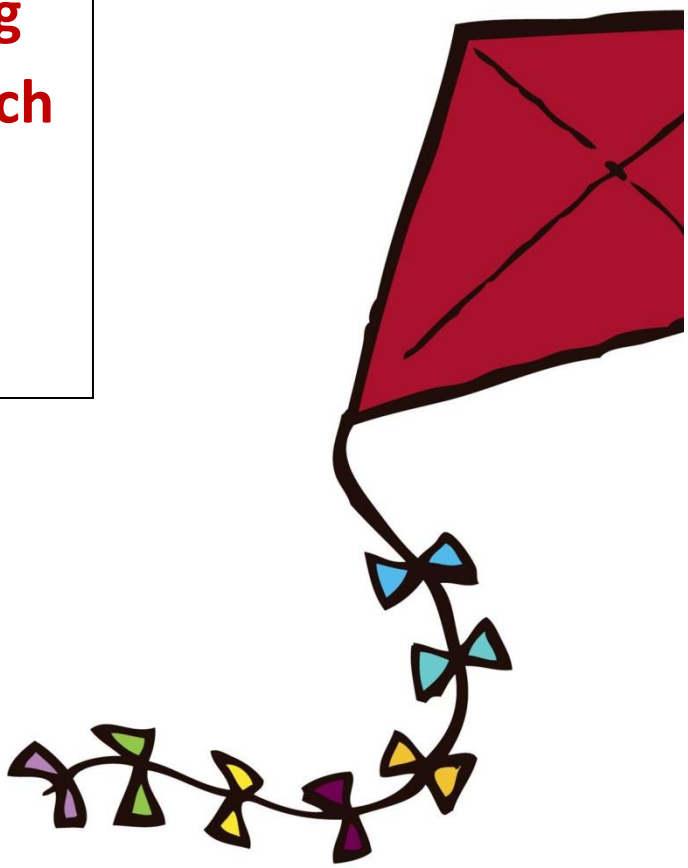
Bradford District NHS
Care Trust

Procedure for Obtaining Sponsorship for Research Studies at BDCT

SOP09



The 5 key messages the reader should note about this document are:

1. **Contact R&D Manager ASAP when developing a research project or applying for a research grant in collaboration with BDCT**
2. **All new protocols should receive Scientific and PPI review**
3. **Ensure your project has been costed appropriately and you have contacted the R&D finance manager**
4. **Submit your request for sponsorship 4 weeks prior to submitting for ethics and NHS permission**
5. **This is a separate procedure to obtaining NHS permission**

This procedure has been approved. Circumstances may arise where staff becomes aware that changes in national policy or statutory guidance (e.g. National Institute for Health Research (NIHR) and Health Research Authority (HRA) guidance, Employment Law may affect this procedure. It is the duty of the staff member concerned to ensure that the policy /procedure author is made aware of this change so that the matter can be dealt with through the review process.

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Contents

1. INTRODUCTION

Bradford District Care Trust (BDCT) will undertake sponsorship for non-CTIMP (Clinical Trials of Investigational Medicinal Products, aka. drug trials) studies on a case by case basis. The investigator seeking sponsorship must be a Trust employee or hold an honorary contract with BDCT.

Please note: The Trust does not sponsor student projects- Sponsorship should be obtained from the University of study.

If you are considering developing a research project in collaboration with BDCT, please contact the R&D Manager as soon as possible, whereupon advice can be obtained concerning grant applications and support available for research projects.

2. PURPOSE

The purpose of this procedure is to support high quality research and to ensure that research in the Trust is managed and conducted in accordance with the legislative requirements relating to the Research Governance Framework (RGF) (2005) and the Health Research Authority (HRA). This guidance and procedure covers only projects that are being developed in collaboration with BDCT.

Please note this is a separate procedure to obtaining NHS permission.

You will need to obtain a letter of agreement from BDCT to sponsor your project prior to obtaining Research ethics approval.

3. Definition

A sponsor is an individual, group or organisation which takes responsibility for the quality, conduct and financial management of a research project. All research conducted within the NHS is required to have a research sponsor.

The sponsor takes primary responsibility for ensuring that the design and conduct of the study meets appropriate standards and that arrangements are in place for the management and reporting of the project. This will include, for appropriate studies, ensuing a favourable opinion from a NHS Research Ethics Committee (REC) has been obtained prior to opening the study. In addition the requirement to ensure compliance with the terms of any approvals, and regulation, means that a sponsor may monitor, audit or inspect a project at any point in the project's duration.

A summary of the Sponsor's responsibilities can be obtained from:
http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/

4. Duties

4.1 The Chief Executive

Overall accountability for all R&D activities in the Trust lies with the Chief Executive. Responsibility for specific processes is delegated by the Chief Executive as set out below.

4.2 Medical Director

The Medical Director has overall delegated responsibility for R&D in the Trust. It is the overall responsibility of the Medical Director to give assurance to the Board that research undertaken in the Trust is of high quality and conducted in compliance with the national and statutory guidance.

With support from the R&D Director and the R&D Manager, the Medical Director will give the final approval for the Trust to sponsor individual research projects.

4.3 The Head of Research/Research Manager

The Manager is responsible for:

- Overseeing the implementation of the process, the required assurance checks and appropriate monitoring for projects are undertaken.

- Ensuring eligible research studies are taken through the sponsorship process.

4.4 Chief Investigator, Academic and Clinical Researchers

Anyone involved in these roles, requesting sponsorship from BDCT are required to;

- Be either an employee of BDCT or hold a valid honorary contract
- Contact the R&D Dept. as soon as possible in order to receive the appropriate advice and support: research@bdct.nhs.uk

- Seek appropriate advice and support from the Research Design Service and Comprehensive Local Research Network when applying for NHIR Grants : Contact and advice available on: http://www.rds-yh.nihr.ac.uk/

- Ensure that the project has been presented to the Heads/Managers of Service and their approval (in principle) has been obtained.

- Read and understand the responsibilities as Chief Investigator: Information available on: http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/

- Undertake the governance checks as outlined in the Research Governance guidance - checklist available from the Research Governance Office.

- Obtain the following reviews for your project/proposals/protocol:

i. Independent academic/clinical review (to be undertaken by suitably qualified individual, other than members of the research team) to ensure quality of study – Scientific Review form available in Appendix A :
ii. Public Patient (PP) review: Local contact: PPI RAG Sarah Kirkland PPI R&D Lead. INVOLVE: Information available: http://www.invo.org.uk/about-involve/how-we-work-with-others/

- Ensure appropriate costings have been undertaken and confirmed by BDCT R&D Finance Manager (this should be part of your protocol).

- Ensure funding is in place: Agreed by R&D Finance Manager and commissioning services, if excess treatment and support costs are required see link: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research
  The Local R&D Finance Manager: Julia.martindale@bdct.nhs.uk

- Submit the request for sponsorship 4 weeks prior to submitting to research ethics (if required)

4.5 Research Governance Lead/Support Office

The designated Research Governance Officer will:

- Provide support and guidance concerning research governance queries.
- Acknowledge and monitor the progress of the application.
- Undertake application checks using National Institute for Health Research (NIHR) Sponsor SOP and assessment tools.
- Forward the application form, protocol and assessments to the Medical and Research Directors for final review and approval.
- Forward a written response (agreement or rejection) to applicant within 20 days of request.
- Advise on next steps according to response.

4.6 Finance Managers

The designated Finance Manager will:

- Provide advice and support to researchers for the costing of projects when developing bids for research funding.

5. PROCEDURE:

1. Prior to request the researcher must ensure:

- You have a substantive or honorary contract with BDCT

- The definition of study is confirmed : evaluation/research/audit:
  For further information:
  http://www.hra.nhs.uk/documents/2013/10/differentiating-audit-service-evaluation-and-research-version-1-1.pdf
- The type of study is within the Trust areas of research interest: See our Research Strategy: Available on http://www.bdct.nhs.uk/wp-content/uploads/RD_DOC01_BDCTResearchStrategy-v2_Oct2013.pdf
- That you have presented your project to the Heads/Managers of Service and have obtained evidence of approval (in principle)
- You have received favourable Scientific and PPI reviews
- The arrangements you describe in the IRAS and grant application forms meets the Trust policies

2. Complete the Request BDCT sponsorship form (See appendix B) 4 weeks prior to IRAS submission and forward to the Research Governance Office at research@bdct.nhs.uk along with the protocol, your CV, Scientific and PPI reviews.

The documentation to be submitted to obtain sponsorship agreement from the Trust is detailed in Appendix B.

Please note that you must obtain Research Ethics Committee (REC) approval (If required) and NHS permission prior to starting any research on BDCT site, involving BDCT staff, or patients, service users of carers thereof, recruited by virtue of their current relationship with BDCT.

For guidance to obtaining Trust and ethical approval please see accompanying documents and guidance below

6. Associated Documentation

Available from the Research Governance office: research@bdct.nhs.uk

6.1 Trust R&D Strategy

Available on: http://www.bdct.nhs.uk/wp-content/uploads/RD_DOC01_BDCTResearchStrategy-v2_Oct2013.pdf

6.2 R&D Registration and NHS Permissions Approval Procedure SOP 01

6.3 Research Governance Check form

6.4 NIHR RSS framework checks

Available on: http://www.nihr.ac.uk/policy-and-standards/research-support-services-framework-documents.htm

APPENDIX A: Scientific Review Form

SCIENTIFIC REVIEWER'S COMMENTS FORM

-**For the review of "in-house" health care research where the Trust is to be the Research Governance Sponsor as defined in the Research Governance Framework for Health & Social Care (2005) and/or the Medicines for Human Use (Clinical Trial) Regulations 2004 as amended from time to time.**

This form is for use when scientifically reviewing an R&D Application and should be returned to your research governance contact in the Research Governance Office, OPD6, Lynfield Mount Hospital, Heights lane, Bradford BD9 6DP: Email: research@bdct.nhs.uk

1. Name of Scientific Reviewer: **Qualifications:** **Contact Details:**	
2. Research Project Title:	
3. Chief Investigator:	
4. Department/ Hospital Site:	

5. I confirm that I do not have a conflict of interest with the project application:

Signature:	**Date:**

6. I confirm that, in my judgement, the application should (mark 1 box):

Be approved	Be approved with suggested amendments in '7' below	Be approved providing requirements specified in '8' below are met:	NOT be approved for the reason(s) given in '9' below:

7. Approved with the following suggested, optional amendments (i.e. it is left to the discretion of the applicant whether or not to accept the amendments and, if accepted, the scientific reviewers do not need to see the amendments):

8. Approved providing the following, compulsory requirements are met (i.e. the scientific reviewers need to see the required changes):

9. Not approved for the following reason(s):

10. Date of Scientific Review:	

Scientific Reviewer's Checklist

- an aid to reviewing a scientific review application form -

Originality	**Reviewers Comments**
Does the proposal add enough to what is already in the published literature? If so, what does it add? Has a gap in knowledge been identified?	
Relevance	
Importance of the work — e.g. Does this work matter to clinicians, staff, service users, carers, public, commissioners or policymakers? Does the study benefit any of the following: The service area, organisation, service user, carer, staff, or community? Does the study promote the strategic objectives of the Trust or the agreed programme of research?	
Feasibility	
Has a time frame been outlined? Is the time scale realistic? Will the objectives be met: i.e. is it doable? - Does the locality have the population to be studied?	
Methodology	
Research question — is this clearly defined and located in the literature with reasonable rational and supported with research evidence? Are the stated objectives clear and justified?	
Overall design of study — is this adequately described and justified?	

- Does the proposal show intention of public patient and carer involvement? e.g. 'Is there a clear plan for how public/patients/carers are to be involved?' 'To what extent will they be involved?' Participants' studied — are they adequately described (inclusion and exclusion criteria given) their conditions defined? Is the size of sample justified?	
Methods — are they adequately described with justification of their selection?	
Resources	
Has the cost of the project been broken down? Are the costs identified relevant and realistic?	
Development	
Does the proposal show potential for development given the appropriate support, for example to apply for : - Postgraduate education? - Grant collaborations? - Innovation awards	

APPENDIX B

Request for Bradford District Care Trust to be Research Sponsor

Please note: BDCT does not sponsor Clinical Drug Trials

Research team details

1.	
Name of Chief Investigator:	
Name of Chief Investigator's Employer:	
Point of Contact details (if different from above):	
Name of trials unit supporting the study (if applicable):	

*(If BDCT is not the Chief Investigator's substantive Employer it will **not** be appropriate for BDCT to act as Sponsor for the study)*

2.	Yes/No
Will any part of this study contribute to an educational qualification?	
If yes:	
*Where the main purpose of the research is to contribute to an educational qualification, **sponsorship is the responsibility of the awarding university**. .*	
If no:	
Is the research to be undertaken by a trainee or other equivalent junior member of staff?	
Mentor name & position:	
Mentor email address:	

Study Title:	
Anticipated start date:	Anticipated end date:
Short summary of proposed research study (maximum 200 words):	
Or submit abstract from the Grant application form	
Statement of relevance/need for research:	

Potential benefit/impact on patient care including how results of research will be translated into changing care (this can be local/wider changes):

Study details 3.	Yes*/No
Does this study involve an Investigational Medicinal Product (IMP) or an Investigational Device?	
*If yes: ***Please note that at present BDCT does not sponsor IMPs***	
4.	Yes/No
If this study does not involve an IMP or device, is this study interventional?	

N.B In interventional studies patients are given a particular 'intervention' using for example a device, medicine or surgical technique. Their outcomes are then compared to patients who did not receive the intervention.

5.	Yes/No
Is this a pilot or feasibility study?	
If yes what are the future plans for this research, assuming the pilot/feasibility is successful:	
6.	Yes/No
Is this multi-centre?	
If yes:	
How many sites are anticipated?	
Will BDCT be the lead centre? If no, which NHS Trust will be the lead centre?	
Will any sites within the UK be Non NHS Sites? (If yes, please give details)	
Are any sites outside of the UK?**	

*** Unfortunately BDCT is **not** able to Sponsor research studies with any sites outside of the UK. If you wish for your study to have an external to UK site you will need to approach a different organisation for Sponsorship.*

Resource

7.	
Which organisation(s) or service may/will be funding the study?	
What is the status of the funding application?*	
If this study is unfunded please provide justification below why you believe the NHS and the Division should support this research given their limited funds to support research activity:	

**Please be aware that we will be unable to issue sponsorship until funding has been awarded.*

Please note that our priority areas for research are: NIHR Portfolio trials, local studies that will support future NIHR grant applications and all other funded (commercial and non-commercial) projects. All research studies, however small, incur costs (service support costs, treatment costs and/or overheads) which will have to be picked up by the service if there is no associated funding. Whilst we would like to support all research, this is not feasible because it could have a significantly negative impact on the Trust's ability to support other research in the Trust. If your study is unfunded please be aware that this will reduced the likelihood of the Trust being able to sponsor your study. If you want to explore funding opportunities please talk to our Research manager; Angela Ross angela.ross@bdct.nhs.uk

8.	Please specify resources to be used, approximate costs and how these costs will be met*:
Staff time	
Equipment	
Consumables	
Drugs and any other treatment costs	
Facilities (e.g. use of clinic space)	
Contract set up/review if applicable (non-NIHR portfolio study)	
Public Patient involvement activity	
Any other resources	

**If study is fully funded then please also send the relevant grant application with this form.*

9.	Yes/No/Not Applicable
Will this study incur any excess treatment costs? *For information on what constitutes treatment costs please refer to the AcoRD guidance.*	
If yes, is the Finance Manager of the service in which treatment costs will be incurred aware* of them?	

**Please provide evidence.*

10.	
Will this study require support from the following support departments: Please give details of the support required:	Yes/No: Details
Pharmacy?	
Lab Medicine?	
Pathology	
Radiology/Radiotherapy?	
Other? (E.g. ECG/ECHO/Medical photography etc.)	

Scientific quality

11.	Yes/No: Details
Have you received any methodological or statistical advice from a research design/support service? (give details if applicable)	
Have scientific/peer reviews of the protocol been undertaken?	
If yes by whom? (please submit any evidence of peer review **with** this form when requesting sponsorship from BDCT)	
Please give details of the Public and Patient Involvement in the development of this study	

Please note peer review will need to be undertaken by appropriately qualified personnel with no conflict of interest with the research study. It will be up to R&D to determine whether any peer review submitted is acceptable and if peer review is required please allow up to 4 weeks to process.

Submission details:

Please submit this form along with your cv, the scientific and PPI reviews and if possible the most up to date version of the proposal/ grant applications to research@bdct .nhs.uk

- You will then be sent an email from a member of the R&D team to acknowledge receipt of your application.
- Your documents will then be reviewed by the R&D Office and forwarded to the R&D Director and the Medical Director for review
- You will receive a response within 20 days of a valid sponsorship application

Please note if your study is eligible to be taken through the sponsorship process you will need to allow 4 - 6 weeks before submitting to Ethics.