Important medical events' may also be considered serious if they jeopardise the subject or require an intervention to prevent one of the above consequences.</p> <p>The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.</p>
UK-CRC Registered Clinical Trials Unit (CTU)	A CTU that has been assessed by an international panel of experts in clinical trials research and has achieved UK-CRC Registration status. The UK-CRC website (http://www.ukcrc-ctu.org.uk/) provides details of all UK-CRC registered CTUs.
SOP	Standard Operating Procedure. A written and formally approved procedure detailing by the method for carrying out a specific task.

2. Scope

This policy applies to all University of Warwick staff and students who wish to apply for institutional sponsorship as defined by the UK Policy Framework for Health and Social Care Research (2017). This includes research which is:

- Concerned with the protection and promotion of public health
- Undertaken in the Department of Health and/or with a non-departmental public body
- Undertaken within the NHS
- Undertaken by or within social care agencies.

Projects defined as a Clinical Trial of an Investigational Medicinal Product (CTIMPs) also fall within the provision of The Medicines for Human Use (Clinical Trials) Regulations 2004, and therefore require additional duties of the sponsor. The University's approach to sponsorship of CTIMPs is also outlined within this policy.

The MHRA algorithm provides guidance on the definition of clinical trials as CTIMPs or non-CTIMPs:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf Guidance can also be accessed via the Sponsor's Office in Research & Impact Services who can be contacted via sponsorship@warwick.ac.uk

3. Principles of University Sponsorship

The University of Warwick operates a model of sole and co-sponsorship, with the final decision as to the preferred sponsorship model being subject to the review and approval of the University Sponsorship and Oversight Committee with regards to CTIMPs and all interventional studies and medium-high risk non-interventional studies, and to the Sponsor's Office with regards to low risk non-interventional studies.

The Committee and Sponsor's Office operate to the principles outlined within this policy, but will assess each sponsorship application on its merits, making a sponsorship decision based on a detailed understanding of the precise nature of the study. The decision will be based upon the 'risk adapted approach' developed and recommended by the MHRA.

3.1 Sponsorship of CTIMPs:

In cases where the University is asked to assume full and sole responsibility for a CTIMP, the University will usually expect the trial to operate within a UK-CRC registered CTU. In cases where the University is asked to co-sponsor a CTIMP with an NHS Trust, the University will usually expect CTIMPs to be overseen by a UK-CRC registered CTU. In all cases, of a proposed sponsored CTIMP or a medical device or product the CI must ensure that the required MHRA approval is received.

3.2 Interventional Studies:

In cases where the University is asked to sole or co-sponsor an Interventional study, the University will usually expect the study to operate within a UK-CRC accredited CTU. In many cases this will be Warwick Clinical Trials Unit (WCTU). This will be assessed on a case by case basis.

- 3.3 Non-interventional Studies:
In cases where the University is asked to sole or co-sponsor a non-interventional study, the University is unlikely to require the oversight of a CTU, subject to the review and approval of the Sponsorship and Oversight Committee.
- 3.4 Quality Management System:
The University requires all CTUs that oversee a University sponsored or co-sponsored trial to hold current UK-CRC registration status.
- 3.5 The Sponsorship and Oversight Committee operates a risk-based approach, under which all CTIMPs and Interventional Studies are referred for full Committee review.
- 3.6 All non-interventional studies categorised as low risk are referred to a sub-committee for review. This sub-committee sits within Research & Impact Services and is comprised of the Head of Research Governance, the Research Governance & Quality Assurance Manager and Research Support Manager.
- 3.7 Where co-sponsorship is agreed, a co-sponsorship contract will be drafted and agreed. This contract will define the responsibilities of the relevant CI, NHS Trust/s, and University/ies (and within that), CTU/s as appropriate.

4. Applying for University Sponsorship

- 4.1 All University staff and students who are developing trials or studies which require a sponsor should contact the University Sponsor's Office in Research & Impact Services via sponsorship@warwick.ac.uk at the earliest opportunity, in order that the full implications of sponsorship can be understood, properly budgeted for and appropriately managed. This early referral is particularly important with regards to CTIMPs and Interventional studies or those where specific additional costs may be required to ensure the necessary levels of quality assurance.

Applications for sponsorship must be made by a substantive member of University staff, or a registered student normally in conjunction with their University employed supervisor who will act as the CI. Holders of honorary contracts will not be eligible to apply for University sponsorship without a University CI.

- 4.2 All University staff and students must receive sponsorship approval prior to submission to the NHS Research Ethics review process. In exceptional circumstances, an intention to sponsor letter may be provided to enable applications to proceed prior to full sponsorship review taking place. This decision will be made at the discretion of the Chair of the Sponsorship and Oversight Committee.
- 4.3 An application for University sponsorship or co-sponsorship should be made in accordance with the University of Warwick Research Sponsorship SOP, available on the Research and Impact Services and Warwick Clinical Trials Unit web pages via the following links:
https://warwick.ac.uk/services/ris/research_integrity/sponsorship/
<https://warwick.ac.uk/fac/sci/med/research/ctu/conducting/planning/sop2016>

- 4.4 In the case of a study which is being undertaken by a student as part/fulfilment of an academic qualification, the application for sponsorship should normally be made in the name of the student's University-employed supervisor. The supervisor will therefore normally take responsibility as named CI.

5. Sponsor Oversight: CTU Managed Studies

For WCTU managed studies, WCTU will take responsibility for provision of appropriate oversight reports to the Sponsorship and Oversight Committee for WCTU managed sponsored studies, through their lifecycle. For University sponsored or co-sponsored that are managed within an external CTU, the Sponsor Office will liaise with the Clinical Trials Unit to provide reports to the Sponsorship and Oversight Committee.

The following reports should be provided, where applicable, to the Sponsorship and Oversight Committee.

Bi-monthly (once every 2 months):

- Progress against Quality Assurance Audit Plans for University sponsored studies and Warwick Clinical Trials Unit (WCTU) managed studies
- Quality Assurance Audit and Monitoring reports completed since the last meeting
- Annual and End of Study REC reports submitted since the last meeting
- Development Safety Update Report (DSUR) reports submitted since the last meeting
- Protocol and/or GCP violations/serious breaches, with any Medicines and Healthcare products Regulatory Agency (MHRA) reported serious breaches also being referred immediately to the Chair of the Committee.
- Suspected Unexpected Serious Adverse Reaction (SUSAR) line reporting, with immediate referral to the Chair of the Committee.
- Report on any SOPs that have exceeded their next review date
- Minutes of the WCTU Governance Committee
- A report on WCTU managed studies, including those:
 - Open and recruiting
 - In follow-up
 - In set up
 - Grants submitted and pending decision
 - Grants in work up

Annually:

- Quality Assurance Audit Plan for WCTU managed studies
- Quality Assurance Audit Reports for external clinical trials units that manage a University sponsored study

6. Sponsor Oversight: Non-CTU Managed Studies

The Sponsorship & Oversight Committee will receive a summary at each of its meetings of low risk non-interventional applications reviewed and approved by the Sponsor's Office via delegated procedures.

Studies that have received Health Research Authority (HRA) or NHS Research Ethics Committee approval will be required to submit annual progress reports and end of study reports to the HRA/ REC and these should also be provided to the Sponsor's Office via sponsorship@warwick.ac.uk

7. Responsibilities of the Chief Investigator (CI)

CIs of University of Warwick sponsored studies will agree to be responsible for the duties outlined in the 'Division of Sponsor Responsibilities Form', the precise wording may vary according to the nature of the project, but will generally involve the CI confirming that:

- They have undertaken GCP training and are otherwise up to date in any required continuing professional development activities.
- There are adequate resources in place for the running of the trial or study, in terms of funds, staff, facilities, and infrastructure.
- The medical care of trial subjects and/or study participants is assured during their participation in the study.
- Staff involved in the trial or study have the appropriate GCP training to deliver their delegated elements of the trial/study.
- Regular and timely communication will be maintained throughout the trial and/or study with the sponsor, the NHS Research Ethics Committee, and the MHRA as appropriate.
- There will be full compliance with the protocol and that any deviations and/or violations are documented and amendments submitted to the appropriate Research Ethics Committee.
- IMP accountability, where required, is assured, with site responsibility clearly delegated to an appropriate pharmacist.
- Where applicable to interventional studies, unblinding and randomisation procedures are followed at all times.
- That GCP guidelines on informed consent are followed at all times.
- That records and reports are appropriately created, managed, stored, and archived, including the Trial Master File, Site Files, CRF and source documentation, financial agreements.

- That all records and reports are readily available for internal or external audits.
- That, where appropriate, the Development Safety Update Report is submitted to the MHRA, and the annual report to the NHS Research Ethics Committee and sponsor.
- That all Serious Adverse Events are included in the annual reporting to the sponsor.
- That trial subjects and/or study participants are promptly informed in the eventuality that the trial or study ends prematurely or is suspended.
- That the final report is provided to the NHS Research Ethics Committee, sponsor, and regulatory authorities, as appropriate.

8. Withdrawal of Sponsorship

The University has the discretion to withdraw its sponsorship of a study where information on the original application changes without prior approval of the Sponsorship and Oversight Committee, including but not limited to changes to:

- The Chief Investigator
- Funding
- Co-sponsor status
- Randomisation strategy

Sponsorship may also be withdrawn if there is a failure to comply with the University's Research Code of Practice by the CI or any member of the study team.

9. Amendments to Studies Approved for Sponsorship

Amendments to studies must be considered by the sponsor on a case by case basis to determine whether they are substantial. The Sponsor's Office can provide information and advice regarding the substantiality of amendments. All substantial amendments should be authorised by the Sponsor's Office before submission.

10. Policy Management

This version of the policy will come into effect from 29 November 2018. It will be reviewed biennially to check compliance with current UK-CRC, University of Warwick, NHS or other relevant policy.