Standard Operating Procedure

DEVELOPING AND DESIGNING YOUR STUDY AND GRANT SUBMISSION THROUGH UHBW

SETTING Trustwide and partner universities

AUDIENCE Researchers undertaking research at UHBW

ISSUE To guide researchers on how to write research proposals to funding bodies and the process of grant submission through UHBW.

QUERIES Research Grants Manager or Research Grants and Contracts Facilitator. Tel 0117 34 20233 or email Research.Grants@uhbw.nhs.uk

SOP number	SOP_003	**SOP Version**	2.1
Effective Date	09/DEC/2024	**Review Date**	14/NOV/2026

Document History

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
Original SOP	1.0	14/OCT/2015	03/NOV/2015	Elinor Griffiths	Diana Benton
NOV/2016	1.1	03/DEC/2016	20/DEC/2016	Elinor Griffiths	Diana Benton & Jess Bisset
DEC/2017	1.2	21/DEC/2017	12/FEB/2018	Elinor Griffiths	Jess Bisset
SEP/2020	1.3	07/SEP/2020	14/SEP/2020	Elinor Griffiths	Jess Bisset
AUG/2022	1.4	26/AUG/2022	26/AUG/2022	Elinor Griffiths	Jess Bisset
FEB/2023	1.5	16/FEB/2023	01/APR/2023	Lucy Riddolls	Jess Bisset
JUL/2024	2.0	29/JUL/24	14/NOV/2024	Elinor Griffiths	Diana Benton
DEC/2024	2.1	06/DEC/2024	09/DEC/2024	Sandra Mulligan	Jess Bisset

Version Number	Reason for change
1.0	N/A
1.1	Review due
1.2	Review due – minor updates
1.3	Review due – minor updates
1.4	Review due – minor updates
1.5	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
2.0	Major update to include additional information about process for grant submissions and extensions included, plus update to terminology of external organisations names and links.
2.1	Minor update to correct typographical errors, information tables and new document system location

1. Introduction

If you are considering a research study and have an idea you wish to discuss, there are various people in UHBW and its partner universities that can help with both the design of the study, and costings. Both take time to work up thoroughly.

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 Bristol and Weston Hospitals Charity (BWHC) or UHBW Research Capability Funding (RCF), but studies funded through these sources will not usually be eligible for NIHR-Portfolio adoption (unless co-funded by NIHR or partner). Further information about local funding is available on the R&D website.

- **Non-commercial unfunded research** is not eligible for adoption on the NIHR Portfolio. 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. Such studies are not prioritised for Sponsorship. Rather, we encourage people to apply for BWHC 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&D 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; the relevant finance manager should be consulted early in the process of applying.

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. This SOP also provides details on the process of grant submission through UHBW, including 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 UHBW from any grant awarding body (including but not limited to NIHR, local and national charities and commercially funded investigator led studies), and anyone who wishes UHBW to sponsor their study.
Out of scope: Commercially sponsored studies or research led and sponsored elsewhere.

4. Responsibilities

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

The R&D 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 UHBW are appropriately supported and facilitated.

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

5. Abbreviations and Definitions

Abbreviations	
ARC West	Applied Research Collaboration West of England
BRC	Biomedical Research Centre
BWHC	Bristol and Weston Hospitals Charity
CI	Chief Investigator
EDI	Equality, Diversity, and Inclusion
IIS	Investigator Initiated Study
IP	Intellectual Property
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PPI	Patient and Public Involvement
R&D	Research and Development Department, UHBW
RDN	Research Delivery Network
RCF	Research Capability Funding
RSS	Research Support Service
SoECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UoB	University of Bristol
UWE	University of the West of England, Bristol

6. Procedure

6.1 Developing your research idea

- You need to ensure that you have the right expertise within your team and develop this into a grant application. Methodological support is available for UHBW small grants and for NIHR and national charity grants from the NIHR Research Support Service (RSS). Contact the UHBW grants team in the first instance who can put you in touch 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&D website You may also be considering a personal award such as a fellowship (e.g. a pre-doctoral or doctoral award, or an earlier internship for non-medical staff), and again there are national funding available for such awards.

Where to apply for funding.

- Small pilot or feasibility studies can be funded through our local charity Bristol and Weston Hospitals Charity (BWHC) and UHBW RCF scheme can also be used to provide backfill time to write grant applications. For further details please see the R&D website or contact R&D.
- Alongside these, UHBW RCF can also be used to develop fellowship applications for nurses, midwives, allied health professionals and clinical scientists (not doctors or dentists). Contact the R&D grants team in the first instance: Research.Grants@uhbw.nhs.uk
- The major funder of research at UHBW 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 NIHR Research Support Service (RSS). 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.

6.2 Designing your study

- Depending on the size and complexity of your study, help and advice may be required from a variety of specialist advisors, such as qualitative, statistical, and 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. Note UHBW does not provide ad hoc statistical advice for unfunded research, or for work already funded where this has not been taking into consideration at the pre-award stage.

6.2.1 Methodological support

- There are various teams and units within UHBW and our partner universities that may be able to advise on the 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 Research.Grants@uhbw.nhs.uk).
- RSS is an organisation funded by the NIHR to help with NIHR and partner organisation grant applications.
- Larger studies and particularly randomised controlled trials would need the support of a trials unit. The Bristol Trials Centre, University of Bristol may be able to help, but the UHBW grants manager or RSS can advise on others available depending on the area of research.
- UHBW was awarded an NIHR funded Biomedical Research Centre in 2017, which was renewed in 2022; please see the NIHR Bristol BRC website for list of themes and areas. 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.

- The Applied Research Collaborative (ARC) West can also provide methodological research support and evidence for a variety of applied health research projects, further details can be found on the ARC West website.
- Bristol Centre for Surgical Research aims to bring together academic and surgical expertise to work in innovative collaborations.

- Intellectual Property (IP) and Commercialisation: most grant applications will require a description of any IP that will be used or generated within the project (even if there appears not to be any you will need to explain why). If a new device is being developed for commercialisation, you will need expert advice on this, which we have access to. Please contact Research.Grants@uhbw.nhs.uk.

6.2.2 Patient and Public Involvement (PPI) and Equality, Diversity and Inclusion (EDI)

- 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&D website under patient and public involvement in research. For any application, consideration needs to be given to how EDI is going to be ensured. The RSS and other methodological support units and Trials Centres can advise during application development.

6.2.3 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?
    - How will patients be recruited and followed up, and are there any special considerations or barriers?
    - 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 R&D office of the organisation where patients will be recruited from, as well as the local Research Delivery Network (RDN), who will need to approve these using a SoECAT form prior to submitting to national funders.
    - 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.

6.2.4 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.

6.2.5 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.

6.2.6 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&D website with links to relevant Department of Health guidance. It is essential to ensure that you have spoken to R&D 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&D: 0117 20233 or email Research.Grants@uhbw.nhs.uk
- The attribution of costs will need to be approved and validated prior to any grant submitted to NIHR and partner organisations by the local CRN (West of England). They can help with deciding on the appropriate allocation, in discussion with R&D.

6.3 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&D website "Preparing your funding application", and guidance document *GD_002 Pre-award checklist*. If you intend to submit your grant through UHBW please contact R&D 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 with R&D finance. 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 Research Sponsorship at UHBW* and the R&D website.
- For commercial grants, often called Investigator Initiated Studies (IIS) UHBW will charge an overhead rate that should be included in the costings. Please contact your divisional finance team and R&D grants team well before any application deadline to ensure that the commercial funding limit will accommodate this.

6.4 Signatures and approvals required before submitting the application.

- Check the funder guidance on their procedure for sign off. Most require electronic and some wet-ink signatures, either before you submit the application, within a week or two of submitting, or both. Even where a signature is not required on the application form, the grant will require internal sign off by UHBW Research Finance before submission. 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&D and R&D finance, all other grants need sign off by your Divisional Finance manager. If you are unsure who needs to sign, please contact R&D.

6.5 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&D 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 Research Sponsorship at UHBW* 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&D can give contact details.

6.6 Extensions and amendments

- Study timelines especially length of recruitment and follow up need to be estimated as accurately as possible during the initial application. However, amendments and extensions are often needed.
  Amendments and extensions to the initial design, timeline, cost or recruitment target need to be discussed with R&D before approaching the funder. Most funders will require a revised application and documents justifying the need for the extension, and these will need to be discussed and approved by R&D and the relevant finance team before sending to the funder (as for the initial submission).

7. Dissemination and training in the SOP

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

Plan Elements	**Plan Details**
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A – replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	N/A
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust MyStaffApp 2. Updated on the R&D website 3. Cascaded in the R&D e-bulletin
Is Training required:	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 UHBW*

RELATED DOCUMENTS AND PAGES	• GD_001 Gaining & Maintaining Authorisations • GD_002 Pre-award checklist • GD_003 Post-award checklist • SOP_002 Research Sponsorship at UHBW • SOP_004 Writing a Research Protocol to Good Clinical Practice • SOP_007 Research Training UHBW • TMPL_017 Research Proposal Draft These are available on the R&D section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development Department on 0117 34 20233 or research@uhbw.nhs.uk
AUDIT REQUIRMENTS	R&D departmental Quality Management System audits are undertaken annually