East and North Hertfordshire NHS
NHS Trust

# Guidance Note on the process to be followed when requesting the Trust to act as Research Sponsor

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## Purpose and background

The purpose of this document is to describe the process to be followed by Trust staff who are requesting the Trust to act as Sponsor for a research project.

Any research requiring the collaboration of the NHS must have an individual or organisation willing and able to take on the responsibilities of the research sponsor[1].

The sponsor is the individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

The costs of undertaking activities to fulfil the role of sponsor for non-commercial NHS research are increasing. As part of the Trust's Research Strategy to increase the number of externally-funded research studies there will be an increased need for the Trust to take on sponsorship. Recovery of costs associated with Sponsorship will enable the Trust to match our ability to Sponsor with our need to act as Sponsor.

The Trust can provide the following Sponsor services:

- **Contract management** — Arrangement, agreement and maintenance of contracts pertaining to the research study including funding contracts, service level agreements and sub-contracts.
- **Study set up** — Provision of site files and delegation logs
- **Monitoring/audit** — Development plans and delivery of monitoring plans and site visits
- **Pharmacovigilance** — To include safety reporting
- **Archiving** — Arranged externally at cost
- **Support and advice** — To meet regulatory approvals.

The Department of Health provides guidance on the funding of Sponsor services in a document called "*Attributing the Costs of Health & Social Care Research & Development (AcoRD[2])".*

Sponsor related activities remain classified as research costs in AcoRD. This means that the cost of these activities should be covered by research funding.

Study specific central trial co-ordination and management, archiving, training and registration of trials should always be included in the grant funding.

[1] http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/
[2] https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

**Process for all staff who are requesting for the Trust to act as Research Sponsor**

1. Before seeking Sponsorship, the applicant is advised to check that their project is viewed as 'research' from an NHS Perspective. A leaflet[3] is available from the Health Research Authority and there is also an electronic algorithm which can also be used. http//www.hra-decisiontools.org.uk/research/index.html Queries regarding the outcome and use of this tool can be directed to HRA.queries@nhs.net If your study is not classified as research then you should discuss it with the relevant service manager (details on the Trust website).
2. Trust employees wishing for their research to be sponsored by the Trust are required to submit information to the Research Office by email to researchanddevelopment.enh-tr@nhs.net Please note the following:
    a. The Trust is unable to Sponsor Phase I CTIMPs, research conducted outside of the UK or commercial contract research.
    b. Co-sponsorship of observational studies will only be considered in exceptional circumstances where clear delegation of Sponsor responsibilities can be agreed in writing by all parties.
    c. The Trust would not usually sponsor research undertaken as part of a qualification, for which the university at which the student is registered should act as Sponsor.
    d. As a minimum, the following documents are needed to undertake this risk assessment: draft protocol, draft participant information sheet, draft consent form.
3. The information will be subject to a proportionate risk assessment that will review:
    a. the contribution of the study to the delivery of the Trust's Research Strategy,
    b. significant clinical, legal, financial or reputational risks,
    c. whether it is well-designed, peer reviewed, and statistically sound (Appendix 1) and
    d. the adequacy of funding provided for the Trust to discharge Sponsor responsibilities (Appendix 2).
4. Where necessary, the risk assessment will be carried out in conjunction with the Chief Investigator and research team. Where required, the research office may request further information to facilitate this assessment, and researchers may be invited to attend a meeting to discuss the project.
5. The Research Office will ensure that an appropriate review is undertaken that includes review by the Research Office, clinicians (appropriate peer review), and comments by the Trust's R&D Steering group and or R&D Board..
6. The Trust has limited capacity to review proposals to act as Research Sponsor and also limited capacity to act as Research Sponsor. This means that requests will be prioritised for review taking into account the number of applications and the contribution that the proposed project will make to the delivery Trust's Research Strategy. Priority given to projects which are eligible for adoption to the National Institute for Health Research (NIHR) portfolio.
7. A recommendation is made to the Associate Director of Research and Development who will decide if the Trust can act as Research Sponsor. Notification of decision to the Chief Investigator will be by email.
8. All requests for amendments to be submitted to the Research Office for review prior to seeking approval from or notification to the Research Ethics Committee. Notification of decision to the Chief Investigator will be by email.
9. If the request is to gain a decision in principle for a research grant application then this will also be made by the Associate Director of Research and Development. In the event that the grant is awarded then a review for the Trust to acts as research Sponsor will also be required and this will take into account previous considerations.

[3] http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf

**Appendix 1: Checklists to be used to aid in the review of all requests for the Trust to act as Sponsor.**

The information will be subject to an assessment that will include to assessing whether the study protocol poses significant clinical, legal, financial or reputational risks, and whether it is well-designed, peer reviewed, and statistically sound. This includes a review of the following non-exhaustive list and will utilise a number of checklists:

- Potential for the study to contribute to the Trust's Research Strategy
- Trust suitability to deliver/sponsor the study
- CI suitability to lead the research
- Study research and sponsorship costs and evidence of funding
- Arrangements for meeting excess treatment costs
- NIHR portfolio eligibility or other arrangements for covering support costs
- Peer review including suitability of study design
- Capacity and capability to undertake the study at the Trust and/or other sites
- Compliance with required regulatory standards
- Standard of the protocol
- Contractual requirements
- Arrangements for managing study data and documentation

Please note that not all checklists apply to all studies:

- Checklist A For all studies
- Checklist B Expectations specific to Clinical Trials of Medicinal Products
- Checklist C Expectations specific to HEI/Student Research
- Checklist D Peer Review

**Research Sponsorship Checklist A – for all studies**

- **Peer review** - Proportionate peer review is in place for all sponsored research activity. This is appropriate according to the type of study and the perceived risk and ensures that the design of the study meets the appropriate standards (See Appendix 2).
- **Supporting information** - All appropriate, valid supporting documentation is supplied at the point of application.
- **Costing** - The proposed study has been subject to a costing review and the relevant funds are in place to cover the Research Costs, the Treatment Costs (including any Excess Treatment Costs) and that arrangements are in place for NHS Service Support.
- **Defined roles and responsibilities** - Division of roles responsibilities of both organisations and individuals are clearly defined and signed off prior to the study commencing.
- **Monitoring and audit** - The required infrastructure is in place to ensure the appropriate level of monitoring and audit is carried out which is proportionate to the type of study being undertaken and ensures the necessary level of oversight throughout the life cycle of the study.
- **Risk assessment processes/tools -** An agreed risk assessment process is in place to identify any potential risks to the organisation or the health, safety and well-being of researchers and research participants
- Patient and Public Involvement - Sponsors will ensure that patients and/or public have been involved in study design, or where this is not appropriate, the reasons are clearly explained in the applications prepared in IRAS.
- **Training and Suitability** - Arrangements are in place for ensuring the CI has the relevant experience and appropriate training to fulfil their role. This should include no unnecessary requirements in place regarding GCP training. Sponsors should only require GCP training for those individuals who are taking part in a clinical trial and should not be a requirement for researchers undertaking all other types of studies.
- **Registration** - Studies are registered on an accessible database (This is a requirement for Clinical Trials, and is expected for all studies as appropriate).
- **Dissemination** - All findings (including negative findings) are disseminated / published in an appropriate manner and intentions are made clear at the time of application.

**Research Sponsorship Checklist B Expectations specific to Clinical Trials of Medicinal Products (CTIMPs)**

- **Responsibilities** - As these are governed extensively by regulators and statutes, sponsors will discharge their responsibilities in accordance with the appropriate legislation and regulations.
- **Training and Suitability** - CIs are eligible "Authorised Health Professionals" – medical doctors, dentists, nurses or pharmacists. Sponsors should require all individuals involved in the conduct of the study to be appropriately trained in the requirements of the Medicines for Human Use (Clinical Trials) Regulations, as amended, and the principles of Good Clinical Practice described within them[4].

**Research Sponsorship Checklist C Expectations specific to Student Research (provided for completeness as the Trust expects educational projects to be externally Sponsored unless at PhD or Prof Doc level)**

- **Project Oversight -** Each student research project is overseen by a named supervisor with current knowledge of research methods and governance/regulatory approvals.
- **Training -** Supervisors of student research are trained in their responsibilities. Both supervisors and student researchers are adequately trained in the relevant research methodology required for both the design and implementation of their research.
- **Research Ethics Committee (REC) review -** Supervisors attend ethics committee meetings with their student (if applicable).
- **Guidance from Supervisors -** Supervisors, as part of their sponsor responsibilities, provide clear guidance to the student on the appropriateness of their research with particular emphasis on
    - Potential unintended impact on participants as a result of the research
    - Appropriate understanding of the legislation around consent and vulnerable groups.
    - Handling disclosure of sensitive information in the research process
    - Vulnerable lone worker arrangements
    - The supervisor ensures that the student is adequately prepared and briefed to conduct their own research safely and without reputational damage to the organisation.
- **Quality Assurance -** Access to appropriate methodological expertise and guidance throughout the duration of the project so that the research is of sufficient quality.

**Research Sponsorship Checklist D Peer Review**

- **Project details:** Has appropriate information been included? (Investigator details and project title, protocol version number and date)
- **Research question:**
    - Is there a clearly defined, answerable question?
    - Is the research **original?**
- **Background:** Is the research question an important one?
    - Is the study **useful to clinical practice**?
    - Is there a **real problem/ knowledge gap** that needs filling?
    - Is the project **in alignment with the strategic objectives** of the programme with which it is associated?
- **Study Design**
    - **Methods:** are these appropriate to the aim, will they address the question being asked and are they likely to produce an answer?
    - **Design:** is the study designed to reduce the risk of bias?
    - **Analysis:** have any analysis techniques, such as statistical methods, been defined, where appropriate?
    - **Outcome measures:** Are these appropriate and achievable?
    - **Setting:** will the project setting appropriate?
    - **Participants:** have the methods used to identify, approach, recruit and consent participants been clearly defined?

[4] see MHRA statement https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

    - **Sampling issues:** Will the proposed sample be large enough for significant findings to be detected? Will the sample collected be reasonably representative of the population in question? Is there sufficient evidence to indicate that it will be possible to obtain the numbers required for the study?
    - **Intervention:** Is the intervention clearly delineated, where appropriate?
    - **Screening tools and questionnaires:** are these relevant to the project and have they been thoroughly tested?
- **Project management:** have adequate arrangements been specified?
- **Expertise:** Does the research team include the necessary expertise?
- Has access to people with relevant expertise at the appropriate points of the project been agreed?
- **Ethical issues:** Have ethical issues been addressed?
- Risk (safety issues), rights to information, confidentiality and privacy, consent, issues concerning racial and cultural diversity
- **Participants:** where appropriate, have they been consulted about the design and outcome measures of the study?
- **Dissemination:** Have suitable plans for dissemination been included, where appropriate?
- **Project plan:** Has an appropriate **plan of the study** in the form of a flow chart / diagram been included? Is the estimated **duration** of the project appropriate?

**Appendix 2: Meeting the costs of undertaking activities to fulfil the role of sponsor for non-commercial NHS research at East and North Hertfordshire NHS Trust**

The derivation for the cost of Sponsorship should be transparent and funded appropriately and the setting of a standard fee does not achieve this.

The Trust will apply a costing model to each project to determine an appropriate costing structure (See Table 1). This method allows risk and workload to be accounted for providing actual and justifiable costs.

The costs to cover actual sponsorship activities should be included in the grant application wherever possible.

This model only applies to studies that are sponsored by the Trust.

The Research and Development Manager is responsible for the identification of the Sponsor fee. Where there is dispute then a final decision will be made by the Associate Director of Research and Development.

**Table 1: Standard Costing template for derivation of Sponsor fees to demonstrate how each project-specific fee will be calculated (based on 2016/7 costings)**

**PLEASE NOTE THAT A PROJECT-SPECIFIC COST WILL BE DEVELOPED FOR EACH PROJECT**

| | Likely Costs Cost (£) | Unit | Likely duration |
|---|---|---|---|
| **Study specific central trial co-ordination and management** | | | |
| Contract management across sites | £526 | per site | 2 days |
| Green light approval - MHRA approved study (site assessment and set up) | £175 | per site | 5 hrs |
| Green light approval non-MHRA study (site assessment and set up) | £105 | per site | 3 hrs |
| Site Initiation Visit - MHRA approved study | £263 | per site | 1 day plus travel |
| Site Initiation Visit - non-MHRA study | £132 | per site | 1/2 day plus travel |
| Close out | £132 | per site | 1/2 day plus travel |
| **Regulatory preparation** | | | |
| Governance and delivery team -MHRA approved study | £263 | 1 day | 1 day |
| Governance and delivery team -non- MHRA study | £70 | per site | 2.5 hrs |
| **Compliance- MHRA approved study** | | | |
| Monitoring | £1051 | per site per year | 4 days plus travel |
| Emergency contact | £140 | per site per year | 4 hrs |
| Safety and compliance reporting | £140 | per site per year | 4 hrs |
| **Compliance - non-MHRA study** | | | |
| Monitoring | £526 | per site per year | 2 day plus travel |
| Emergency contact | £70 | per site per year | 2 hrs |
| **Other** | | | |
| Archiving | To be agreed | Per year per box | Study-specific |
| Miscellaneous | To be agreed | Per site per year | Study-specific |

Costings based @ £254 per day or £33.82 per hour derived from the following assumptions

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| • Salary (Mid Band 6 inc London weighting) | £35,000 |
| • Employment costs | £43,750 |
| • Number of working days working days | 260 |
| • A/L and Bank Holidays | 222 |
| • 75% utilisation rate (i.e. to take into account other non-working time) | 167 |
| • **Cost per day** | **£263** |
| • **Cost per hour** | **£35** |