FAQs

Q1: Is my project research?

Your project is research if it will generate generalisable new knowledge and addresses clearly defined aims and objectives, usually involving data collection. **All** research conducted in South West Yorkshire Partnership NHS Foundation Trust needs to be approved by the Research and Development Department – contact us at Research@swyt.nhs.uk or telephone 01977 605 285.

There are two main types of research; quantitative and qualitative. Quantitative research is designed to test specific hypotheses whereas qualitative research examines meanings and interpretation, focusing on 'how' and 'why' questions (e.g. how do people feel about issues or why do they behave in a particular way). The aim of any research is to develop new knowledge which proves a theory right or wrong and can be generalised to other settings.

If a project is not research, it is usually classified as a service evaluation or a clinical audit. Service evaluation aims to define or judge the current care of a particular service and determine the standard of the service. Clinical audit aims to improve the quality of patient care through systematic review and determine if the service is meeting a predetermined standard.

The National Research Ethics Service (NRES) provide guidance on the categorisation of research, service evaluation and clinical audit. Further information can be found in the Defining Research Leaflet.

Projects from all of these categories require approval of the Trust(s) they are conducted in. But the process of approval varies. Research projects need Research Ethics Committee (REC) and approval from the Trust(s) Research and Development Department (NHS R&D Approval). Service evaluation and clinical audit projects require registration with the Trust's Clinical Governance Team. South West Yorkshire Partnership NHS Trust's Clinical Governance Team can be contacted via cgst@swyt.nhs.uk

Q2: Does my project require Ethical [REC] Approval?

All research projects conducted in the NHS require ethical approval, with the exception of most research involving NHS or social care staff recruited as research participants by virtue of their professional role. Clinical audit or service evaluation projects are not classified as research and do not require ethical review by an NHS Research Ethics Committee (NHS REC).

The National Research Ethics Service provide guidance about whether a project requires REC Review which can be found at: Does my project require review by a Research Ethics Committee?

For further guidance, see the answer to the "Is my project research?" question (Q1) or guidance from the National Research Ethics Service's Defining Research Leaflet.

If you still are unsure how to classify your project, you can send a one page summary using the document template to research@swyt.nhs.uk for advice.

Q3: What is the difference between NHS R&D Approval and REC Approval?

Research Ethics Committee (REC) Approval assesses patient safety and other related ethical dilemmas involved in a research project, such as participant confidentiality, informed consent and ability for participants to withdraw from the study without consequence.

NHS Research and Development (R&D) Approval is the individual Trust(s) who have been requested to take part in the study assessing whether the trust is able to facilitate the research on their premises with the support available. All projects will be checked for compliance with research governance policy and legislation. If your project is non-portfolio (not adopted onto the NIHR portfolio) it will also be scientifically reviewed internally and may be reviewed

for participant sensitive issues by the service user and carer approval panel. It is worth noting here that different terms can be used for 'NHS permission'; R&D approval and NHS R&D approval are used interchangeably. All of these terms essentially have the same meaning; the Research and Development Department in a specific Trust issuing permission to conduct a research project on their premises.

Methodology can also be assessed by both approval processes but mostly tends to be assessed by the funding organisation (where relevant) or the academic institution (for student projects).

Q4: Where can I apply for ethical approval?

Everybody wishing to conduct research within the NHS must apply for ethical approval online, via the Integrated Research Application System (IRAS). Access to IRAS can be found at: https://www.myresearchproject.org.uk/

Q5: What is IRAS?

The Integrated Research Application System (IRAS) is a single system used to apply for permission and approval for health and social care and community care research in the UK. It uses filters which certify whether or not the intended data collection is suitable for the study type. It also helps you meet regulatory and governance requirements. IRAS gathers all information required for all relevant approvals.

Q6: How can I apply for ethical approval?

If you have never used IRAS before, you will need to set up an account at https://www.myresearchproject.org.uk/Users/CreateAccount.aspx

You can also complete the free and easy to use online at IRAS elearning Module to help familiarise yourself with the system if you want to. You can also access free IRAS local training courses – contact us at Research@swyt.nhs.uk or telephone 01977 605 285 for details of upcoming dates.

You don't have to complete your applications all at once as you can save your work and return to it later. The "Project Filter" page will ask questions which filters out sections irrelevant to your project, so you don't need to record the same information more than once. For this reason, it is essential all questions on the project filter page are answered accurately; remember that you can save and return later if you are unsure at any stage.

Once your study has been approved you must not commence your study until you have the relevant NHS Research and Development (R&D) Approval. NHS R&D Approval must be applied for separately via each Trust Research and Development Department.

Your research must start within 12 months of being approved by the Research Ethics Committee. If this does not happen, you will have to submit a substantial re-amendment to the REC and if you do not commence within 24 months, you will have to reapply.

Q7: What support is available for guidance with the NHS R&D Approvals process?

The Research and Development Department supports researchers through the NHS Research and Development (R&D) Approvals process in their Trust.

South West Yorkshire Partnership Trust's Research and Development Department ensures that all research is conducted in accordance with the Research Governance Framework for England and the framework which needs to be followed in order to gain NHS R&D Approval. Research must also be approved by the Trust Director of Research, be in accordance with the protocol, Good Clinical Practice (if relevant) and be approved by the relevant Research Ethics Committee.

For queries to the Research and Development Department, please contact us at Research@swyt.nhs.uk or telephone 01977 605 285.

Q8: How long does it take to get NHS R&D Approval?

We aim to complete NHS Research and Development (R&D) Approval as quickly as possible. Once we have a full set of documents we will check through your research application in detail and confirm within 7 days whether we are in receipt of a full valid set of documents or request further information from you. Once we have confirmed your research application is valid, it will take approximately 4-6 weeks to complete the checks before we can issue you with a decision letter.

Please note we cannot accept draft versions of R&D Forms or SSI Forms or partial sets of documents. Please also ensure you send in the fully signed versions of the application forms. CV's for investigators should be signed and dated and all participant documents should have the date and version number which corresponds to the research ethical approval letter versions and dates.

Q9: I would like to conduct some research in South West Yorkshire Foundation Trust but have a limited time to do so, would this be possible?

It is possible, but not always practical, depending on your time restrictions. You should allow at least 3 months between submitting an application via IRAS(*see "What is IRAS?"*(Q5)for further information) and gaining ethical (REC) and NHS Research and Development (R&D) Approval. You must obtain both NHS R&D and REC Approval as these are different processes *(see "What is the difference between NHS R&D Approval and REC Approval?"* (Q3) for further information), both of which need to be completed (and approved) before your research begins.

If you are not employed by South West Yorkshire Partnership NHS Trust, you may also need a Letter of Access (see *"What is a 'Letter of Access' and do I need one?"* (Q25) for further information) or an Honorary Research Contract (see *"What is an 'Honorary Research Contract' and do I need one?"* (Q26)) to conduct your research here. If so, this application process will take additional time to complete and you may need to produce up to date documents in person to the Research and Development Department.

Q10: What is a NIHR portfolio and non-portfolio research study?

Portfolio studies: The National Institute for Health Research (NIHR) has a 'Portfolio' of clinical research studies that are of high-quality and clear value to the NHS. Portfolio studies are high-quality clinical research studies that have gone through rigorous checks and are eligible for consideration for support from the Clinical Research Network (including access to local Clinical Support Officers, who can help with recruitment). Portfolio studies are usually larger projects which are based at a number of different research sites (and so require NHS R&D Approval from a number of local Trusts). There is particular eligibility criteria for portfolio studies, which is described on the NIHR Website

Non-portfolio studies: Non-portfolio studies are often smaller scale studies which are undertaken by staff members or Masters/PhD students. These studies are usually based at only one or two sites and are managed and co-ordinated independently by the researcher. They are not eligible for adoption onto the NIHR Clinical Research Portfolio and are funded by the researcher themselves or smaller grants.

Q11: Where can I access information and advice on the methodology of my research?

(Potential) Portfolio Studies:

The National Institute of Health Research (NIHR) Research Design Service for Yorkshire & the Humber (RDS YH) supports researchers to develop and design high quality research proposals for submission to the NIHR and other national, peer-reviewed funding competitions for applied health or social care research**.** This support is provided free of charge. More information about this service can be found on their website at: Research Design Service

Clinical trials using medicinal products must be conducted in accordance with Good Clinical Practice (GCP) standards. This has been the law since May 2004.

The GCP standards to follow within the EU can be found at the following websites:

- Commission Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001
- Commission Directive 2005/28/EC of 8 April 2005
- International Conference on Harmonisation (ICH)

For clinical trials, you can access the Clinical Trials Tool Kit which provides practical help when trying to meet requirements of the UK Medicines for Human Use Regulations, 2004.

The Data and Tissues Tool Kit provides practical help focussing on the planning and approvals stage of setting up a research project.

Non-Portfolio Studies:

For student research projects, the first port of call for information and advice about methodology is your academic supervisor. The Research and Development Department is also able to provide some advice to researchers – contact us at Research@swyt.nhs.uk or telephone 01977 605 285 to book an appointment.

If you are unsure if your project is portfolio or non-portfolio, see the answer to *"What is a NIHR portfolio and non-portfolio research study?"*(Q10) for further information.

Q12: Where can I get funding for my research project?

The National Institute for Health Research (NIHR) provides funding through their NIHR schemes. Information can be found on their website at Comprehensive Local Research Network. The NIHR do not implement service development, this is the role taken up by external organisations such as the National Institute for Clinical Excellence (NICE).

Funding opportunities can also be found on the National Institute of Health Research Design Service website at the Research Design Service

Other research grants are also available for smaller studies from various sources.

Q13: What is Site Specific Information?

Site specific information is information that each site involved needs to know about the research project. This includes details of local leads, the local research team, local recruitment targets and details about how participants will be recruited locally. Different information is provided to each Trust that is involved in the project to enable them to complete the necessary local governance checks that allows NHS Research and Development (R&D) Approval. The Principle Investigator of the study is required to complete the Site Specific Information form.

Q14: What is a Chief Investigator (CI)?

The Chief Investigator of a research project is usually employed by the project sponsor organisation and takes overall responsibility for the design, management and reporting of the study. The Chief Investigator usually writes the study protocol (see *"Where can I apply for ethical approval?"* (Q4) and *"What is IRAS?"*(Q5)for further information).

For student projects (up to doctorate level), the academic supervisor acts as the Chief Investigator. For all doctoral research projects, the PhD student is the Chief Investigator. For some smaller projects running only at one site, the same person may be both the Chief Investigator and the Principal Investigator.

Q15: What is a Principle Investigator (PI)?

The Principal Investigator is a local lead for the project and is the person responsible for the conduct of the study at a particular research site (see *"What is a Research Site?"*(Q18)for further information).

For large portfolio studies, the Principle Investigator usually works for the local NHS Trust which is hosting the study. For some smaller projects running only at one site, the same person may be both the Chief Investigator and the Principal Investigator.

Q16: What is a Sponsor?

The Sponsor is the organisation that takes on the overall responsibility for the project (including confirming there are appropriate arrangements to initiate, manage, monitor and finance the study). The Sponsor is normally expected to be the lead employer of the research team, the lead health or social care organisation, or the main funder. Usually the sponsor is the employer of the Chief Investigator. For student projects, the sponsor is the academic institution connected to the study.

Q17: What is a Local Collaborator?

A Local Collaborator is an individual willing to collaborate and assist in a research project at a local research site (see *"What is a Research Site?"*(Q18) for further information).

Q18: What is a Research Site?

A Research Site is an organisation which is participating in a study but is not acting as a Sponsor (see *"What is a Sponsor?"*(Q16) for further information). Individual NHS Trusts are different Research Sites. A Research Site will conduct local checks to ensure that the study passes certain approval criteria and can be supported in that organisation before giving permission for the study to commence at that site.

Q19: What is a Participant Identification Centre (PIC site)?

A Participant Identification Centre is an organisation which identifies and informs potential participants about a study taking place in another organisation. A Participant Information Centre is not responsible for the recruitment of participants or the delivery of the research.

Q20: What is a Participant?

A Participant is an individual who consents to take part in a study. A Participant can be a patient, service user, carer, relative of the deceased, professional carer, other employee or member of the public.

Q21: What is a Participant Information Sheet?

A Participant Information Sheet is a document explaining in clear language all relevant study information to allow individuals to understand the expectations and requirements of a particular study and decide if they want to be a participant (see *"What is a Participant?"*(Q20) for further information).Participant Information Sheets tell potential participants what a research project is about, what they are being asked to do if they take part, and what will happen to the information that is collected.

In most cases where you are involving service users, carers or staff in a research project, you will need to develop clear participant information sheets to clearly explain to each individual what participating in the study involve. Further guidance is provided by the National Research Ethics Service (NRES): National Research Ethics Service. Their Info Sheet and Consent Form Guidance' Document is particularly useful and provides templates for researchers.

Q22: What is a Consent Form?

A Consent Form is a document that participants sign to confirm (and evidence) their informed consent to take part in a project. In most cases where you are involving service users, carers or staff in a research project, you will need to develop consent forms for each participant to fill in (and sign) before taking part in a study. The participant, a carer or advocate sign the Consent Form to say they understand what they are being asked to do in taking part in the research, that they can withdraw if they wish, and have had any questions answered. The main exception to this is

when participants are completing an online questionnaire or survey (as consent is implied via completion of the questionnaire). Further guidance is provided by the National Research Ethics Service (NRES): National Research Ethics Service Their 'Info Sheet and Consent Form Guidance' Document is particularly useful and provides templates for researchers.

Q23: I'm having difficulties recruiting, can anyone advise me?

Contact us (at Research@swyt.nhs.uk or telephone 01977 605 285) if you are having problems recruiting as we will try our best to provide advice and information that will help you recruit more participants to your study. We also facilitate a Service User and Carer Group which can provide helpful advice for studies where participant sensitive issues may be affecting recruitment. For portfolio studies *(see "What is a NIHR portfolio and non-portfolio research study?"* (Q10) for further details), South West Yorkshire Partnership Trust's Clinical Support Officers may be able to actively assist with recruitment.

Q24: What is a 'Research Passport' and do I need one?

All researchers who are not employed by the NHS are required to complete a Research Passport application form if they are conducting research on NHS premises. A Research Passport is the standard way to issue NHS Honorary Research Contracts or Letters of Access to those with "no contractual relationship with the NHS, wishing to conduct studies in the NHS". Research Passports address issues of responsibility, accountability, patient safety and duty of care for studies where external researchers complete research projects within a Trust. Enhanced Criminal Record checks and Occupational Health checks are often included as part of the application process. The Research Passport system also provides a streamlined, standard application system which saves valuable time and resources of NHS departments and researchers. Importantly, it minimises the demand for repeated checks for every external researcher by providing guidance on the circumstances when it is reasonable to rely on assurances offered by those who have already conducted these checks.

The Research and Development Department processes the Research Passport application and issues either a Letter of Access *(*see *"What is a 'Letter of Access' and do I need one?"* (Q25) for further information*)* or an Honorary Research Contract *(see "What is an 'Honorary Research Contract' and do I need one?"* (Q26) for further information*)* for the external researchers who will conduct the research in the Trust.

If you have any queries, please contact the Research and Development Department, at Research@swyt.nhs.uk or telephone 01977 605 285.

Please see the Research Passport Procedure or the Research in the NHS - HR Good Practice Resource Pack for more information.

Q25: What is a 'Letter of Access' and do I need one?

Letters of Access are required for researchers who are completing research in the NHS which do not change interventions or patient care in any way, such as conducting interviews or questionnaires. A Letter of Access is a document issued to researchers which will have certain restrictions applied (e.g. not affecting patient care). They will be bound by certain codes of conduct but are employed by an external organisation (e.g. a University). Enhanced Criminal Record checks and Occupational Health checks may be included as part of the application process.

Letters of access are issued by the Research and Development Department based on the information provided in the Research Passport application. If you require a Letter of Access, you do not require an Honorary Research Contract. If you have any queries, please contact the Research and Development Department, at Research@swyt.nhs.uk or telephone 01977 605 285.

For more information on Letters of access and Honorary Research Contracts please see the Research in the NHS - HR Good Practice Resource Pack.

Q26: What is an 'Honorary Research Contract' and do I need one?

Honorary Research Contracts are required by researchers who are not employed by the NHS and who are completing research which impacts on patient care in the NHS. Honorary Research Contracts are often put in place if a researcher wishes to undertake a longer standing or more complex role in a research project running in a Trust than those simply requiring a Letter of Access. The contract provides insurance protection and binds the individual to abide by applicable organisation rules and regulations (e.g. the contract does not allow the individual to access confidential information without consent).

Honorary Research Contracts are issued by the Research and Development Department based on the information provided in the Research Passport application. f you require an Honorary Research Contract, you do not require a Letter of Access. If you have any queries, please contact the Research and Development Department, at Research@swyt.nhs.uk or telephone 01977 605 285.

For more information on Letters of access and Honorary Research Contracts please see the Research in the NHS - HR Good Practice Resource Pack.

Q27: How can I learn more about research?

Local training opportunities in South West Yorkshire Partnership Trust are updated onto the 'Training' section of this site.

The internet has a wealth of in depth information about research and training available locally and nationally. RDInfo is one useful resource, with details about opportunities ranging from short courses and workshops to postgraduate qualifications for UK health professionals: http://www.rdlearning.org.uk

We are always happy to help and signpost to other useful information when we can – please contact us at Research@swyt.nhs.uk or telephone 01977 605 285.

Q28: How can Trust Service Users/Patients or Carers get involved in research?

South West Yorkshire Partnership Trust highly values input from service users and carers into the health research projects that run within the trust.

A common way for service users and carers to be involved in research is as participants in research projects running in the Trust. A key aim for researchers is to generate new knowledge that will allow future services to be more effective for service users and carers. Information about research projects that service users and carers can get involved in as participants are circulated widely in the Trust (often posters are put up and leaflets distributed as well as 'word of mouth' via Trust 'Steering Group' events) and advertised in Trust publications (e.g. via the Intranet, 'Staff Focus' and 'Like Minds' magazine).

The Research and Development Department also facilitate a working consultation group which comprises of service user and carers that are interested in health research and represent the trust in terms of both geography (i.e. comprising members from Kirklees, Calderdale, Wakefield and Barnsley) and the different services the Trust includes. This group provides key input into the health research projects that run in South West Yorkshire Partnership Trust to ensure that the ethical standard and quality of research projects remains high. The aims of the group are:

- To provide important service user and carer input/advice to researchers setting up studies which include participant sensitive issues in the Trust.
- To help researchers recruit more service users and carers as participants to research projects in the Trust.
- To form an important part of the research project approvals and review process for non-portfolio studies which involve service user and carers in the Trust (alongside Research and Development approval and

scientific peer review). Crucially this involves providing approval for smaller research projects that include a range of participant sensitive issues.

- To undertake focussed pieces of research work, as agreed with the Research and Development Department.

If you would like more information about the group, including information about how to get involved and what getting involved requires, please contact the Research and Development Department, at Research@swyt.nhs.uk or telephone 01977 605 285.