

### Guidance for Researchers seeking Sponsorship

This document provides an outline of what Research and Development (R&D) department reviews as part of an application for Sponsorship by the Oxford University Hospitals NHS Foundation Trust. This review is necessary to warrant that the Trust will take legal responsibility for the research proposed.

In addition to acting as Sponsor representative, we have a role in promoting and supporting high quality research. We provide advice and support about legal requirements and good practice, and specific considerations of approving bodies (REC, MHRA, HRA) in order to facilitate progress through necessary approvals.

R&D deals with numerous new applications each year from every medical field, ranging from Clinical Trials of Investigational Medicinal Products (CTIMP) to qualitative research, single site student research to large multinational trials. Because our expertise is in governance rather than the content of any clinical research itself, we will work closely with you to gain understanding of your project in order to advise on its particular governance requirements and how best to guide your research through approvals to initiation. As medical non-specialists, we are in the same position as members of approving bodies; if something is not clear to us, then it will probably not be clear to others.

Following the guidance should reduce the time that an application spends in Sponsorship review and the number of iterations before it is ready for submission to the relevant Research Ethics Committee (REC), HRA and regulatory authority. Our written guidance comprises:

- Documents necessary for sponsorship (below)
- Protocol template(s)
- PIS and Consent form template
- IRAS form Oxford-specific information, and FAQ

Further resources and information are also available on our website:

<http://www.ouh.nhs.uk/researchers/>

## Documents Required for Sponsorship and Ethics Review

### Main Study documents

The following are the main study documents, all of which must provide consistent information and must be approved by the Sponsor, relevant REC and regulatory authority.

#### Protocol

A study protocol describes the purpose of the study and provides the detailed plan for how it will be conducted. It acts as the manual for the research team. The protocol describes in detail the objectives, design, methodology and organisation of the research and is also used to monitor its progress and outcomes.

R&D must review the protocol not least in order to ascertain that appropriate insurance cover can be provided for the study.

R&D offers GCP-compliant protocol templates for Clinical Trials, Clinical Research Studies, and Device studies.

<http://www.ouh.nhs.uk/researchers/documents/default.aspx>

### Participant-facing documents

Some studies may involve only the use of already collected data or samples, and not require interaction with research participants. Where people themselves will be contributing to a research project, it is necessary to inform them of what their participation would involve, and to obtain their consent.

#### *Invitation Letter*

If intended participants are patients who will be identified by their clinician, it is necessary for the clinical team (who hold personal information of individuals for clinical purposes) to invite them on behalf of researchers (who do not have legal access to patient details). An invitation letter comes from an individual's clinical care team, alerting them to research in which they may be interested and forwarding the participant information sheet. The invitation establishes a line of communication but does not continue it: those who are interested can then contact researchers directly, rather than communicating back through their care team. This avoids any issues that may arise out of dependent relationships.

#### *Advertisement*

This may be the first information viewed by potential participants. Advertisements are intended to inform about research, not to market: information must be factual and balanced. They may state that compensation will be provided where this is the case, but not state the £ amount. They should provide a first contact point.

#### *Participant Information Sheet*

The Information Sheet must describe, in language easily understood by potential participants, the aims of the project and fully explains all aspects of participation. Potential participants should be clearly informed of their rights and any risks and burdens associated with participation. In the information sheet, the research team also details how they will safeguard the welfare of participants and respect their dignity and privacy.

Providing an information sheet is one part of the process of seeking consent to participate. Discussion with a member of the research team is the most effective way to ensure that the study is understood and any agreement to participate is well informed. Participants should be given sufficient information to weigh their options, and time to consider their decision.

See R&D's Template PIS and Consent Form for specific guidance.

The content of the PIS is not only an ethical requirement, but is essential in assuring the insurers of the research that fully informed consent has been given.

### *Informed Consent Form*

This form is the formal documentation of a prior process of communicating study aims and requirements and the voluntary, informed decision of a participant to join the research.

Informed consent is essential before enrolling a participant and is ongoing; participants may withdraw at any time. In some cases where new information arises or terms of the original study change, it may be necessary to seek consent again.

Consent forms include specific clauses requiring confirmation. These arise from requirements of law, policy, and established good practice.

See R&D's Template PIS and Consent Form for specific guidance.

### Study-specific documents

#### *Questionnaires, web-based tools, interview schedules*

Please supply all questionnaires and other written materials you will use in the course of the research proposed.

#### *GP Letter*

This can have various functions.

- It is necessary to advise GPs of any aspects of the project which may affect the day-to-day treatment given by them. Information on any medication taken as part of the study should be provided, making clear any side effects or potential interactions with other drugs.
- A letter may be sent to a GP requesting confirmation that a participant is eligible for the study. If confirmation is requested, eligibility criteria should be provided.

In both these instances, a participant information sheet should be sent with the GP letter.

Information that GPs will be contacted and consent to do so should be included in the participant information and the consent form.

### Supporting documents

#### *Chief/Principal Investigator CV*

It is the responsibility of the Sponsor to ensure that research staff, in particular the CI/PI, is qualified by education, training and experience to conduct the research. This is assessed by review of their CV.

It is important that experience relevant to the specific research project is detailed, but the whole document should be kept concise. It is not necessary to provide a complete record of professional and academic background. CVs should not include lengthy lists of publications.

#### *Peer Review*

The purpose of peer review is to demonstrate that the study has been reviewed by a body completely independent of the research team. If the research has not been reviewed by the funder via a competitive process to ensure quality then an independent peer review should be submitted. The review of the protocol should be carried out by experts in the relevant fields able to offer independent advice on its quality. R&D supplies an [Independent Peer Review Template](#) .

#### *Funding arrangements*

It is a Sponsor responsibility to ensure appropriate funding is in place for the full length of the study. We will therefore require proof of funding prior to agreeing to take on the role of sponsor.

## Ethics applications and forms

Any research project that involves humans, their tissue and/or data must be reviewed by a Research Ethics Committee prior to commencing. This applies whether the study is to be conducted in the UK or overseas. The principles of research ethics have their origin in the Declaration of Helsinki and ethical review establishes whether a study is consistent with these and subsequent relevant legislation, policy, and established good practice.

Research sponsored by the Oxford University Hospitals NHS Foundation Trust will either be reviewed by an NHS REC or by agreement via the University Research Ethics Committee.

Under the Governance Arrangements for Research Ethics Committees (GAfREC) set out by the Department of Health, NHS REC review is required for research projects involving:

- individuals recruited by virtue of being NHS patients,
- material subject to the Human Tissue Act 2004;
- participants lacking capacity (provided for by the Mental Capacity Act 2005)

NHS REC applications are made through the online Integrated Research Application System (IRAS) at [www.myresearchproject.org](http://www.myresearchproject.org). See R&D IRAS guidance and wording.

Clinical research outside the remit of NHS RECs will by agreement be reviewed by the University Medical Sciences Division REC by means of CUREC forms. Which form is appropriate will depend on the complexity of research proposed. More information can be found at <https://www.admin.ox.ac.uk/curec/apply/ms-idrec-process/>

## Health Research Authority (HRA) Approval

Any research project that involves recruitment of NHS patients, staff, premises, resources (pharmacy, radiology or laboratories) or data/tissue in England must go through the HRA Approval process. The approval process comprises an assessment of regulatory compliance, and study-wide research governance checks. These are undertaken by dedicated HRA staff. More information can be found at <http://www.hra.nhs.uk/research-community/applying-for-approvals/>

If NHS organisations in England will be involved in the research, you must submit a Statement of Activities and Schedule of Events. These replace the NHS SSIs for England, formerly generated as part of the IRAS dataset and are to enable participating NHS organisations in England to assess and confirm their capacity and capability to deliver the research. More information can be found at <http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/>. R&D can provide a Statement of Activities Guidance sheet.