SEEKING APPROVAL FOR RESEARCH

Version 11, September 2018

Contents

Purpose of this document

Research involving human participants (or their organs, tissue or data) hosted in or through the NHS requires approval. The Trust's Research & Development (R&D) department is responsible for ensuring that all research undertaken in the Trust has undergone the appropriate checks and that sponsorship is in place (see glossary for sponsorship definition).

This document is to inform Trust staff of the process for seeking the necessary approvals for research*. This guide also applies to students undertaking research involving Trust service users, staff or data. This guidance is intended to supplement the existing procedural document *Project Approvals and Monitoring Procedure RD-001* which can be found on StaffNet or by contacting the R&D department.

The document is split into three sections:

1. Preparing your application for approval
2. Setting up research sites
3. Useful information to support your research

*projects meeting the accepted definition of research i.e. the attempt to derive generalisable and/or transferrable new knowledge. If you are unsure please check using this decision tool:

http://www.hra-decisiontools.org.uk/research/redirect.html

A glossary can be found at the end of the document.

1. Preparing your application for approval

Library services support

It is recommended that you contact Library & Knowledge Services as early as possible to discuss the support that you need. It is particularly important that a scoping literature search is undertaken in the early stages of your proposal development to evidence that the research is necessary and has not already been carried out or is in progress. A scoping search will provide an overview of the literature on your research topic. Library & Knowledge Services can:

- Carry out your scoping search
- Undertake a comprehensive literature search/review
- Advise on the literature search section of funding bids
- Help estimate the size of the review and by extension its cost
- Provide advice and support about databases, search terms and searching methodology if you want to carry out your own search
- Provide copies of journal articles and other papers, reports etc.
- Provide access to books and other materials that support the research process
- Help with writing up your research and referencing.

Contact Library and Knowledge Services at libraryandknowledgeservices.lypft@nhs.net or by telephone 0113 85 55652.

Research protocol

A protocol is required for all research projects. The length and content will vary depending on the type of research and the level of complexity.

You can use the template below as a guide - please note that not all sections may be relevant for your study.

Protocol template.docx

You can also find protocol templates on the HRA website:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

Sponsorship

The sponsor is the individual, organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project. All health and social care research will have a sponsor.

LYPFT will usually act as sponsor for studies where the Chief Investigator (the research lead) is a Trust employee. If this is the case you should contact us as early as possible to arrange review of your project and authorisation of your Integrated Research Application Service (IRAS) application. It may be necessary for your project to be independently peer reviewed where this has not been already done e.g. as part of a grant application.

If you are undertaking research as part of an educational qualification e.g. MSc, the university will usually act as the sponsor.

Service user and carer involvement – Help from Experts by Experience for Researchers (HEER)

The Trust has a dedicated service user and carer group who can offer advice and guidance on research project design, participant information etc. The group meets once a month. Please ring the department on 0113 85 52387 for further information or to book a review. This service is available for all researchers i.e. not just Trust staff. **Please note that service user and carer involvement should take place prior to applying for approvals.**

Participant information and consent

The information given to potential participants is a key element of the recruitment and informed consent process. A participant information sheet is required for all studies and the level of content will depend on the type of research e.g. a drug trial is likely to need more information than a questionnaire study. A written consent form is required for most types of research.

A separate version should be produced for the different participant types e.g. staff, carers and service users.

Comprehensive guidance on information sheets and consent forms, including examples can be found here:

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/

HEER, the Trust's service user and carer group, can play an important role in reviewing documents before they are submitted to research ethics and the HRA to ensure that they are appropriately written and contain the necessary information. The documents are also reviewed by the R&D department as part of its sponsorship role.

Indemnity

In general, research that is taking place in the NHS will be covered by the NHS Indemnity Scheme; applicants do not need to provide evidence of NHS indemnity.

Where the study is being sponsored by a university or commercial organisation, this organisation will provide indemnity. Evidence of indemnity will be required and should be submitted with the application.

Other things to consider when planning your research

There are many other things to consider when preparing your application for approval. The HRA website contains lots of advice about all aspects of setting up research.

https://www.hra.nhs.uk/planning-and-improving-research/

Approvals required

There are two main approvals required for research undertaken in the NHS; NHS Research Ethics Committee (REC) Approval and Health Research Authority (HRA) approval.

You must also get agreement from each site that they are able to host the study (confirmation of capacity and capability). These approvals are explained further below.

Research Ethics Committee (REC) approval

Ethical approval is required for most research undertaken in the NHS. Research Ethics Committees (RECs) undertake an ethical review of research to safeguard the rights, safety, dignity and wellbeing of research participants, independently of research sponsors.

RECs review research applications and give an opinion about the proposed participant involvement and whether the research is ethical. RECs are entirely independent of research sponsors (that is, the organisations which are responsible for the management and conduct of the research), funders and investigators.

Studies not requiring NHS ethical review.

Some studies do not require NHS REC approval e.g. research involving staff only, research using previously collected anonymised data.

The HRA has developed a tool to help determine whether you need NHS Research Ethical review.

http://www.hra-decisiontools.org.uk/ethics/

Further guidance is available here:

http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/

NOTE: If you are doing research as part of an educational project e.g. MSc, PhD you may need university ethical review. Your supervisor or university research office can advise further.

Please check whether you need ethical approval before you start to complete the IRAS application. If you are unsure please contact the R&D department to discuss further.

HRA Approval

HRA Approval is the new process for the NHS in England* and replaces the approvals issued by each NHS organisation (R&D approval or NHS permission). All research requires HRA approval. HRA Approval combines an assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK research ethics service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. All project-based research requires HRA approval.

Please see the link below for details on how to apply for HRA Approval in the following link:

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

*HRA Approval does not apply to research sites in Scotland, Wales or Northern Ireland

IRAS (Integrated Research Application System)

All applications for research approval are done via the Integrated Research Application System (IRAS), an online system. You will need to create an account in order to use the system. Please click on the link below and choose the Create Account tab.
https://www.myresearchproject.org.uk/Signin.aspx

NB Before you start completing the IRAS form

If you haven't used IRAS before or if it has been a while since you last did, we recommend that you complete the free e-learning module. It does not require registration or a login. This will give you an overview of the system and its functionality. The e-learning can be accessed in this link: **IRAS e-learning.**

Other help and guidance

The HRA have produced a step-by- step guide to using IRAS which you can find at this link:

https://www.hra.nhs.uk/about-us/news-updates/hratips-our-guide-hra-approval-applicants/

The IRAS application provides useful question-specific guidance which you can access by clicking the buttons alongside each question. We recommend that you read this additional information for each question.

IRAS form contact details

Where the Trust is acting as the sponsoring organisation and the Chief Investigator is employed by LYPFT, the Research Manager's name should be provided in the IRAS form for:

- The Sponsor contact (question A4)
- Lead Sponsor (question A64-1)
- The NHS R&D Lead (question A68-1)

Please use the generic email address for the email contact research.lypft@nhs.net

Electronic authorisations

Once all sections are completed, and before the form is submitted to the HRA it will need to be authorised by the Chief Investigator and Sponsor (R&D). This is done via the IRAS application. To request Sponsor authorisation, please use the generic email research.lypft@nhs.net

NB in the case of educational projects the academic supervisor will also need to authorise the IRAS form.

https://www.myresearchproject.org.uk/help/hlpsignatures.aspx

Booking in your application for HRA Approval

Before electronically submitting your application for approval (via IRAS) you need to contact the Central Booking Service (CBS) to book in your application. See link for further information:

http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/

Submitting your application to the HRA

Your application documents must be submitted electronically via IRAS. Make sure that you upload your supporting documents to the Checklist tab (you will see this when you have opened the form). The submission checklists ask you to indicate the version of each document you submit. This can be added in the footer so it appears on each page.

Documents to submit to the HRA

The documents listed below are an example of the types of documents you may be using; it will depend on the type of study. NB include version numbers and dates on documents and the IRAS ID on the consent form and participant information sheet

Completed and authorised IRAS form (mandatory)
Protocol/proposal (mandatory)
Chief Investigator short CV* (mandatory)
Consent form/s
Participant information sheet/s
Invitation letter
Questionnaires
Interview topic guide
Copies of advertisement material e.g. poster
Statement of Activities
Schedule of Events

*A CV template is available from StaffNet or from the HRA website:

http://www.hra.nhs.uk/resources/applying-for-reviews/applying-for-approvals-template-documents/

Templates for some of the above documents, along with guidance and information can be found here:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/

R&D review (confirmation of capacity and capability)

For studies that are being led by other organisations i.e. when LYPFT is a participating site, the R&D department will review all applications to check the feasibility of running the study in the Trust. This is done in parallel with HRA Approval. Applicants should send a copy of the protocol to the R&D department when they contact clinical services.

2. Setting up other NHS sites

If you plan to recruit from other NHS organisations at other research sites you should contact them early as possible in the process i.e. when you are applying for your approvals. It is important to contact their R&D department as well as the clinical service. The process is described on the HRA website but the key points are below.

Before finalising the IRAS form, it is recommended that you contact other NHS organisations to check if they have the potential to be involved. As a minimum you should send a copy of the protocol being submitted to the HRA. The organisation's R&D department should be copied into this email. A list of current R&D contacts can be found here: http://www.rdforum.nhs.uk/content/contact-details/

Organisations that have agreed that they might be able to participate in the study should be named in Part C of the IRAS Form. If additional participating organisations are identified after initial submission then these can be added afterwards as an amendment.

Once you have made an application for HRA Approval and have received the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter needs to be issued), you can work with NHS sites to put the local arrangements in place to deliver the study. You may choose to set up sites after HRA Approval.

Documents to send to NHS sites

Please send the following local document package simultaneously to the clinical service, the R&D office and to the Local Clinical Research Network (where applicable) once you have received the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter is issued). Click here for contact details for R&D staff and the relevant Local Clinical Research Network.

- Copy of IRAS Form
- Protocol
- Any amendments
- Participant information and consent documents
- Statement of Activity
- Schedule of Events
- Relevant template contract/model agreement (if needed in addition to Statement of Activity)
- Any other documents to support the set up and delivery of the study
- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions

Please also send a copy of final documents to the LYPFT R&D department research.lypft@nhs.net

Approval from other NHS sites (confirmation of capacity and capability)

Once all the arrangements have been put in place to provide the capacity and capability to deliver a study, the participating NHS organisation will provide you with confirmation of this by email, indicating that they are ready to start the study. The actual date at which you wish to start research activities at the site should have already been agreed and may be dependent on a site initiation visit or similar that you wish to conduct.

Participating NHS organisations in England should provide confirmation to you as outlined in the HRA Approval letter. This will usually be by mutual agreement of the Statement of Activities or by signature of the template agreement – this will be made clear in the HRA Approval letter. The HRA will provide a suggested template email that participating NHS organisations in England may choose to use to accompany this agreement.

3. Useful information to support your research

Amendments to approved studies

Amendments are changes made to the protocol, study documentation or research team during a project i.e. once all approvals are in place. Amendments fall into two categories: Substantial or non-substantial (minor).

A substantial amendment is defined as an amendment to the terms of the application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree: the safety or physical or mental integrity of the subjects of the study; the scientific value of the study; the conduct or management of the study.

Notices of Substantial Amendments are created in IRAS and need to be authorised by the Chief Investigator and study Sponsor (the R&D office). This is then emailed to the Research Ethics Committee who reviewed the original study, along with any revised documents (with tracked changes and updated version numbers and dates).

Non substantial amendments are small changes which do not have any significant impact on the study design e.g. minor changes to study documents; updates to contact details. These types of amendments should be submitted using the form below.

notification-non-subs tantialminor-amendm

Examples of substantial and non-substantial amendments can be found on the HRA website. Please contact the R&D department if you are unsure whether your amendment is substantial or non-substantial.

The HRA Assessment team will categorise the amendment according to the UK amendments process and inform the applicant within 5 days. The applicant can then send the amendment and the categorisation information to participating NHS organisations so that, where necessary, arrangements can be put in place to continue the site's capacity and capability to deliver the study. It is the applicant's responsibility to communicate the categorisation and the amendment to English sites (i.e. the local research team, the R&D office and the LCRN, where appropriate).

Further information can be found here:

http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/

http://www.hra.nhs.uk/documents/2016/03/hraapproval-amendments.pdf

NIHR Portfolio adoption (for funded research)

If you have received funding for your research from a NIHR grant or other source, your study may be eligible for adoption onto the NIHR Portfolio. The NIHR Portfolio consists of high-quality clinical research studies that are eligible for consideration for research support from the Clinical Research Network in England.

Portfolio adoption can facilitate feasibility of studies and provide staffing. Recruitment information from these types of studies NIHR portfolio is used to inform NHS research infrastructure funding. Please contact the R&D department to discuss further (before you start your application for approval).
Further information about the Portfolio can be found here: https://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/

Clinical Trials Toolkit

The Clinical Trials Toolkit provides practical advice to researchers in designing and conducting publicly funded clinical trials in the UK. Through the use of an interactive route map, the site provides information on best practice and outlines the current legal and practical requirements for conducting clinical trials.

The toolkit is primarily focused on Clinical Trials of Investigational Medicinal Products (CTIMPs) and the regulatory environment and requirements associated with these. However, it contains useful information and links for all types of research.

http://www.ct-toolkit.ac.uk/

Good Clinical Practice (GCP) training

Compliance with Good Clinical Practice is a legal obligation in the UK and Europe for all drug trials i.e. clinical trials of investigational medicinal products (CTIMPs).

LYPFT R&D recommends that researchers working on all types of NIHR Portfolio studies should undertake GCP training. This should be renewed every 3 years (or more often, depending on changes in legislation, Sponsor requirements etc.) The R&D department will contact you if GCP training is required.

Evidence of training i.e. certificates should be submitted with your application. GCP training is available from the Clinical Research Network. See training link for further details:

https://learn.nihr.ac.uk/

Non Portfolio research

All researchers responsible for obtaining consent should follow the R&D Standard Operating Procedure for Informed Consent which can be accessed on StaffNet or by contacting the R&D office.

Research Passport/Honorary Research Contract/ Letter of Access

External researchers may require an Honorary Research Contract or a Letter of Access from the R&D department in order to carry out the research activities. The R&D department will

You can find comprehensive information about the Research Passport process here:
https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

Applications for research funding

If you plan to submit an application for research funding, please contact the R&D department when you start writing the bid, or at the latest six to eight weeks before the submission deadline. This is so that we can assist you with identifying and attributing costs and to arrange R&D review and sign-off in time for the submission deadline.

For information about the latest NIHR funding opportunities, please check the NIHR website via the following link:

https://www.nihr.ac.uk/funding-and-support/current-funding-opportunities/

Research Design Service

The NIHR Research Design Service (RDS) supports researchers to develop and design high quality research proposals for submission to NIHR and other national, peer-reviewed funding

competitions for applied health or social care research. Further information and contact details for the local RDS can be found here: https://www.rds-yh.nihr.ac.uk/

Further questions?

Please email research.lypft@nhs.net or call the office on 0113 85 54462 if you have any further queries.

Glossary

Chief Investigator (CI)	The designated lead for a research project, with overall responsibility for the conduct of that project. For multi-site projects, a CI may be based within another institution, with the responsibility for the local (Trust based) running of the project devolved to the Principal Investigator. They have responsibility for ensuring compliance with all monitoring and audit procedures.
HRA	The Health Research Authority (HRA) was established on 1st December 2011. Its primary role is to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research. It is responsible for Research Ethics Committees (RECs), the National Social Care Research Ethics Committee, Gene Therapy Advisory Committee and the Confidentiality Advisory Group, which advises on the use of patient identifiable data without consent. http://www.hra.nhs.uk/
HRA Approval	The new approval process for NHS research in England. HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK research ethics service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England
Integrated Research Application Service (IRAS)	The Integrated Research Application System (IRAS) is an online (web-based) system for preparing regulatory and governance applications for health and social care research. It is a UK-wide system, which is provided by the HRA. See more information at http://www.hra.nhs.uk/resources/applying-for-reviews/integrated-research-application-system-iras/
Local Collaborator	This is a role undertaken by Trust staff where the research is primarily being conducted by an external researcher e.g. student. Where the activities at the site are minimal and the CI will undertake most activities, a PI may not be required but a Local Collaborator based at the site must be identified. The Local Collaborator will normally be the individual with whom the CI has negotiated access to the site or the head of the department where the research will take place, e.g. Head of Pharmacy for research involving questionnaires to pharmacy staff
Local Clinical Research Network (LCRN)	These local networks coordinate and support the delivery of research across the NHS in England.
National Institute for Health Research	A virtual institute created following the *Best Research for Best Health* strategy. The goal of the NIHR is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public.
National Institute for Health Research Portfolio Studies	Research projects fitting the criteria for entry onto the NIHR portfolio. These are often multi-site, multi-organisational projects attracting funding resulting from national competition e.g. from NIHR funding sources.
Principal Investigator (PI)	The local (Trust based) lead in a multi-site project. They will report to the Chief Investigator (the overall lead). They have responsibility for the conduct of the research at their site.

Research	The UK policy framework for health and social care defines research as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods
Research Ethics Committee (REC)	Performs independent review of NHS based research to ensure compliance with ethical standards.
Service Development	Can be defined as work directed towards introducing an innovation or the improvement of a service or process, often based on findings of research. An important element of development is the dissemination and implementation of research findings. Development projects are locally focussed with no intention to generalise beyond this local setting.
Sponsor	The organisation providing assurance for the quality of a research project. It may be an NHS organisation, university or commercial body.
UK policy framework for health and social care research	This framework sets out principles of good practice in the management and conduct of health and social care research.

FIGURE 1: RESEARCH APPROVAL FLOWCHART

Richard Sherburn