Standard Operating Procedure

DEVELOPING AND DESIGNING YOUR STUDY

SETTING Trustwide and partner universities

AUDIENCE Researchers undertaking research at UHBristol

ISSUE To guide researchers on how to write research proposals to funding bodies and factors to consider when planning a study.

QUERIES Research Grants Manager or Research Grants and Contracts Facilitator. Tel 0117 3420233 or email Funding@uhbristol.nhs.uk

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Original SOP	1.0	14/OCT/2015	03/NOV/2015	Elinor Griffiths	Diana Benton
November 2016	1.1	03/DEC/2016	20/DEC/2016	Elinor Griffiths	Diana Benton & Jess Bisset
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1. Introduction

There are many costs involved in conducting clinical research. Therefore, once you have a research idea the design of the study and how the various costs of the study will be met, should be considered.

1.1 Funding

There are various funding sources:

- In the NHS **non-commercial research** can be funded by government organisations like the National Institute for Health Research (NIHR), or charitable organisations (many of which are designated NIHR partner organisations). Research that is funded by the NIHR or partner organisations and undergoes peer-review through a competitive national application process is eligible for adoption by the NIHR-Portfolio; a list of non-commercial NIHR partners is provided on the NIHR website. Portfolio-adopted studies are eligible for NHS support funding (see section 6.3.6). Funding is also available from local sources such as Above and

Beyond (A&B), David Telling or UHBristol Research Capability Funding (RCF), but studies funded through these sources will not be eligible for NIHR-Portfolio adoption. Further information about local funding is available on the R&I website.

- **Non-commercial unfunded research** is not eligible for adoption on the NIHR Portfolio. Where possible it is preferable to apply for local funding to conduct your research, as there is support available to help prepare these applications. Unfunded studies will need to undergo peer review as part of the sponsorship application process, and the Chief Investigator (CI) will be asked to suggest reviewers. We encourage people to apply for A&B or RCF rather than conduct unfunded studies, as the former have the advantage of rigorous peer review and methodological support which improves the quality of the research and likelihood of it succeeding. Due to limited resource R&I has to prioritise which studies to support in line with Trust and national objectives set by the NIHR, and these unfunded studies are therefore not considered a high priority for support.
- **Commercial grants** are investigator led studies that are funded but not sponsored by commercial organisations. They are sometimes awarded in open competition, and so can be eligible for adoption by the NIHR-Portfolio, but often result from an individual relationship between a researcher and a commercial company. There can be complex negotiations about intellectual property ownership and the amount of funding. The same general principles apply as for non-commercial research, but the costing can differ, for example as well as full research costs, overheads, support and treatment costs should be included on commercial grants.

1.2 Designing your study

Once you have had an idea for a research project, the idea should be written down and developed into a grant application and/or protocol. Funders have specific application forms that must be completed, and detailed remit and guidance about the research they will fund. The protocol is a separate document that is not normally required for the grant application, but needs to be written before sponsorship and ethical approval can be obtained. This Standard Operating Procedure (SOP) applies to studies that are applying for funding, but the principles are the same for unfunded research.

2. Purpose

The purpose of this SOP is to provide general guidance on how to write an investigator-led research proposal, explain factors that need to be considered when applying for funding, and where to go for support. Furthermore this SOP also provides details of the UH Bristol requirements for specific aspects of study design and management according to study type and in accordance with applicable research legislation.

3. Scope

In Scope: Any researcher considering applying for research funding through UH Bristol from any grant awarding body (including but not limited to National Institute for Health Research, local and national charities), and anyone who wishes UH Bristol to sponsor their study.
Out scope: Commercially sponsored studies, unfunded research, or research led and sponsored elsewhere.

4. Responsibilities

Any staff wishing to conduct research at UH Bristol have a responsibility to ensure the research is fully funded, appropriately designed and of a high quality.

The R&I Research Grants Manager and Research Grants and Contracts Facilitator have a responsibility to ensure that all staff who wish to apply for research funding through UH Bristol are appropriately supported and facilitated.

The R&I operational team has a responsibility to provide appropriate support and guidance to anyone who requests sponsorship from UH Bristol.

5. Abbreviations and Definitions

6. Procedure

Abbreviations	
A&B	Above and Beyond (local charity that fundraises for UH Bristol)
BRC	National Institute for Health Research Biomedical Research Centre
CI	Chief Investigator
CLAHRC	Collaboration for Leadership in Applied Health Research and Care
NIHR	National Institute for Health Research
PPI	Patient and Public Involvement
R&I	Research and Innovation Department, UH Bristol
RCF	NIHR Research Capability Funding
RDS	Research Design Service
SOP	Standard Operating Procedure
UHBristol	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol
UWE	University of the West of England, Bristol

6.1 Developing your research idea

- Once you have had an idea for a study, you need to develop this into a grant application. If you are new to research *TMPL_017 Research proposal draft* may be useful. It contains questions that you need to be able to answer for any research funder. Further guidance can be found on the R&I website.

6.2 Where to apply for funding.

- Small pilot or feasibility studies can be funded through local charities and our RCF scheme can also be used to provide backfill time to write grant applications. For further details please see the R&I website.
- The major funder of research at UHBristol is the NIHR. There are various funding streams depending on the type of research. Details are available on the NIHR website, and further advice from the grants manager or Research Design Service (RDS). There are many charities that support research into specific areas; a list is available from the NIHR website.
- Commercial companies will also sometimes fund investigator-lead research.

6.3 Designing your study

- Depending on the size and complexity of study, help and advice may be required from a variety of specialist advisors, such as qualitative, statistical, health economics. Having the right research team is essential to success, and should include relevant clinical input and patient and public involvement. Please note that students and trainees should obtain advice

from their supervisor (UHBristol does not provide ad hoc statistical advice for unfunded applications, or for work already funded where this has not been taking into consideration).

6.3.1 Methodological support

- There are various teams and units within Bristol that can advise on the study design and be part of the ongoing study once awarded. Contact details for these can be obtained from the Research Grants Manager or Grants and Contracts Facilitator (tel 0117 3420233 or email Funding@uhbristol.nhs.uk). The RDS and trials units have a common website where you can apply for support: Bristol Research Support Partners.
- RDS is an organisation funded by the NIHR to help with NIHR and partner organisation grant applications.
- University of Bristol has two NIHR-accredited trials units that provide support in a collaborative manner for larger studies: the Clinical Trials and Evaluation Unit and Bristol Randomised Trials Collaboration.
- Biomedical Research Centre (BRC). UH Bristol was awarded an NIHR funded BRC in 2017, incorporating our 2 existing units and an additional 3 themes:
    - Cardiovascular Disease,
    - Nutrition, Diet and Lifestyle including Obesity
    - Surgical Innovation
    - Mental Health
    - Perinatal and Reproductive Health

  If your idea relates to one of these areas the BRC may be able to provide support and guidance to conduct preliminary studies, or help with a grant application in that area. Collaboration for Leadership in Applied Health Research and Care (CLAHRC): CLAHRC-West. CLAHRC can provide methodological research support and evidence for a variety of projects, further details on the CLAHRC-West website.
- Bristol Surgical Trials Centre, which aims to bring together academic and surgical expertise to work in innovative collaborations

6.3.2 Patient and Public Involvement (PPI)

- PPI in research refers to ways in which patients and members of the public can become involved in designing or helping with research studies; it does not refer to people who take part in research studies. PPI is essential for all NIHR applications and for other funders. Involving patients who have had experience of a particular disease can help design research that is relevant to patients. Further information is on the R&I website "Patient and public involvement in research"

6.3.3 Feasibility

- This forms part of research design, but is often where studies fail. Feasibility includes background work before a study starts to check that it is practical to run the study, for example:
    - Is it possible to recruit the number of patients necessary?
    - Are there staff who can perform the research and/or can staff be recruited staff in time?
    - Discuss support and excess treatment costs with the Research & Development office of the organisation where patients will be recruited from
    - Discuss with support departments such as pharmacy and radiology that they have resources to support the study, and whether they need any research costs added to the grant application
    - Discuss with your departmental clinical colleagues and management to ensure that the department will support the study

6.3.4 Dissemination and Impact.

- Most funders will ask for a dissemination plan, and/or what impact the results of your research will have. You need to think about this at the application stage, to cost in money for dissemination, such as conference presentations, publication costs, public and/or professional dissemination events. You also need to consider how your research is going to get out into the wider NHS – for example to be incorporated into NICE guidelines.
- If your research will lead to commercially exploitable results, and/or produce something that needs to be made available to health professionals, then you will need specialist advice at grant application stage to ensure this is included in the plan and costs.

6.3.5 Study management

- Funders will ask how you are going to manage the study; some will provide detailed guidance on what is required, for example a study steering group and, data monitoring committee. Day to day running of the study is the responsibility of the CI, and it is good practice to hold regular team meetings (weekly or two-weekly), plus less frequent study management meetings (usually monthly), plus a steering group that meets every 6 or 12 months and includes independent members where appropriate.

6.3.6 Costing the research.

- NIHR and partner charities attribute cost into 3 categories: research, support and treatment, and NHS costs can be incurred under any category. It is important to ensure that all research costs are fully funded, whether they take place in a university or NHS organisation.
- Attributing costs to "support" and "treatment" categories is not always straightforward. Detailed guidance can be found on the R&I website with links to relevant Department of Health guidance. It is essential to ensure that you have spoken to R&I about how support and any excess treatment costs will be met before submitting an application. If you are unclear about whether your research will incur support or excess treatment costs, please contact R&I: 0117 20233 or email funding@uhbristol.nhs.uk

6.4 The application form and process.

- Funders usually have online application forms, and strict deadlines. Ensure that you have checked the requirements for funding, and that your study is within remit – see the R&I website "Preparing your funding application", and *GD_002 Pre-award checklist*. If you intend to submit your grant through UH Bristol please contact R&I as early as possible. Two weeks is the minimum time required for sign off, but all costs should be discussed, obtained and categorised before this time. You will also need to discuss which organisation should sponsor your research, as sign off by the sponsor is often required. For details see SOP_002 Sponsorship and the R&I website.

6.5 Signatures and approvals required before submitting the application.

- Check the funder guidance on their procedure for sign off. Some require electronic and some wet-ink signatures, either before you submit the application, within a week or two of submitting, or both. You also need to contact whoever needs to sign well in advance to check they support your application, especially if separate supporting statements are required, and that they will be available to sign by the deadline.
- NIHR grants require sign off by R&I and R&I finance, all other grants need sign off by your Divisional Finance manager. If you are unsure who needs to sign please contact R&I.

6.6 What to do when funding is awarded.

- If your grant is awarded, you will usually be asked to answer reviewers' comments about the methodology, plus finance and intellectual property queries. Then the funder will issue a contract - please contact R&I for help with these, and use *GD_003 Post-award checklist*. You will also then need to apply for sponsorship and approvals from the relevant regulatory

bodies. Please refer to *SOP_002 Sponsorship* and *GD_001 Gaining & Maintaining Authorisations*. Studies usually take longer to set up than anticipated, especially if new staff have to be recruited. Most studies now run through our research units, and the unit managers can advise on staff appointments. The research units should also be contacted at the costing stage to ensure resources are covered – R&I can give contact details.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in SOP_007 Research Training.

8. Related documents

- GD_001 Gaining & Maintaining Authorisations
- GD_002 Pre-award checklist
- GD_003 Post-award checklist
- SOP_002 Sponsorship
- SOP_004 Writing a Research Protocol to Good Clinical Practice
- SOP_007 Research Training