**Integrated Research Application System (IRAS) Guidance and Wording**

**GENERAL INFORMATION**

This guidance provides additional information to enable you to negotiate your way through IRAS, find explanations of commonly misunderstood questions, and provided the specific wording required when you would like the University or Trust to take on the role of Sponsor.

We have structured this guidance under the main headings of the IRAS on-line system. Please note: From 1 January 2022 applications for all new CTIMP and IMP/Device trials must be made via the combined review service, which can be accessed using the new part of IRAS.

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)
* Health Research Authority (HRA) and Health and Care Research Wales (HCRW) for projects seeking HRA & HCRW Approval
* NHS / HSC R&D offices
* NHS / HSC Research Ethics Committees
* Confidentiality Advisory Group (CAG)
* Her Majesty's Prison and Probation Service (HMPPS)
* 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 

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

**INFORMATION ON SPECIFIC QUESTIONS**

*NB. the numbers below refer to the question numbers listed in the IRAS form.*

FILTER QUESTIONS

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

For projects taking place in NHS/HSC in the UK select 'IRAS Form'.

If your study involves administration of radioactive substances and you require an ARSAC license, RGEA will advise on how to generate this.

**5 NHS Involvement**

If the NHS is involved in the study, you will need to have HRA approval and local agreement (confirmation of capacity and capability) from the relevant NHS Trusts.

There are several levels of possible NHS involvement (as Site, Continuing care Site or Patient Identification Centre) and these entail various kinds of additional documentation: an [Organisation Information Document](https://www.myresearchproject.org.uk/help/help%20documents/Organisation_Information_Document_Non-Commercial_v1-5.docx) and [Schedule of Events/SoECAT](https://myresearchproject.org.uk/help/help%20documents/IRAS%20schedule-events-excel-template-1_0_.xls) for sites, and a [PIC agreement](https://www.myresearchproject.org.uk/help/help%20documents/Model_NC_PIC_Agreement_v1-2_September2019.docx) for PICs.

Please select **Yes** when NHS/HSC is Site or Continuing care site:

1. **Site:** Where the Trust / GP practices is acting as a site for the research; recruiting patients and conducting the study according to the protocol.
2. **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.

**5b NIHR Clinical Research Network (CRN) support**

CRN support: In order for a study to be considered for CRN support it requires two independent, expert peer reviews. The peer review of the study should be carried out by experts in the relevant fields able to offer independent advice on its quality. RGEA supplies an [Independent Peer Review Template](https://www.admin.ox.ac.uk/media/global/wwwadminoxacuk/localsites/researchsupport/documents/ctrg/downloads/initialconcepttosubmission/Independent_peer_review_Form_V1.3.doc), please refer to [RGEA resources](https://researchsupport.admin.ox.ac.uk/ctrg/preparation/documents#collapse396651) or a copy.

The peer review can also occur as part of funding application for a specific project (not a programme grant).

**7 Lack of Capacity**

Provision for research involving individuals lacking capacity/adults with incapacity differs by nation. There is sufficient parity between England, Wales and Northern Ireland that a flagged REC in any of these administrations is considered an appropriate review body. Research in Scotland will require review and approval by a designated REC in Scotland, separate to approval from a flagged REC in England/Wales or Northern Ireland for research in those nations. See [HRA REC SOPs 13.10](http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf); Contact RGEA for further advice.

**9 Educational Project**

Academic Supervisor authorisation will be required in addition to CI and Sponsor before IRAS form will be complete for submission.

**PART A CORE STUDY INFORMATION**

ADMINISTRATIVE DETAILS

**A3-1 – Chief 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 (you would have usually answered YES to Question 9).
* 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 investigator in other studies

* Where the student is a researcher 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 contact named here receives copies of all correspondence from REC and as Sponsor, this is key to maintaining oversight of the study.

**For University sponsored studies**, please add the following:

Title / Forename/Initials / Surname:

N/A / University of Oxford / Research Governance, Ethics and Assurance

/

Address: Joint Research Office
Boundary Brook House
Churchill Drive

Headington
Oxford OX3 7GB

E-mail: rgea.sponsor@admin.ox.ac.uk

Telephone: 000000000

Fax: 0000000000

*Please do not include telephone and fax numbers only add* 000000

**For Oxford University Hospitals NHS Foundation Trust (OUHFT) sponsored studies**, please add the following:

Title / Forename/Initials / Surname: N/A / N/A / OUHFT Research and Development Department

Organisation:Oxford University Hospitals NHS Foundation Trust

Address: Joint Research Office

Second Floor, OUH Cowley

Unipart House Business Centre

Garsington Road

Oxford

OX4 2PG

Telephone: 000000

Fax: 000000

Email: ouh.sponsorship@ouh.nhs.uk

*Please do not include telephone and fax numbers only add* 000000

**A5.1 – Research reference numbers**

Applicant's/organisation's own reference number, e.g. R & D (if available): This should be the number (**PID number**) RGEA (or OUHFT R&D) assigns to a study when it comes for sponsorship review.

**Sponsor's/protocol number**: if there is no internal number, add “000000” to satisfy IRAS validation.

**Protocol Version:** this should be the version of the protocol (filled in before submission) – we recommend that you set all study documents as version 1.0 for submission in IRAS.

**Protocol Date:** should be the date of the protocol (at point of submission in IRAS).

**Funder's reference number**: if there is no funder's reference number, add “000000”.

**Project**: if there is no number, add “000000”.

**Website:** if there is not a website, add “000000”.

OVERVIEW OF RESEARCH

**A6-1 – Summary of the study**

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, include information 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 – Summary of main issues**

The key thing here is to identify what the main ethical, legal, or management 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; investigators may have a conflict of interest regarding their research and clinical duties or commercial interests.

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 refers to 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 or final collection of their data for the purpose of the study. 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.  Include measures proposed to manage such issues.

RECRUITMENT AND INFORMED CONSENT

**A27-2- Screening of identifiable personal information**

This relates to access to personal information under data protection regulation, common law obligations of confidentiality, 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 patients meet the inclusion criteria or to approach patients to discuss the study.

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**

The answer here should explain how and by whom the approach will be made. This should take into account data protection regulation and obligations of confidentiality in the same way as A27-2 above.

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 as a volunteer to a research aim.

Participation in a research project must be entirely voluntary, and no one must be made 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.

CONFIDENTIALITY

**A43 – Retention of identifiable Personal Data**

This question refers to retention of **personal** **data** after the study has finished, Retention of personal data for longer than 12 months should be justified.

**A44, A45 – Storage of Research Data**

Studies may have different requirements for the retention period of their research data.

For guidance and the University minimum retention period, please refer to the University Policy on research data:

<http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/> and in particular, clause 3.5: “Researchers will preserve and provide appropriate access to their research data supporting outputs after the end of their project for as long as it has continuing value, in accordance with legal and funder requirements and paying due regard to discipline norms and cost. Notwithstanding, the minimum retention period for research data and records is three years after publication or public release of the work of the research.”

**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. These documents are to be provided to the Sponsor and REC for review. 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 [HRA Research Summaries](https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/) . HRA Make It Public strategy makes project registration mandatory (for further details refer to the HRA webpage <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/make-it-public-transparency-and-openness-health-and-social-care-research/> ). 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 for publication.

SCIENTIFIC AND STATISTICAL REVIEW

**A54-1. Scientific quality of the research**

Select an option to indicate how the scientific quality of the research has been assessed. If the study has not been peer reviewed as part of the funding application, consider independent peer review. The peer review of the study should be carried out by experts in the relevant fields able to offer independent advice on its quality. RGEA supplies an [Independent Peer Review Template](https://www.admin.ox.ac.uk/media/global/wwwadminoxacuk/localsites/researchsupport/documents/ctrg/downloads/initialconcepttosubmission/Independent_peer_review_Form_V1.3.doc), please refer to <https://researchsupport.admin.ox.ac.uk/ctrg/resources> for a copy.

**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.

**A64-1. Sponsor Details**

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

For University sponsored studies, please add the following:

Name of Organisation: University of Oxford / Research Governance, Ethics and Assurance

Given name / Family name: N/A / RGEA

Address: Joint Research Office
Boundary Brook House
Churchill Drive

Headington
Oxford OX3 7GB

Telephone: 000000

Fax: 000000

E-mail: rgea.sponsor@admin.ox.ac.uk

*Please do not include telephone and fax numbers only add* 000000

**For Oxford University Hospitals NHS Foundation Trust (OUHFT) sponsored studies**, please add the following:

Title / Forename/Initials / Surname: N/A / N/A / OUHFT Research and Development Department

Organisation:Oxford University Hospitals NHS Foundation Trust

Address: Joint Research Office

Second Floor, OUH Cowley

Unipart House Business Centre

Garsington Road

Oxford

OX4 2PG

Telephone: 000000

Fax: 000000

Email: ouh.sponsorship@ouh.nhs.uk

*Please do not include telephone and fax numbers only add* 000000

**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 study.

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.

**If you are seeking portfolio support (IRAS question 5b),** it will be necessary to provide assurance in this section that there will be sufficient funding.  Please state:

Both researcher and sponsor are confident that funding will be available to complete the study.

If you receive “in kind funding”, you should also list it in this section and provide details.

**A68-1. Details of the Lead NHS R&D**

**Contact details for Oxford** **Trusts are listed below.** For Trusts outside of Oxford, 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**

Title / Forename/Initials / Surname: N/A / N/A / OUHFT Research and Development Department

Organisation:Oxford University Hospitals NHS Foundation Trust

Address: Joint Research Office

Second Floor, OUH Cowley

Unipart House Business Centre

Garsington Road

Oxford

OX4 2PG

Telephone: 000000

Fax: 000000

Email:ouhtma@ouh.nhs.uk

*Please do not include telephone and fax numbers only add* 000000

**Oxford Health NHS Foundation Trust**

Title / Forename/Initials / Surname: N/A / N/A / Oxford Health NHS Foundation Trust

Organisation: Oxford Health NHS Foundation Trust

Address: Research and Development Department

Warneford Hospital

Headington

Oxford OX3 7JX

Telephone: 000000

Fax: 000000

Email: Research@oxfordhealth.nhs.uk

*Please do not include telephone and fax numbers only add* 000000

**Studies involving GP practices only**

**NIHR Clinical Research Network: Thames Valley and South Midlands**

Vicki Clatworthy

Study Support Service Facilitator

TVCN Offices Block-8 Nuffield Orthopaedic Centre

Windmill Road

Headington

Oxford OX3 7HE

Tel: 07900 407260

Email: vicki.clatworthy@oxfordhealth.nhs.uk

**A69 – Study duration**

The study duration should match the information listed in the protocol. There should be funding to cover the study to its planned end date. Where this is not the case, please discuss with the sponsor concrete plans for extension or further grants.

**A72. Which organisations in the UK will host the research?**

If Trust / GP practice is to be used **ONLY** as **PIC** (i.e. they will not be hosting the research) then they **DO NOT** need to be indicated in this section. Instead, choose **YES** in **A73-1** and **A73-2**. Further details regarding Trust /GP practice as PICs will then be added in **PART C RESEARCH SITES.**

If the CRN support was identified in question **5b** by answering **YES**, please add in **A73-3** that costs will be covered by the CRN.

**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:

*The study may be monitored or audited by responsible individuals from the University Sponsor [& NHS Trust\*].*

\*If there is NHS involvement

**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 University sponsored studies, check the second box (“*Other insurance or indemnity arrangements will apply (give details below*”) for each section of A76 and add the following wording provided by the insurance officer:

***Text in each section of A76:***

*The University has a specialist insurance policy in place – Newline Underwriting Management Ltd, at Lloyd’s of London – that would operate in the event of any participant suffering harm as a result of their involvement in the research.*

***If you will have an NHS Trust as a site, check both boxes and add the following to A76-3 only:***

*NHS indemnity operates in respect of the clinical treatment that is provided.*

**A77 – Compensation for harm where liability does not arise**

This question should only appear if one of the first four categories or ‘Other study’ is selected in Filter question 2.

For University Sponsored studies where the research intervention is identical to the intervention being undertaken for clinical treatment, and where it would not be appropriate for the University to offer a non- negligent provision, - the answer to the question should be **NO**.

If, however, the above isn’t the case and you answer **YES**, add the following statement:

For OU sponsored studies:

*The University has arrangements in place to provide for non-negligent harm arising from participation in the study for which the University is the Research Sponsor.*

Please be aware for **OUH Sponsored studies**, non-negligent harm is not covered by the NHS indemnity scheme and the Trust cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered - the answer to the question should be **NO.**

**A78 – Research lead to the development of a new product/process or the generation of intellectual property.**

The statement below confirms what arrangements the sponsor has in place to protect intellectual property rights. It is not possible to add this to this form, but if it is applicable, it should be added in the protocol, as studies requiring HRA approval may be asked for this confirmation.

*For University of Oxford sponsored studies, add the following text to the protocol:*

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

*For OUH sponsored studies, add the following text to the protocol:*

Ownership of IP generated by employees of the OUH vests in OUH. The protection and exploitation of any new IP is managed by the IP and Research Contracts Team at OUH unless it is generated in collaboration with the University of Oxford in which case this is led by the University’s technology transfer office, Oxford University Innovations.

**PART B ADDITIONAL INFORMATION**

* B.3 Ionising Radiation (If this is part of clinical care of research participants, this section will need to be completed).  Clinical Radiation Expert (CRE) and Medical Physics Expert (MPE) will need to review and approve Part B Section 3 before submission.

If the study will involve ionising radiation exposures in the NHS/HSC and in the areas of cardiology, neurology, oncology, rheumatology, or general radiology in any clinical area, an application through the Radiation Assurance will need to be made which also involves a fee. There are two review routes through HRA Radiation Assurance – self-managed and HRA-managed. Please see the [flowcharts on the HRA website](https://www.hra.nhs.uk/about-us/committees-and-services/technical-assurances/radiation-assurance/applying-radiation-assurance/) for an overview and detailed guidance on how to apply is available on the [IRAS website](https://www.myresearchproject.org.uk/help/hlpradiationassurance.aspx).

**PART C RESEARCH SITES and INVESTIGATORS**

In this section, enter details of all participating NHS/HSC organisations and/or non-NHS/HSC organisations that you plan to include in the research project and identify the Principal Investigator.

Answering yes to A73-1 will add an option to specify Participant Identification Centres (PICs). For instance, if participants are being identified by local clinicians, OUHF Trust may be listed as a PIC for the University of Oxford.

When participants are being recruited through local GP surgeries, primary care sites should be listed either as specific practices (if practices are already known) or at the LCRN level. If sites are listed at LCRN level then there is no need to submit an amendment to add further practices within this LCRN area.

**Note: Non-NHS/HSC Site:**

For CTIMP or Clinical Investigations of Medical Devices, if the study is taking place at a Non-NHS/HSC Site – thise needs to be listed here and the study requires a [Non-NHS/HSC Site Assessment Form](https://www.myresearchproject.org.uk/help/help%20documents/Non-NHS-HSC_Site_Assessment_Form_v1-1.docx).

**Pharmacy assurance**

Pharmacy Assurance is available for Phase I - III clinical trials involving investigational medicinal product(s) (CTIMPs) which are taking place in multiple secondary care sites in the NHS/HSC. An application through the Pharmacy Assurance will need to be made and these also involves a fee. There are two review routes through HRA Pharmacy Assurance – self-managed and HRA-managed. Please see the [flowcharts on the HRA website](https://www.hra.nhs.uk/about-us/committees-and-services/technical-assurances/radiation-assurance/applying-radiation-assurance/)for an overview and detailed guidance on how to apply is available on the [IRAS website](https://www.myresearchproject.org.uk/help/hlppharmacyassurance.aspx).

**PART D DECLARATIONS**

When sponsorship has been agreed, please obtain all necessary electronic signatures (the academic supervisor(s) should sign the declaration in Part D3 of IRAS for all projects undertaken in fulfilment of educational qualifications) before requesting sponsor authorisation via rgea.sponsor@admin.ox.ac.uk