

A teaching trust of Brighton
and Sussex Medical School

Sussex Partnership 
NHS Foundation Trust

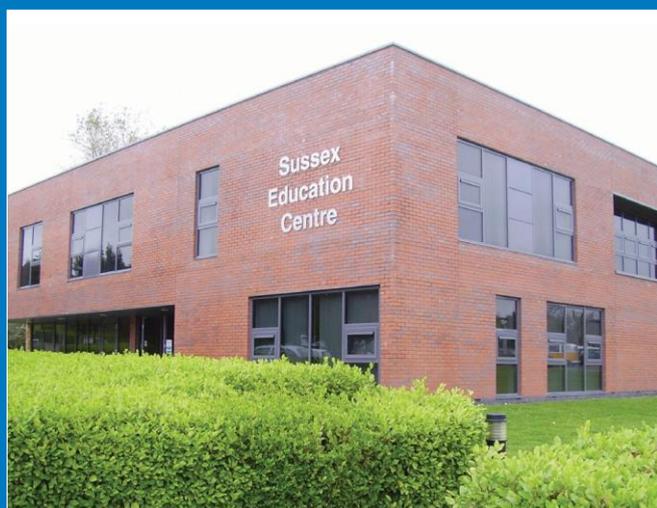
Research Approvals Guide



Research & Development
Enhancing understandings and Improving Practice

Contents

Research at Sussex Partnership NHS Foundation Trust	3
Research and Development Department	3
R&D Approvals in Sussex	4
Audit or Research?	4
R&D Theme Approval	4
Patient and Public Involvement	4
Funding	4
Sponsorship	5
Local Feasibility Assessment	5
R&D Criteria for Research	5
Completing Application Forms – IRAS	6
Top Tips for Completing your R&D Forms	6
Approvals	7
Research Passports	8
Monitoring and reporting	8
Research Themes	8
Flowchart	11



Telephone:

0300 304 0088

Email:

research@sussexpartnership.nhs.uk

Website:

www.sussexpartnership.nhs.uk/research

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.

Audit or Research?

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 Wendy Harlow, Clinical Audit Team Lead on Wendy.Harlow@sussexpartnership.nhs.uk

For further information on the definition of NHS research or audit please see the Research Policy (2015) 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 receive 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 Research 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:

Research for Patient Benefit (RfPB) - This is a National Institute for Health Research (NIHR) funding stream. You will need to log your intention to apply for this funding stream 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. Research Design Service (RDS) South East are available to help support you complete an application. Grants are also available to support the development of an Involvement strategy within your design. Please contact RDS or your R&D office for more information.

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

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 Clinical Research Networks such as Mental Health Research Network and Dementias and Neurodegenerative Diseases Network. For more information contact your R&D office.

Sponsorship

Each research study needs a Sponsor under the Research Governance Framework (2005). 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).

If you wish Sussex Partnership to act as your sponsor you will need to submit a study protocol, study documents and CV of lead researcher to ResearchGovernance@sussexpartnership.nhs.uk. We will need to be assured about the design and conduct of your study and will liaise with you to ensure that it is of the highest quality. If we agree in principle we will instruct you to complete your IRAS forms (see section on IRAS) which will need to be authorised by the Governance team – you need to send your forms to them for review and authorisation and you should allow two weeks to do this.

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 funding and resources available, recruitment targets and available population. If the study is considered to be high risk this will also include obtaining management sign off for the study. The R&D office will contact the manager of the service from which your study is recruiting or where you are carrying out research.

R&D Criteria for Research

In order to support your project R&D ask that you have considered the following criteria:

- Your research must have anticipated benefit to service users and carers
- Evidence of meaningful service user/ carer involvement. To develop a strategy of involvement within your research methodology please email Sam.Robertson@sussexpartnership.nhs.uk who is the Lead for Service User and Carer Involvement.
- Study matches with Trust research themes – there are several research themes within the Trust which you will find listed on our web pages (<http://www.sussexpartnership.nhs.uk/research-themes-research>). Each theme is aiming towards a full programme of research activity with fully funded research studies, dedicated resources (such as funded research fellows) and collaborative partnerships with relevant agencies. More information can be obtained from the theme leaders which you can find out through our web pages or by emailing Research@sussexpartnership.nhs.uk.
- Likelihood of completion – as part of local R&D approvals we will assess if your project is feasible in terms of site and resources.
- Collaborations – it is expected that you will have consulted experts about your methodology (whether this be academic supervisors, Research Design Services if you intend to submit a grant application – see Funding, or collaborations with academic partners) and that your project is led by a research team that is multi professional or collaborative.

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)	
A statement of activities and schedule of events	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.

Some studies require HRA approval but 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 statement of activities 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 clarifications 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 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)

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 Leads: Dr Naji Tabet & Professor Jennifer Rusted

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 Jane Edmonds

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 Jane Edmonds at Jane.edmonds@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 Neil Harrison

The Brain and behaviour theme seeks to explore new advances in the treatment of neurobehavioural 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 Neil Harrison at N.Harrison@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 Care And complex Needs (PECAN)

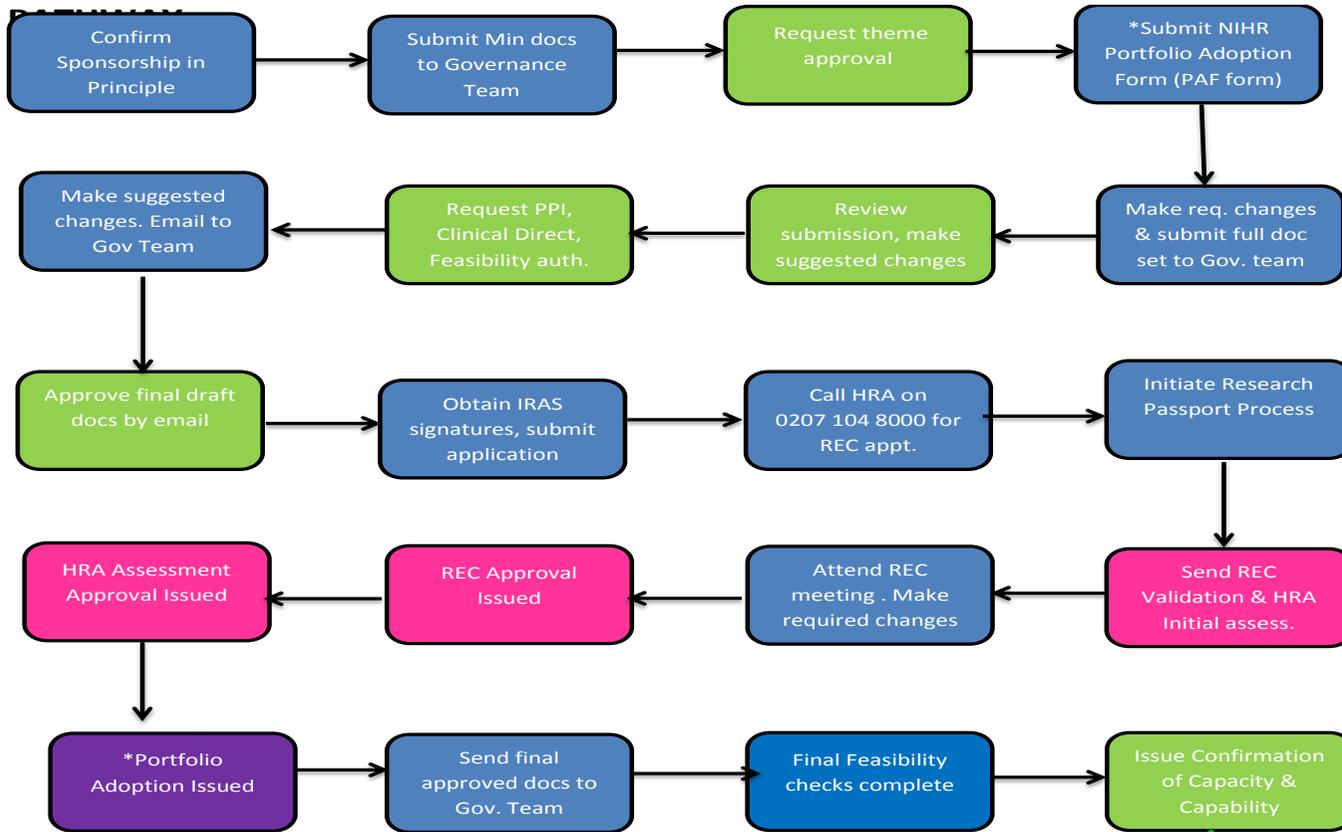
Theme Lead: Dr Helen Startup and Professor Gillian Bendelow

The PECAN 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

RESEARCH APPROVALS PATHWAY



KEY	
*	NIHR Portfolio studies only
	CI/ Sponsor/ PI/ Research Team
	Governance Officer
	HRA & REC Committee
	NIHR Portfolio Adoption

Research Approvals Pathway v 1
September 2016