South West Yorkshire Partnership NHS Foundation Trust

Document name:	Procedure for set-up and sponsorship of Research Projects at SWYPFT
Document type:	Procedural document
What does this policy replace?	Research and Development Project Approvals Procedure V2.0
Staff group to whom it applies:	All staff and external researchers wanted the Trust to host or Sponsor their research projects
Distribution:	The whole of the Trust
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Approved by:	Medical Director
Developed by:	Research and Development Manager
Director leads:	Medical Director
Contact for advice:	Research and Development Manager

1. Introduction

This procedure describes how researchers obtain the appropriate permissions to undertake their research project at SWYPFT. It also describes how researchers can apply for SWYPFT to act as research 'Sponsor' for their project. It replaces the previous procedure 'Research Project and Sponsorship Approval Procedure V2.0'.

Health and social care research in the UK is regulated, to ensure that research is carried out to the highest ethical and scientific standards, and to prevent poor performance, adverse events where possible, research misconduct and fraud. The regulatory environment also helps ensure that lessons are learned and shared when poor practice is identified. Organisations involved in clinical research have a duty to foster a high quality research culture and individuals have a duty to ensure that they, and those they manage, are appropriately qualified by training, education and experience for the roles that they undertake.

The Health Research Authority (HRA) was established in December 2011 to promote and protect the interests of patients in health research and to streamline the regulation of research. In accordance with the new Care Act provisions of 2014 it was established as a new, statutory Non Departmental Public Body as of 1 January 2015. HRA Approval is now the route for all project-based research to commence in the NHS in England and replaces the previous arrangements for NHS (management) permission ('local R&D approval') which each individual NHS organisation undertook (described for SWYPFT in the previous version (V2.0) of this document).

HRA Approval combines an assessment of governance and legal compliance, with the independent NHS Research Ethics Committee (REC) opinion provided through the HRA's 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.

This procedure describes how researchers make an application for SWYPFT to take part in or sponsor their research study, how this relates to HRA approval and the local arrangements to 'assess, arrange, confirm capacity and capability'.

This procedure has been developed with reference to resources provided by HRA, the National Institute for Health Research (NIHR) and the NIHR Clinical Research Network.

1.1. UK Policy Framework for Health and Social Care Research

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK. It replaces the Department of Health's Research Governance Framework for Health and Social Care, (2005) and applies to all research undertaken within the NHS and within a social care setting.

The Framework sets out a number of principles which protect and promote the interests of participants in health and social care research through ethical conduct and proportionate management of high quality research. Responsibilities of organisations and individuals with specific roles in health and social care research

are also described. NHS organisations are required to 'have regard' to the Framework in accordance with the Care Act 2014.

1.2 Health Research Authority Approval

HRA approval is required for **all** projects to be undertaken within the NHS and defined by the UK Framework as 'research'. Such projects may involve staff, service users, carers or members of the public and/or their data or information. HRA approval provides assurance to participating NHS organisations that the research project conforms to the requirements of the Framework and relevant legislation.

Participating NHS organisations are required to 'assess, arrange and confirm' that they have the 'capacity and capability' to take part given the requirements of each particular study. Formal written 'confirmation' of capacity and capability replaces what was 'NHS management permission' (often referred to as 'local R&D approval' and described for SWYPFT in previous versions of this document) and can only be issued once HRA approval has been granted.

1.3 Integrated Research Applications Service (IRAS)

Applications for all research-related permissions are made via the Integrated Research Applications Service (IRAS); an online tool helping researchers to avoid unnecessary duplication of effort when preparing regulatory submissions. Information is entered once and used to automatically populate whichever application forms are required.

HRA provides guidance to help researchers determine which approvals are required for their project in addition to HRA approval and all applications are prepared using IRAS. For example, NHS Research Ethics Committee (REC) 'favourable opinion', required for many projects, is sought via a combined application with HRA approval.

1.4 National Institute for Health Research Clinical Research Network Portfolio

The NIHR Clinical Research Network provides researchers with practical support necessary to deliver their studies within the NHS. Studies which are included in the NIHR Clinical Research Network portfolio (often referred to as 'portfolio studies') have the potential to access support provided through the network; at SWYPFT this support includes the Clinical Research Officers within the Research and Development team. Studies not included in the portfolio (often referred to as 'non-portfolio') are unable to access this support. With the implementation of HRA Approval the permissions process is now the same for both 'portfolio' and 'non-portfolio' studies - with the exception of an additional application step (made via IRAS) for eligible studies to join the portfolio where appropriate.

2. Purpose of document

2.1 Procedural statement

This procedure details how the UK Framework for Health and Social Care Research and Health Research Authority approval are implemented within the Trust. It describes the local process by which researchers gain permission to undertake their projects at SWYPFT and can request that SWYPFT acts as Sponsor.

2.2 Purpose of the document

This procedure aims to inform all those considering undertaking research activity within the Trust and to clearly state the procedures required before a research project can commence at SWYPFT.

This procedure excludes service evaluation, practice development and clinical audit projects which are managed locally as part of the Clinical Audit and Practice Evaluation Policy (Jan 15; available on the Trust's intranet).

2.3 Development process

This procedure has been developed to ensure SWYPFT can participate in research and development that is compliant with national guidance and legislation.

This procedure will be reviewed in two years unless national guidance or legislation requires an earlier review. This policy will be reviewed by consultation with stakeholders along with the results of any monitoring of the compliance and effectiveness of this procedure.

Identification of stakeholders

Stakeholder	Level of involvement
Research and Development Manager Medical Director Associate Director for Research Honorary Professor of Applied Mental Health Research Research Administrator Clinical Research Officers	Development
Information Governance Manager Finance Manager Human Resources Manager Independent R&D colleagues from other NHS organisations	Consultation
Medical Director	Approval

2.4 Equality impact assessment

The completed equality impact assessment is in Appendix C.

3. Definitions

3.1 Type of procedural document

This is a procedure document describing the "how"; and will give detailed guidance to researchers wanting to undertake their research projects at SWYPFT or who would like SWYPFT to act as research sponsor. The procedure provides a step-by-step guide, which someone not familiar with the work can follow. It is a mandatory procedure relevant to all staff wanting to undertake a research project at SWYPFT.

It will ensure research and development activity is carried out in accordance with national standards and guidance.

Appendix A includes a glossary of acronyms and definitions.

4. Duties

4.1 Medical Director

Responsible for assuring themselves of the compliance with the related aspects of this procedure and representing such assurances at Trust Board. In addition they should ensure appropriate approval and ratification of this procedure, and be the signatory for agreements pertaining to research (including but not limited to the agreed 'Statement of Activity' or Clinical Trial Agreement). This includes responsibility for confirming that:

- a research project that SWYPFT sponsors or participates in is compatible with organisational priorities,
- SWYPFT has the necessary capacity and capability to undertake the research project.

The Medical Director may delegate these duties to a senior clinical researcher (Associate Director for Psychological Therapies Research) where appropriate.

4.2 Director of Finance

Authorised signatory on contracts pertaining to research projects (e.g. Clinical Trial Agreement) where finances are exchanged. Joint signatory, with the Medical Director, for any research project involving a commercial Sponsor.

4.3 District Director or delegated Deputy District Director, Clinical Lead/General Manager

Responsible for approving that the research project is appropriate to be carried out and accommodated within the service. This ensures any likely impact on services has been considered throughout the conduct of the study.

4.4 Associate Director for Psychological Therapies Research

The Associate Director for Psychological Therapies Research has delegated authority from the Medical Director to, in the Medical Director's absence, be the signatory for research approvals and agreements (including but not limited to the agreed 'Statement of Activity' or Clinical Trial Agreement). This includes the responsibility for confirming that:

- a research project that SWYPFT sponsors or participates in is compatible with organisational priorities,
- SWYPFT has the necessary capacity and capability to undertake the research project.

4.5 Research and Development Manager

Responsible for the effective implementation, compliance and operation of this procedure, managing studies through the relevant permissions process and ensuring all relevant staff are aware of the procedure. Also, has the responsibility for allocation of staffing resource from the Research and Development (R&D) team to support delivery of studies included within the NIHR Clinical Research Network

portfolio and is the authorised signatory for Letters of Access under the Research Passport scheme.

4.6 Procedural document author
Responsible for actioning the Trusts 'Policy on Policies document' and ensuring all procedural documents for which they have responsibility are developed, reviewed, authorised, ratified and implemented in accordance with the requirements of the policy, and that they have been put onto R&D website:
http://nww.swyt.nhs.uk/research-development/Pages/default.aspx

4.7 Chief Pharmacist (or delegated representative)
Responsible, in consultation with the Medical Director, for supporting the assessment and arrangement of capacity and capability for any research projects involving medicinal products, including clinical trials. This would include consideration of all aspects of supply, storage and pharmacovigilance aspects of the study, as appropriate.

4.8 Information Governance Manager (or delegated representative)
Responsible for provision of advice on research related information governance issues to the R&D team and all those involved with research. This may include supporting the assessment and arrangement of capacity and capability for research projects where appropriate.

4.9 Human Resources Manager
Responsible for provision of advice and support to employees and managers in the application of this procedure with regard to employment issues. They will provide guidance on the interpretation and application of the Research Passport scheme and may also provide support for the assessment and arrangement of capacity and capability for research projects where appropriate.

4.10 Line Managers
Responsible for ensuring that staff participating in research within their areas of responsibility, are aware of, and follow, this procedure. They have the responsibility to ensure that their research active staff are appropriately trained and have the adequate support (e.g. time, resource and supervision) to undertake the research.

4.11 Finance Manager
Responsible for advising and supporting researchers preparing applications for research funding with costing of projects. They will support the assessment and arrangement of capacity and capability for research projects where appropriate by helping to assess any financial risks associated with a study with reference to costings outlined in the Statement of Activities, Schedule of Events and/or Clinical Trial Agreement.

4.12 Research & Development Staff
Responsible for maintaining an up to date knowledge and awareness of HRA guidance, the requirements of the UK Framework for Health and Social Care Research and any legislation or policy relevant to research (including local standard operating procedures). Acts as a source of support and guidance to research active staff helping to coordinate the timely assessment, arrangement and confirmation of

capacity and capability for each study. Responsible for providing practical support for set-up and delivery of studies included in the NIHR Clinical Research Network portfolio.

4.13 Members of research involvement group and scientific reviewers
Responsible for providing objective reviews in a timely manner for accepted research projects. Responsible for maintaining confidentiality with respect to research project information submitted for review, in accordance with Trust guidelines.

4.14 Research Active Staff
Responsible for seeking written approval (email) from their line manager to work on a particular research study. Any member of staff who becomes aware of any practice that is not in accordance with this procedure, or where there are difficulties with implementing this procedure, has a responsibility to report this to their line manager who will assess the problem. If there is a problem specifically with this procedure this should be reported to the document author, who will consider if immediate changes to the procedure are required or note for consideration at the next review of the procedure.

There are specific responsibilities as outlined in the UK Framework for Health and Social Care Research for the research roles as follows (and for those involved with Clinical Trials of Investigational Medicinal Products these are subject to specific legislation):

- Chief Investigators
- Principal Investigators and Research Teams
- Project Sponsors
- Project Funders
- Research Sites
- Those responsible for the care of participants involved in research projects.

Staff undertaking these roles should ensure they are aware of, and accept their responsibilities as outlined in the UK Framework for Health and Social Care Research.

5. Procedure

The following sections provide basic guidance for researchers wanting to set up a research study within the NHS and specifically within SWYPFT. The actual steps researchers need to take will vary from study to study as outlined below. We advise all researchers to familiarise themselves with HRA guidance and to make early contact with the R&D team at research@swyt.nhs.uk and the relevant local clinical service expected to host the research in order that the local process for assessing, arranging and confirming SWYPFT's capacity and capability to undertake the study can be carried out in parallel to HRA and other regulatory reviews.

5.1 How do I know that my project is 'research'? – How do I establish which permissions I need?

An important first step is confirming that your project is defined as 'research' (i.e. rather than another type of project such as service evaluation or audit). Only

projects defined as ‘research’ fall within the scope of the UK Framework for Health and Social Care Research and this procedure.

The HRA website includes guidance and a decision tool to help researchers define whether their project is ‘research’: http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research/

If you think your project is service evaluation, rather than research, please contact research@swyt.nhs.uk. Please include the findings from the HRA decision tool and any relevant information to support your conclusion. If your project is defined as ‘service evaluation’ the R&D department will confirm this in writing and you will be asked to submit a CAPE project registration form to the Quality Improvement and Assurance Team – see http://nww.swyt.nhs.uk/clinical-governance/Pages/Clinical-audit-practice-evaluation.aspx for more information.

If you have read the HRA guidance and completed the decision tool but are still unsure whether your study is research please contact research@swyt.nhs.uk together with your project proposal. The R&D team will work with you to confirm whether or not your study is defined as research.

If your study is defined as ‘research’, the permissions required will depend on the type of study you are undertaking. All research taking place within the NHS requires HRA approval. Many research studies also require NHS Research Ethics Committee favourable opinion. Other types of research study require additional permissions. The HRA website includes guidance to help you categorise your research project and determine which permissions are required. Depending on how your study is funded, it may be eligible to be included in the National Institute for Health Research (NIHR) Clinical Research Network portfolio (see section 5.5) which requires a separate application. If you are still unsure which permissions are required for your study after reviewing the HRA information please contact research@swyt.nhs.uk.

5.2 Will SWYPFT sponsor my research study?

All research studies require a ‘Sponsor’; defined as the organisation taking responsibility for the initiation, management and financing of a research study (see HRA website for more detail: http://www.hra.nhs.uk/research-community/before-you-apply/roles-and-responsibilities/).

For a study undertaken as part of a postgraduate qualification (for example Masters or PhD), the Sponsor will usually be the relevant University. For other studies, the Sponsor may be a University, NHS Trust or Pharmaceutical company.

The ‘Chief Investigator’ acts on behalf of the sponsor and is responsible for the conduct of the whole research project (see above link to more detail on the HRA website). The employing organisation of the Chief Investigator for a study often acts as the Sponsor.

If you are employed by SWYPFT, do not have formal links with a University for your research project or any other potential Sponsor and would therefore like SWYPFT to

act as Sponsor for your study, please contact research@swyt.nhs.uk with a summary of your project. The R&D team will work with you to undertake an assessment (including risk) of the study (using tools provided by the National Institute for Health Research) and confirm whether SWYPFT can accept the role of Sponsor for your project. SWYPFT is unable to act as Sponsor for Clinical Trials of Investigational Medicinal Products or for research studies where the Chief Investigator is employed elsewhere.

Sponsor organisations are required to complete a declaration within applications for HRA approval and other permissions. The Medical Director completes the declaration on behalf of SWYPFT and is ultimately responsible for deciding whether SWYPFT will act as Sponsor for a given study. It is therefore important that you contact the R&D team at research@swyt.nhs.uk as early as possible in the process if you would like SWYPFT to act as Sponsor so as not to delay your application.

Please note that if you intend for SWYPFT to act as Sponsor for your study, researchers are still expected to prepare all relevant study documentation and supporting information and to submit all relevant regulatory applications for their study. The R&D team are happy to help advise and guide researchers but unfortunately we can't fill in the IRAS form for you.

5.3 How do I prepare approval application(s) for my research project?

5.3.1 Prepare applications in IRAS

All applications for permissions for research, including HRA, NHS Research Ethics Committee (REC), application for inclusion in the NIHR Clinical Research Network portfolio and other approvals are generated using the Integrated Research Application System (IRAS): www.myresearchproject.org.uk.

IRAS allows researchers to enter information about their study **once**. The system then automatically populates relevant application forms with the information, thus minimising unnecessary duplication.

New users will need to create an account for the system and are strongly advised to complete the e-learning guide. IRAS also has an extensive online 'help' section to guide users through the various applications.

Having established that your project is defined as 'research', you will be required to categorise your study within IRAS, this in turn dictates which approvals are required. This is an important step – IRAS displays only the questions needed for those approval applications relevant to your selected category of study. Categories are listed on the HRA website and IRAS includes further guidance to help you decide which to select. If you are unsure which category to choose please contact research@swyt.nhs.uk.

5.3.2 Application to include study in NIHR Clinical Research Network Portfolio (if relevant)

Depending on how it is funded, your study may be eligible to be included within the National Institute for Health Research (NIHR) Clinical Research Network (CRN)

portfolio and applications for portfolio status are also made within IRAS. Portfolio studies are eligible for NHS service support (funding and infrastructure provided through the NIHR CRN). The R&D department includes a team of Clinical Research Officers funded by the NIHR CRN who are available to help set up and deliver portfolio studies at SWYPFT. If you think your study might be eligible for the NIHR CRN portfolio and you would like our Clinical Research Officers to help with your study, please contact research@swyt.nhs.uk for advice.

5.3.3 Prepare study documentation and participant information
In addition to completing the relevant application forms in IRAS you will also need to prepare appropriate documentation for your study; for example a study protocol or participant documents (for example Participant Information Sheets and Consent Forms).

Guidance on preparing study documentation is available on the HRA website – including links to protocol templates and detailed guidance on preparation of participant information and consent documents: http://www.hra.nhs.uk/research-community/before-you-apply/.

5.3.4 Seek input from representatives of your participant population ('Patient & Public Involvement)
HRA advises researchers to seek input on study design and participant information from representatives of those they intend to recruit to the study. SWYPFT has a Research Involvement Group comprising service users and carers who offer comment and advice to researchers on participant documentation from the perspective of the participant. The Group meets monthly and if you would like them to review your research and associated participant information please contact research@swyt.nhs.uk. Documents for review need to be submitted to the Group at least a week ahead of the meeting (planned for the first Wednesday of every month). The Chief Investigator is invited to attend and discuss any issues raised in terms of participant recruitment and procedures and a written summary of feedback is provided.

5.3.5 Ensure the study protocol has been appropriately peer reviewed
It is the Sponsor's responsibility to ensure the study has been subject to appropriate scrutiny and for academically Sponsored studies we would usually expect this to be organised via the University or be part of the funding application for the research. HRA and REC review include seeking assurance that the project has been subject to appropriate scientific scrutiny. The R&D department can help arrange scientific peer review for your study if you have not been able to arrange this elsewhere. Please contact research@swyt.nhs.uk for advice.

5.3.6 Prepare supporting documentation (as advised by regulatory bodies)
In addition to study documentation, you will also need to prepare and provide supporting information for each application. Guidance is available in IRAS and on the relevant regulatory body's website. Good preparation and an awareness of the supporting documentation required is essential for a timely application so it is never too early to start finding out what is required!

5.3.7 Liaise with participating sites to assess, arrange and confirm local capacity & capability for the study

As soon as you have identified potential participating sites for your study, we advise you to contact the local clinical team identified to host the research and the organisation's R&D team; for SWYPFT contact research@swyt.nhs.uk. HRA outlines a process and specific expectations for how researchers (acting on behalf of the Sponsor organisation) should work with the NHS organisations participating in the research. Expectations of participating NHS sites are outlined by the Sponsor in a 'Statement of Activities' and 'Schedule of Events'. Participating NHS sites are required to 'assess, arrange and confirm' that they have the 'capacity and capability' to undertake the study as per the requirements specified in the Statement of Activities and Schedule of Events.

If you would like SWYPFT to participate in your study you will need to submit **as a minimum** the study protocol (version submitted for HRA and other approvals), Statement of Activities and Schedule of Events and all relevant HRA correspondence (e.g. HRA approval or initial assessment letter) to research@swyt.nhs.uk.

5.3.8 Have regard to relevant legislation, regulation and local policies

Applicants are advised to be aware of local SWYPFT policies and any legislation relevant to their study and have regard for this as they develop their study design, protocol and participant documentation. The regulatory reviews will be assessing the study to ensure it conforms to the UK Framework for Health and Social Care Research and any relevant legislation and therefore it helps if applicants have a good awareness of legislation relevant to their study as they develop the study design, protocol and participant documentation. The HRA website includes information and links to legislation relevant to research: http://www.hra.nhs.uk/resources/research-legislation-and-governance/.

Examples are given below:

Mental Capacity Act 2005

A framework for decision making on behalf of adults aged 16 and over who are unable to make decisions for themselves. Relevant to studies involving participants who may lack mental capacity to consent (or where loss of capacity may occur during a study). More information is available here: http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/

Note that the Medicines for Human Use (Clinical Trials) Regulations 2004 make specific provision for involving adults who lack capacity in Clinical Trials of Investigational Medicinal Products (CTIMPs).

HRA's tool to help researchers design participant documentation includes sections relevant to involving individuals who may lack capacity: http://www.hra-decisiontools.org.uk/consent/

Data legislation and information governance

The HRA website includes information and resources on legislation relevant to use of personal data in research:
http://www.hra.nhs.uk/resources/data-legislation-and-information-governance/.

Medical Research Council (MRC) has a helpful website dedicated to research which includes e-learning on 'research data and confidentiality':
http://www.mrc.ac.uk/research/facilities/regulatory-support-centre/

SWYPFT Policies & Procedures
SWYPFT staff involved in research activity must be aware of the requirement to comply with relevant SWYPFT procedures, including:

- Information governance
- Fraud and misconduct
- Health and safety

Researchers must also be aware of the requirements outlined within the SWYPFT Research Project Monitoring & Audit Procedure.

SWYPFT policies and procedures including those referred to above, elsewhere in this document and others that may be of relevance to staff involved in research can be found on the document store on the Trust's intranet:

5.4 When should I submit my application(s)?

Applicants are advised to apply for relevant permissions for their project across all review bodies in parallel and to make early contact with research@swyt.nhs.uk if you would like SWYPFT to take part in your study.

A research project can only commence at SWYPFT once Health Research Authority (HRA) Approval and all other relevant approvals are in place **and** SWYPFT has confirmed in writing that it has the capacity and capability to undertake the study (in practice via the Statement of Activities or Clinical Trial Agreement where relevant).

The HRA outlines how it expects Sponsors and Chief Investigators to work with their participating sites: http://www.hra.nhs.uk/resources/hra-approval-guidance-for-sponsorschief-investigators-working-collaboratively-with-nhs-organisations-in-england/

As part of the assessment of local capacity and capability (coordinated by the R&D team on behalf of SWYPFT), researchers will be expected to work with the R&D team to demonstrate that:

- Chief/Principal Investigators at SWYPFT have support from their line manager to undertake the research study and the impact on the proposed host service has been considered
- Relevant Deputy District Director (or delegated Clinical Lead/General Manager) is aware of the study and has confirmed that the study can be accommodated by the proposed host service

The R&D department have developed a checklist and guidance to help document the 'assess, arrange, confirm capacity and capability' process (Appendix B).

'Confirmation' is issued by the Medical Director (via a signed Statement of Activities or Clinical Trial Agreement. Where appropriate the Finance Director, Caldicott Guardian, HR Manager or Chief Pharmacist will be consulted as part of the assessment of capacity and capability for relevant studies (see part 4).

5.5 Will I be able to get any help with my study?

If your research study is eligible for inclusion in the NIHR Clinical Research Network portfolio you may be able to access practical support to help with your study. If your study is funded through open, national competition with peer review then it may be eligible – more information is available here. You can apply for inclusion in the NIHR CRN portfolio via the IRAS system by completing a 'Portfolio Application Form'. Portfolio status will only be confirmed once your study has the relevant approvals in place – i.e. HRA and any other necessary regulatory approval. Studies included in the portfolio will be assigned a 'lead' Local Clinical Research Network which will help coordinate network support for your study. The 'lead' network is usually allocated based on the Chief Investigator's location; SWYPFT is part of the Yorkshire & Humber network. More information is available here.

SWYPFT is measured on set-up and delivery performance for NIHR Clinical Research Network portfolio studies that we support. In addition, SWYPFT has an annual target for recruitment of participants to portfolio studies and researchers can contribute by ensuring eligible studies are included in the portfolio where appropriate. The R&D team includes Clinical Research Officers who work alongside researchers and clinical services to provide practical support to set-up and deliver portfolio studies. If you think your study might be eligible for inclusion in the portfolio and you would like help with your study please contact research@swyt.nhs.uk to discuss this further.

5.6 When will I be able to start my study at SWYPFT?

If you are a SWYPFT employee, you can commence your study once HRA approval has been granted (which will also require all other relevant regulatory approvals to be in place) **and** SWYPFT has confirmed capacity and capability to undertake the study (via a signed Statement of Activities or Clinical Trial Agreement). In exceptional circumstances the HRA approval letter will state that local sites are not expected to confirm capacity and capability and that the study can start after a specific period of time unless the NHS site objects or requests further consideration time. Under these circumstances we would still expect researchers to work with the R&D team (as advised by HRA) and we will provide a signed Statement of Activities confirming capacity and capability (consistent with HRA's preference for sites to support researchers to commence such studies as soon as possible).

External researchers conducting research within SWYPFT may require a letter of access or honorary research contract **before** the project can commence at the trust. We operate the Research Passport scheme – see http://www.nihr.ac.uk/policy-and-standards/research-passports.htm and where possible Letters of Access or Honorary Contracts will be issued in parallel with confirmation of capacity and capability to undertake the study. The SWYPFT research passport procedure gives further details

5.7 How long will it take to gain approval for my study?
This will depend on the nature of your study and how long it takes you to prepare for your submission. Some regulatory approvals are subject to statutory timelines or performance targets; in most cases the 'clock' starts only when an applicant has submitted a complete application and resolved all outstanding queries.

If your study requires NHS Research Ethics Committee favourable opinion, you can expect to receive that within 60 days of a valid submission (or sooner if your study is eligible for 'proportionate review' – see http://www.hra.nhs.uk/research-community/applying-for-approvals/research-ethics-committee/); HRA approval will only be granted after REC favourable opinion is issued but HRA's aim is to review in parallel so there are minimal further delays.

SWYPFT aims to complete the 'assess, arrange, confirm capacity and capability' process in parallel to the HRA review so that we are ready to issue 'confirmation' as soon as HRA approval is granted. In practice this requires researchers to make early contact with the R&D team and submit relevant documents and information in parallel to the HRA and other regulatory submissions; we can then work with you to agree a mutually acceptable timetable for the set-up of your study that allows appropriate time for the permissions process.

Good preparation is therefore essential - if you are thinking about setting up a research study in the NHS we strongly recommend you familiarise yourself with what will be required and make early contact with your proposed participating sites so that they can help and advise you. Contact research@swyt.nhs.uk for further advice.

5.8 What if I want to make changes to my study once it has started?
If you need to make any changes to the study once it has started, or to any of the study documents submitted for the regulatory review (or indeed whilst the regulatory review is underway), this is known as a study 'amendment'. The HRA website provides guidance on what researchers need to do **before** any changes can be implemented: http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/

Amendments are classified as non-substantial or substantial and the research sponsor is responsible for determining whether the proposed changes represent a 'substantial' amendment. Further guidance is available on the HRA website via the link above including which regulatory bodies require notice or approval for substantial and/or other amendments. Notifications themselves are generated within the IRAS system and further guidance is also available within IRAS.

Amendments that require regulatory approval must have those approvals in place before the change can be implemented unless they relate to urgent safety measures for the study. For HRA approved studies, researchers must notify the HRA of both non-substantial **and** substantial amendments. A system of categorisation has been agreed by HRA to streamline the administration of amendments for R&D offices and researchers and ensure a proportionate approach. This approach involves an 'assumed implementation' following regulatory approval unless the participating NHS

site raises an objection within a reasonable timeframe. HRA will confirm the amendment category to applicants within 5 working days of submission. Applicants then share the information with participating NHS sites who can ensure arrangements are in place to continue capacity and capability to undertake the study given the changes. A flowchart has been provided which summarises the process for applicants.

If you intend to submit an amendment for a study that is underway at SWYPFT please ensure you let the R&D team know – contact research@swyt.nhs.uk – as well as the local clinical team(s) hosting the study.

5.9 What ongoing reports or information about my study will I need to provide?
The R&D team will write to Chief Investigators of studies where SWYPFT acts as Sponsor and studies that are not included in the NIHR CRN portfolio on an annual basis to confirm that information regarding the study and recruitment activity remains current. This is detailed in the SWYPFT Research Project Monitoring & Audit Procedure. Chief Investigators will be asked to report recruitment activity to the study and inform the R&D team when the study has completed recruitment, any follow up and when results are available for dissemination. A project outcomes form is provided to Chief Investigators for completion and return to research@swyt.nhs.uk to help document the findings of the study for dissemination.

Funding bodies and regulatory authorities may have specific reporting requirements. Please refer to the relevant organisation for advice.

5.10 What happens when my study has ended?
All applications submitted for approval, and related project documents are to be stored by SWYPFT for a minimum of 5 years following the guidance on in line with the records management NHS code of practice issued by Department of health (Annex D1 – health records retention schedule available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093027.pdf).

The Chief and Principal Investigators (or a delegated person) are expected to supervise, and be accountable for, the storage and protection of all project documentation such as project master files; case report forms etc. in line with the principles of Good Clinical Practice (GCP).

5.11 Who do I contact for further information?
Contact research@swyt.nhs.uk.

6 Approval and ratification process
This procedure will be approved and ratified by the Medical Director in accordance with the Policy for the development, approval and dissemination of policy and procedural documents (policy on policies).

The Medical Director may also bring this procedure to the Executive Management Team or other delegated authority group for further ratification and review as deemed appropriate. The checklist for the review and approval of procedural documents is available in Appendix D.

7 References and additional documents

Department of Health, *Best Research for Best Health* (2009)

Department of Health/Medical Research Council, Clinical Trial Toolkit, www.ct-toolkit.ac.uk

EU Directive 2001/20/EC
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF

Governance arrangements for research ethics committees: a harmonised edition
https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements

Health Research Authority
http://www.hra.nhs.uk/

International Committee on Harmonisation Good Clinical Practice Guidelines (1996), http://www.ich.org/LOB/media/MEDIA482.pdf

Integrated Research Application System (IRAS)
www.myresearchproject.org.uk

Mental Capacity Act (2005)
Medicines for Human Use Regulations (2005)

Medicines and Healthcare Products Regulatory Agency (MHRA)
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

National Institute for Health Research
http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/faster-easier-clinical-research.htm

National Institute for Health Research Clinical Research Network
http://www.nihr.ac.uk/research-and-impact/nihr-clinical-research-network-portfolio/

UK Framework for Health and Social Care Research

8. Document Control and Archiving

See Appendix E.

Version	Date	Author	Status	Comment changes
0.1	08/02/1	Research Management	Draft	Review by Development Group

	0	& Governance Manager, LPfT		identified Changes needed to make compliant with RMS format
0.2	08/03/10	Research Management & Governance Manager, LPfT	Draft	Comments from consultation feedback led to correction of typographical errors and minor amendments.
0.3	29/03/10	Research Management & Governance Manager, LPfT	Draft	Comments following review and approval at Partnership Joint Research Governance Committee led to formatting changes
1.0	13/04/10	Research Management & Governance Manager, LPfT	Final	Comments following LPFT Ratification led to formatting changes
1.1	24/12/12	Research Management & Governance Manager, SWYPFT	Draft	Review of procedure due to changes in practice since R&D Department brought in house and the addition of Barnsley community and mental services.
2.0	13/06/13	Research Management & Governance Manager, SWYPFT	Final	Comments following draft consultation with R&D TAG and colleagues in support services. Approved by EMT on 13/06/13
2.2	05/01/17	Research & Development Manager, SWYPFT	Draft	Review of procedure due to change of R&D Departmental Structure and changes in practice as a result of implementation of Health Research Authority Approval.

9. Dissemination and Implementation

9.1 Dissemination

This procedure will be disseminated as follows

- Trust internet R&D section document store
- Trust intranet R&D section and document store
- Headlines weekly update e-mail to all staff

All previous versions of this document will be removed from the Trust intranet and internet.

9.2 Training and support for the implementation of the procedure

This procedure provides guidance which someone not familiar with the process can follow.

Specific training for approvals process enquiries will be provided to all new Research and Development Team members.

In addition the R&D department will provide support to individuals as and when required. This will be in a variety of means including:

- How to guides

- Access to research specific training
- Good Clinical Practice
- Advice and information

10. Monitoring compliance with this procedure

The R&D department will conduct an annual audit of 10% of the studies processed through the R&D department for set-up at SWYPFT. This audit will check that the necessary documentation is available as follows:

- Planning tool (for studies that SWYPFT Sponsors) and relevant documentation – e.g. evidence of appropriate scientific peer review and Patient & Public Involvement review (for example via the Research Involvement Group) and financial review where relevant for SWYPFT- sponsored studies.
- Health Research Authority approval (and other relevant approvals)
- Written confirmation of Capacity & Capability (Medical Director) and confirmation from Deputy District Director that relevant service can accommodate the study
- External researchers have valid Letters of Access or Honorary Research Contracts as appropriate

The audit results and performance against the NIHR and CRN performance metrics will be reviewed by the R&D Senior Management Team on a quarterly basis.

Appendix A- Glossary and definitions

Advice Sessions	These are one to one meetings with a member of the Research and Development staff. The aim is to provide advice and support to individuals or services wishing to undertake research projects. Advice can be sought on a range of topics including: research design, questionnaire or survey design, applying for project and ethical approval, dissemination and courses on research.
Chief Investigators (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) conduct of the project devolved to the Principal Investigator. They have responsibility for ensuring compliance with all monitoring and audit procedures.
Clinical Trial of an Investigational Medicinal Product (CTIMP)	A Clinical Trials of Investigational Medicinal Product is any investigation in humans, other than non-investigational trial, intended to a) discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; b) to identify any adverse reactions to one or more such products or c) to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety or efficacy of those products.
Local Clinical Research Network (LCRN)	The 15 local networks which comprise the National Institute for Health Research Clinical Research Network in England and help provide practical support and resource to set up and deliver research studies in the NHS. The Trust is part of CRN:Yorkshire & Humber.
EUDRaCT	European Database of Randomised Controlled Trials. Registration is compulsory for all UK Randomised Controlled Trials.
Funder	The organisation providing finance for a project. (NOTE this is not necessarily the same as the project Sponsor)
GAfREC	A policy document titled: Governance Arrangements for Research Ethics Committees: a harmonised edition, published in May 2011. This explains in detail when Research Ethics Committee (REC) review is required and what is expected of RECs.
GCP	Good Clinical Practice (GCP) refers to internationally recognised quality standards for the management and conduct of clinical trials which serve to protect the rights and wellbeing of participants and the integrity of the research. The principles of Good Clinical Practice should be applied to all research conducted within the NHS in a manner proportionate to the risk inherent in the study. Specific legal requirements regarding

	the application of the principles of Good Clinical Practice apply to Clinical Trials of Investigational Medicinal Products (CTIMPs). Free training in Good Clinical Practice is available via the NIHR Clinical Research Network and is recommended for all Principal Investigators and those involved in conducting research at SWYPFT. Appropriate training in GCP is mandatory for researchers involved in conducting Clinical Trials of Investigational Medicinal Products (CTIMPs). Typically training is completed before the study commences and then refreshed every two years. The SWYPFT R&D Department has put together additional information and links to training – contact research@swyt.nhs.uk if you would like a copy.
HEI	Higher Education Institutions including Universities
HRA	Health Research Authority is a statutory Non Departmental Public Body with a remit to promote and protect the interests of patients in health research and to streamline the regulation of research. HRA Approval is now the route for all project-based research to commence in the NHS in England.
Integrated Research Applications Service (IRAS)	Is a single system for applying for the permissions and approvals for a research project. The applicant enters the information once into the IRAS application system for all the necessary regulatory approvals. For example, Research Ethics Committees (REC), Health Research Authority, Confidentiality Advisory Group, Medicines and Healthcare Products Regulatory Authority (MHRA). Filters are applied to ensure information is populated according to the relevant category of study and regulatory approvals applicable to that study.
IRCTN	International Randomised Controlled Trial Number. Unique identifier required for all Randomised Controlled Trials.
Mental Capacity Act (2005)	The Mental Capacity Act 2005 (implemented in 2007) is a framework to protect people who may lack capacity to make some decisions themselves about such things as their property and affairs, health care treatment, where they live, and their personal care[1]. The Act also sets out a framework for the approval and regulation of research, and introduces safeguards and controls for the inclusion in research of those people who lack capacity to consent to participate.
Medicines and Healthcare products Regulatory Agency (MHRA)	The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates new medicines and devices. Licences for new drugs are only granted when a product meets high standards of safety and quality and works for the purpose intended. MHRA is the competent authority for the UK in relation to the EU Clinical Trials Directive and the UK Medicines for Human Use (Clinical Trials) Regulations. MHRA (Devices) is the competent authority for the UK in relation to the Medical Devices Regulations 2002.

[1] It should be noted that the Mental Capacity Act refers to people over the age of 16 years.

MRC	The Medical Research Council (MRC) supports research with the aim of maintaining and improving health.
National Institute for Health Research (NIHR)	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.
Non-portfolio Projects or 'Own Account' Projects	Research projects that are not eligible for inclusion in the NIHR Clinical Research Network portfolio. In general, these tend to be single site projects initiated by a student or staff member with support coming exclusively or largely from within the Trust.
NIHR Clinical Research Network Portfolio Studies	Research studies (clinical trials and other well designed studies which involve the NHS) funded by NIHR, other areas of Government and NIHR non-commercial Partners are automatically eligible to be included in the National Institute for Health Research Clinical Research Network portfolio. These projects are often multi-site projects where funding has been awarded through open, national competition with peer review. Other studies, such as those that are commercially sponsored or those with industry funding that are led by a local investigator, may be considered for inclusion in the NIHR CRN Portfolio via a 'portfolio application' process. NIHR CRN Portfolio studies have access to infrastructure support and funding for service support costs via the NIHR CRN. Visit www.supportmystudy.nihr.ac.uk for more information.
PIC	Participant Identification Centre – an organisation which participates in a study by helping to identify and refer on potential participants to research teams based in other organisations (acting as 'research sites').
Principal Investigator (PI)	The individual who is responsible for the conduct of a research study at a specific research site, reporting to the Chief Investigator of the study. There is usually a single named PI for each site, and they may be supported by other local investigators and researchers. In the case of a single-site study, the CI and the PI will usually be the same person. They also have responsibility for ensuring compliance with local monitoring and audit procedures.
Research	For the purpose of this procedural document, research is as defined in the UK Framework for Health and Social Care Research – briefly the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods. This excludes audits of practice and service evaluations. Please refer to the UK Framework for the full definition and clarifications. The Health Research Authority website includes guidance and a decision tool to help determine whether projects are defined as research: http://www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-

	research/
Research Site	An organisation participating in a research study.
R&D	Research and Development: work which is designed to provide new knowledge and provide findings that are of potential value to the development of services. Research can influence the development of Trust services and promote evidenced based practice.
Research Ethics Committee (REC)	Performs independent review of all NHS based research to ensure compliance with ethical standards.
UK Policy Framework for Health and Social Care Research	The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK in order to protect and promote the interests of participants in health and social care research through ethical conduct and proportionate management of high quality research.
Costs of research	Guidance on the Attribution of costs for research is available here: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research Costs fall into three categories: Research costs (met by the Sponsor typically), Service support costs (met by the NIHR Clinical Research Network for relevant studies) and Treatment costs (met by the NHS typically as part of usual commissioning arrangements). If you are thinking of undertaking a research project and would like advice about costing your project, sources of funding or attribution of costs please contact research@swyt.nhs.uk for advice.
Sponsor	This is the individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research. http://www.hra.nhs.uk/research-community/before-you-apply/roles-and-responsibilities/

Appendix B Assess, Arrange, Confirm Capacity & Capability Checklist

Purpose

This template (to be completed by the R&D department) helps document the discussions involving research sponsors and their representatives (researchers, trial coordinators etc.), host services and NIHR Clinical Research Network staff required to ensure all necessary arrangements are in place to deliver a given research study according to agreed timescales and targets. It documents the main considerations when assessing and arranging local capacity and capability for a Health Research Authority approved[1] research project and serves as an *aide memoire* for the R&D team who coordinate the process on behalf of SWYPFT.

It is intended to support a 'pragmatic and tailored approach to site set-up[2]' and should be used together with relevant guidance issued by the Health Research Authority and NIHR Clinical Research Network (Study Support Service); e.g. 'Assessing, arranging and confirming: clarification on HRA terminology' and 'Principles of good practice in assessing, arranging and confirming capacity and capability for CRN studies' included within the HRA training resources.

Use of the checklist will help ensure a consistent approach. It is not intended to be exhaustive and not all items will be relevant to all projects. It can help ensure that essential points when assessing and arranging local capacity have been considered and can be extended and adapted to include additional points of relevance.

Study acronym/short title: xxxxxxx
IRAS #: xxxxxx

Version	Completed by:	Summary of changes	Date

1. **'Assess' (*Site selection*)**

Starts: SWYPFT is invited to take part in a study by the Sponsor.
Ends: SWYPFT/Sponsor agrees that SWYPFT will participate.
Minimal information required: Study protocol (version submitted to HRA)

Note: Preliminary discussions with the Sponsor may predate the formal start of assess (see CRN Study Support Service guidance on 'early contact/engagement') and documented elsewhere, e.g. Expression of Interest for commercial studies.

Points to consider:	Y/N or N/A	Initials	Comment
Is SWYPFT participating in or sponsoring the study? Research site or PIC? Lead R&D office? NIHR CRN portfolio study?	Y/N		List
Note protocol version number and date and whether HRA initial assessment/approval letter received – this includes information relevant for the 'assess, arrange, confirm' process which cannot proceed formally without it.			

[2] NIHR CRN Principles of Good Practice in Assessing, Arranging & Confirming for CRN studies.

Do we have the relevant participant population (or relevant 'clinical pathway')? Is the proposed target achievable in the required timescale?	Y/N		List
Do we have the relevant service – interest/capacity to undertake the study? BDU?	Y/N		List – which service, who has been approached and their response.
Are there any financial implications for SWYPFT – e.g. involvement of Excess Treatment Costs?	Y/N		List – e.g. intervention represents ETC.
Is a PI or LC required? Has anyone ***suitable*** been identified? Particular requirements ('***suitability***' – specific expertise, training etc.)?	PI/LC or N/A		Named PI. CTIMP – GCP training required. Non-CTIMP – GCP training recommended.
Is Clinical Research Officer support required? Capacity? Allocation of recruitment activity agreed? Lead CRO assigned? 'Suitability' – e.g. any specific training needs?	Y/N		Lead CRO named. Training needs? Allocation of recruitment activity.
Any specific equipment requirements (e.g. IT)?	Y/N		List
Access to service or specialist support required e.g. pharmacy, radiology, pathology? 'Suitability' – e.g. QA requirements, required standards etc.	Y/N		List
Can the protocol be implemented at SWYPFT – i.e. are there changes compared with standard clinical practice (or to the 'clinical pathway') and can they be accommodated (e.g. via training etc.)? Safety or emergency procedures required?	Y/N		List
Is a risk assessment required? Note relevant risks and mitigating actions (e.g. lone working, separate Risk Protocol). Consider risks to participants, researcher, organisation.	Y/N		Identify who will undertake the risk assessment.
Any HR requirements – e.g. Letters of Access for external researchers?	Y/N		List
Are the arrangements for 'confirm' clear? Statement of Activities? Clinical Trial Agreement? Any additional specific requirements outlined in HRA assessment and/or approval letter?	Y/N		List

2. 'Arrange'

Starts: SWYPFT selected as a site (end point of 'arrange'), named in Part C of IRAS form (or via amendment).
Ends: HRA Approval and Sponsor confirmation in writing (email) – with final Statement of Activities or Clinical Trial Agreement (for sign off).
Minimal information required: Relevant study documents in versions reviewed by HRA, HRA approval and/or initial assessment letter, Statement of Activities/Schedule of Events.

Arrangements required to deliver the study ('*Action plan*')	**Person responsible**	**Progress**
• Management approval in place for host service (and any support departments) confirming capacity to undertake the study. • Deputy Director confirmation that relevant BDU can accommodate the study.	•	•
• Principal Investigator (or Local Collaborator) identified.	•	•

• Lead CRO assigned. • Roles and responsibilities of local research team agreed and documented (e.g.delegation log).		
• Training requirements organised and documented (e.g. CV's, GCP certificates, training dates arranged). •	•	•
• Plan agreed with PI/LC, local clinical service and research sponsor for screening, approaching and recruiting participants. •	•	•
• Arrangements for Site Initiation Visit confirmed (if relevant) •	•	•
• Information technology requirements confirmed and in place (e.g. encrypted USB sticks, access to online databases, electronic Case Report Forms (CRFs) etc).	•	•
• Financial arrangements confirmed and in place (e.g. completion/negotiation of costing template for commercial studies and arrangements for invoicing).	•	•
• Human Resource requirements confirmed and in place (e.g. honorary research contracts or letters of access for external researchers).	•	•
• Risk assessment completed and mitigation in place	•	•
• Arrangements specific to the study confirmed and in place (see 'assess' outcomes above). •	•	•
• Arrangements for activities undertaken by any support or specialist departments confirmed and in place (e.g. Pharmacy – see 'assess' outcomes above).	•	•
• Study documents localised (as required). •	•	•
• Investigator site file prepared. •	•	•
• EDGE record created.	•	•

3. 'Confirm'

Starts: HRA Approval and Sponsor confirmation in writing (email) – with final Statement of Activities or Clinical Trial Agreement (for sign off).
Ends: Signed Statement of Activities or Clinical Trial Agreement returned to Sponsor.

Arrangements required for 'confirm' ('*Action plan*')	**Person responsible**	**Progress**
• Statement of activities (or Clinical Trial Agreement) submitted to Medical Director for signature. Meeting to discuss scheduled. •	•	•
• Signed Statement of Activities (or Clinical Trial Agreement) returned to Sponsor (copied to relevant representatives and Principal Investigator/Local Collaborator). •	•	•

Appendix C - Equality Impact Assessment Tool

Date of Assessment: 3 January 2017

	Equality Impact Assessment Questions:		Evidence based Answers & Actions:
1	**Name of the document that you are Equality Impact Assessing**		Procedure for set-up and sponsorship of Research Projects at SWYPFT
2	**Describe the overall aim of your document and context?** **Who will benefit from this policy/procedure/strategy?**		The overall aim of the policy is to describe the Trust's approach to the set-up and sponsorship of research projects at the Trust. All staff and external researchers
3	**Who is the overall lead for this assessment?**		Research & Development Manager
4	**Who else was involved in conducting this assessment?**		
5	**Have you involved and consulted service users, carers, and staff in developing this policy/procedure/strategy?** **What did you find out and how have you used this information?**		The Research Involvement Group were initially involved in review of an earlier version of this procedure. Informed development of earlier versions.
6	**What equality data have you used to inform this equality impact assessment?**		This policy impacts on everyone therefore no equality data required.
7	**What does this data say?**		N/A
8	**Taking into account the information gathered above, could this policy /procedure/strategy affect any of the following equality group unfavourably:**	**Yes/No**	**Evidence based answers & actions. Where negative impact has been identified please explain what action you will take to remove or mitigate this impact.**
8.1	**Race**	No	N/A
8.2	**Disability**	No	N/A
8.3	**Gender**	No	N/A
8.4	**Age**	No	N/A
8.5	**Sexual orientation**	No	N/A

	Equality Impact Assessment Questions:		Evidence based Answers & Actions:
8.6	**Religion or belief**	No	N/A
8.7	**Transgender**	No	N/A
8.8	**Maternity & Pregnancy**	No	N/A
8.9	**Marriage & Civil partnerships**	No	N/A
8.10	**Carers*Our Trust requirement***	No	N/A
9	**What monitoring arrangements are you implementing or already have in place to ensure that this policy/procedure/strategy:-**		Monitoring arrangements are described in section 10 of this procedure.
9a	**Promotes equality of opportunity for people who share the above protected characteristics;**		As above.
9b	**Eliminates discrimination, harassment and bullying for people who share the above protected characteristics;**		As above.
9c	**Promotes good relations between different equality groups;**		As above.
9d	**Public Sector Equality Duty – "Due Regard"**		As above.
10	**Have you developed an Action Plan arising from this assessment?**		N/A
11	**Assessment/Action Plan approved by**		**Signed:** Rachel Moser **Date:** 12/10/17 **Title:** Research & Development Manager
12	***Once approved, you must forward a copy of this Assessment/Action Plan to the partnerships team:*** partnerships@swyt.nhs.uk **Please note that the EIA is a public document and will be published on the web.** **Failing to complete an EIA could expose the Trust to future legal challenge.**		

If you have identified a potential discriminatory impact of this policy, please refer it to the Director of Corporate Development or Equality and Engagement Development Managers together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact the Director of Corporate or Equality and Engagement Development Managers.

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any policy document when submitted to EMT for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	YES	
	Is it clear whether the document is a guideline, policy, protocol or standard?	YES	Confirmed with EMT
	Is it clear in the introduction whether this document replaces or supersedes a previous document?	YES	
2.	**Rationale**		
	Are reasons for development of the document stated?	YES	
3.	**Development Process**		
	Is the method described in brief?	YES	
	Are people involved in the development identified?	YES	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	YES	
	Is there evidence of consultation with stakeholders and users?	EMT	
4.	**Content**		
	Is the objective of the document clear?	YES	
	Is the target population clear and unambiguous?	YES	
	Are the intended outcomes described?	YES	
	Are the statements clear and unambiguous?	YES	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	YES	
	Are key references cited?	YES	
	Are the references cited in full?	YES	
	Are supporting documents referenced?	YES	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	YES	
	If appropriate have the joint Human Resources/staff side committee (or equivalent)	YES	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	approved the document?		
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	YES	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	YES	
	Have archiving arrangements for superseded documents been addressed?	YES	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	YES	
	Is there a plan to review or audit compliance with the document?	YES	
10.	**Review Date**		
	Is the review date identified?	YES	
	Is the frequency of review identified? If so is it acceptable?	YES	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible implementation and review of the document?	YES	

Appendix E - Version Control Sheet

This sheet should provide a history of previous versions of the policy and changes made

Version	Date	Author	Status	Comment / changes
0.1	08/02/10	Research Management & Governance Manager, LPfT	Draft	Review by Development Group identified Changes needed to make compliant with RMS format
0.2	08/03/10	Research Management & Governance Manager, LPfT	Draft	Comments from consultation feedback led to correction of typographical errors and minor amendments.
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2.2	05/01/17	Research & Development Manager, SWYPFT	Draft	Review of procedure due to change of R&D Departmental Structure and changes in practice as a result of implementation of Health Research Authority Approval. Confirmation from EMT of procedural document status therefore not requiring EMT approval.