



# Research at Sussex Community NHS Foundation Trust (SCFT): An Overview.

Our priority is to ensure the safety and well-being of our patients, carers and staff when they participate in research.

The Research department works to help all research interested staff. Whether you are new to research or an experienced researcher we can help to navigate you through your journey and that of the project's life cycle.

This guide will signpost you to Trust information, local and national resources.

For the Research policy go to the Pulse or contact us for a copy.

## Our responsibility to our patients.

Our top priority is patient safety.

Research is regulated and monitored to ensure patient safety.

Patients choose to take part in research. Research is always voluntary.

As healthcare professionals it is our responsibility to act as advocates for our patients and facilitate their participation.

The research team work to increase opportunities for our patients, carers and staff to take part in meaningful research.

#### Research is:

- The attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods.
  (UK Policy Framework for Health and Social Care Research)
- Carried out to improve patient outcomes.
- Considered NHS Core business NHS England » Business Plan
- Part of SCFT's strategic vision <u>Trust Strategies</u>, <u>Reports and Plans</u> (sussexcommunity.nhs.uk)

## Is your project Research?

Use the decision tool below to see if the work you are undertaking is classified as research or considered audit or service evaluation.

www.hra-decisiontools.org.uk/research

If you are unsure after using this tool please contact us for further advice.

If you are conducting audit or service evaluation, please contact The Quality Development Team on sc-tr.qualityeffectiveness@nhs.net

#### What research is conducted at SCFT?

Common types of research we carry out and support include:

- National Institute for Health and Care Research (NIHR) Portfolio studies.
- Home Grown studies. A study that is designed and conducted by SCFT staff.
- Commercial studies. Designed and conducted by pharmaceutical and device companies.
- Non-Commercial studies written and designed by organisations external to SCFT e.g. NHS trust, university, charity
- Smaller scale student research projects which form part of an academic qualification such as PhD or Masters Projects.

#### Before research starts in SCFT

All research activity involving SCFT patients, carers or staff must be reviewed and authorised by the research department. This process can take between 2-4 weeks depending on the complexities of the review and our workload at the time.

#### How do we conduct research at SCFT?

Before starting any research at SCFT the study must be assessed to see if it is feasible to conduct in our trust. Many factors are considered, here are just a few:

- Are there enough potential participants in our services to recruit the amount of people required?
- Does the clinical service want to support the research?
- What training is required to carry out the research?
- How much time and resources are needed to care for participants?
- Are blood tests, x-rays or other clinical tests required?

The research team can help with planning and organising the practicalities of carrying out a research study. This includes guidance on study documentation, site file management and how to document patient's consent and participation in the medical record.

The Research team reviews research governance, approves and signs research contracts and costings.

## Health Research Authority (HRA) approval

The HRA is the external regulator which provides approval for all research in England. No research activity can commence until HRA approval is in place. This may include a NHS ethics committee review.

To find out more information and/or apply for HRA approval please follow this link:

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

#### **Research Protocol**

The HRA defines a research protocol as:

"The research protocol is an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure everyone adheres to the methods outlined. As the study gets underway, it can then be used to monitor the study's progress and evaluate its outcomes."

## **Agreements and Contracts**

All study activity carried out by SCFT staff will be subject to an agreement or contract. A typical contract covers indemnity, intellectual property, confidentiality and financial issues.

Only the Research Director and Research Management staff sign agreements and contracts. This includes pharmaceutical non-disclosure agreements.

## **Funding**

All research carried out in the NHS must have the appropriate funding in place. This must cover the cost of all research procedures and related expenses.

# **Project performance and management**

Studies are registered on SCFT and national systems. This is so that studies can be tracked and reported. This is a requirement for all studies. SCFT along with all organisations in Kent, Surrey and Sussex use EDGE as their local performance management system. Please contact the Research team to register your study.

#### **Amendments**

Studies require regular review and aspects of the study often change during the study lifecycle. Amendments require regulatory approval from the HRA and/or NHS ethics.

All amendments must be reviewed and authorised by the Research team prior to implementation.

# **Research Training Requirements**

The type of research you are carrying out will determine the training you should undertake. It is SCFT policy that all staff undertaking research complete Good Clinical Practice (GCP) training.

GCP is an online or face-to-face course which gives an overview of best practice for conducting research. <a href="https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm">https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm</a>

For researchers intending to receive informed consent from participants training must be undertaken. Valid Informed Consent training is offered by the NIHR online. https://local.nihr.ac.uk/lcrn/kent-surrey-and-sussex/training.htm Study specific training is usually necessary for our clinical and research team to undertake.

Staff are required to record and demonstrate their training, competence, and compliance via a research CV. You can find the standard template here: <a href="https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/">https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/</a>

#### **Letters of Access**

If you, or someone else, involved in the research are not directly employed by SCFT a Letter of Access will be required for some research activities.

If you are a NHS employee external to SCFT you will need a NHS to NHS pre-engagement checks pro forma form and NHS to NHS letter of access.

If you are not a NHS employee you may need a letter of access via a research passport form.

Only the research department is responsible for issuing letters of access. Please contact us and we will advise as appropriate.

The relevant forms and information can be found here: <a href="https://www.myresearchproject.org.uk/help/hlphrqoodpractice.aspx">https://www.myresearchproject.org.uk/help/hlphrqoodpractice.aspx</a>

## Research grants

If you are carrying out your own research there are a number of routes to obtain funding. If you are applying for a grant please contact us for advice.

### Further information:

The SCFT website Research page can be found here: Research (sussexcommunity.nhs.uk)

To contact us email on <a href="mailto:sc-tr.research@nhs.net">sc-tr.research@nhs.net</a>

Social media: Twitter @scft\_research Facebook @scftresearch