A teaching trust of Brighton and Sussex Medical School

NHS
Sussex Partnership
NHS Foundation Trust

Research Approvals Guide

Research & Development

Enhancing understandings and Improving Practice

Contents

Telephone:

0300 304 0088

Email:

research@sussexpartnership.nhs.uk

Website:

www.sussexpartnership.nhs.uk/research

Research at Sussex Partnership NHS Foundation Trust

Sussex Partnership strives to develop a culture of learning and professional development encouraging the use of best practice to improve the quality of care offered to people who use our services.

Our strategic aim is to be a leading teaching and research Trust and we are proud of our culture which promotes learning, research and professional development.

The R&D Department have put together this booklet to facilitate the research application process. The information in this booklet explains the steps that need to be taken and the issues that need to be considered when undertaking research within the Trust.

At the back of this booklet you will find a flow diagram detailing the research application processes.

If you have any questions whilst completing your application please let us know and we will assist you in any way we can.

Research and Development Department (R&D)

R&D Director – Mark Hayward Mark.Hayward@sussexpartnership.nhs.uk

The R&D Director develops and implements the Trust R&D strategy this involves ensuring the Trust meets its business objectives of increasing research activity and developing a quality research culture.

R&D Assistant Director – Clara Strauss Clara.Strauss@nhs.net

The R&D Assistant Director oversees the day-to-day running of the research department and is responsible for managing operational systems for research governance and approval of all research projects within the Trust. The R&D Assistant Director also supports the Director with strategy decisions and helps facilitate collaborative partnerships with key stakeholders.

R&D Manager – Taffy Bakasa Taffy.Bakasa@sussexpartnership.nhs.uk

The R&D Manager works closely with the Trust R&D Team, clinical teams, researchers, and research networks to ensure the smooth set up and conduct of research activity in the Trust.

R&D Improvement Manager – Anna-Marie Jones
Anna-Marie.Jones@sussexpartnership.nhs.uk

Anna-Marie Jones is the R&D Improvement Manager who leads on research design advice in the trust, manages the 4 research clinics (ImmunoPsychiatry, Voices, Flourishing Families and OCD) and leads on Early Career Researcher development

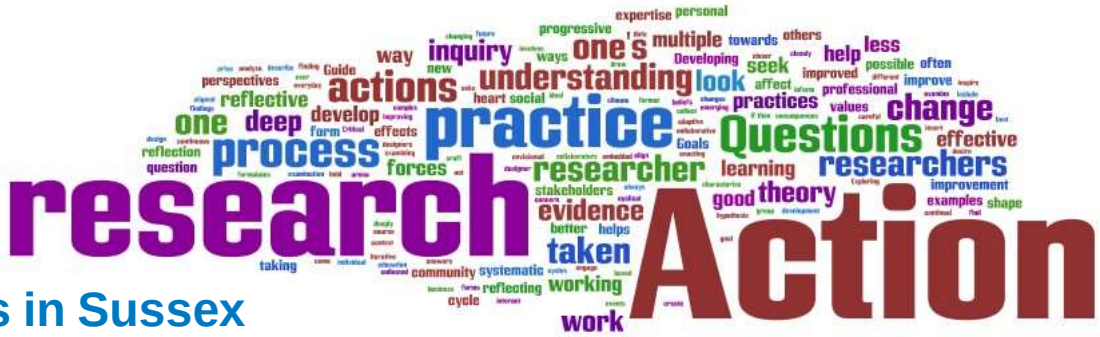
Research Governance Team – ResearchGovernance@sussexpartnership.nhs.uk

The Research Governance team supports researchers through the set up and approvals process and offer advice and training on these processes. They are also able to support researchers in making grant applications and have responsibility for monitoring research data and reporting.

Lead for Service User and Carer Involvement – Sam.Robertson@sussexpartnership.nhs.uk

The Service User and Carer Co-ordinators work with researchers, service users and carers to develop meaningful involvement within research activity within the Trust.

Should you have any queries about research in Sussex please email:
Research@sussexpartnership.nhs.uk or telephone 0300 304 0088.



R&D Approvals in Sussex

In order to conduct research within Sussex Partnership, researchers must seek Health Research Authority (HRA) approval which comprises an assessment of governance and legal compliance, alongside an independent Research ethics committee (REC) opinion. In addition to HRA approval, researchers must seek confirmation from the R&D department of capacity and capability to support the study. The flow diagram in the back of this booklet details the application process.

Research/ Audit/ Service Evaluation/ Quality Improvement?

It is essential to first determine if your project is audit or research as both involve very different approval processes. The best way to establish this is to send a summary of your proposal (no more than one or two sides of A4) to ResearchGovernance@sussexpartnership.nhs.uk

We will assess whether the project is research and support you to complete an application to carry out research in the Trust. If your project is audit then you will need to log it with the audit department by emailing the Clinical Audit Team Lead at ClinicalAudit@sussexpartnership.nhs.uk

For further information on the definition of NHS research or audit please see the Research Policy (2020) or use the HRA decision tool http://www.hra-decisiontools.org.uk/research/ .

R&D Theme Approval

Research within Sussex Partnership must be adopted onto one of the Trusts research themes. For an up to date list of these themes please go to the R&D web pages http://www.sussexpartnership.nhs.uk/research-themes-research

When the R&D department receives a summary of your project it will be sent to the appropriate theme leader and to the R&D leadership team to review. The proposed research must contribute and add value to an existing programme of research within the theme.

Please note: National Institute for Health Research Portfolio studies are not expected to be themed. For advice about developing a research theme not currently commissioned by the Trust please speak with the R&D Director.

Public and Patient Involvement

The Trust supports involvement in research and has a dedicated Service User and Carer Involvement team who work with researchers, service users and carers to develop meaningful involvement in the design of research studies.

The Trust also has a Lived Experience Advisory Forum (LEAF) who consult on research proposals and offer advice and guidance to researchers.

When you are developing your research ideas you should contact the Lead for Service User and Carer Involvement, **Sam Robertson** at Sam.Robertson@sussexpartnership.nhs.uk for support and advice.

Funding

Research studies will need funding or dedicated resource in order to reach completion. Student research will have dedicated student time to ensure the project is successful; any financial commitment within the project (i.e. payment of participants travel expenses) will need to be evidenced to show that money has been committed to the project.

R&D will ask you to show that the research can be carried out with the resources provided. If no such funding has been awarded you are encouraged to submit a grant application to obtain this. Different sources of funding include:

National Institute for Health Research (NIHR) funding streams. You will need to log your intention to apply for one of these funding streams with the Research Governance team who will guide you through a support system for applying for the grant. You will find all information about this funding stream on the NIHR website.

Other sources of funding – there are several sources of funding available which are dependent on the topic of your research and amount of funding you seek. For more information email Research@sussexpartnership.nhs.uk

Research Design Service (RDS) South East are available to help support you complete an application.

If your funding application will include NHS and Academic Partners across Sussex, you may be eligible for support from the Brighton and Sussex Joint Clinical Research Office (JCRO). The JCRO offer practical help and support through the lifetime of clinical research projects including during the grant application stage.

Please make sure that you liaise with the R&D office prior to any funding application so that we can support you to ensure that each application is to a high standard. We will help you to cost the study and liaise with Finance to ensure the correct costs are included.

Should you obtain a grant for your project it may be adopted onto the NIHR Portfolio of studies which gives you access to support from the Clinical Research Network. For more information contact your R&D office.

Sponsorship

Each research study needs a Sponsor under the UK Policy Framework for Health & Social Care Research (2018). The Sponsor has overall responsibility for the project. It is usually the case that the employing organisation for the lead researcher will act as sponsor (for student projects this is normally their university).

Pre-sponsorship Review Panel From November 2020 all studies taking place within the NHS that are developed by one of the following organisations: University of Sussex, University of Brighton, Sussex Partnership NHS Foundation Trust, Brighton and Sussex University Hospitals NHS Trust, will be reviewed by the Pre-Sponsorship Review Panel (PSRP).

The PSRP will provide feedback and advice to researchers to meet the quality and safety criteria expected by Sponsoring organisations. The Panel will then make recommendations of each application for sponsorship to the Sponsoring organisation.

For more information about the PSRP submission and review process please visit https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx or contact psrp@sussex.ac.uk

Upon receiving a recommendation for sponsorship from the PSRP, the **Sussex Partnership Sponsorship Committee** will consider the application for sponsorship and provide a final decision and letter of sponsorship.

As sponsor, Sussex Partnership will continue to monitor research projects throughout their lifecycle.

Peer Review – it is a requirement that all research projects have undergone peer review by two independent peer reviewers. If your project has not undergone this process the R&D office will arrange for this to be carried out.

Local Feasibility Assessment

The R&D office will conduct a feasibility assessment on your study. This will include considering the funding and resources available, with regard to both personnel and any required equipment. We will give consideration to study procedures and whether there are any specific training needs. In addition, we will review recruitment targets and whether we have access to the proposed study population. Key to our feasibility assessment is the question of risk, both to patients and on an organisational level and any risks would be raised both with yourselves and senior leadership at SPFT before we could confirm support for your study. We will endeavor to use the study documents to answer any questions we have but our R & D office will contact you or designated members of your study team should we require any additional information.

Completing Application Forms – IRAS

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK
IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- Her Majesty's Prison and Probation Service (HMPPS)
- Social Care Research Ethics Committee

IRAS can be accessed by the following link www.myresearchproject.org.uk. You will need to register on the site and it is recommended to first go through the online tutorial. There are also helpful guidance documents under the "Help" section.

You begin by creating a "new project" and completing the "IRAS Project Filter" which will generate an IRAS form depending upon your responses (such as study type and details of your project).

If you have obtained funding for your research through open competition and would like it to go on the NIHR Portfolio please ensure you select "YES" to Question 5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio?– this will generate a NIHR Portfolio Application form which you must complete before the other forms. You will need to submit this form electronically through IRAS so that the NIHR can determine if you study is eligible to go on the Portfolio.".

Top Tips for Completing your IRAS Form

- Include as much practical detail as possible and ensure that this is clear and consistent throughout your application.
- Research data must be kept for 10 years
- Indemnity will be provided by the sponsoring organisation.
- Obtaining informed consent constitutes a non-clinical intervention and should be listed in A18
- Sponsor – you will need someone to authorise your forms as Sponsor. If this is Sussex Partnership, you should contact the R&D office to discuss how to do this.
- Each research site should be listed in Part C of your IRAS form.
- Review of draft forms – Before submitting your forms on IRAS, please save your responses as a pdf using the save/print tab and email them to the Governance team (ResearchGovernance@sussexpartnership.nhs.uk). We will review your forms prior to submission.
- Submitting forms – If your study requires NHS ethical approval, once your forms have been authorised and agreed with all parties, you need to use the Online booking service to schedule your appointment with an NHS Research Ethics Committee. You will receive an email confirming your booking and REC reference number. You will need to return to the application form in IRAS and add the REC name, REC reference number, and submission date at the start of the form.
- You must then electronically submit your application. This must be done on the same day as making your booking. Return to the form's e-submission tab and click 'e-submit application'..
- There is a checklist on IRAS for the documents you need to submit with this form to the Health Research Authority. This may include some or all of the following:

Document	Resources available
Study Protocol	Template available on request
Participant facing documents (e.g. Participant Information Sheets, Consent forms, posters)	Guidelines available on request
Research team CVs	Template available on request
Evidence of insurance/indemnity	
Proof of funding (if applicable)	
An Organisation Information Document and Schedule of Events/SOECAT	Templates available on the HRA website
Further study agreements	

Approvals

HRA approval

HRA approval combines an assessment of study compliance with applicable regulations and standards and a separate but coordinated review by an independent Research Ethics Committee (REC), where applicable.

All NHS research studies require HRA approval but some do not require review by an NHS Research Ethics Committee (REC). This includes studies limited to the use of previously collected, non-identifiable information which has been collected in the course of normal care, and studies involving NHS staff as participants alongside other study types. If you think your study may not require REC approval please contact the research governance team.

Once you have met with the Ethics Committee you will receive a letter confirming their decision, this will either be:

- **Favourable opinion** – your research has ethics approval
- **Conditional approval –** the committee have certain conditions they need you to fulfil before they will grant a favourable opinion. They will instruct you how to do this.
- **Unfavourable opinion** – you will need to submit a completely new application to ethics as this project did not receive a favourable opinion.

After a favourable opinion has been received from the ethics committee, and all outstanding questions relating to the HRA assessment have been answered, you will receive a letter of approval from the HRA. This letter will instruct you to share your study documents with all participating NHS organisations in order that they can put arrangements in place to deliver the study. The letter will also advise on any training requirements for the study team and whether HR arrangements need to be made for the issuing of research passports.

Other Regulatory approvals

Some studies will require additional regulatory approvals that are not reviewed by the HRA. This includes:

- **Confidentiality Advisory Group Approval** – required for research studies that intend to access or use identifiable NHS patient information without consent.
- **National Offender Management Service Approval** – required for any research undertaken within prisons, young offender institutions or probation areas
- **Medicines and Healthcare products Regulatory Agency MHRA medicines Approval** – required for clinical trials of medicinal products

Please note that we have no control over the length of time it takes for you to receive external approvals. Please ensure you submit your applications in plenty of time.

Confirmation of capacity and capability

The HRA approval letter will state whether confirmation of capacity and capability by participating NHS organisations is required.

A review of capacity and capability will be conducted by the Research Governance team once they have received all relevant, HRA approved study documents. This will include consideration of the suitability of the local research delivery team, the adequacy of local facilities, local arrangements to support research participants, and ability to comply with the HRA approved protocol.

The Research Governance team will also review and sign off any study agreements at this stage including the Organisation Information Document and any other agreement as outlined in the HRA Initial Assessment and HRA Approval letters.

Clarifications – the Research Governance team will email you with any request for clarification they have about your application. Once clarifications have been worked out the Research Governance office will issue Confirmation of capacity and capability via email.

Research Passports

As part of the approvals process anyone on the research team who is not employed by the NHS nor has a contractual relationship with the NHS will need to go through the Research Passport Scheme. It is recommended to start this process as soon as possible as this often involves pre-engagement checks e.g. DBS/ Occupational Health checks and can take a while. The HRA approval letter will confirm the type of contractual agreement required. On receipt of the required pre-engagement checks, the Research Governance team will issue a research passport.

Monitoring and Reporting

The R&D department undertakes annual monitoring of all research studies. Please respond to any requests for information. Failure to do this will result in the suspension of research governance approval. In addition to requests for information, research studies that are sponsored by the Trust may be selected for audit. If your project is selected you will be given 4 weeks' notice to prepare all documentation for inspection.

When a study is closed within the Trust, we ask that the research team send their REC final research report, or a summary of the study's findings to ResearchGovernance@sussexpartnership.nhs.uk. You will also be asked at this stage to give evidence that you are disseminating the findings of your research in accordance with the dissemination strategy approved at the time confirmation of capacity and capability was issued.

Research Themes

Approaches to Involvement and Recovery (AIR)

Theme Lead: Sam Robertson

The AIR theme aims to deliver on and develop NIHR funded research focusing on the involvement of lived experience experts in mental health research, service delivery and related educational contexts and/or research coproduced with lived experience experts which does not have a clinical focus.

For more information about the theme please contact Sam Robertson at Sam.Robertson@sussexpartnership.nhs.uk

Children and Adolescents

Theme Lead: Mary John

This theme explores all aspects of mental health for children and young people. The theme is a working collaboration with University of Sussex.

For more information about the theme please contact Mary John at M.John@surrey.ac.uk

Dementia and Older People's Mental Health

Theme Lead: Dr Naji Tabet

The Dementia and Older People's Mental Health theme includes several studies exploring the issues of old age including clinical trials for Alzheimer's disease. The theme is a working collaboration with University of Sussex, Brighton and Sussex Medical School & University of Brighton

Studies within the Dementia and Older People's Mental Health will be reviewed for theme approval by the Dementia Research Review Board. For more information about the theme please contact ResearchGovernance@sussexpartnership.nhs.uk

Learning Disabilities

Theme Lead: Dr Lilly Lines and Viki Baker

The Learning Disability theme has a very broad remit that encompasses a wide range of potential studies, including positive psychology with people with challenging behaviour and the use of virtual worlds in capacity to consent. The theme is a working collaboration with University of Brighton.

For more information about the theme please contact Dr Lily Lines at lily.lines@sussexpartnership.nhs.uk or Viki Baker at viki.baker@sussexpartnership.nhs.uk

Mood and Anxiety Research in Sussex (MARS)

Theme Lead: Dr Clara Strauss

The Mood Research Theme includes research concerning the role of mood in mental health and wellbeing. It encompasses research into a variety of mental health conditions, including bipolar, affective and anxiety conditions. The types of studies possible within the theme include investigations into assessment methods, the development and evaluation of interventions, service user and carer experience and involvement, and the development of theory relevant to any of the above conditions.

The theme is a working collaboration with University of Sussex & Brighton and Sussex Medical School.

For more information about the theme please contact Clara Strauss at Clara.Strauss@sussexpartnership.nhs.uk

Brain and Body

Theme Leads: Professor Hugo Critchley and Dr Alessandro Colasanti

The Brain and behaviour theme seeks to explore new advances in the treatment of neurobehavioral problems such as Attention Deficit Hyperactivity Disorder. The theme is a working collaboration with University of Sussex and Brighton and Sussex Medical School.

For more information about the theme please contact Hugo Critchley at H.Critchley@bsms.ac.uk and Alessandro Colasanti at A.Colasanti@bsms.ac.uk

Sussex Psychosis Research interest Group (SPRiG)

Theme Lead: Dr Kathy Greenwood

SPRiG is a joint venture from the University of Sussex, Sussex Partnership NHS Foundation Trust, and Brighton and Sussex Medical School. Our research group comprises mental health professionals, researchers, mental health service users, carers, and students. Our research explores understandings of the experience of psychosis. We aim to translate our research into meaningful health and well-being benefits for people who experience psychosis, their families and carers. We also aim to enhance knowledge and understandings of psychosis in the general public including young people, challenge stigma and promote positive attitudes towards help-seeking.

There is also a SPRiG web site www.sussex.ac.uk/spriglab

For more information about the theme please contact Kathy Greenwood at K.E.Greenwood@sussex.ac.uk

Personality, Emergency and Complex Care (PECC)

Theme Lead: Dr Helen Startup and Dr Claire Warrington

The PECC theme has a focus on complex presentations, socially marginalised and vulnerable people, and those who challenge or slip between existing services. Areas of research include, but are not limited to: Suicide prevention and alternatives to s136 detention, personality disorders, eating disorders and psychological treatment of unexplained physical symptoms.

For more information about the theme please contact Helen Startup at Helen.Startup@sussexpartnership.nhs.uk
Or Claire Warrington at C.Warrington2@brighton.ac.uk

Research Approvals Pathway

Researcher contacts Sussex Partnership NHS Foundation Trust (SPFT) Research Governance team (researchgovernance@sussexpartnership.nhs.uk) to discuss sponsorship options.

At this point the Governance team will address initial queries relating to feasibility, management and local policies. For non-portfolio studies this will include leadership and theme approval

Researcher submits document set to Pre Sponsorship Review Panel (PSRP) before deadline for meeting (psrp@sussex.ac.uk) *

PSRP conduct a review of documents. Representatives of SPFT will conduct internal assessments during this period relating to PPI inclusion, research governance considerations and local feasibility

Researcher is invited to PSRP meeting to respond to any questions

PSRP provide outcome of review and recommendation for sponsorship. This may include a request for changes before support can be confirmed by the PSRP

SPFT consider request for sponsorship in sponsorship committee meeting

SPFT communicates outcome of sponsorship review to researcher.

SPFT provides letter of sponsorship once any revisions have been completed

Researcher makes submission for HRA and REC review via IRAS website

Researcher attends REC meeting and responds to REC and HRA assessments

REC and HRA approval issued

Portfolio adoption issued (where required)

SPFT Governance team collate final documents and make final assessments relating to capacity and capability

SPFT Governance team arrange research passports if required

SPFT confirm capacity and capability via email

Study team are able to start recruiting

*PSRP website: https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx