

Policy and procedure

Commercial research activity

1 Scope

Cross-boundary: This policy and procedure applies to all research active staff and external parties, ie commercial companies.

2 Aim

The aim of this document is to fully inform all relevant parties of the processes to be followed when carrying out commercial research that involves Trust facilities, staff, patients, their data or tissue.

According to Health Service Guidelines (HSG(97)32), NHS Trusts are expected to recover all costs of commercial research and development from the company concerned.

The NHS is encouraged to support commercially sponsored research as it is an opportunity to:

- participate in drug and device development;
- evaluate new equipment;
- become involved with the development of improved treatment for current and future NHS patients;
- generate income for re-investment back into research, facilities and patient care.

This document seeks to ensure that:

1. the Trust is in a position to identify all research activity undertaken within the Trust which makes a call on its resources;
2. there is a clear process for charging;
3. all research activity is managed both efficiently and cost effectively.

The Trust is the legal body with whom all contracts / agreements must be made. Failure to comply with this places both the Trust and the researchers at risk where legal liability is concerned.

3 Responsibilities

3.1 Principal investigator (PI)

The leader responsible for the conduct of the study at the Trust.

3.2 Sponsor

The commercial company responsible for the finance, conduct and management of the study.

3.3 R&D Commercial Trials Group

Comprises commercial trials manager and research governance officer. The group is responsible for:

- giving R&D approval for conduct of commercial studies in the Trust;
- liaising with commercial companies and principal investigators to ensure that the costs to the Trust of hosting commercial research are met in full.

4 Definitions

4.1 Commercial research

Commercial Research is defined as research that is sponsored and funded by commercial companies (usually pharmaceutical or device manufacturers) and is directed towards product licensing and commercial exploitation.

4.2 Clinical Trials Agreement (CTA)

A contract which is required before any research can commence at the Trust.

4.3 Principal investigator (PI)

The individual responsible for leading the research at the Trust.

4.4 The Trust

Cambridge University Hospitals NHS Foundation Trust, the site at which the study is conducted.

4 Costing commercial research

Departments undertaking commercial studies are responsible for ensuring that the Trust recovers the cost of NHS resources used in commercial research. These costs should cover all additional staff time, clinical and administration activity required by the trial. Costs to the departments should be determined by the PI in collaboration with the unit manager and they must be clearly defined in the CTA with the sponsor.

4.1 Funds for capacity building (profit)

Departments have many funding requirements over and above what can be attributed to an individual trial. For example, 'profit' from trial work could be used for books, journals equipment and training – all of which provide an incentive for staff to participate in commercial research as well as providing the sponsor with well-trained motivated staff.

The charge levied must be made clear in the study costings and this element (if added) is not subject to an additional overhead charge.

4.2 Costing template

An [industry costing template](#) has been developed on behalf of the National Institute for Health Research. The R&D Department recommends the use of this template for costing commercial research at the Trust.

4.3 Core department cost

The Trust's core departments (Pharmacy, Radiology, Pathology, Biochemistry etc) may be involved in clinical trials. These departments operate their own charging mechanisms for research activity and negotiate directly with the company.

The costs agreed will be incorporated in the CTA with instructions for invoicing and bank details.

It is the responsibility of the PI to ensure that University of Cambridge costs are included in the trial budget and that the University is reimbursed accordingly.

4.4 Charges for the use of Addenbrooke's Clinical Research Centre (ACRC)

Research carried out within the ACRC (Wellcome Trust Clinical Research Facility [CRF] and Clinical Investigation Ward [CIW]) is subject to separate charges.

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Charges related to the use of ACRC must be agreed with the ACRC clinical manager, communicated to the R&D Department and clearly defined in the CTA with the sponsor.

4.5 R&D charges / indirect costs (overheads)

4.5.1 Administration fee

A one-off non-refundable setup fee shall be paid by the sponsor on sending the protocol for the proposed study to the R&D Department. This is to cover the administrative costs of undertaking the governance checks and reviewing and approving the contract and costings.

Currently the R&D setup fee is:

- £1500 for clinical trials and
- £1000 for research studies involving data collection only.

For studies that have been costed using the [industry costing template](#) only, the R&D setup fee is charged at £700 + PbRF (payment by results market forces factor - currently 1.139 for the Trust) ie £797. This lower setup fee is offset by a higher overhead rate for studies costed with the industry template.

4.5.2 Indirect costs (or overheads)

Indirect costs in contrast with direct costs, are costs that have been incurred for purposes common to all research activity, but which cannot be easily or conveniently identified and charged directly to each individual commercial research study without an excessive amount of bureaucracy.

Examples of indirect costs include:

- insurance,
- heat, light, water, power and cleaning,
- building maintenance and renovation,
- purchasing,
- personnel and payroll.

An overall indirect cost rate has been established for all commercial research throughout the Trust. For simplicity this average rate of 40% is used for each individual commercial research study.

For studies that have been costed using the [industry costing template](#), the indirect cost rate applied is 70%.

It must be stressed that the indirect costs referred to here are the **Trust's indirect costs** and do **not** include any extra expenses that the study team may incur as a result of the research. Such additional expenses (extra administrative help, office supplies etc) should be included, if possible, in the budget as direct costs to the project.

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It is important to note that all indirect cost monies received from commercial research contracts by the R&D Department are recovered by the Trust and are not kept for use by the department.

The Trust recognises that itself, or the NHS in general, may receive benefit in kind from commercial research activity. Where the research involves direct or indirect benefit to service provision (eg drug costs, staff or equipment) the value of these may be set against overhead charges. In such cases, each application will be reviewed on an individual basis by the commercial trials manager. Indirect costs should be shown in a separate column on the financial schedule for transparency.

5 Clinical Trials Agreement (CTA)

The Trust is the legal body with whom all contracts / agreements must be made. PIs should not, for governance reasons particularly concerned with personal and institutional risk management, enter into contracts to carry out any research on their own account.

The R&D Department, with support from the PI and the finance manager, will take responsibility for reviewing all contracts between the Trust and sponsor and for dealing with any legal / technical issues that arise. The Trust has a legal obligation to carry out this review and to approve contracts in order that the legal liabilities are understood and the researchers and the Trust are appropriately indemnified.

The director of Corporate Development is responsible for approving such contracts on behalf of the Trust.

5.1 Signatures

Commercial research can only proceed when a Commercial Trial Agreement has been signed by all parties involved (and an R&D Trust approval letter has been issued to the PI).

Space for three signatures on the CTA will be required:

1. sponsor(s);
2. Trust's authorised signatory (director of Corporate Development or director of Finance or chief executive);
3. The PI's signature, as an indication that he/she has read and understands the contract and agrees to the obligations under the contract.

Contracts should be signed by the issuing party before signature by the Trust.

6 Application process

Procedures are in place for all research studies carried out within the Trust, which also apply to commercial research projects.

Please refer to the Trust's [management of clinical trials of investigational medicinal products \(CTIMPs\)](#) and [management approval for research studies](#) policies and procedures.

Due to the complexity of the legal issues around contracting and recovering of full costs, the R&D Department must be fully informed and involved in the process at an early stage.

To carry out commercial research at the Trust two documents must be in place:

1. The CTA signed by all parties as listed above.
2. The Trust R&D letter of approval .

To start the application process **the pharmaceutical company should** send:

- a cheque for the setup fee made payable to Cambridge University Hospitals NHS Foundation Trust ;
- name/ details of the contact at the pharmaceutical company;
- a copy of the protocol;
- the IRAS (Integrated Research Application System) R&D form.

to:

Commercial Trials Group,
R&D Department,
Box 277, Addenbrooke's Hospital,
Hills Road, Cambridge, CB2 0QQ
R&DEnquiries@addenbrookes.nhs.uk

An email will then be sent to the named contact outlining any additional documents/ details required.

The R&D Department will assess the indirect cost percentage rate to be levied. Indirect costs should be shown in a separate column on the financial schedule for transparency and ease of administration. In most cases, procedure costs within the Trust include overheads. Therefore indirect costs are only applied to disaggregated direct costs for staff and services.

Once the company has reviewed and completed the model CTA it should:

- print three copies (one copy each for the company, Trust and the PI);
- obtain the signatures by the company's authorised officer;
- send all copies of the CTA to the Commercial Trials Group.

Principal investigators **are not authorised** to sign commercial agreements, nor indemnify the company or themselves.

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The R&D Department will then review the CTA and if acceptable will obtain the relevant signatures from the Trust (including the director of Corporate Development and PI).

The CTA and the Trust R&D letter of approval will usually be sent to the company at the same time.

6.1 Indemnity

General indemnity issues are addressed throughout the 'Indemnities and Liabilities' paragraph of the Clinical Trial Agreement. Indemnity against non-negligent harm must be provided by the commercial sponsor through the ABPI ([Association of the British Pharmaceutical Industry](#)) form of indemnity. With regard to indemnity for negligent harm, researchers who are employed by the NHS or hold an honorary NHS contract are covered by the Trust under the NHS indemnity arrangements.

Any queries regarding indemnity will be referred to the Trust R&D solicitor.

6.2 Pharmacy

Where handling of drugs is concerned, principal investigators involved in clinical trials must contact Pharmacy.

All drug supplies must be managed by Pharmacy.

Approval for research staff to hold and distribute supplies must be within an agreed procedure with Pharmacy.

7 Financial management

The financial management of commercial studies is the responsibility of the PI and the relevant department with support and advice from the commercial trials manager and the finance manager.

In order for invoices to be raised to sponsors in a timely and accurate manner, it is important that the PI notifies the Finance Department when the payment 'triggers,' detailed in the CTA, are reached. Failure to do so could result in loss of income to the Trust.

Indirect costs (overhead) payments should be invoiced at the same time as payment of the patient fees.

Research and Development (R&D)

Corporate Development Directorate

8 Contacts

Department	Contact	Name	Telephone number	Box no.
R&D	R&D Manager	Stephen Kelleher	01223 217418 extension 3418	277
	R&D Solicitor	Mary Kasanicki	01223 256481 extension 56481	277
	Commercial Trials Manager	Fiona Bull	01223 348455 extension 58455	277
	Commercial R&D Officer	Priya Shimoga	01223 274486 extension 4486	277
Finance	Finance Managers	Evgeny Dmitriev	01223 257251 extension 57251	130
	Deputy Finance Manager	John Carew	01223 596163 extension 6163	130
Pharmacy	Chief Pharmacist	Helen Howe	01223 217299 extension 3299	104
	Pharmacy Clinical Trials Coordinator	Naval Vyse	01223 217045 extension 3045	55
CRF/ CIW	Clinical Manager	Caroline Saunders	01223 586057 extension 6057	127
Pathology	Pathology Services Manager	Colin Carr	01223 216726 extension 2726	232
Radiology	Clinical Trials Administrator	Wendy Philips	01223 256419 extension 56419	162
Biochemistry and Immunology	Operations Manager	Nicola Matache	01223 216741 extension 2741	232
Cardiology	Senior Chief Cardiac Clinical Scientific Officer	Tim Eller	01223 217477 extension 3477	125
Clinical Engineering	Head of Clinical Engineering	Dr Paul White	01223 216471 extension 2471	152

9 Monitoring compliance with and the effectiveness of the policy and procedure

The metrics generated by the R&D Commercial Trials Group will be reviewed on a yearly basis by the R&D Department to ensure that the policy and procedure are effective.

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

Disclaimer

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Document management

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