Standard Operating Procedure

# DEVELOPING AND DESIGNING YOUR STUDY

**SETTING** Trustwide and partner universities

**AUDIENCE** Researchers undertaking research at UHBristol

---

## Standard Operating Procedure (SOP)

| | | | |
|---|---|---|---|
| Author: | Elinor Griffiths | Role: | Research grants manager |
| Approved by: | Trust Research Group | | |
| Date for review: | November2017 | | |

| Review date | Version number | Version Date | Effective Date | Reason for change | Author/Responsible person | Authorised by |
|---|---|---|---|---|---|---|
| - | 1.0 | 14/10/2015 | 03/11/2015 | New SOP | Elinor Griffiths | Diana Benton |
| **November 2016** | 1.1 | 03/12/2016 | 20/12/16 | Review due | Elinor Griffiths | Diana Benton & Jess Bisset |
| | | | | | | |

### 1. Purpose

(i) 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.
(ii) To provide details of UH Bristol requirements for specific aspects of study design and management according to study type and in accordance with applicable research legislation.

### 2. 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 of scope:** Commercially sponsored studies, unfunded research, or research led and sponsored elsewhere.

### 3. Definitions/Abbreviations

| | |
|---|---|
| **A&B** | Above and Beyond (local charity that fundraises for UH Bristol) |
| **BRU** | National Institute for Health Research Biomedical Research Unit |

| | |
|---|---|
| **CI** | Chief Investigator |
| **CLAHRC** | Collaboration for Leadership in Applied Health Research and Care |
| **DMS** | Document Management System |
| **NIHR** | National Institute for Health Research |
| **R&I** | Research and Innovation Department, UH Bristol |
| **RCF** | NIHR Research Capability Funding |
| **RDS** | Research Design Service |
| **SOP** | Standard Operating Procedure |
| **UH Bristol** | University Hospitals Bristol NHS Foundation Trust |
| **UoB** | University of Bristol |
| **UWE** | University of the West of England, Bristol |

## 4. Introduction

### 4.1 Funding

**4.1.1** **Non-commercial funded research.** In the NHS non-commercial research can be funded by government organisations like the 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 5.3.6, this SOP). Funding is also available from local sources such as Above and Beyond, David Telling or UH Bristol 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.

**4.1.2** **Non-commercial unfunded research.** These studies are not eligible for adoption to 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 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. Unfunded studies often come from new researchers, who need a lot of help and support to get the protocol to the required standard, and we advise people to link with an established research team rather than work alone. 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.

**4.1.3** **Commercial grants.** These 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 (see 4.1.1), 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.

### 4.2 Designing your study

Once you have had an idea for a research project, you will need to write down your ideas and develop it 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. Section 5 assumes you will be applying for funding, but the principles are the same for unfunded research.

## 5. Procedure

### 5.1 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 you may find it helpful to use the "research proposal draft template" form, appendix 1. 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.

### 5.2 Where to apply for funding.

**5.2.1** 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 Research and Innovation website.

**5.2.2** The major funder of research at UH Bristol 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 RDS. There are many charities that support research into specific areas; see the NIHR list of partner charities.

**5.2.3** Commercial companies will also sometimes fund investigator-lead research – see section 4.1.2, this SOP.

**5.3 Designing your study.** Depending on the size and complexity of your study, you will need help and advice 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 (UH Bristol does not provide *ad hoc* statistical advice)

#### 5.3.1 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 each 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 Units. UH Bristol has two BRU's funded by the NIHR:
  NIHR Bristol BRU in Cardiovascular Disease,
  NIHR Bristol BRU in Nutrition, Diet and Lifestyle including Obesity
  If your idea relates to one of these areas the BRU may be able to provide support and guidance to conduct preliminary studies, or help with a grant application in that area.
  From April 2016 there will be one Biomedical Research Centre in Bristol which incorporates the two existing BRU themes and additional themes of surgical innovation, reproductive and perinatal health, and mental health.
- Collaboration for Leadership in Applied Health Research and Care: 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

**5.3.2 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 trials. 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"

**5.3.3 Feasibility**

This forms part of research design, but is often where studies fail. Feasibility includes background work before you start a study 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 your study, and whether they need any research costs added to the grant application
- discuss with your departmental clinical colleagues and management that the department will support the study

**5.3.4 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 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.

**5.3.5 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. See also the Study Setup and Management Plan template, appended to the Sponsorship SOP.

**5.3.6 Costing the research.**

NIIHR 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 is irrelevant. Attributing costs to "support" and "treatment" categories is not always straightforward. Detailed guidance can be found on the R&I website:, including 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

**5.4 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 our "pre-award checklist" (appendix 2). If you intend to submit your grant through UH Bristol please contact R&I as early as possible. Two weeks is the minimum times required for sign off, but all costs should be 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 the "Sponsorship SOP" and the R&I website.

**5.5 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 whomever 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.

**5.6 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 our post-award checklist (appendix 3). You will also then need to apply for Sponsorship and approvals from the relevant regulatory bodies. See the "Sponsorship" and "Gaining and Maintaining Authorisations" SOPs. Studies usually take longer to set up than anticipated, especially if new staff have to be appointed. 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.

## 6. Dissemination and training in the SOP

### 6.1 Dissemination of this SOP

**6.1.1 New SOPs and new versions of existing SOPs:** The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the SOP "Authorship, review, revision and approval of research procedural documents produced by Research & Innovation". Internal Trust Staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates, as communicated in the Training SOP.

Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly);
- Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade ;
- Direct email to Chief Investigators of CTIMPs sponsored by UHBristol;
- Direct email to the Head of Research Governance at the University of Bristol (as relevant).

### 6.2 Training in this SOP

**6.2.1** All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

**6.2.2** The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.

## 7. Appendices

**Appendix 1: Research idea template**
**Appendix 2: Pre-award checklist**
**Appendix 3: Post-award checklist**

**IMPORTANT NOTE:**

This procedure has been screened for equality impact; it was not assessed as having adverse effects on any section of the community.

| | |
|---|---|
| **RELATED DOCUMENTS** | Sponsorship SOP |
| | Writing a research protocol SOP |

| | |
|---|---|
| **AUTHORISING BODY** | Trust Research Group |
| **QUERIES** | Research Grants Manager or Research Grants and Contracts Facilitator based in the Research and Innovation Department. Tel 0117 3420233 or email Funding@uhbristol.nhs.uk |

**Appendix 1**

**Research proposal draft template**

*The first table is designed to get you thinking about what, why and how you are going to do it, and what resources you need. This can help you get down your ideas on paper, without the formality of a grant application layout.*
*The second table is designed as a mini grant application using headings that are found on most application forms (adapted from our Above and Beyond and Research Capability Funding grants).*

| **TABLE 1. Get down your ideas** |
|---|
| What do you want to do? |
| |
| Why do you want to do it (why is it important)? |
| |
| Have you talked to colleagues? What were their comments? (positive and negative) |
| |
| Have you talked to patients/public (e.g. friends/family)? What were their comments? (positive and negative) |
| |
| What has already been done (do you need to do a literature review)? |
| |
| What specifically do you want to do (goals)? |
| |
| How are you going to achieve your goals? |
| |
| What do you need in order to achieve your goals (resources; including personnel with specialist expertise)? |
| |
| How much will it cost? (personnel, equipment, consumables; computers, software etc.) |
| |

| TABLE 2. Grant application style |
|---|
| **1. Principal Investigator:** |
| **2. Title:** |
| **3. Lay Summary (150 words):** |
| **4. Summary (250 words):** |
| **5. Co-applicants:** |
| **6. Collaborators:** |
| **7. Roles and expertise of each applicant/collaborator:** |
| **8. Background (300 words):** |
| **9. Objectives (200 words):** |
| **10. Study design 400 words:**<br>*Methodology/Protocol/how many patients/length of study/type of study etc.* |

**11. Gantt chart**
*This should show the timescale for each stage of the project – can append separately*

**12. Patient and Public Involvement (PPI) in research.**
*Have you involved patients or the public? If so explain how, and what their comments were regarding study design, feasibility, need for the work etc.*
*If not explain why.*

**13. Intellectual Property**
*You may not have answers to this section yet. Contact Research & Innovation if you are unsure and need help.This section is now on most larger grant applications and needs to be thought about early on*:

**a) Who will be bringing what previous knowledge or other information**?
*(this is known as background IP, e.g. software, questionnaires, novel equipment)*

**b) How will the IP be managed and exploited (Foreground IP)?**

**14. Past track record of the PI in research:**
**a) Publications**

**b) Previous grants held** *(state whether you were the principal investigator or co-applicant)*

**15. Finance**
*Give a detailed breakdown of all costs by year, including personnel, equipment, consumables, salaries, travel, PPI expenses.*

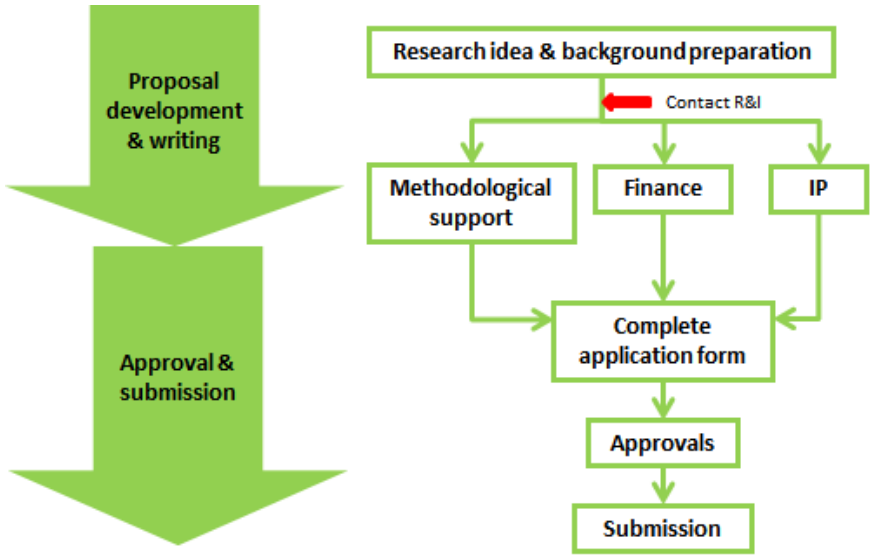
Appendix 2

Pre-Award Checklist

University Hospitals Bristol NHS
NHS Foundation Trust

**PRE-AWARD PROCESSES - IDEA TO SUBMISSION**
**Quick Reference Guide**

MAY TAKE 3 – 24 MONTHS






## ❖ Research idea & background preparation

THIS STAGE MAY TAKE 3 - 22 MONTHS - MAKE SURE YOU ALLOW PLENTY OF TIME

➢ **Visit** http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/research-funding-and-applying-for-grants

➢ **Download**

- http://www.uhbristol.nhs.uk/media/1815281/research_proposal_draft_template_v3.doc and use it to sketch your research idea and gather as much information as possible
- http://www.uhbristol.nhs.uk/files/nhs-ubht/Costing_Checklist.pdf , and use it to guide you in preparing an initial outline of costs

➢ **Contact R&I as soon as possible (**funding@uhbristol.nhs.uk**)**

- You will be directed to methodological, costing and Intellectual Property advice and support.

## ❖ Proposal development & writing

THIS CAN TAKE A FURTHER 1-3 MONTHS

➢ **Methodological support**

- Contact appropriate methodological support service
- Identify funder and scheme
- Read the relevant funding scheme guidance and check deadline
- Download the application form template for the relevant funding scheme (usually available as a Word document)
- Start to complete application form template

➢ **Finance & IP**

- Read the relevant funding scheme costing & IP guidance
- Identify:
  - Required financial signatories for UHBristol and finance (costing) contacts for UHBristol & other organisations

- IP contact details at partner organisations
- Collate (with input / guidance from R&I Finance or Divisional Finance):
  - Outline of UHBristol costs
  - External costing information (e.g. University fEC, costs from other sites)
- Arrange Finance & IP Meeting (may be virtual) - Invite / contact:
  - R&I Accountant (NIHR grants only)
  - DFM of host Division (or representative) and D&T Division if appropriate
  - R&I (RGM and/or RGCF)
- Circulate in advance:
  - Summary of research
  - Outline of identified costs
  - Copy of finance section of application form
  - External costing information
- Agree responsibility for completion of application form sections, collation of Finance and IP information

## ❖ Application form

**BEGIN APPLICATION FORM AS SOON AS FUNDING STREAM IDENTIFIED**

### ➢ Read the relevant funding scheme guidance

### ➢ Identify:

- Applicants and signatories required to provide confirmation / approval
- Submission method (e.g. online, hardcopy, email) & location (portal URL / postal address / email address)

### ➢ For online applications, arrange in plenty of time:

- Registration of all individuals on system (if input required)
- Confirmation of participation by all applicants and signatories (if required)
- Availability of all applicants and signatories to provide input when required

### ➢ Complete application form:

- All sections of form, all uploads / attachments
- Check Finance sections of application form match costing

## ❖ Approval and submission

**ALLOW A FURTHER 2 WEEKS**

- Check required order of approvals / submission
- Ensure all Approvals completed
- Submit application form (online and hardcopy if required)

## ❖ Checklist

| ➢ Research idea & background preparation | | | | | | | |
|---|---|---|---|---|---|---|---|
| Literature search | ☐ | Discussed with patients | ☐ | Possible collaborators identified | ☐ | R&I contacted | ☐ |
| Discussed with colleagues | ☐ | Research ideas drafted | ☐ | Possible co-investigators identified | ☐ | Initial outline of resources prepared | ☐ |

### ➢ Proposal development & writing

#### ○ Methodological Support

| | | | |
|---|---|---|---|
| Staff/institution eligibility checked | ☐ | Host | ☐ |
| Funding remit checked | ☐ | PPI planned | ☐ |
| Available funding (max/min) checked | ☐ | Possible referees identified | ☐ |
| Methodology discussed | ☐ | Chief / Principal / Co-investigators identified | ☐ |
| Protocol discussed | ☐ | Sponsor | ☐ |

#### ○ Finance & IP

| | Contact details | Contacted | Availability checked |
|---|---|---|---|
| R&I / Divisional signatories | | | |
| Finance contacts (UHB & other orgs) | | | |

**Meeting to discuss Finance & IP**

| Arranged | Individuals invited / contacted | Documents circulated |
|---|---|---|
| | | |

**Responsibilities (name/contact details)**

| Complete application form | Prepare uploads / attachments | Collate finance information | Collate IP input | Complete finance section of form |
|---|---|---|---|---|
| | | | | |

### ➢ Application Form

#### ○ Submission method/s

| Method | Address | Deadline |
|---|---|---|
| Online | | |
| Email | | |
| Hardcopy | | |
| Wet signature required? | Y/N | |

| People | Availability checked | Registered on portal | Participation confirmed | Approval of application confirmed |
|---|---|---|---|---|
| Lead applicant | | | | |
| Co-applicants | | | | |
| Administrator | | | | |
| Signatories | | | | |
| Sponsor | | | | |
| Department Head | | | | |
| Financial Director | | | | |
| NHS facilities Manager | | | | |
| Additional signatories | | | | |

## ○ Complete Application Form Sections

| Section | Req'd | Who | Done | Section | Req'd | Who | Done |
|---|---|---|---|---|---|---|---|
| Anonymity reqs checked | | | | Relevant expertise | | | |
| Research details | | | | Outline budget | | | |
| Contact info | | | | Detailed budget | | | |
| Lead Applicant details | | | | Justification of costs | | | |
| CVs | | | | Mgt & Governance | | | |
| Admin contact details | | | | IP | | | |
| Co-I details | | | | Wider context | | | |
| PPI | | | | DH Monitoring | | | |
| History of application | | | | RDS involvement | | | |
| CfS | | | | Referees | | | |
| Research plan | | | | Mandatory uploads identified | | | |
| Background & rationale | | | | Optional uploads identified | | | |
| Changes from 1st stage | | | | Word / char count / format / doc type checked | | | |
| Dissemination & output | | | | | | | |

## ➢ Approval And Submission

| | Online approval & submission | Hardcopy approval (wet signature if required) |
|---|---|---|
| Required order of approvals / submission checked | | |
| Lead applicant approved | | |
| Co-applicants approved | | |
| Head of Department or Senior Manager / Director of Research, Grants and Contracts Manager, Clinical Director or Chief Executive signature (D Benton or E Griffiths) | | |
| Host Organisation - Administrative Authority or Finance office signature (Director of Finance or Deputy) | | |
| NHS facilities Manager | | |
| Additional signatories | | |
| Forwarded to R&I | | |
| Forwarded to R&I Accountant | | |
| Forwarded to R&I | | |
| Submitted to funder | | |

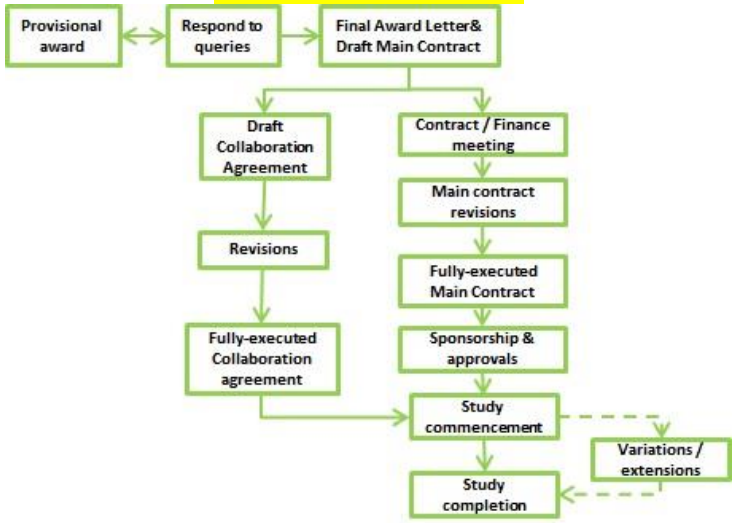
Appendix 3

Post-Award checklist

University Hospitals Bristol NHS
NHS Foundation Trust

**POST -AWARD PROCESSES - CONTRACTS, AGREEMENTS, MANAGEMENT & REPORTING**
**Quick Reference Guide**

**MAY TAKE 3 – 24 MONTHS**




- **Main Contract**
- **Collaboration Agreement**
- **Variations**

## ❖ MAIN CONTRACT

## ❖ Provisional Award ➔ Final Award

**THIS STAGE MAY TAKE 1-6 MONTHS**

➢ **Provisional award letter**

- If provisional award notification sent directly to CI (rather than R&I) forward all provisional award documentation to R&I (funding@uhbristol.nhs.uk)
- Meet with R&I to discuss if necessary
- Reviewers' comments
  - Respond to reviewers' comments (with input from collaborators if required)
- Finance queries - R&I / Finance will respond to finance queries
- IP queries / checks - R&I will respond to IP queries

➢ **Receive Final Award Letter & Draft Main Contract**

- **Final Award letter ➔ Fully-executed Main Contract**

**THIS STAGE MAY TAKE 1 WEEK – 2 MONTHS**

➢ **Final Award Letter & Draft Main Contract**

- If sent directly to CI (rather than R&I), please forward to R&I (funding@uhbristol.nhs.uk)
- R&I will initiate Collaboration Agreement processes

➢ **Contract / Finance meeting / discussion (may be virtual)**

- R&I will arrange meeting with CI, R&I Research Accountant, Research Management Facilitator, other appropriate members of study team
  - discuss phasing of payment schedule with R&I Research Accountant
  - Ensure appropriate contractual agreements in place e.g. Site Agreement(s), Pharmacy Technical Agreements; collaboration agreements
  - Discuss staff recruitment
  - Discuss collaborating institutions
- Start UHBristol recruitment processes as early as possible
- CI will submit sponsorship request to R&I (RMFs) (Quote EDGE Local Reference ID in request)

➢ **Main Contract revisions**

- R&I will request revisions from funder if necessary and return payment schedule

➢ **Receive Main Contract from NIHR**

- Forward Main Contract to R&I (funding@uhbristol.nhs.uk) if necessary
- R&I will check, sign and return Main Contract to funder
- Fully-executed contract will be received and filed in R&I
- Submit approval/s request to R&I (RMFs)

➢ **On receipt of Start Certificate via email from NIHR**
(and once Ethics approval received, if required), Start Certificate signed by CI & forwarded to R&I

- Start Certificate signed by R&I and returned to NIHR

## ❖ COLLABORATION AGREEMENT

➢ **Draft Collaboration Agreement**

**THIS STAGE MAY TAKE 1-6+ MONTHS (AFTER RECEIPT OF FINAL AWARD LETTER & DRAFT MAIN CONTRACT)**

➢ **On receipt of Final Award Letter & Draft Main Contract, R&I decides on type of agreement/s required e.g. collaboration, subcontract, framework**

- R&I notifies UHBristol Contract Adviser (Lynne Austin, Lynneaustin64@aol.com (LA)) that collaboration / other agreement needed and forwards:
  - Grant application
  - Main Contract
  - PoCs for all collaborators

➢ **LA generates template agreement**

➢ **Check draft Collaboration Agreement (or other) details (draft information already gathered at pre-award stage):**

  - Payment details for each party
  - Staff list & contact details for contract
  - Combined Financial Summary
  - Lead Party's representative for the purpose of receiving reports and other notices
  - Collaborating Party's/Parties' representative/s for the purpose of receiving reports and other notices (name, position, address) checked
  - Information for Schedule 1: Co-Investigators (name & organisation)
  - Payment schedule (totals for organisations & financial years)
  - Detailed breakdown of funding and WTE for each organisation if applicable
- Forward template agreement to all PoCs for review (with deadline for comments)

➢ **Draft Agreement Revisions**

**THIS STAGE MAY TAKE 1-6+ MONTHS AFTER SENDING DRAFT AGREEMENT TO OTHER ORGANISATIONS**

- Receive comments back from other organisations
- Respond to other organisations' comments
- Revise agreement if necessary, and return to collaborators
- Send agreed copy to R&I (EG & CN)
- Email out final copy of Collaboration Agreement to collaborators for signature with instructions (each will return xx signed pages)

### ➢ Fully-Executed Agreement

**THIS STAGE MAY TAKE 1+ MONTHS AFTER SENDING FINAL COPY OUT FOR SIGNATURE**

- Fully executed Collaboration Agreement received by R&I
- Collaboration Agreement scanned & saved in R: Active studies folder
- PDF (& wet ink if requested) signature pages sent out to collaborators
- Original filed in Study folder

## ❖ EXTENSION REQUESTS & VARIATIONS TO CONTRACT

### ➢ Cost and no-cost extensions and variations may require contract amendments

- Please discuss any required changes to the Main Contract with R&I (funding@uhbristol.nhs.uk). These may include:
  - Change to completion date
  - Change to approved cost
  - Amendments to research plan
  - Change profile of expenditure

### ➢ Extension /Variation

- Discuss with R&I
- Submit Extension /Variation Request to funder
- Formal extension / variation
  - signed & sent by funder (VtC)
  - signed by UHBristol
  - returned to funder

### ➢ Amendments to Collaboration Agreement/s

- If amendments to the agreement/s are required, discuss with R&I
- Amendments sent to collaborator/s for signature
- Signed amendments returned to UHBristol

## ❖ Checklist for CIs

### ➢ Main Contract

| Provisional award letter forwarded to R&I | Reviewers' comments - input from collaborators required | Reviewers' comments - input from collaborators received | Responded to reviewers' comments |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |
| Final Award Letter & Draft Main Contract received & forwarded to R&I | Sponsorship request submitted to R&I | Approval/s request submitted to R&I | Start Certificate signed & forwarded to R&I |
| ☐ | ☐ | ☐ | ☐ |
| UHBristol recruitment processes started | Contract / collaboration variations discussed with R&I | | |
| ☐ | ☐ | | |

## ❖ Checklist for R&I

| | |
|---|---|
| ➢ **MAIN CONTRACT** | |
| ➢ **Provisional Award ➔ Final Award** | |
| 1. Finance queries forwarded to R&I Finance (Elizabeth.Wilkinson@uhbristol.nhs.uk) | ☐ |
| 2. Input / agreement from other organisations' finance (if necessary) (R&I Finance) | ☐ |
| 3. IP queries / checks | ☐ |
| 4. Confirm funding total | ☐ |
| 5. Agree / write wording for Schedule C | ☐ |
| 6. Agree / write wording for Schedule D | ☐ |
| ➢ **Respond to funder queries** | ☐ |
| ➢ **Final Award Letter & Draft Main Contract** | |
| 7. Forward payment schedule to R&I Finance | ☐ |
| 8. Contract checked | ☐ |
| • Check wording for Schedule C | ☐ |
| • Check wording for Schedule D | ☐ |
| • Check dates on draft contract | ☐ |
| 9. Payment schedule discussed with CI | ☐ |
| 10. Contract / finance meeting / discussion | ☐ |
| • Recruitment discussed | ☐ |
| • Collaborating institutions discussed | ☐ |
| • Payment schedule | ☐ |
| 11. Revisions requested from funder if necessary (R&I Finance) | ☐ |
| 12. Payment schedule returned to NIHR | ☐ |
| ➢ **Main Contract received by R&I** | |
| 13. Main Contract checked | |
| 14. Main Contract signed | |
| 15. signed Main Contract returned to funder | |
| ➢ **Fully-executed contract received** | |
| 16. Scan & save electronically | |
| 17. Make up new study file and file original copy | |
| 18. Notify CI that Collaboration agreement fully-executed | |
| 19. Signed Start Certificate received from CI | |
| 20. Check Ethics approval received (if required) | |
| 21. Start Certificate signed | |
| 22. Start Certificate returned to NIHR | |

## ➢ COLLABORATION / OTHER AGREEMENT/S

### ➢ Agreement/s required

| | Required | Details |
|---|---|---|
| • Main contract | | |
| • Collaboration agreement | | |
| • Subcontract/s | | |
| • Material Transfer Agreement (MTA) | | |
| • Framework Agreement | | |
| • Site Agreement | | |
| • Data-sharing Agreement | | |
| • Non-Disclosure Agreement | | |
| • Service Level Agreement | | |
| • Letter of Intent to enter into a Collaboration Agreement | | |
| • Partnership Agreement | | |

| | |
|---|---|
| ➢ **Collaboration Agreement process initiated** | ☐ |
| 23. UHBristol Contract Adviser notified that agreement/s required: | |
| • Grant application<br>• Main Contract<br>• PoCs for all collaborators | |

## ➢ VARIATIONS

| ➢ Main Contract | | ➢ Collaboration / Other Agreements | |
|---|---|---|---|
| 24. Extension /Variation Request submitted to funder | ☐ | 25. Amendments discussed with R&I | ☐ |
| 26. Formal extension / variation signed & sent by funder (VtC) | ☐ | 27. Amendments sent to collaborator/s for signature | ☐ |
| • signed by UHBristol | ☐ | 28. Signed amendments returned to R&I | ☐ |
| • Returned to funder | ☐ | | |