Oxford University Hospitals NHS
NHS Foundation Trust

Integrated Research Application System (IRAS) Guidance and Wording

GENERAL INFORMATION

This guidance aims to provide additional information to enable you to negotiate your way through IRAS, find explanations of commonly misunderstood questions, and to provide the specific wording required when you would like the Oxford University Hospitals NHS Foundation Trust to take on the role of Sponsor.

We have structured this guidance under the main headings present in the on-line system.

IRAS is a single system for applying for the permissions and approvals for health and social care / community care research in the UK and such acts as a repository for all the information required for the relevant approvals from the following bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NRES/ NHS / HSC Research Ethics Committees
- Confidentiality Advisory Group (CAG), formerly the National Information Governance Board (NIGB)
- National Offender Management Service (NOMS)
- Social Care Research Ethics Committee

In addition to the points in this document, on-line guidance is available in IRAS wherever you see a hyperlinked word or this symbol within the form

Further help can be found at: https://www.myresearchproject.org.uk/Help/HelpPage.aspx

INFORMATION ON SPECIFIC QUESTIONS

FILTER QUESTIONS

In its original state, the form is very long. However, as soon as you fill out the filter section on the left of the IRAS screen, it will be cut down considerably, to provide you with only those questions that are relevant to your study. It is important to select the correct answers for this section; otherwise, you will miss out important information required for your study.

2 List of categories

For non-CTIMPs involving drugs, ‘Other study’ is the most appropriate category since this enables questions about the medication and safety issues.

4 Review bodies

If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate

NHS organisations in England no longer use NHS SSIs. It is necessary to complete separate documents: A Statement of Activities and Schedule of Events. If your study involves administration of radioactive substances and you require an ARSAC license, R&D will advise on how to generate this.

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

5 NHS Involvement

If the NHS is involved in the study, you will need to have agreement from the relevant NHS Trusts.
There are several levels of possible NHS involvement:

a) Site: Where the Trust is acting as a site for the research; recruiting patients and conducting the study according to the protocol.
b) Patient Identification Centre (PIC): Where potential participants are identified by the Trust and put in touch with the researchers. No consent process or any other research procedures, including provision of data is undertaken by that Trust.
c) Continuing care site: where patients are transferred to the Trust for ongoing care and study conduct, having been recruited and consented by an external organisation.

PART A CORE STUDY INFORMATION

ADMINISTRATIVE DETAILS

A3-2 – Investigator

When students are CIs

- It is normally expected that a doctoral student undertaking a project will be named as the Chief Investigator rather than their academic supervisor.
- However, in some cases it may be more appropriate for a clinical supervisor to take on the role of Chief Investigator for a project undertaken by a doctoral student. An NHS organisation may, for example, make such a decision in the case of a clinical trial of an investigational medicinal product or a study involving significant risk.

Student participation in other studies

- Where the student is participating in a project that is not purely educational, the CI may be another experienced researcher such as a health professional or academic researcher; for example, where a DPhil is embedded within a larger study (e.g. biochemistry within a vaccine trial).

A4 - contact on behalf of the Sponsor

The person named here receives copies of all correspondence from REC and as Sponsor this is key to maintaining oversight of the study.

For Trust sponsored studies, the contact on behalf of the Sponsor is Heather House:

Ms Heather House
Research and Development Department
Joint Research Office
Block 60, Churchill Hospital
Headington
Oxford OX3 7LE
E-mail: ouh.sponsorship@ouh.nhs.uk

Please do not include a telephone number

OVERVIEW OF RESEARCH

A6-1 – Summary

This should be written in lay language and is limited to 300 words. This summary is published on the HRA website to enable transparency in research and allow the general public to access information about ethically approved research.
Although brief, information should be included on the background to the research, why it is important, the questions it will answer and potential benefits, the study design and what is involved for participants, funding source(s) and recruitment site(s).

A6-2 – Main ethical, legal, or management issues arising and how they will be addressed

The key thing here is to identify what the main issues are and explain how they will be addressed. For example: you could discover incidental findings on MRI scans; you might be enrolling vulnerable participants or those with a dependent relationship to the researcher; the consent process may not be conventional; there may be implications for any genetic or blood tests.

PURPOSE AND DESIGN OF RESEARCH

A10 *– Principal research question/objective*
A11 *– Secondary research questions/objectives if applicable*
A12 *– Scientific justification*
A13 *– Summary of the design and methodology*
The key for all of these sections is that they should not be a simple reproduction of the protocol. Answers should be in lay language so that they are understandable to all members of the REC. The protocol may contain scientific detail but this is not appropriate for the IRAS form.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A21 – Duration of participation

This should be the time that each participant is expected to be in the study and is measured from provision of consent to final contact with the researchers. It is not the duration of the study as a whole.

A26 – Potential risks for the researchers themselves

There may be situations where there is some risk to researchers and these should be addressed here. For example, there may be risks for lone researchers visiting participants at home, or researchers doing work related to infectious diseases. Measures proposed to manage such issues should be included.

RECRUITMENT AND INFORMED CONSENT

A27-3 - Screening of identifiable personal information

This relates to access to personal information under the Data Protection Act and Trust procedures to ensure only authorised staff have access patient records. Explicit verbal consent from potential participants is required if the researcher is not part of the clinical care team in order for them to check whether they meet the inclusion criteria or make the initial approach to patients.
If the participants are identified via a register, this should be made clear to them in the Information Sheet and the detail of the consent and confidentiality arrangements of the register provided.

A29 – First approach to participants

There is a difference between clinical care and research; patients consult physicians with a view to deriving individual benefit from doing so; whereas research involves contributing to provision of generalizable knowledge as a volunteer.
Participation in a research project must be entirely voluntary, and no one must be coerced to participate in a research project against their will. Researchers should avoid exerting undue influence when approaching potential participants; for example through suggestion that their physician will be pleased that they have participated; or, where students are being recruited, they should feel assured that participation (or otherwise) will not affect their studies. No sanctions should follow if the participant decides to leave the research at any time.
The answer here should explain how and by whom the approach will be made. This should take into account the Data Protection Act in the same way as A27-3 above.

A40 – Access for Data

This question refers to access of the personal identifiable information during the course of the study. The answer should include who within the study team will have access, in addition the Trust requires access for monitoring and audit purposes and the following line should also be included.
"Responsible members of the Oxford University Hospitals NHS Trust and hosting organisations may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations".

CONFIDENTIALITY

A43 – Retention of identifiable data

This question refers only to retention of personal data rather than study data. Consent forms may contain names i.e. personal identifiers, but they form part of the study data.
Identifiable personal data may be retained with explicit consent; for example, with a view to being contacted for participation in future research.

A44, A45 – Storage of Research Data

It may be useful to refer to the Trust Policy on research data.
The minimum retention period for research data and records is **Five (5) years after publication** or public release of the work of the research. In many instances, researchers will resolve to retain research data and records for a longer period than the minimum requirement."

A49 Notification of GP

GPs should be notified if study participation could affect clinical care of participants. GPs should be provided with a letter and the study information sheet. There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.

PUBLICATION AND DISSEMINATION

A50-1 Registration on public database

A lay summary will be agreed and published on the HRA website. In addition to this, for interventional trials, you will need to register on Clinical Trials.gov, ISRCTN, or other. Most journals have this as a requirement when you come to publish.

A57, A58 - Primary outcome measure, Secondary outcome measures

Outcome measures should be the same as those in the protocol, expressed in lay language if necessary.

MANAGEMENT OF THE RESEARCH

A63 – Key collaborators

The CI's research team and other collaborators should be named here to ensure that at least all the people listed on the protocol are included. Details of researchers at local sites will be provided elsewhere (SSI form) unless they are key collaborators at a national level.

A64- Sponsor Details

In the case of OUH sponsored research the following details should be used:
Name of organisation: Oxford University Hospitals NHS Foundation Trust

Ms Heather House
Research and Development Department
Joint Research Office
Block 60, Churchill Hospital
Headington
Oxford OX3 7LE
E-mail: ouh.sponsorship@ouh.nhs.uk

Please do not include a telephone number.

A65 – Funding

This information is to assure the sponsor and the REC that the study has sufficient funding. If the funding is part of a large programme grant, indicate the proportion of that grant to be used for this purpose. Alternatively, it may be that you have not yet secured all of the funding required and that a future grant application will be submitted to supplement the exiting funds. If this is so, make this clear.

A68 - Details of the Lead NHS R&D contact

Heather House is also the lead NHS R&D contact for the Oxford University Hospitals NHS Foundation Trust. For all other Trusts, please contact the relevant R&D department for appropriate contact information. There is a directory of departments on the NHS Research and Development Forum website: http://www.rdforum.nhs.uk/content/contact-details/

Oxford University Hospitals NHS Foundation Trust
Ms Heather House
Research and Development Department
Joint Research Office
Block 60, Churchill Hospital
Headington
Oxford OX3 7LE
Email: ouhtma@ouh.nhs.uk

Please do not include a telephone number

A74 – Monitoring and Audit of the research

The level of monitoring and audit is relative to the nature of the study. From time to time we may visit the study to ensure that it is being conducted according to the terms of the REC approved documents.
The recommended wording is:
CTIMPS:
The study will be monitored by responsible individuals from the Oxford University Hospitals NHS Foundation Trust.

All other studies:
The study will be monitored via the study amendments and progress reports. If any issues arise the study may be monitored, or audited in accordance with the current approved protocol, ICH GCP, relevant regulation and standard operating procedures.

A76 - Insurance/indemnity to meet potential legal liabilities

Indemnity is an assurance that payment will be made to cover the legal liability of another person in the event of a claim.

Insurance is a contractual arrangement to pay a sum of money to another person in the event of verified loss or damage.

No fault compensation is an arrangement to pay compensation for harm where no legal liability arises or is admitted.

Legal liability may arise from fault in the management, design or conduct of the research. The liabilities may fall on different parties in each case.

For all these Sections normal NHS indemnity will apply.

PART B ADDITIONAL INFORMAITON

- Medicinal Products
- Medical Devices
- Ionising Radiation - If this is part of clinical care of research participants, this section will still need to be completed.
- Existing Samples
- New Samples

PART C RESEARCH SITES

The number of sites mentioned in A72 need to be added in this section.
Answering yes to A73-1 will add an option to specify a Participant Identification Centres (PICs) to specific sites. For instance, if participants are being identified by local clinicians, they need to be listed as a PIC for the Trust.
When participants are being recruited through local GP surgeries, 'Oxfordshire PCT' should be selected from the list of PICs.

PART D DECLARATIONS

When sponsorship has been agreed, please obtain all necessary electronic signatures before requesting sponsor authorisation via ouh.sponsorship@ouh.nhs.uk