RESEARCH INTEGRITY AND GOVERNANCE OFFICE SPONSORSHIP GUIDANCE (NON-CTIMP)

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UNIVERSITY OF SURREY

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Scope and Purpose

This document has been created to outline the process for investigators who wish to request University of Surrey sponsorship for their research project (non-CTIMP).

In accordance with the UK policy framework for health and social care research, all research projects require an organisation to act as sponsor who will take the legal responsibility for the management and the conduct of the trial.

As sponsor, the University of Surrey takes on responsibility for confirming that suitable arrangements are in place to ensure:

- that the dignity, rights, safety and wellbeing of participants are given priority at all times
- the research proposal is worthwhile, of high scientific quality and feasible, and remains so for the duration of the research
- appropriate arrangements are in place for the registration of research on a public database and that arrangements are proposed for appropriate dissemination of the research findings
- the chief investigator, and other key researchers, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully
- adherence to the UK policy framework for health and social care research
- proposed research activities are consistent with all laws, guidance and regulation applicable to the research and that all necessary approvals are granted before initiation
- the adequate provisions are made for insurance and indemnity to cover liabilities that may arise during the research
- research receives all necessary approvals before initiation

To acknowledge the collaborative working with NHS trusts, the process allows for joint review where appropriate. Instances which would require joint review include but are not limited to; Educational projects where the student is an employee of the trust, studies utilising Trust, facility or staff, Clinical Trials of Investigational Medicinal Products and non-licensed medical devices.

Sponsorship

The sponsor is an individual, company, institution, organisation or group of organisations that takes on responsibility for the initiation, management and financing (or arranging of financing) of the research.

A sponsor can delegate specific responsibilities to any other individual or organisation that is willing and able to accept them. Any delegation of responsibilities to another party should be formally agreed and documented by the sponsor.

All research falling under the remit of the Secretary of State for Health must have a formal sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information. There are similar requirements for research involving social care practitioners,

clients and resources, where this falls under the Secretary of State for Health's remit.

Any research outside the NHS should also have a sponsor to take on the specific responsibilities of the role, such as research where participants lack capacity to consent, in Her Majesties Prison and Probation Service, Ministry of Justice, and Ministry of Defence.

Research Eligible for University Sponsorship (non-CTIMP)

The University of Surrey is able to take on sponsorship in the following instances;

- research where the Chief investigator (CI) is a substantive employee of the University of Surrey
- research that forms part of an educational programme
- funding is available to cover the cost of the study

The University of Surrey is not able to take on sponsorship for the following types of research studies:

- where the CI holds only an honorary contract with the University of Surrey
- where no University employee performs a significant role in the research team

The following studies may require collaborative review with an NHS Trust;

- Where project is being completed as part of an educational project and the CI is a NHS employee and University Student
- Where a NHS Trust is the primary employer of the lead researcher
- Where the staff researcher wants to complete a research project and the NHS is a site

It is recommended that before researchers submit documentation to RIGO that they request a meeting with RIGO/NHS (if employed) for guidance and suitability of sponsorship.

Research Eligible for University Sponsorship (CTIMP)

The University of Surrey will consider the sponsorship of CTIMPs, this is a separate process than described here, please contact RIGO and read the CTIMP SOPs available on the intranet. Please note the University is not able to sponsor CTIMPs which form part of an educational programme for a student.

What approvals will I need?

The HRA has online tools for helping to evaluate which approval you will need.

Is My Project Research? Do I need NHS REC Approval?

Service Evaluation and Clinical Audit

Service evaluation is designed and conducted solely to define or judge current care and should answer the question: "What standard does this service achieve?"
It should measure current service without reference to a standard and involve an intervention in use only (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference and this should happen before service evaluation).
Service evaluation usually involves analysis of existing data but may include administration of interview or questionnaire. There should be no randomisation and service evaluation does not require NHS REC review.

Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

Examples of Approvals needed

HRA and NHS REC Approval	NHS REC Approval Only	HRA Approval Only (Local FEC/UEC may be required)
Patients recruited through their use of a NHS service on NHS Property	Patients recruited through their use of a NHS service NOT on NHS Property	Recruiting NHS staff though their trust and on NHS Property
Example Diabetes patients recruited through their use of a clinic	Example Patients recruited though use of third party NHS provider (Health Visitor)	Example Ambulance personnel recruited for research into staff fitness

*This is no definitive and is project Specific, please contact RIGO

Requesting Sponsorship

To request sponsorship by the University of Surrey, researchers are required to submit to the RIGO team all documents which they intend to uploaded through IRAS. RIGO will review documentation and provide confirmation of sponsorship once this has been completed. Please

allow at least 5 working days for the first round RIGO review to be completed. (Please note this is dependent on researcher engagement and timely submission of all appropriate documentation)

The researcher must submit, as a minimum, the following documents to the RIGO team in order for sponsorship to be confirmed:

- IRAS form
- Study Protocol
- Recruitment materials (e.g. recruitment email, flyers etc.)
- Patient related documents – patient information sheets and consent form
- Questionnaires/survey/interview topic guide – dependent on research methodologies
- Statement of Activities & Schedule of Events
- CI & Supervisor CV (if applicable)

This list is not exhaustive and all documentation intended for submission through IRAS should be submitted to RIGO before signatures are requested

RIGO will review the submission for completeness, frequent queries from RECs and governance. A member of the RIGO team will be available for a face to face meeting and discussion of the project, and how best RIGO can assist with your submission.

NHS Research and Development

To conduct research in NHS Trusts you must engage with the relevant Research and development offices in those trusts. It is recommended you engage with the NHS before you submit to RIGO. The R&D office can give you advice on how best your research can be conducted within the NHS setting and if they have the capacity to perform any research activities you require from the trust.

NIHR Portfolio adoption

Some research performed in the NHS will qualify for adoption into the NIHR portfolio, this could help researchers with some of the costs of the research. NHS R&D offices are keen on adopted studies as this directly impacts their funding. For more information click here

Submitting Through IRAS

Once RIGO has reviewed the application we will provide you with confirmation of sponsorship letter and a copy of the University Clinical Insurance certificate. Signatures must be obtained via the IRAS portal and the sponsor representative signature requested from rigo@surrey.ac.uk. You must contact the central booking service at the HRA and submit you application within 24 hours of this call. (HRA guidance). Once you application is received you will receive a validation email form the HRA.

HRA & NHS REC

HRA Validation

The HRA will provide a validation notification this may ask for further details or let you know your application has gone for review. If they require further information this must be sent back to the HRA before your application can go to a committee.

Full Review

If your study is eligible for a full review you will be asked to attend a meeting, you may choose not to attend and call/video call in. RIGO would advise that you either attend or call, this enables most queries to be resolved immediately.

Proportionate Review

Proportionate review is no less rigorous than full but can lead to a quicker FEO, proportionate reviews are either completed in a closed door meeting or via correspondence with the committee. You may be asked to be available at a set time should the committee have any questions.

After Ethics Review

The committee may ask you for further clarifications on your application, you will be given instructions on how the committee would like this to be completed.

HRA Review

Once you have completed the committee responses, the HRA may have some final question relating to governance on your application. Once these queries have been resolved you may receive your favorable ethical opinion and your HRA approval.

Throughout the process RIGO will assist with REC queries and HRA queries

Confirmation of capability and capacity

Once you have obtained the necessary REC and/or HRA approval. The trust(s) with which you are working will issue confirmation of capability and capacity, it is important that you have previously liaised with the R&D offices so they are aware of your research.

Green Light

Once you have received your confirmation of capability and capacity the sponsor will issue a green light to begin your research at each site. You must notify the sponsor of each sites confirmation before you commence research related activity.

First participant first visit

If you have participants that will be require face to face visit or intervention, then you will be asked to inform RIGO when your first participant has been recruited and consented in to the study.

Research passport/letter of access

A Research Passport is the mechanism for researchers and non-NHS staff to obtain an Honorary Research Contract or Letter of Access (LOA) when they propose to carry out research in the NHS. The research passport provides evidence of the pre-engagement checks undertaken on the researcher in line with NHS Employment Check Standards.

The Research Passport system and associated procedures have been developed in parallel with national arrangements for obtaining permission from NHS organisations to undertake research, and aims to clarify accountability and responsibility for researchers, thereby increasing patient safety, improving risk management, and for employers improving quality assurance of research staff.
You will not need a Research Passport or an Honorary Research Contract if:

- you are employed by an NHS organisation
- you are an independent contractor (e.g. GP) or employed by an independent contractor
- you have an honorary clinical contract with an NHS Trust e.g. clinical academics (in this situation if you wanted to research in another NHS Trust you would need to apply to their R&D department directly for a Letter of Access)
- you are a student conducting research as part of your healthcare placement
- you are conducting research within the NHS where the participants are NHS staff only
- when NHS employees take part in research as participants outside work e.g. through professional bodies

How do I obtain a Research Passport?

A Research Passport may be project-specific or may be valid for a period of three years for a number of projects. In order to apply for a Research Passport, the application form found at the link below should be sent to the relevant faculty HR to process, as they have access to the required information and are able to request any required pre-engagement checks. For more information Click Here

Amendments

You can request amendments to your approval, these can be substantial amendments and non-substantial amendments (examples). In each instance you should contact RIGO for advice as it is a sponsor decision on the categorisation of the amendment. RIGO will also guide you through the different amendment procedures.

With the exception of Urgent Safety measures which can be implemented immediately with approval from the CI or suitably qualified researcher, the RIGO team should be notified within 24 hours and this must be followed by a substantial amendment within 3 days.

Sponsor Audit

To ensure sponsor oversight you may be subjected to an Audit. The audit may take place during the active or follow up phase of your study, you will be given a minimum of 30 days' notice along with full instructions. Projects will be randomly selected from those which have been given the green light in the previous 12 months.

Progress Reports and End of Study Reports

A condition of your favorable opinion form the Ethics committee is to submit annual progress reports to the REC on the anniversary of your opinion (progress reports). You must also notify the REC from which you gained your opinion that the study has concluded with 90 days of the finish, the forms for submitting can be found here (end of study).

Chief Investigator responsibility

In taking on the role of sponsor for a study the University requires the Chief Investigator to agree to conduct the research in accordance with the UK policy framework for health and social care research, the concordat and the conditions stated below:

All research falls under the requirements of the UK policy framework for health and social care research and Good Clinical Practice and all research conducted at the University of Surrey must abide by University policies.

University sponsorship requires that the Chief Investigator meets the responsibilities listed below, and takes responsibility for the design, conduct, analyses and reporting of a clinical study.

Participants

- Ensures research team give priority at all times to the dignity, rights, safety and well-being of participants
- Potential participants are fully informed before deciding whether or not to join a study

Research Team

- Have suitable experience and expertise in the conduct of research so that you can either:
- Undertake the design, conduct and reporting of a study to standards set out in regulations and the UK policy framework for health and social care research
- Lead and manage others with delegated responsibility for some of these aspects
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented
- To ensure researchers have the right permissions to enter NHS premises i.e. research passport
- Ensures the research teams carry out the study in accordance with the UK policy framework for health and social care research.
- CI ensures adequate medical cover is in place at all times.
- To ensure the research team is adequately staffed for the duration of the project and to

meet the research goals

Deviations/Breaches of GCP

- All deviations of the protocol, breaches of GCP regulations must be documented and serious breaches reported to the RIGO office

Safety Reporting

- Document all Adverse Events in ISF and medical notes
- Escalate the reporting of all serious Adverse Events (SAE, including SAR/SUSAR) to sponsor and hosting Trust; unless certain SAE excluded from escalated reporting by REC/UEC approved protocol

Trial Master File (TMF)

- Set up and maintain Trial Master File (TMF) containing essential Documents
- A Trial Master File is held and maintained to include all with essential documents. TMF must be stored in a secure location with authorised access only.
- Ensure that PIs have obtained local R&D approval before commencing recruitment or substantial amendment approval before implementing new document versions at their sites
- Keep a copy of superseded documents versions (i.e. tracking alterations, marked as superseded (dated)
- Procedures (such as SOP's) are in place to ensure collection Is high quality, accurate data and for the integrity and confidentiality of data during processing and storage
- Appropriate arrangements in place to archive the data when the research has finished and to ensure it is still accessible at the request of the inspection and auditing authorities. Study documents and source data must be retained in accordance with current data protection regulations.

Reporting

- Reports on progress and research outcomes are to be supplied to the sponsor, research funders or others with a legitimate interest,
- Report on progress to be submitted to the REC/HRA on an annual basis and RIGO are copied in.
- Update the RIGO on changes to study status eg study is closed to recruitment.
- Findings are disseminated promptly and fed back as appropriate to participants.

Useful resources

HRA Website - https://www.hra.nhs.uk

NIHR Portfolio - https://www.nihr.ac.uk

Is my project research - http://www.hra-decisiontools.org.uk/research/

Do I Need NHS ethics - http://www.hra-decisiontools.org.uk/ethics/

Good Clinical Practice - http://ichgcp.net//

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

MHRA - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency