SPONSORSHIP OF RESEARCH PROJECTS: Position Statement 2023

Version 6: Replaces Version 5, November 2023, for renewal April 2026

This document sets out the position of University Hospitals Coventry & Warwickshire NHS Trust (UHCW NHS Trust) with regard to research sponsorship arrangements for research projects that involve the Trust.

There is a requirement to identify a Sponsor:

i). for all research in the NHS (UK Policy Framework for Health and Social Care) [1]

ii). for all clinical trials involving a medicine (Clinical Trials Regulations) [2]. This is a legal requirement.

Who will Sponsor?

1. For commercial trials, the pharmaceutical company typically acts as Sponsor.

2. For non-commercial trials, it is expected that one of the research funders will act as Sponsor. However, some funding bodies are not prepared to take on the role of sponsor.

3. If none of the study funders will act as Sponsor, then:

   3.1. If the Chief Investigator is a Trust employee, then it is expected that the Trust will coordinate Sponsorship.

   3.2. If the Chief Investigator is not a Trust employee, then it is expected that their employing organisation will coordinate Sponsorship.

4. If there is no Sponsor, then the research cannot take place.

5.

Studies by UHCW staff

Where a member of UHCW staff (substantive contract) is undertaking research involving UHCW patients and where a funding body is not able to take on the role of sponsor, the sponsorship role will usually be accepted by UHCW. This also applies to 'own account' research being undertaken by UHCW staff (provided it fulfils Research Governance requirements). **However, it cannot be assumed that the Trust will take on sponsorship** and each study will be considered on an individual basis.

Studies by University staff involving UHCW patients

In general, where the funder is not able to take on the sponsor role, where the Chief Investigator is employed by a University, where the study population involves UHCW NHS Trust patients and where clinical interventions are taking place, the University are expected to take on the role of Sponsor and UHCW are set up as a host site.

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[1] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

[2] http://www.ct-toolkit.ac.uk/routemap/within-the-scope-of-the-uk-regulations/index.tm

Operational arrangements

For all research, researchers must contact the Trust's Research & Development (R&D) Team (*R&D sponsorship email*) at the earliest possible stage to discuss sponsorship arrangements as these will need to be clear before the Ethics application be submitted.

Projects will be reviewed on a case by case basis by the Trust R&D Team as to whether or not the Trust is prepared to take on the role of Sponsor (see Research & Development Standard Operating Procedure number 3). As part of this process, the Chief Investigator is required to submit a copy of the protocol for a full risk assessment to be completed by the Research Governance and Sponsorship team.

For all invasive trials (i.e. those that fall under the Clinical Trials Regulations 2004 and those that involve new devices or surgical procedures), that are medium or high risk, these will be presented to the Research Governance and Operational Group (RGOG) for consideration of Sponsorship. UHCW NHS Trust will require evidence that the staff involved are trained to ICH-GCP standards. Chief Investigators will be required to complete Investigator training prior to being able to lead a Trust sponsored study.

Sponsorship costs must be included within all funding applications that require UHCW sponsorship ot governance involvement.

In order to meet the legislative requirements for sponsored studies, in particular for invasive trials (i.e. those that fall under the Clinical Trials Regulations 2004 and those that involve new devices or surgical procedures), the Trust process for providing sponsorship can take up to 3 months. It is essential that researchers contact the R&D Office as early on in the process as possible.

Chief Investigators carrying out Trust sponsored studies are required to follow Trust R&D Standard Operating Procedures, available on the Trust intranet: http://trustnav/research-and-development/research/sops/

A flow diagram of the decision process is provided in Appendix 1.

Appendix 1: Flow Diagram for determining the sponsorship.