Development and Submission Process for Research Projects for Health Research Authority (HRA)/NHS Research Ethics Committee (REC) Favourable Opinion via the Integrated Research Application System (IRAS)

Table of Contents

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Introduction

The Health Research Authority (**HRA**) and NHS Research Ethics Committees (**RECs**) are central to the UK's framework for safeguarding the interests of patients and the public in health and social care research. The HRA provides oversight and guidance on the ethical dimensions of health research, while the RECs, which are managed by the HRA as one of its core functions, critically assess research proposals to ensure they adhere to stringent ethical standards and regulations. These committees are essential in protecting the rights, safety, dignity, and well-being of research participants, while also promoting ethical research that can benefit participants, science, and society.

The HRA and NHS RECs do not grant "ethical approval" but rather give a "favourable opinion"; this terminology reflects the role of these bodies in assessing the ethical acceptability of proposed research, ensuring that it meets certain ethical standards designed to protect participants. A favourable opinion means that the committee has reviewed the research proposal and found that it meets the required ethical standards, allowing the research to proceed. Favourable opinion does not equate to approval to begin your research as other steps (e.g., obtaining a Research Passport, University ethics approval) may be required to be completed after favourable opinion is received.

The Integrated Research Application System (**IRAS**) facilitates a streamlined application process for obtaining the necessary permissions and approvals for health and social care/community care research across the UK. This single-entry system reduces duplication and administrative burdens by allowing researchers to submit all required information for NHS REC favourable opinion, HRA favourable opinion, and other regulatory approvals through one portal. IRAS acts as a central hub, enhancing the efficiency of regulatory submissions and enabling researchers to navigate the complex landscape of research governance and ethics with ease.

LINKS

- ***HRA***: https://www.hra.nhs.uk/
- ***Research Ethics Service and RECs*** *Link*: https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/
- ***IRAS*** *Link*: https://www.myresearchproject.org.uk/

*** PLEASE *ensure you read this document*** *thoroughly before commencing your application via IRAS. Failure to provide all the correct documentation for internal review or to include all relevant information may cause delays to your study being ready for submission.*

The process outlined below is for submitting applications to receive favourable opinion from NHS REC and/or HRA favourable opinion for studies where Leeds Beckett University will act as the sponsor. It is the sponsor's responsibility to ensure that any applications submitted to NHS REC for review meet the necessary ethical guidelines and policies. This process is designed to pre-emptively identify any potential issues with your application so they can be addressed ahead of the HRA/REC panel review. This process now includes considerations for People-Centred Clinical Research (PCCR), incorporating the HRA's recently published hallmarks for good, people-centred clinical research.

Link to ***HRA's guidelines on people-centred clinical research***: https://tinyurl.com/4b8ztaux
****Please be aware that*** *the internal review process does not guarantee* favourable opinion *by the HRA/NHS REC panel, nor does it ensure that no amendments will be required.*

Approved Sponsor signatories for all IRAS applications

Only the following staff are permitted to authorise applications to be submitted via IRAS on behalf of the sponsor. You should contact the member for your School (or either if you are from a school not represented) as early as possible in your application process to request they act in this role and to make arrangements for your document review.

Dr Angela Murphy A.M.Murphy@leedsbeckett.ac.uk

- For applications from School of Health, School of Humanities and Social Sciences or other schools

Dr Theocharis Ispoglou t.ispoglou@leedsbeckett.ac.uk

- For applications from Carnegie School of Sport or other Schools in exceptional circumstances.

The **emergency contact** for urgent sign-off of IRAS forms when both the above signatories are away from the University for a period of time (e.g., you have received an out-of-office response saying both are unavailable) will be identified in the out-of-office response of one of the two signatories if both are on holiday at the same time.

***Please note** the emergency contacts are not there to review and approve initial IRAS submissions but will provide cover for urgent approvals (for example, urgent study amendments once a study has received favourable opinion). It is an applicant's responsibility to have contacted and arranged review with a sponsor signatory well ahead of planned submission.

***Please note** that you need to allow plenty of time for gaining a favourable opinion via IRAS. Internal review usually takes 4-6 weeks including you making any suggested changes to the paperwork. You then need to allow **approximately 3-4 months** from submission via IRAS to the point where you may start recruitment. It may be longer than this depending on your feedback from the internal and HRA/REC panel reviews and how quickly Trusts turn around the Capacity and Capability assessment and Research Passport once favourable opinion is gained. Currently Capacity and Capability is taking several weeks to progress through and may be a number of months in some NHS Trusts.

***Please note** if you are not an NHS employee, you will need to gain a **Research Passport** to be able to conduct research on NHS sites (see later section) or where you may be in direct contact with patients or their supporters recruited via the NHS but not on NHS premises. You should commence this process immediately as this also takes time – see section on Research Passports later in this document**.**

For an example (e.g., detailed checklist) of the required documents and timeline for a clinical trial application, please refer to **Appendix 1**.

To facilitate the sponsor review process, please complete the Sponsor Feedback Form provided in **Appendix 2**.

Student research

Students studying at the undergraduate and some postgraduate taught levels are not eligible to conduct primary research in the NHS. Anyone who is a student or supervisor applicant through IRAS will need to complete and submit a copy of the 'Student Research Assessment' tool to say they are eligible to undertake their research, as part of the IRAS process.

- Information and the tool can be found here: https://tinyurl.com/3fwbkys3

The application and favourable opinion process

1. It is important that you get in touch with your sponsor signatory as soon as possible once you identify your project may need NHS/HRA favourable opinion.
   Please send this by e-mail with the following fully completed documents/information:

- Stage 1 University Research Ethics Approval Form in word format https://tinyurl.com/y6r7794e
- Any further information regarding the University's Research Ethics Policy and Procedures can be found here https://tinyurl.com/5n6mx6ue
- Pdf versions of the HRA decision tools – Is my study research? and Do I need NHS REC approval? http://www.hra-decisiontools.org.uk/research/
- Research timetable including when you would wish to be collecting data, timeframes for analysis and any submission/other deadlines.
- If you are a doctoral student, include your school and names of supervisor(s).

Firstly contact the sponsor (TI or AM) who ***will agree on a date for email submission of the completed IRAS documents for internal review*** by themselves or another sponsor signatory. Once a time has been arranged, the documents reviewed by the sponsor, and feedback has been responded to the sponsor signatory (AM or TI) will then confirm that your study is appropriate for consideration by the HRA or an NHS REC. Even if your study may not require favourable opinion from an NHS REC, it may still need a favourable opinion from HRA, which is also obtained through the completion of an IRAS form.

Please make sure you consult the HRA website carefully as you prepare your application since it contains lots of helpful guidance. ***You should also read the UK Policy Framework for Health and Social Care Research which should be adhered to when designing and conducting research*** https://tinyurl.com/3t3hf88u

You can find example IRAS forms and accompanying documents that have been approved by REC committees on the following Google Drive **https://drive.google.com/drive/folders/15HZXmuzSaMqTCpYeuFwS6UX_u-wt_B_l?usp=sharing**

The sponsor will usually need at least 1-2 working weeks to review your application and they may take up to four weeks at busy times. It is important to arrange the dates for submission of documents in advance and to stick to them as failure to do so could result in delays to you receiving feedback and thus to being able to submit your application via IRAS.

2. You will need to email the relevant sponsor signatory a full version of all your IRAS documents including the application form in PDF format and all accompanying documents in Microsoft Word format by the agreed date.*****Please do not upload and transfer the IRAS form to them for the purposes of internal review***.

The documents should already have been seen and approved by your supervisors – they should be copied into the email and there should be confirmation that they have reviewed and signed off the content (this might be as part of an earlier email trail for example). See the following link for details of required documents: https://www.hra.nhs.uk/planning-and-improving-research/researchplanning/prepare-study-documentation/

3. If you are conducting research in NHS sites you will also need to complete the Organisation Information Document and Schedule of Events documents. This free on-line training https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/ and guidance https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-LocalInformation-Pack-OID will help you complete these.

   Some bite sized learning modules have been created to support research teams in completing the Organisation Information Document and Sharing the UK Local Information Pack. These are available on the UK 4 nations compatibility website.

4. These documents will be reviewed, and you may be asked to make some amendments.

5. It is unlikely the sponsor signatory will have time to further review any of the documents, unless they have asked for substantive amendments to be made and they feel this is necessary. It is your responsibility to ensure you carefully read and address **ALL feedback** ahead of preparing the IRAS form and documents for submission.

   You will be asked ***to submit a word document to the sponsor signatory, via email, detailing each point of the original sponsor feedback given and how you have addressed it*** (as you would in responding to journal reviewer comments or amendments to a doctoral thesis). The sponsor will check this ahead of completing the electronic sign-off of the revised documents on the IRAS system.

   ***Please** note the internal review process does not guarantee that your application will receive favourable opinion by the HRA or an NHS REC or that they will not require amendments to be made.

There is a section within the IRAS form that asks about any review process the study has gone through. It is a requirement for most types of projects that some form of expert peer review has been undertaken and that you can provide evidence of this in the application. The internal review process can act as this expert review, and you will be able to submit any feedback you receive as part of the application.

1. The validation of the form ensures that all required fields and sections in the IRAS form have been correctly completed and meet the necessary standards before submitting it for sponsor authorisation. These steps are crucial as it helps identify any issues or missing information that could invalidate the submission, necessitating the removal of signatures, and restarting the request process s again.

2. Booking a REC appointment (if needed) is done via a new on-line booking service, which is available 24/7. You will be directed to a new part of IRAS which hosts the online booking service.

A separate login will be required, but support will be provided. You will need to set up a new login and password for this area unless you already have a login for a NIHR system or as part of the Combined Ways of Working (CWoW) pilot. In this case you can use your existing log in details. Applicants will need to answer a series of questions online before being able to book a slot. This directs the applicant to either proportionate review or to a full REC meeting. Your answers will be reviewed on submission and if you have been flagged for proportionate review you may be redirected to full REC review based on assessment of your study. The questions will be familiar to anyone who has used the previous telephone Central Booking Service. Once you have completed your online REC booking, you will still need to electronically submit your application in IRAS using the normal process.

Please note when asked 'Does the application involve any highly sensitive areas or topics?' you MUST tick yes if the research topic is anything that could potentially cause distress or upset e.g. asking about someone's health status or health and care experiences. If you fail to do so the study will be flagged for proportionate review – but then on HRA review will be marked as needing full REC favourable opinion**.** This will lead to delays in your application being processed. Check proportionate review toolkit here **https://tinyurl.com/324txsvb** as well as in relevant section later below.

Once you have gained NHS REC favourable opinion you will need to do the following things:

- Notify the Sponsor that a favourable opinion has been granted. In the case of a clinical trial, please also notify the Insurance and Risk Manager – Martin Watson at m.watson@leedsbeckett.ac.uk – to ensure that appropriate insurance is in place; you should have already liaised with Mr Watson before the submission of the ethics application through the IRAS system.

- The project documents submitted to IRAS, along with the REC/HRA letter of favourable opinion, should be submitted as soon as possible through the Research Ethics Online system for **ethical approval in the University**. This process is a formality, as the University LREC is not permitted to request any further changes. However, it is a requirement you also gain formal University ethical approval as this ensures the University maintains a central record of all research and also ensures that aspects such as the data management plan (DMP), not required as part of the IRAS application, are approved in the standard University format. University insurance may not be valid if your study has not been given formal University ethical approval as well as NHS REC/HRA favourable opinion. Once LREC approval is received please inform the Sponsor (AM or TI).

- The inclusion of DMP (staff only and PhD students) (https://tinyurl.com/yue9am8h) is necessary to be in line with the University policy http://libguides.leedsbeckett.ac.uk/research/research_data.

- If appropriate, send all your documentation in the form of a 'Local Information Pack' to the Research and Innovation office in the NHS Trust(s) you plan to conduct the study in, in order to gain site level approval. This is generally necessary when your study involves NHS patients, staff, or facilities. You can find out more about this here https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx

Other useful information

Student projects

There is specific guidance on the HRA web-site about student projects. https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/
See also section 9.3 of the UK policy framework for health and social care research.

PhD/doctoral level students are permitted to be involved in primary research within the NHS and are eligible to also act as Chief Investigator for their study.

From September 2021 Undergraduate students will not be permitted to conduct stand-alone research that requires HRA/NHS REC review.

Masters or equivalent students on health and care courses will only be permitted to undertake stand-alone studies requiring NHS REC/HRA review under specific circumstances. Those on non-health and care Masters level courses will not be permitted to undertake studies requiring HRA/NHS REC review. See the following information for more details https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/#table1

The Student Research Assessment tool must be completed and attached for all student projects that are eligible to apply via IRAS.

The IRAS form – common errors

- Make sure you answer all of the opening questions accurately as they open up different sections of the application form based on the answers you provide. Changing them later may result in you losing information already inputted into the form.
- If you are undertaking a PhD study then the answer to question 9 is 'Yes' this is an educational project
- Question A4 – The person named here should be the sponsor signatory i.e. Angela or Theocharis
- Question A6-2 In this section provide a short, clear summary of the main ethical, legal or management issues that arise in your study and how you plan to address them. This should be in a language accessible to a lay audience. Do not provide an overview of the full study and its methods here.
- A13 Make sure this is a succinct summary of your methodology and methods that is accessible to a lay audience.
- A64 The sponsor is the University and the contact person should be the sponsor signatory – this means we will be copied into all correspondence so we can keep a record.
- A76 – Other insurance or indemnity applies – University insurance. Documents should be available from the University web-site (see section on insurance below) otherwise contact insurance@leedsbeckett.ac.uk
- You will need to request for electronic authorisation from supervisors (for student projects) and from the sponsor. The form must be ready to submit before you do this, otherwise any changes

to the form invalidate the electronic signatures. Please check you have completed everything using the 'validate form' option before requesting signatures. Common validation errors including needing to put n/a under some sections of the form if you do not provide an answer as blank spaces are not permitted. If in doubt just put n/a in any blanks to be on the safe side!

Research protocol

- It is a common error for applicants to fail to produce and submit a research protocol for review. This is a compulsory document for any submission via IRAS. It is useful to write the protocol alongside completing the IRAS form as this process helps you to identify and iron out issues and processes.
- You can find more details on the content of research protocols here – not all content items are required so use your discretion https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/ You can find example protocols in the Google Drive link provided on page 1.

Organisation Information Document (OID) and Schedule of Events (SoECAT)

- Please make sure you complete a template organisation information document that will be used for each participating NHS site (where relevant) and a Schedule of Events (one schedule of events covers all participating organisations providing they are carrying out the same activities), which will now include guidelines to address the new streamlined processes for quicker approvals. Following the latest updates, these documents also ensure the inclusion of diverse participant groups as a crucial aspect of effective health and social care research. The OID and SoECAT are required to ensure that the research site is appropriately equipped and accurately attribute and plan for the costs of research activities. These documents provide essential details for the ethical review committee to assess the feasibility and financial planning of the study.

- The Organisation Information Document for data processing only has been updated to add definitions and account for the status of the UK outside of the European Economic Area.

- Read more about these changes here: https://content.govdelivery.com/accounts/UKNHSHRA/bulletins/38f78b4

- This video gives details of how to choose the right oversight model for your research – not all studies need a local Principal Investigator (PI) and can be conducted with a local collaborator https://www.youtube.com/watch?v=sbRDhICkz7w

  The SoECAT form should be the Funder Export from the online SoECAT, obtainable via the NIHR Central Portfolio Management System (CPMS).

- In order to create a SoECAT, you will need to create an account in CPMS. After creating the account, you will need to login to CPMS to activate this account. If any assistance is required in creating the account, please refer to the user guide. Once your account has been created and is active, you can proceed.

- Guidance for the completion of the SoECAT by the applicant is present in the online tool to assist at each page and stage of the application process and further details can be found on the Online SoECAT Guidance page.

- There is also an Online SoECAT Guidance Module (https://tinyurl.com/fhau54bp) which includes video tutorials and linked resources (an NIHR Learn account is required to access and enrol onto the module) and a helpful Study Representative - Online SoECAT Top Tips infographic.

- Please make sure you download the draft version of the SoECAT form to submit to the sponsor representative as part of your documents to review. DO NOT submit via CPMS to the Clinical Research Network (CRN) for approval until you have sponsor sign off that they have approved its content.

- You will need to have the SoECAT approved by the local CRN ahead of submission to the HRA/REC. You will need to make sure you allow enough time for this to be obtained. In addition to submitting the SoECAT to the CRN via the online CPMS system in which you created it, you will also need to send the CRN an email providing evidence of approval by the sponsor. If you have received external funding – for example via the National Institute for Health Research (NIHR), then your SoECAT will already have been sponsor and CRN approved prior to funding being awarded. For all other studies, whether or not they require CRN support to conduct, approval will be needed from the sponsor and CRN ahead of submission via IRAS.

Participant Information sheets (PIS) and consent forms

There is guidance on the required content to cover within participant information sheets and consent forms on the HRA web-site. http://www.hra-decisiontools.org.uk/consent/

From December 2023 it will be a requirement that ALL participant facing information, whether this be a written document, video or other form of recruitment materials) be reviewed by Patient and Public Involvement members ahead of submission to the Research Ethics Committee. We will be operating this process with immediate effect in the University. Please make sure you also read the section on Public Involvement in Research (p11) to follow University processes for conducting Public reviews.

- Please make sure you have read and that your materials comply with the Participant Information Quality Standards https://tinyurl.com/mj93b8jt
- Please make sure you have read and your materials have followed the Participant Information Design and Review Principles https://tinyurl.com/ya8b53e6

The HRA have specific requirements around wording in relation to General Data Protection Regulation (GDPR) within PIS. You MUST include this wording in your PIS otherwise you will be asked to make amendments by the HRA/REC. You can find all the details on their web-site: https://tinyurl.com/3ajryy5r

You need to include a link to the LBU Research Participant Privacy Notice and should read the document to check you are doing everything it asks.
HRA also state that:

- It is expected that somewhere in the Participant Information Sheet (PIS), the name of the sponsor organisation is given. It should therefore be clear to readers that any reference to 'we' means the sponsor and not the local site.
- A statement should still be included to make it clear how long patient identifiable data will be stored for.
- A statement should still be included to make clear who the data controller for the study is

Please note that HRA have requested the following information be included on consent forms for studies needing HRA favourable opinion:

- *"I understand that regulatory bodies may access research and other relevant records to ensure that the research has been carried out properly"*

They have also requested previously that applicants confirm the following:

- *Please can you confirm that you will retain one copy of the consent form and provide one copy to the participants*

And the following

- *Please confirm how hard copies of study documents (e.g. consent forms) will be securely transferred from the NHS site to the storage location at Leeds Beckett University.*

Interviews and audio devices

The HRA have asked previous applicants to confirm the following

- "I note an audio device will be used. Please briefly confirm the security of the transport of this device and/or confirm that the device will be encrypted"
- Please note that many of the audio devices you can borrow from the library are not encrypted so you will need to ensure you have an appropriate encrypted and password protected device in place.
- "Please confirm who will be transcribing the interview recordings. If an external person/company is used for transcription, please confirm that a confidentiality agreement will be in place. A brief statement should also be added to the PIS to explain that recordings will be sent to an external company for transcription."

This will not be the case for the majority of studies e.g. PhD students generally transcribe their own interviews and most other projects utilise research pool staff. However, please note the above if interviews are to be externally transcribed.

Study documents

When completing any study document e.g. information sheets, consent forms, protocol etc you need to ensure each has a version number and date on it somewhere (header or footer is usually the best place). These need to be the same version number and date as you add to the IRAS checklist.

You also need to include copies of any questionnaires or measures (standard/validated ones or ones you have developed) and interview schedules as part of your application.

GDPR, Data storage and Management

The data controller is the Chief Investigator or the Director of Study (DoS) for PhD and other student projects. Data retention periods are usually:

- Up to 12 months for personal information after study completion to allow a summary of research findings to be sent to participants
- 3 years after completion of award for doctoral or Masters research
- 5-10 years after study completion for all other research

If you wish to place data in an open access repository or make it open access via other routes after study completion you will need to ensure details of this are clear in the GDPR, PIS and consent forms.

Information about the University's data management policies and who to contact about requirements for making data open access can be found here: https://libguides.leedsbeckett.ac.uk/research_support/topics/research_data

Reminder: Producing a DMP is compulsory for all University staff and PhD ethics applications (https://tinyurl.com/yue9am8h) that will also be eligible for IRAS submission. It is not essential to submit this as part of your IRAS documentation, but it will be required for University ethical approvals and should therefore be completed alongside your documentation submitted for favourable opinion via IRAS. A robust DMP is essential for maintaining transparency in research. This transparency not only supports the integrity of the research process but also enhances public trust and engagement by ensuring that data are accessible, understandable, and reusable. By clearly outlining how data are collected, stored, processed, and shared, a DMP makes the research open and accessible to other researchers, stakeholders, and the public. This openness is crucial for facilitating collaboration, verification of results, and promoting innovations that benefit society.

If you are asking an NHS Trust to collect and/or share data with you, you may be required to prepare a Data Protection Impact Assessment (DPIA). For example, a DPIA is necessary if your research involves processing sensitive personal data, large-scale data collection, or data sharing between organisations. The DPIA will not need to be submitted as part of your IRAS documentation. However, it is advisable to consider this alongside your IRAS submission to ensure that any processes in the DPIA align with those detailed in your IRAS documentation. You are advised to contact the Information Compliance team about this at an early stage – they can provide advice and support on this and will also need to approve it ahead of use Infocompliance@leedsbeckett.ac.uk

No research data is to be stored on personal laptops or other personal devices. Staff and students must make arrangements to conduct all data collection and analysis using password protected and

encrypted University IT equipment or ensuring immediate cloud rather than local storage of data on other devices.

You can find a summary of University guidance on appropriate storage of data (this relates to GDPR and personal data, but should be considered/applied for all research data): Information Compliance | Public Information | Leeds Beckett University

You also need to have appropriate deletion and/or archiving processes in place, that are usually covered within the DMPs of funders or of the university (https://tinyurl.com/yue9am8h).

Public involvement in Research (PIR) also known as Patient and Public Involvement (PPI)/Service user and carer involvement

The HRA has produced guidance to help applicants identify where the public have been involved in their research and the difference it made. This relates particularly to QA14-1 and A6-2, A13, A22, A30-1 and A51.
The IRAS process now emphasises the importance of public involvement, ensuring that participant information is easily understood and research findings are accessible. Transparency and diversity have been identified as crucial for building trust and confidence in research.
https://www.hra.nhs.uk/about-us/news-updates/our-new-public-involvement-guidance-researchapplicants/

Patient and Public Involvement work does not require ethical approval or favourable opinion either from an NHS REC or from University ethics. Patients and the public involved in this way are classed by the NHS and social care as acting as specialist advisers, not as research participants. However, Leeds Beckett University has its own good practice guidance and oversight mechanisms to ensure all PIR activities are conducted in ways that are safe and protect participants and staff. Please ensure you have followed all required guidance and School-level procedures for PIR oversight in any PIR activities you undertake.

You can find all the guidance here: https://libguides.leedsbeckett.ac.uk/research_support/research_data/research_ethics and please speak to your local Research ethics Co-ordinator for details of oversight processes in your School if you are usure.

There is a range of information available from NIHR, HRA and INVOLVE about PPI work in the NHS and social care and also about payments to PPI representatives.

https://www.invo.org.uk/wp-content/uploads/2011/12/INVOLVENRESfinalStatement310309.pdf
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-do/
https://oxfordbrc.nihr.ac.uk/ppi/patient-and-public-involvement-ppi-briefing-notes-for-researchers/

Involvement of Children and Young People

A video – https://youtu.be/VlI6V1MgZgY – developed for children and young people to make an informed choice about research participation, created by University College London in association with Penta, is now recommended as a resource. This ensures that young participants are well informed about their personal data handling in research.

Proportionate Review

Some studies that are low risk are eligible for proportionate review which is much quicker and does not require attendance at a formal REC panel meeting. The questions you answer when completing the online form to book onto a REC panel will help determine if your study is eligible for proportionate review. You can read more on this on the HRA website: https://tinyurl.com/2mubyswt

Please only state the study does not cover potentially sensitive issues if this is the case – otherwise it will be marked for proportionate review when this is inappropriate and this will be flagged upon HRA review, who will then contact you about arranging review by full REC.

HRA Favourable Opinion

Research that takes place with NHS staff and on NHS premises will need HRA favourable opinion (which is still gained via completion of an IRAS form) even if REC review is not required.
The HRA policy is that if researchers approach staff via their own private networks, or a non-NHS source (e.g. professional organisation), to conduct interviews outside of NHS premises and work time, then HRA favourable opinion is not required on the grounds that it is not considered to be taking place in the NHS.

Participant Identification Centres (PICs)

These are NHS sites that only support participant identification and do not conduct any other research activities. For example, if you want a site to identify eligible participants from their clinical records and post out study invites, or to invite patients who are eligible when seen in clinic.
The HRA has released guidance clarifying that research just advertising via posters in NHS settings does not class as research in the NHS, therefore does not require HRA favourable opinion. Sites which put up a poster do not need to be set up as sites.
There are specific agreements that need to be in place for PIC sites that avoid requirement of completion of an Organisation Information Document or Schedule of Events. You can read more here https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC
You must submit your PIC agreement as part of the IRAS documentation. Please note the University as an entity is the sponsor and should be named as such in the document (not the sponsor signatory). The Chief Investigator is permitted to sign the agreement on behalf of the sponsor – do not put the sponsor signatory as signing the PIC agreements.
This document also gives useful information about when sites are and are not considered PIC sites https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/UK_SW_Criteria_updated_19.11.2021.pdf
In previous feedback applicants with PIC sites have been asked to provide for review the covering letter to be sent to PIC sites that details inclusion and exclusion criteria to inform their identification of participants.

We have also had feedback that where screening of Patient Records in order to send out study invites from PIC sites is being carried out, this must be undertaken by a clinician unless administrative staff are considered part of the care team and would usually have access of this nature to patient records.

Insurance

The University insurance documents can be found at the following page on the Leeds Beckett Staff site – students and other non-staff members will not be able to access these pages direct. https://www.leedsbeckett.ac.uk/staffsite/services/financial-services/procurement-andinsurance/insurance-and-risk/

Research Passports

Researchers conducting research within the NHS who do not have an existing contract with the NHS Trust where the research is taking place will need a Research passport. This document is essential for those collecting data onsite or directly from patients.

Steps to obtain a Research Passport:

1. **Start early** Begin the process as soon as possible, as obtaining a passport can be time-consuming.
2. **Complete the application form** Fill out your sections of the Research Passport form. The form and additional guidance are available here https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx
3. **Manager and supervisor endorsement** Have your line manager or supervisor complete Section 4 of the form.
4. **Submission to HR** Submit the completed form to HR for processing. HR will advise on any required occupational health checks and discuss the process for obtaining necessary Disclosure and Barring Service (DBS) clearance.
5. **Contact University's Quality Assurance and Governance Administrator** Helen Brady is currently the contact person for guidance on the Research Passport process at our university. She can be reached for advice on DBS clearance and other procedural matters.
6. **Liaise with NHS Trust** Once HR has processed your form submit your Research Passport application to the NHS Trust (if not already an employee) in order to gain a Letter of Access. Once gained from one site you can take this to other sites to gain quicker access if working in more than one Trust. You cannot have this approved until you have HRA/REC favourable opinion, but you should begin the process of getting the application form completed and submitted to the relevant Research and Development Department so it is ready to be processed by then as soon as you have your HRA/REC favourable opinion. Please check link here https://tinyurl.com/yc4xbu4y for useful information for research taking place in NHS

Research Training

You will also need to have done appropriate training to satisfy REC requirements this might include Good Clinical Practice (GCP) (including consolidation training),Safeguarding, MCA assessments etc. Please see the following web-site through which you can access on-line NIHR Good Clinical Practice (GCP) training and information about NIHR Learn https://tinyurl.com/2p8uasup There is a drive within NIHR and the NHS and social care to improve representation of diverse communities in research.

Cultural competency in research training can be accessed via NIHR Learn and NIHR Open Learn (for people unable to create an NIHR Learn account).

Other useful training is available from this NIHR website link: https://tinyurl.com/cacat9ts

Clinical trial registration

It is a condition of NHS REC favourable opinion that any clinical trials are registered on an appropriate database. You will need to ensure you meet all requirements and can read more here https://tinyurl.com/2nr472ud This will now happen automatically for clinical trials submitted through IRAS for combined review e.g. clinical trials of investigational medicinal products (CTIMPs) and combined trials of an investigational medicinal product and investigational medical device (IMP/device trials). Any trials falling outside of this will need to be registered by the research team on an appropriate trial registry. There is a cost associated with this.

Making changes to your study once favourable opinion is granted.

If you wish to make a change to your study once favourable opinion has been granted e.g. to procedures, data collection methods, participant information sheets etc you should complete the amendment form and then contact either Angela or Theocharis to confirm whether this is a substantial or non-substantial amendment. Please read the HRA guidance on amendments. https://www.hra.nhs.uk/approvals-amendments/amendingapproval/

Violations and breaches of protocol in the conduct of research

Mistakes can happen when conducting research that mean the processes or criteria set out in the protocol may inadvertently not have been followed. It is important such mistakes are identified and addressed appropriately. NHS RECs distinguish between protocol violations which are errors that do not put participants at risk and breaches which may put participants at risk or mean they have been recruited incorrectly. The Standard Operating Procedures for RECs provide further information on this. If you identify a protocol violation/breach it is important to get in touch with your Sponsor Signatory asap to discuss the level (violation/breach) and what appropriate action should be taken. They are there to help you rectify the situation and not to judge or blame in any way, so do not worry about getting in touch.
The REC SOP (see section 10.68 onwards – p150) https://tinyurl.com/yc5raen

Angela Murphy and Theocharis Ispoglou IRAS sponsor signatories

Appendix 1

IRAS/NHS Ethics Application – An example of a clinical trial requiring one hospital as a participant identification centre (PIC)

Use the following as a checklist and note the time taken for certain documents to be provided.

- IRAS Form – Complete (this can take months and must be reviewed by the sponsor)
- IRAS authorisation and submission
    - The meeting with a REC must be made on the same day you submit. You can only submit once you have gained all necessary authorisations. You can usually book a meeting about 3 weeks on from the submission date.
    - The IRAS submission must contain all of the following documents:
        - Study Protocol
        - Participant Information Sheet (PIS)
        - Informed Consent Form (ICF)
        - Letter to GP
        - CV for the researcher
        - Research Passport
            - Requires up-to-date DBS check (this could take up to 6 months) and may require Occupational Health Clearance (this could take up to 6 weeks) depending on the research. If this is needed, contact Ann Coulson (A.Coulson@leedsbeckett.ac.uk).
        - Research Timetable
        - HRA Statement of Activities
        - SoECAT Summary of Questions and Costs Outline
        - Data Management Plan
        - Study Contact Document
        - All questionnaires/data collection forms you will be using.

All of the above need to be uploaded onto the checklist section on IRAS before you gain authorisations and submit your application. The authorisations are required from ***your academic supervisors, sponsors, and any other parties involved in the research or ethical process***.

After submission, the hospital requires a Local Information Pack. This is to obtain Confirmation of Capacity and Capability (CCC) and is separate from ethical approval – research cannot commence until CCC has been issued which will be after ethical approval. The Local Information Pack requires the following information/documents:

- Covering email using standard template format
- Localised Organisation Information Document
- SoECAT
- Contract
- Delegation Log

- Protocol
- IRAS Form
- Patient facing documents (i.e., PIS, ICF, GP Letter, questionnaires etc.)
- HRA Approval
- REC Approval

If you require access to the hospital, you will need an ID badge. This requires the research passport to be fully signed off and OH clearance. The local collaborator at the hospital will then need to sign a form for you to collect and take to the main reception at the hospital. Here they will provide you with an ID badge.

Sponsor Feedback Form **Appendix 2**

Name and title of applicant		
Project title		
IRAS number		
Number of documents submitted		
Confirmation of having read guidance document (above) – please make bold to tick YES or NO		
Anything sponsor should be aware of….		
Date agreed for sponsor review		
Has the study proposal and documents had peer review? Please make bold to tick YES or NO		
Checked insurance? YES or NO		
OID needed and included in application? YES or NO		
PDF of IRAS form included? YES or NO		
Document name and section	Feedback from Sponsor	Applicant feedback to sponsor Please all changes and responses.