Research Questions & Answers for Sussex Partnership NHS Foundation Trust Staff

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Anna-Marie Jones, Research & Development

1. Where can I go for funding?

A popular source for funding is the NHS research funding body, the National Institute of Health Research (NIHR). NIHR offer a funding stream called Research for Patient Benefit (RfPB) which is especially for clinicians wanting to do research, and so is a good option. NIHR offer other funding streams and alternative sources of funding include Wellcome Trust and the British Academy. You can find a list of funders below or use a funding search engine such ResearchProfessional.com (BSMS, Brighton University and Sussex University staff and students all have access). Sign up to their RSS news feeds to get regular updates on calls for applications.

List of Funders

- Arts and Humanities Research Council (AHRC)
- Alzheimer's Society
- AMRC (Association of Medical Research Charities)
- Biotechnology and Biological Sciences Research Council (BBSRC)
- British Academy
- British Heart Foundation
- BUPA Health foundation
- Cancer Research UK (CRUK)
- Charity Commission (UK)
- Dunhill Medical Trust
- European Commission Horizon 2020 UK
- Economic and Social Research Council (ESRC)
- Health Innovation Challenge Fund (DoH & Wellcome Trust)
- Leverhulme Trust
- Medical Research Council (MRC)
- NIH
- NIHR (National Institute for Health Research)
- Public Health Agency – Health & Social Care Research and Development Directorate
- Research Councils UK
- Royal Society
- Science and Technology Facilities Council (STFC)
- The Health Foundation
- US Federal Agencies
- UK Clinical Research Collaboration (UKCRC)
- UK Research Office (UKRO)

2. How do I find out if my research has been done before?

Funders will only fund research studies that are answering a novel, important research question. Sometimes we think up research ideas and then find that someone else has done the study we wanted to do! It can be tricky to know for sure that your research idea is completely new but there are some simple steps and some excellent resources available online to help you find out what you need to know.

A good place to start is by talking to other researchers, clinicians and experts in the field. Conducting a basic literature search using engines such as PubMed, Medline, Nice Evidence or Web of Science with key words; ask for help from your librarian. Don't forget to check the 'grey literature' including conference presentations and publications from relevant research groups.

Click here for a YouTube video produced by the NIHR RDS Yorkshire and the Humber on checking that a research idea is really novel. It describes websites such as:

- For NIHR funded projects try searching through the UKCRN portfolio
- NIHR Journals library which comprises a suite of five open access journals providing an important and permanent archive of research funded by the National Institute for Health Research.
- NIHR UK Clinical Trials Gateway provides information about clinical research trials running in the UK.
- www.controlled-trials.com which lets you carry out a search across national and international clinical trial registration sites.
- WHO Trial Search: searches through a wide set of databases.

3. When do I let my R&D department know about my study?

Contact the R&D department as soon as you start to put your proposal together. **You must get provisional R&D approval for your research before you start preparing your funding application**. This provisional approval is to say that the R&D department are willing, in principle, to support your study. It is not uncommon that R&D are unable to grant this, so, to avoid disappointment it is crucial that you seek provisional approval right from the start. Bear in mind that once your study is funded you will first need to obtain formal NHS research ethics and R&D approval before starting your study. The R&D department can provide you with guidance throughout the process. For information about the support that is available to you, email researchgovernance@sussexpartnership.nhs.uk**.**

4. How do I write a successful funding application?

You can start by:

- Seeking advice early on.
- See this presentation on applying for funding from an SPFT researcher's perspective (go to the useful resources for researchers tab).
- Requesting support from the NIHR Research Design Service (RDS) SE which offers free advice and support to NHS researchers who are developing applications to suitable funders.

- Asking a lay review panel to assess your application through the NIHR RDS SE or SPFT's Lived Experience Advisory Forum (co-ordinated by Ruth Chandler and Jean Southey).
- Applying for an NIHR RDS SE PPI grant to support PPI consultation on design.
- Attending a NIHR training workshop on preparing funding bids. A range of research information about training, workshops, news, funding deadlines or national and local events is available via the NIHR Research Design Service South East e-bulletin each month. Sign up for regular bulletins.
- Checking the funders scope criteria – is your research topic relevant?
- Reading the funders guidance notes for the specific competition to which you are applying very carefully.
- Referring to the R&D grant proposal checklist (go to the useful resources for researchers tab).

5. What is PPI, do I need it and how can I fund it?

PPI stands for Patient and Public Involvement and the answer is yes you do need to incorporate it into your study. For NIHR grant applications previous PPI work will be expected. At Sussex Partnership we have our own PPI team called the Lived Experience Advisory Forum which is co-ordinated by Ruth Chandler and Jean Southey so get in touch with them at an early stage for more information on how they can support you.

The NIHR Research Design Service South East (RDS SE) team also has a PPI specialist, Duncan Barron, who can provide one-to-one guidance on how to carry out PPI activities.

There is a small PPI grant of up to £300 that you can apply for to help support PPI consultation on design and development of your study. You will need to register with the NIHR RDS SE first. For information about how to apply and application deadlines see
http://www.rds-se.nihr.ac.uk/patient-and-public-involvement/

6. What is the difference between a pilot and a feasibility study?

Essentially a feasibility study is testing whether or not your main study can be done and you would conduct this if you had a lot of unknowns e.g. no effect size on which to carry out a sample size calculation, no primary outcome, if you are unsure whether or not people would be willing to be randomised to different arms in your study. Importantly, they do not evaluate the outcome of interest; this is left to the main study.

A pilot study is a mini version or test run of your main study to check you haven't overlooked something in the process that could delay, disrupt or prevent the full achievement of the research objective. So a pilot study you would assess whether your strategies for recruitment, randomisation, treatment and follow-up assessments were robust.

The NIHR has produced guidance on the distinction between feasibility and pilot studies which applies to their EME, PHR, HTA and RfPB programmes.

Two more general papers on the topic are:

- What is a pilot or feasibility study? A review of current practice and editorial policy, Mubashir Arain, Michael J Campbell, Cindy L Cooper, Gillian A Lancaster, BMC Med Res Methodol. 2010; 10: 67.

- A tutorial on pilot studies: the what, the why, and the how, Lehana Thabane, Jinhui Ma, Rong Chu, Ji Cheng, Afisi Ismaila, Lorena P Rios, Reid Robson, Marroon Thabane, Lora Giangregorio, Charles H Goldsmith, BMC Med Res Methodol. 2010; 10: 1.

7. I have to include a Plain English section, what do they mean by plain?

So this means:

- No acronyms
- No Jargon
- No technical terms
- Use of common English words
- Short sentences
- Active phrases

The NIHR started a 'make it clear' campaign (see http://www.invo.org.uk/makeitclear/) and since the 14th May 2014 a plain English summary must be submitted as part of an NIHR funded application. Helpfully they have published the following guidance: http://www.invo.org.uk/wp-content/uploads/2014/05/Plain-English-summary-overview-website-140514.docx

8. Does SPFT provide support for qualitative research?

Yes. Contact Duncan Barron who is a part of the SPFT R&D team as a qualitative methodologist.

9. Does SPFT provide support for quantitative research or statistical methods?

Yes. For advice from a statistician contact: anna-marie.jones@sussexpartnership.nhs.uk

10. Where can I get help to put my finance section together?

For help calculating the finances for your project contact the R&D Governance team at researchgovernance@sussexpartnership.nhs.uk

11. What sample size do I need?

Before that can be answered have you checked that you have got the right research design to answer your research question? If so, other questions will follow before you can attack the sample size calculation such as:

- Is this a feasibility, a pilot or a main study?
- Is this an exploratory study using qualitative methods?
- Are you doing clinical trial, an observational study or developing/refining an intervention for instance?

- Are you developing a new scale or outcome measure?
- What is your primary outcome and how is it distributed? Is there any information on the mean value or standard deviation for your population under similar test conditions?
- What is the minimum clinical difference on your primary outcome measure?
- What is your estimated attrition rate?
- What might the response rate look like?
- How will you analyse your data –simple data summary, compare two means, hypothesis testing?
- What power are you aiming for (some NIHR grants look for 80 and some 90%)

In your application you **must** give a **justification** for your sample size, the reviewer must be able to follow your description to make the calculations for themselves.

NIHR RDS London has produced a useful guide on Justifying Sample Size for a Feasibility Study

For advice from a statistician contact anna-marie.jones@sussexpartnership.nhs.uk

12. Where can I get general information or tips on how to manage my trial?

See:

- NIHR Clinical Trials Toolkit
- The 2015 NIHR Clinical Trials guide for NIHR trainees (excellent set of links at the back)
- Trial Managers Network (TNM) Guide to Efficient Trial Management.
- HRA Specific Questions that need answering when considering the design of clinical trials

13. How should I write my research protocol suitable for R&D governance checks and publication?

The R&D team have developed a research protocol template for you (go to the useful resources for researchers) which covers the core elements of what is needed in a fully informative document. Work through the template and you will have a good recipe for your research project. You will start with the information you put in your funding application and build it up with a higher level of detail.

It is good practice to publish your research protocol and a quick and easy way to get a publication early on in your project. Use a site like http://www.trialsjournal.com/

14. How do I put together a good consent form or a Participant Information Sheet?

The Health Research Authority (HRA) have an excellent set of guidance on the ethical and legal principles of gaining consent in general, in a paediatric setting and in situations where adults lack capacity. They also provide Consent and

Participant Information Sheet Preparation Guidance as well as listing a number of HRA Examples and Templates for use in your study.

The SPFT R&D Clinical Research Co-ordinators (CRC) team also provided the following top tips for preparing consent forms**:**

- Make sure it is **concise**; some trials can have very long consent forms with a lot of boxes to initial. Although sometimes this may be necessary, it can be hard to get a participant to concentrate if there are two pages of boxes to initial.
- Use **large fonts** for the participant to read it clearly
- Explain the **information sharing** intentions and when you would share information e.g. if someone is at risk or if the clinical care team need to be informed; explain that no information will be fed back to the participant
- Reference the 1998 Data Protection Act
- Make sure you use **lay terms**.
- It's handy to have a **space** for both the **patient identification number** and their **Local Trust ID** at the top of the consent form. Although this is not compulsory, it means that if you are searching for their documents a while after you have consented them, you can find them easily and confirm that it is the correct person (e.g. If you consent John Smith and have 400 people on your study then you could have a duplicate and you then have to start searching through recruitment logs to confirm you have the right person).
- Explain that one copy (often the original) will be put in the Investigator Site File, one will go in the patient's medical notes and one will be given to the patient. This is a GCP requirement but is often forgotten.
- If you plan to carry out **future research** based on samples you are taking for this study make this clear – the participant should sign a separate consent form for this.
- Date and include a version number
- You may find it helpful to look at some of the recently accepted other forms as a guide.

15. Which statistical analysis do I need to use on my data?

There are few things to consider before you start clicking buttons in SPSS.

First of all what type of data have you got? Is it Nominal, Ordinal, Interval or Ratio?

Second of all do you know what the distribution looks like? Is it Normally distributed, non-Normal, Binomial?

Third of all, what do want to do with your data? Describe one group, compare two or more groups or find an association between two outcomes?

If you know the answers to these questions, start exploring your data using a decision tree to help you choose a statistical test

- Choosing the correct statistical test made easy by *N Gunawardana Senior Lecturer in Community Medicine, Faculty of Medicine, University of Colombo*

- Choosing a statistical test on the GraphPad FAQ website

For statistical methodological support for your application email anna-marie.jones@sussexpartnership.nhs who is the R&D team statistician.

16. How should I report my findings?

In February 2014 the British Medical Journal published the 12 item TIDieR checklist as an extension of the CONSORT 2010 statement (item 5) and the SPIRIT 2013 statement (item 11). To improve the completeness of reporting, and ultimately the replicability, of interventions, an international group of experts and stakeholders developed the Template for Intervention Description and Replication (TIDieR) checklist and guide. The resultant checklist covers:

- Brief name
- Why
- What (materials)
- What (procedure)
- Who provided
- How
- Where
- When and how much
- Tailoring
- Modifications
- How well (planned)
- How well (actual)

While the emphasis of the checklist is on trials, the guidance is intended to apply across all evaluative study designs.