Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department, Sheffield

STANDARD OPERATING PROCEDURE

NIHR Research for Patient Benefit (RfPB) Application Process

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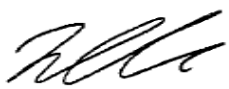
Approved by (name & role)	Lydia Harris Clinical Research Manager	**Date:** 20/11/14	

Standard Operating Procedure

NIHR Research for Patient Benefit (RfPB) Application Process

This Standard Operating Procedure (SOP) has been produced in accordance with the aims for the Committee to Increase NIHR Grant Activity. This SOP will outline the Clinical Research Office, Sheffield (CRO) procedure for guiding researchers through the process of applying to the NIHR Research for Patient Benefit (RfPB) programme and to facilitate institutional authorisation prior to submission.

Background

The Committee to Increase NIHR Grant Activity comprises members from the CRO (Sheffield Teaching Hospitals NHS Foundation Trust [STH] and University of Sheffield [UoS]), NIHR Research Design Service for Yorkshire and Humber (NIHR RDS YH), NIHR Clinical Research Network Yorkshire and Humber (NIHR CRN YH) and the Sheffield Clinical Trials Research Unit (Sheffield CTRU). The Committee's aim is to support and promote applications by STH clinicians or Clinical Academics (joint STH and UoS post holders).

The NIHR RfPB programme does not specify topics for research proposals. Projects are selected for funding on the basis of the quality of the research proposal and its likely transition to patient benefit locally and for the wider NHS.

The NIHR RfPB programme supports:

- Studies of the provision and use of NHS services.
- Evaluations of the effectiveness and cost effectiveness of interventions.
- Examination of the resource utilisation of alternative means for healthcare delivery.
- The scrutinising of innovations and developments.
- Pilots or feasibility projects to help reach the next step of a definitive trial.

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1. Acronyms

CRN YH	Clinical Research Network, Yorkshire and Humber
CRO	Clinical Research Office
CTRU	Clinical Trials Research Unit
NIHR	National Institute for Health Research
R & D	Research and Development
RDS YH	Research Design Service, Yorkshire & Humber
RfPB	Research for patient benefit
SOP	Standard Operating Procedure
STH	Sheffield Teaching Hospitals
UoS	University of Sheffield

2. Definition

This SOP will enable researchers to be guided through the process of:

- obtaining guidance and input from the NIHR RDS YH, and the Sheffield CTRU where applicable
- timely submission for internal review
- costing of the final application, by the STH Research Accountant
- obtaining institutional authorisation signatures on the final application form.

3. Procedure

3.1. Preparation

1. The CRO RfPB Coordinator and Clinical Research Manager agree the submission and internal review deadlines for the next online submission deadline for the RfPB programme. The CRO RfPB Coordinator documents this in the timetable template.
2. The CRO RfPB Coordinator and the Clinical Research Manager consult with STH Research Finance and the NIHR RDS YH on the proposed timetable.
3. The CRO RfPB Coordinator finalises the action timetable based on feedback received in step 1.2. The CRO RfPB Coordinator prepares the draft email advert and distribution list. The Head of the CRO reviews the prepared documents.

3.2 Advertisement

1. The CRO RfPB Coordinator advertises the RfPB application procedure by e-mail. The text for the advertisement is stored at S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Email templates

3.3. Application

1. All CRO Coordinators and the research nurses of the Clinical Research Facility are instructed to alert the CRO RfPB Coordinator and the Clinical Research Manager of potential applicants.
2. The CRO RfPB Coordinator contacts all potential applicants from previous communications individually to inform them of the RfPB application procedure and deadlines.
3. The CRO RfPB Coordinator creates the RfPB Competition folder, for all communications, in S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB specific for that round.
4. The CRO RfPB Coordinator records the details of all potential applicants on an RfPB tracking spreadsheet. The spreadsheet is shared with the Clinical Research Manager and NIHR RDS YH and stored in the Competition specific folder in the S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Application Metrics
5. The CRO RfPB Coordinator informs Academic Directors\Research Leads of all potential RfPB applications within their Directorate and encourages their support in the preparation process. The CRO RfPB Coordinator also supplies the Academic Directorate checklist (see :\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Review and guidance) to the Academic Directorate leads, to ensure Academic Directorate support for submission is received by the CRO.
6. The CRO RfPB Coordinator determines the research governance implications of each proposal by contacting the relevant Clinical Research Coordinator responsible for that directorate, and if necessary contacting the researchers via e-mail or telephone. The Clinical Research Manager is informed of all potential Investigational Medicinal Product, device or high-risk studies.
7. Where applicable, for high-risk research proposals, the CRO RfPB Coordinator sets up a pre-award meeting with the applicant, the Clinical Research Office Coordinator for that Directorate and Clinical Research Manager to discuss research governance implications and the proposal's suitability for RfPB submission.
8. The CRO RfPB Coordinator contact the NIHR RDS YH and updates the RfPB tracking spreadsheet with regards to whether there has been any consultation and adds any other relevant information.
9. The CRO RfPB Coordinator reminds applicants, that while **not** compulsory, involvement of NIHR RDS Yorkshire and Humber may strengthen an application.
10. The CRO RfPB Coordinator follows up on an ongoing basis, via e-mail and telephone, with potential applicants and maintains the RfPB tracking spreadsheet, sharing the latter with the Clinical Research Manager and NIHR RDS YH.

3.4. Review

1. The CRO RfPB Coordinator collates applications received by the internal deadline and provides them to the reviewers and the finance team. Reviewers will normally include the CRO RfPB Coordinator, Clinical Research Manager, Head of CRO, STH R&D Director, Head of Clinical Research Facility (CRF) and a representative from RDS. A timeline is set for review, usually ~ 10 working days.

2. The CRO RfPB Coordinator sends an acknowledgment e-mail to researchers who submitted their applications and confirms the dates that feedback will be provided
3. The CRO RfPB Coordinator collates feedback received from reviewers, and sends collated, anonymised feedback to the applicant on the agreed deadline.
4. The STH Research Accountant liaises directly with applicants with regards to costing and informs the CRO RfPB Coordinator and Clinical Research Manager of any issues.

3.5. Authorisation and Submission

1. The CRO RfPB Coordinator and Clinical Research Manager liaise with the researcher to arrange the submission of the final application form for wet-ink signature on the declaration page (by STH Research Finance and the CRO). Researchers are reminded to sign the 'Lead Applicant' section of the application form declaration page and send it to the NIHR RfPB office themselves.
2. The CRO RfPB Coordinator facilitates wet-ink signatures on the declaration form of the final application by STH Finance and the CRO.
3. The CRO RfPB Coordinator files a scanned copy of the wet-ink signed declaration page and final application form in the folder specific for that round, and e-mails a copy to the applicant. S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB
4. The CRO RfPB Coordinator sends the wet-ink signed declaration page to the NIHR RfPB office, by next-day delivery at the Royal Mail Post Office.

3.6. Submission Tracking

1. The CRO RfPB Coordinator updates the RfPB metrics spreadsheet with all submissions for each competition and stores in the RfPB metrics folder in the S:\Drive. S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Application Metrics
2. The CRO RfPB Coordinator contacts applicants with respect to whether their applications have been successful and updates the RfPB metrics spreadsheet, informs the Clinical Research Manager, the relevant CRO Coordinator and updates the CRO database.

Appendix 1

Associated Documents

	Document	Research Department Network Location	Created by
1	RfPB timetable template	S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Review and Guidance\	Ramila Patel
2	Alert email template (inc distribution list)	S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Email templates	Martin Collins
3	Academic Directorate checklist	S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Review and Guidance\Application review form	Lydia Harris
4	RfPB tracking spreadsheet	S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Competition xx\Application Tracker	Ramila Patel
5	RfPB metrics spreadsheet	S:\General\DoH\BRfBH\NIHR\NIHR Funding Streams\BRfBH calls for funding applications\6.2 RfPB\Application Metrics	Ramila Patel