R&D Registration and Project Authorisation Procedure

SOP 01

R&D Registration and Permission Procedure

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Amendment Summary:	Opt in process and reduced turnaround times as designated by NIHR for review panel. Additional procedures for Head of Research Addition of procedures for gaining Project Authorisation via HRA process and review of process for researchers.

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

i) It is a legal requirement that all research conducted at a NHS trust site is registered and approved by the HEALTH REASEARCH AITHORITY (HRA) and that local Research and Development (R&D) Departments confirm their capacity and capability in accordance with the Health Research Authority (in England). Established in the Care Act 2014 with functions relating to co-ordination and standardisation of practice relating to the regulation of research in health and social care, functions relating to ethics committees (appointing authority for English RECs), functions as a member of UKECA and functions relating to approvals for processing confidential information relating to

ii) This document sets out the procedure for researchers to register projects and gain R&D authorisation for all research proposed in BDCFT.

iii) All NHS research is required to be approved and set up within the National Health Institute for Research (NHIR) time frames and the HRA map illustrates the time scales.

1. Introduction

Following the Care Act 2014, on 1 January 2015 the HRA took responsibility for issuing guidance for research in England in place of the Research Governance. They are responsible for ensuring that all such research complies with the Care Act 2014 and later The UK policy framework for health and social care research(2018) in respect of:

- Ethics
- Scientific quality
- Data protection and information governance
- Financial probity
- Exploitation of intellectual property
- Health and safety (including safety reporting).

No health or social care research with human participants, their organs, tissue or data, may begin before:

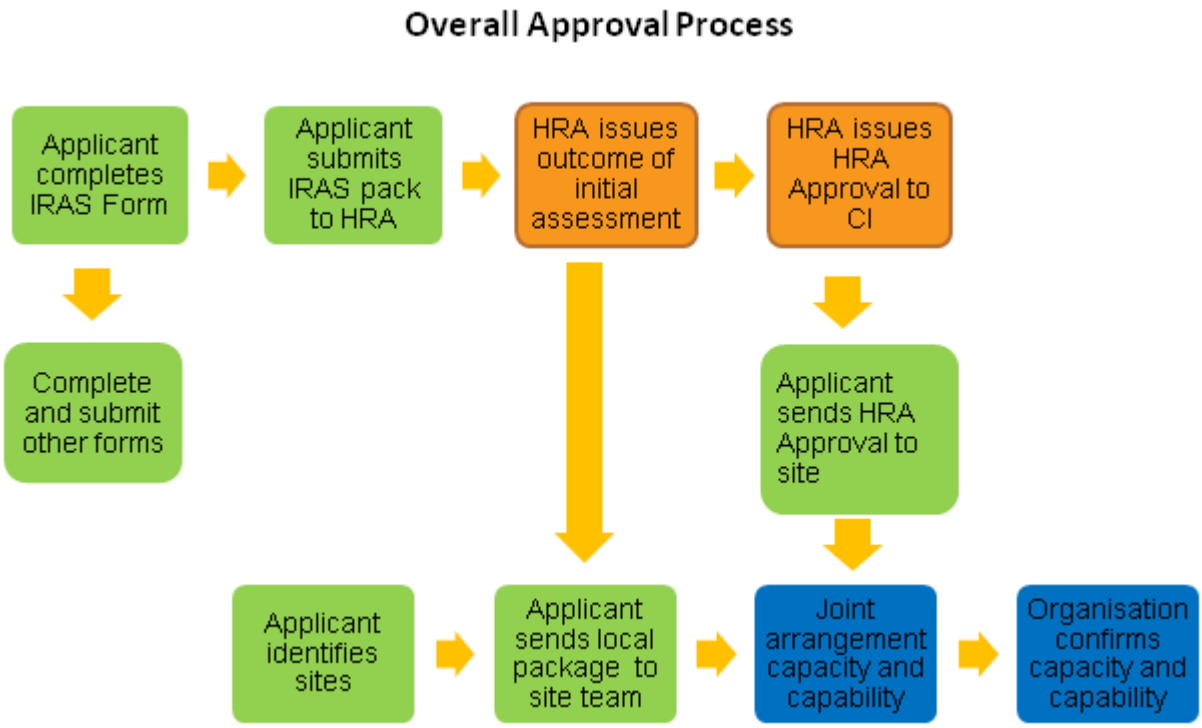
- an identified sponsor has taken on responsibility for that research;
- the study has received a favorable ethical opinion, and
- The allocation of all responsibilities is agreed and documented.

Study sponsors are no longer be required to obtain NHS Permission or R&D Approval from NHS organisations for studies which have HRA approval.
A simplified process facilitates the need for and eases of communication between sponsors and research sites throughout the study, and especially in determining the feasibility of opening a study at a given site as shown in Diagram
This feasibility process is the focus for BDCFT set-up activity and comprises:

Assess – assessing whether or not BDCFT has the capacity and capability to participate in the study (skills and resources available)
Arrange – putting the practical arrangements in place to provide the capacity and capability to participate in the study
Confirm – confirming that BDCFT has the capacity and capability in place to deliver the study and will deliver the study via a formal contract or a statement of activities, depending on the complexity of the study

Key governance checks that BDCFT previously did will be undertaken once at a national level and BDCFT will receive assurance that these have been carried out.

BDCFT will no longer issue 'NHS Permission' for research studies but will confirm that we are ready to start delivering the study activities after we have completed the '*Assess, Arrange & Confirm'* process on this is done the Statement of Activities (SOA) and Schedule of Events (SOE) should be returned to the study sponsor after gaining Trust authorisation
Figure 1



Key proposed changes that BDCFT research staff and all stakeholders should be aware of are that research sites (i.e. locations where a research project is carried out):

- Must not duplicate or repeat checks undertaken by research ethics committees (RECs) or other approval bodies such as the HRA or MHRA. It is considered reasonable for research sites to rely on checks carried out by these bodies, therefore, the liability for any harm to a research participant that arose from failure to carry out these checks properly would shift from the site (e.g.: BDCFT) to the approval body.
- Must keep themselves in a position to be able to promptly, efficiently and proportionately assess their ability to carry out an individual research project.
- Are expected to accept reliable assurance from recognised authorities and each other and must not repeat checks that have already been carried out. This includes assurances about the ethics and safety of the research project, the legal compliance of the proposed research project, the acceptability of contracts and costs and the competence, character and indemnification of members of the research team who are not substantively employed at the site.
- Where there is an urgent need or small window of opportunity for research, such as public health emergencies or in the wake of a terrorist attack, this must command quick co-operation among relevant parties to enable the research.
- BDCFT retains the ability to refuse participation in a study. Studies may not proceed if BDCFT does not confirm we have the capacity and capability to deliver the study by providing a signed contract or statement of activities.

This procedure sets out the procedure for researchers to register projects and gain authorisations for all research proposed in BDCFT.

Registering projects is important for a number of reasons:

- It is good practice.
- We are required by NHS funding arrangements to register research. The Trust needs to maintain a record in order to demonstrate to the Department of Health, NIHR, and the Care Quality Commission (CQC), the level of research activity in the Trust. In addition, Quality Accounts require the demonstration of increased participation in research activity and an account of the number of research participants recruited each year in the Trust.
- The Trust Board requires assurance of the level and quality of research conducted by their staff and/or on their premises.
- One of the conditions by which the Trust receives NHS R&D funding is the provision of active project information to the Local Clinical Research Networks (LCRN)
- It helps the R&D department to establish links with researchers and offer appropriate advice and support.
- The registration process enables researchers to gain mandatory peer review for their projects.
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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 UK policy framework for health and social care research(2018) of the Department of Health and the Care Act 2014

This guidance covers all research projects whether internally funded, externally funded, or unfunded, including student projects.

3. Type of Procedural Document

This is a procedural document describing the “how”; and gives guidance about how R&D authorisation for research in the Trust is obtained. It provides a step-by-step guide, which someone not familiar with the process can follow. It is considered binding, and a breach of a procedure may have contractual consequences for the member of staff. The procedure will ensure research and development activity is carried out in accordance with national standards and guidance.

4. Duties

4.1 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 & Caldicott Guardian

The Medical Director has overall delegated responsibility for R&D in the Trust. It is the responsibility of the Medical Director to ensure and give assurance to the Board of compliance with the systems and processes described in this procedure.

The Medical Director, in the role of the Caldicott Guardian also has responsibility for checking and confirming applications for research comply with the Trust's rules on patient confidentiality. Sign-off by the Caldicott Guardian will be required before final authorisation can be given for any research that involves accessing patient information.

4.3 Research & Development Director

The R&D Director has the delegated authority and responsibility for providing R&D authorisation for applications for research projects in the Trust, as part of the overall authorisation process.

The R&D Director will be responsible for providing Trust authorisation for all potentially high and moderate risk research projects, (as defined in sections 4.5 and 5.2.3below). In the absence of the R&D Director, the Medical Director will assume this responsibility.

It is the responsibility of the R&D Director, supported by the Head of Research, BDCFT, to ensure all relevant staff are aware of the Authorisation Procedure, and to facilitate compliance with its contents.

4.4 Head of Research

The Head of Research, BDCFT is responsible for the effective implementation and operation of the procedure. They also have responsibility to ensure all researchers working at any Trust site are aware and compliant with the R&D policy and procedures.

The Head of Research will oversee the coordination of the authorisation processes to risk assess projects. If further review is required, he/she will facilitate this process, and ensure that reviews of projects are conducted in a timely manner.

The Head of Research has the delegated authority to provide final sign off for low risk research projects in conjunction with service leads (as defined in section 5.2.3). In the absence of the Head of Research, the R&D Director will assume this responsibility.

The Head of Research is responsible for maintaining up to date knowledge of the Research Passport Procedure, and issuing honorary contracts, research passports, or letters of access as required.

All applications for R&D authorisation should be made in accordance with procedures outlined below further guidance can be obtained by the R&D Department and intranet sites.

The Data, Information Systems and Governance Officer or allocated CSO will make a preliminary assessment of the potential risks of a proposed project and arrange for review and sign-offs appropriate. There is a Feasibility Checklist form to be completed as part of our in-house recording systems. The aim is to ensure the process is efficient and proportionate to the potential risks of a project.

Any research involving an Investigational Medicinal Product (as defined by the Medicine Healthcare Regulatory Agency) or a clinical trial will be judged to be 'High Risk' and sent for full review by the Head of Research, Service leads and Caldicott Guardian

The R&D Department will provide reports on project authorisation for the Research Forum. These reports will contribute to the information used to provide assurance to the Trust Board.

4.5 Additional requirements for project Authorisation

Where project authorisation requires further input the R&D Department will contact other services including but not limited to

- Clinical Specialists,
- Pharmacy
- Pathology
- Radiology/Imaging
- Information Governance
- Finance
- Human Resources

4.6 Finance Managers

The designated Finance Manager should:

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

- Review and authorise costings provided by researchers when applying for permission to undertake research within the Trust. The Finance department will provide Feedback to R&D to the Lead CSO as appropriate, in a timely manner to facilitate authorisation within designated timescales.

4.7 Human Resources (HR) Manager/Advisor

The designated HR manager will advise and support employees and managers in the application of the procedure with regard to recruitment and employment issues.

4.8 Head Pharmacist or delegated representative

The Head Pharmacist, or their delegated representative, has the responsibility for providing authorisations for all projects involving medicinal products, including clinical trials. Such authorisations should include consideration of all aspects of supply, storage pharmacovigilance aspects of the study, as appropriate. This should include all costings, as laid out in the Pharmacy Directorate Clinical Trial Charges Scale of Charges (see Appendix 3).

4.9 Researchers, Clinical Studies Officers and Research Support Staff

There are specific duties and responsibilities as described in The UK policy framework for health and social care research(2018) for the following research roles:

- Chief Investigators
- Principal Investigators
- Other Investigators
- Project Sponsors
- Project Funders
- Those responsible for the care of participants involved in research projects.

Anyone involved in these roles should consult The UK policy framework for health and social care research (2018) and the R&D Department for further details.

Researchers should contact the R&D Department as early as possible in the development of research projects in order to receive appropriate support.

4.10 Information Governance Managers
Information Governance representatives have the responsibility to provide advice to all those involved with research and development activity on information governance issues as appropriate.

4.11 Line Managers
It is the responsibility of all line managers to ensure that staffs participating in research within their service area of responsibility are aware of this Authorisation procedure and of the need to follow the processes outlined within.

4.12 All staff
Any member of staff who becomes aware of any practice that is not in accordance with this procedure, or where there are difficulties with implementing this procedure, has a responsibility to report this to their line manager who will assess the problem. If there is a problem specifically with this procedure, this should be reported to the Document Authors, who will consider (i) if immediate changes to the procedure are required or (ii) whether to include for consideration at the next scheduled procedure review.

4.13 Document Authors
It is the responsibility of the Document Authors to develop a schedule to review, authorise and ratify the Authorisation Procedure accordingly and ensure that it is uploaded onto the R&D department's Intranet (SharePoint) page.

5. Procedures

5.1 Overview
Most applications for registering research in the Trust require the Trust to authorise their involvement by undertaking the process of Asses Arrange and Confirm (AAC),

Applications to Bradford District Care Trust (BDCFT) should be submitted to the R&D Department at the Lynfield Mount Hospital site via email **research@bdct.nhs.uk** .

BDCFT no longer issues 'NHS Permission' for research studies but will confirm that we are ready to start delivering the study activities after BDCFT has completed SOA and SOE and return these to the study sponsor after gaining Trust authorisation. Studies will be able to commence once sponsors have acknowledged receipt of this SOA and SOE
The R&D Department will require assurances that the relevant permissions, including favourable research ethical approval, have been obtained. This will be in the form of the HRA approval letter which will form part of the. 'valid application' procedure below. Obtaining these permissions and regulatory authorisations are the responsibility of the Chief/Principal Investigator.

Valid Application - BDCFT operates a 'valid application' procedure for all studies This means that BDCFT will only commence processing a researcher's submission on receipt of a valid application. A valid application is one where the following documents are sent to BDCFT with an invitation to take part in the study using the new HRA process

•HRA Approval Letter
•IRAS form
•Protocol
•Statement of Activities
•Schedule of Events

5.2.1 Preparation

Before applying for HRA Permission and Trust Authorisation, regardless of whether researchers have been contacted to take part in a national study or have a research idea of their own, they should first ensure that the project is defined as research and not audit or service evaluation. The Chief investigator can determine whether their study requires ethical review or the R&D Department can give project specific advice.

For student projects, their university ethical review application process should be followed. There is also **R&D Student guidance** on Connect and in Appendix 4. For studies involving staff only In general no ethical review is required. Contact the R&D Department for further advice.

For studies that do not require review by Research Ethics Committee, follow the guidance on the IRAS or on the HRA website, submit application along with research proposal, consent forms, sponsor arrangements and CV of Chief investigator.

Researchers are advised to discuss their application at an early stage with the proposed Sponsor, the lead NHS R&D department and the NIHR Design Service (if appropriate). Protocols and/or research proposals should be forwarded to research@bdct.nhs.uk, indicating the level of support required. One to one appointments can also be arranged where required. A feasibility check list should be utilised. SAE and SOE should only be sent after the feasibility check is done

- Researchers understand their roles and responsibilities when carrying out clinical research in the NHS and have undertaken the appropriate training. This usually takes the form of Good Clinical Practice (GCP) training. GCP is the standard and guidelines to which all research is conducted

- Local Trust researchers must ensure their projects have been subjected to peer review prior to ethics application. Generally, two reviews are required by the research ethics committee. If these are not included in the application for authorisation it will be considered as an invalid application and the researcher will be advised to resubmit. The R&D Department can give further advice on gaining peer review.

- Researchers external to the Trust who wish to conduct research at BDCFT Sites need to ensure that they have identified a Local Principal Investigator or Collaborator. Further advice is available from the R&D Department .

- BDCFT can act as sponsor for projects, further advice is available from the R&D Department .

- Research projects should be adequately costed, including sufficient funds to reimburse participant travel costs and extra research costs. See finance guidance SOP02. All projects will be subjected to financial R&D Authorisation.

5.2.2 How to prepare an R&D Application for gaining HRA permission

(i). Create an IRAS Account here (if account not already held). Under new HRA guidelines, only the CI will now submit to NHS REC by email using IRAS. This is now done by the Central Team/Study sponsor who generates the online Integrated Research Application System (IRAS).

IRAS is a single online system for applying for a number of permissions and approvals for health and social care research in the UK. This system streamlines the process for seeking relevant approvals by ensuring that, as far as possible, details only need to be entered once for a single project.

(ii). Complete the R&D application forms

Under new HRA process, the Central Study Team now only need to send the following documents to the participating research teams.

- HRA Approval Letter
- IRAS form
- Protocol
- Statement of Activities
- Schedule of Events

A simplified process facilitates the need for and eases of communication between sponsors and research sites throughout the study, and especially in determining the feasibility of opening a study at a given site

Guidance on the use of IRAS is available by selecting the 'help' and 'e-learning 'tabs. There is an excellent e-learning training module within the 'e-learning' tab and it is highly recommended that researchers familiarise themselves with this before starting their own application.

Before completing the IRAS dataset, researchers should first determine the type of study they are proposing and whether the project is eligible for adoption onto the NIHR Portfolio database, known as *'portfolio projects.'*

(iii). Determine the type of study

There are two routes for seeking HRA permission for research – the NIHR portfolio route (adopted) or the non portfolio (not adopted route)

NIHR Portfolio Studies
These are high quality studies that are either funded by NIHR grants, government and NIHR non-commercial partners. These projects are often multi-sited, multi-organisational and have been awarded funding through a national competition. Other studies may be considered for 'adoption' onto the national portfolio database by completing a portfolio application form (PAF) in IRAS.

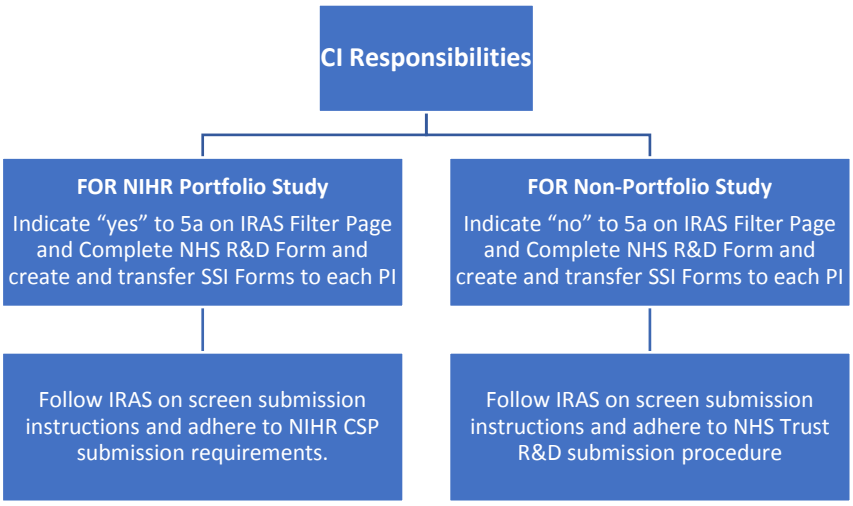
Important Note: Projects that are adopted onto the NIHR Portfolio can obtain support from the R&D team for recruitment and obtain support costs from the Clinical Research Network (CRN) Yorkshire and Humber. Further guidance on portfolio eligibility criteria can be found here. Contact details for the CRN Yorkshire and Humber team can be found here.

Non-portfolio studies
These are usually studies that have a local or specific focus and include research projects that are undertaken as part of a qualification. They may be sponsored locally, by the Trust or university, and in some cases, sponsored by Industry. Once it has been established whether a study is a portfolio or non portfolio, the IRAS filter questions can be completed.

(iv). Complete IRAS Filter Questions

It is very important to complete these questions correctly because the answers determine the format for the remainder of the form and determine the direction of the approval process.

Figure 2.



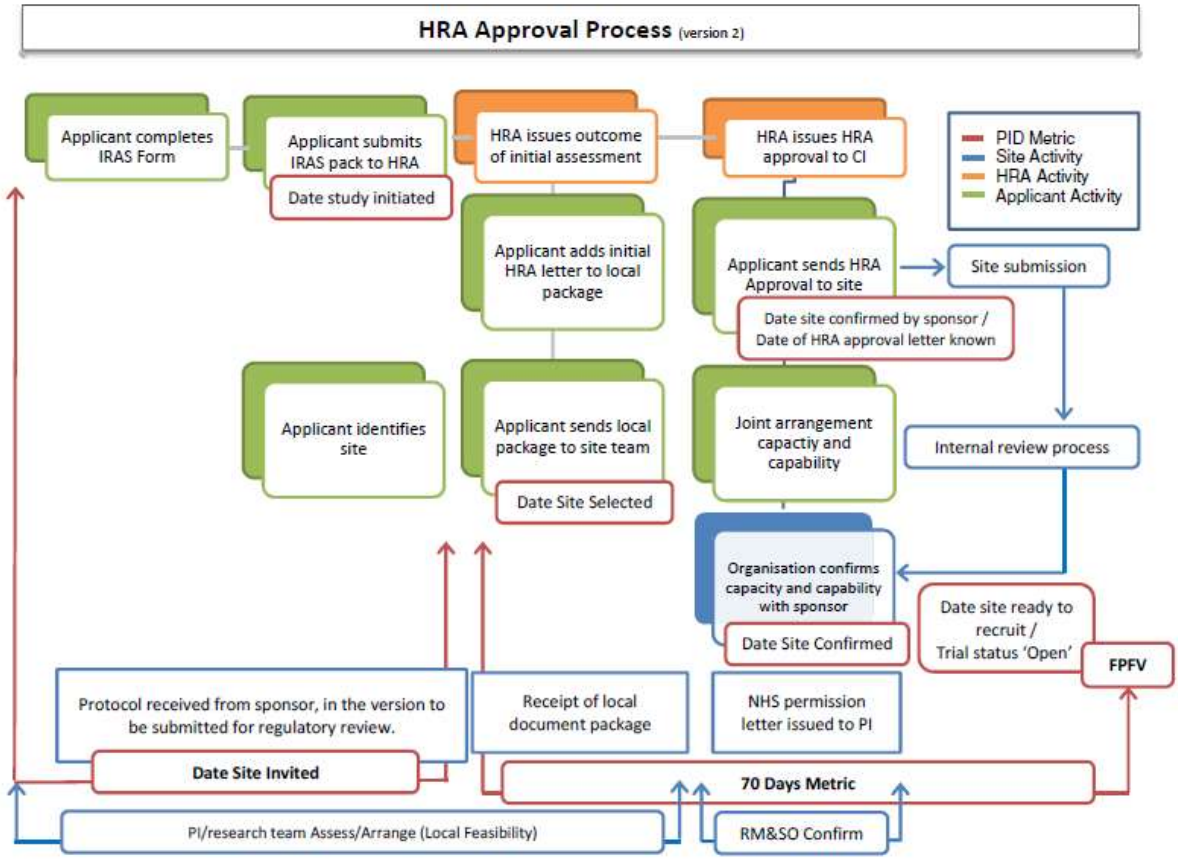
(V). Complete the SAE and SOE

If you are a PI/Local Collaborator participating in either an NIHR Portfolio study or a non-portfolio study**,** in both cases you will need to complete an SAE and SOE form. See new HRA guidance on how to complete an SAE and SOE forms. If you are experiencing difficulties please contact the R&D Department.

(vi). Make application to HRA

Once all documents are in place the application can be passed to the HRA they will organise the completion of both Ethical review and the HRA application.

Figure 3



(vii). After HRA Approval

After the HRA approval, the study team can apply to the site, who will confirm their capacity and capability to take part in the study.

(viii) Contact BDCFT for Authorisation

It is essential that studies are set up and recruited to in a timely way in accordance of the NIHR timescales. The R&D Department can help with this.

NIHR TARGET TIMESCALES:

The only current timescale for is 70 days from the date site selected to take part in the study (and the full document set being sent to BDCFT) to the date of the First Patient First Visit

NB
Although there have been no official timescales set by the CRN we are currently working on the premise of 40 days from the date site selected to the date that all Authorisations have been confirmed and a further 30 days until the date of the First Patient First Visit (FPFV) to tie in with the NIHR target

To do this, ensure that **before** submission of approval applications, the following have been considered:

- The regulatory documents required for submission have been collated.
- Local research team(s) and Clinical Studies Officer/Research Nurse support (where required) has been arranged.
- Local training needs have been identified.
- Sponsorship arrangements have been agreed.
- The relevant service managers have been approached where required, to assist in the implementation of the study .
- Costings have been considered and financial review has been started, using the industry costing template if required.
- Local support departments. e.g. pharmacy/pathology have been approached
- Recruitment figures and starting time have been agreed with research support team and or services involved .
- Agreed other contractual arrangements and prepared contract if required
- Agreement with the R&D Department when SAE and SOE forms should be submitted.
- A simplified process facilitates the need for and eases of communication between sponsors and research sites throughout the study, and especially in determining the feasibility of opening a study at a given site.

5.2.3 BDCFT process

- **The Trust will consider all the above points where required and obtain all relevant departmental agreements.**

- **The Appropriate final Authorisations will be sought for the study to be conducted at BDCFT.**

- From the initial review, projects will be assessed according to risk.

- **(i) Low risk:** Some qualitative and observational projects will not require full panel review but can be authorised by the Head of Research (BDCFT) and relevant Head(s) of Services only. In the absence of Head of Research, the R&D Director will be responsible for authorisation of these projects.
- **(ii) High/medium risk**: Interventional projects e.g. Drug trials and randomised control trials of therapies will always require full review, i.e. review by the Head of Research (BDCFT) and relevant Head(s) of Services, Finance, and other departments as appropriate. Once all checks have been conducted and authorising signatures received from the appropriate departments within BDCFT, the project will then be finally authorised and approved by the R&D Director or, in their absence, the Medical Director.
- To prevent delay in the setup of the study it is recommended that researchers discuss their project and obtain authorisations form the relevant services prior to submission of applications.
- Externally or commercially sponsored research will need to be approved by the Medical Director, R&D Director, and the Director of Finance. However, where the Trust Chief Executive is required to sign any indemnity agreements and contracts, this will not take place until authorisation to undertake the project has been granted by the R&D Department and HRA (where relevant).
- When all necessary checks have been carried out and are deemed to be satisfactory.

- **The localised SAE and SOE will be returned to the Study Team once the Trust Authorisation has been gained and on confirmation by the Study Team that BDCFT is now a recruiting site the FPFV clock starts.**

5.3 Additional requirements:

Access to BDCFT for External researchers

All researchers who are employed by an organisation external to the Trust, or who do not hold substantive contracts with a NHS Trust will need to apply for an honorary contract to allow their work for the duration of the project.
This usually takes the form of a 'Research Passport'. NHS employees will need to complete a 'NHS to NHS' Proforma to obtain a letter of access (LOA). A flowchart demonstrating the principles of sharing pre-engagement checks by universities with NHS organisations and of accepting checks across NHS organisations can be found here. Full details of how to apply, including downloadable application forms for research passports can be found here. Forms are also available from the R&D Department, following project authorisation and evidence of completion of the relevant CRB checks etc. Further details should be sought from the R&D Department if required.

It is the responsibility of the Sponsor of the Project to ensure that researchers coming into the NHS have the necessary pre-employment checks undertaken and that all contractual arrangements are in place prior to commencement of the project.

5.4 When to start the study

It is essential that researchers have identified their target population and are ready to recruit the first participant into the study within 30 days of the study opening. This is to ensure BDCFT meets its NIHR target times and avoids the risk of financial penalties. If there is any concern that this target may not be met, researchers should contact the R&D Department to discuss further before submitting their application.

5.5 Progress of the study

It is a requirement of Authorisation that the R&D Department and the ethics committee are kept informed of the progress and status of the study. Researchers are required to complete the monitoring forms and to keep R&D informed of the recruitment and the status of the study. See Monitoring Procedure, SOP07.

6. Consultation, Approval and Ratification Process

6.1 Consultation Process

Stakeholder	Level of involvement
• Research Forum • Human Resources Dept. • Information governance • Heads of Service • Finance	Consultation
• Research & Development Director • Head of Research • Senior Clinical Studies Officer • Data, Information Systems and Governance Officer	Development
• Research Forum	Consultation and Ratification

7. Review of the Procedural Document

This document will be reviewed every 3 years or when deemed necessary as a result of statutory or operational change in line with Trust policy

8. Dissemination of the Procedural Document

This document will be held in the R&D Department and in the library services across the Trust. It will be available on the intranet once ratified. The policy will be disseminated to all service leads and all researchers and staff involved in research will be informed how to access this policy.

9. Training and support for the implementation of the Procedure

The R&D department will provide support to individuals as and when required. This will take various means including:

- Procedural documents
- Guidance available on the intranet and internet web sites
- Access to training e.g. Good Clinical Practice (GCP)
- Introduction to Health and Social Research courses
- Circulation of research courses available via the 'Comprehensive Local Research Network'

10. Monitoring Compliance and effectiveness of the Procedural Document

Criteria	Evidence identified to indicate compliance with policy	Method of monitoring i.e. how/where will this be gathered?	Frequency of Monitoring	Lead responsible for monitoring
Process for checking that staff are compliant with good clinical practice and research guidance as outlined by the NHIR Study Support Service (SSS)	Research Project Monitoring and Audit Procedure	As outlined in the Research Project Monitoring and Audit Procedure (SOP 07)	As outlined by procedures and assessment of project – See SSS	Head of Research and Data, Information Systems and Governance Officer

11. References

Department of Health/Medical Research Council, Clinical Trial Toolkit, www.ct-toolkit.ac.uk

EU Directive 2001/20/EC
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

International Committee on Harmonisation Good Clinical Practice Guidelines (1996), http://www.ich.org/products/guidelines.html

Mental Capacity Act (2005)
http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf

Medicines for Human Use Regulations (2005)
http://www.legislation.gov.uk/uksi/2005/2789/made

National Institute for Health Research, *Research in the NHS - HR Good Practice Resource Pack*

https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-passports/Hr%20Good%20Practice%20Resource%20Pack/HR-Good-Practice-Info-for-researchers-RD-and-HR-staff-in-the-NHS-and-HEIs.pdf

Research Support Services Framework;
https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/framework-for-research-support-services.htm

UK Policy Framework for Health and Social Care Research (2018)
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

12. Associated Documentation

12.1 Trust R&D policy

Available on Connect (Intranet)

12.2 Research Passport Procedure:

Guidance available on Connect (Intranet) and NHIR link:

https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

12.3 Research Project Monitoring and Audit

Guidance available from R&D Department and SOP07

12.4 Recording of Adverse Events

Guidance available from R&D Department and Connect (Intranet)

12.5 Recording of research in patient records keeping and site file management

Guidance available from R&D Department and Connect (Intranet)

12.6 Trust Data Protection Policies: see Connect (Intranet)

12.7 Guidance on Research Finance (SOP02)

12.8 BDCFT Capacity and Capability Statement

Available from the R&D Department and Connect (Intranet)

13. glossary

Glossary of Definitions and terms used in Research

APBI	Association of the British Pharmaceutical Industry
BIHR	Bradford Institute for Health Research
Caldicott Guardian	A Caldicott Guardian is a senior person within each NHS trust responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. The guardian plays a key role in ensuring that the NHS, Councils with Social Services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information
Chief Investigators (CI)	The designated lead for a research project, with overall responsibility for the conduct of that project. For multi-site projects, a CI may be based within another institution, with the responsibility for the local (trust based) running of the project devolved to the Principal Investigator. They have responsibility for ensuring compliance with all monitoring and audit procedures.
Clinical Audit	'Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.' (NICE, 2002, Principles for Best Practice in Clinical Audit, p.1) Clinical audit is a continuous process and re-audit which aims to measure care against criteria and assess the impact of the implementation of change.
Clinical Studies Officer	Member of Research Support team. CSOs facilitate study set up and recruits to portfolio studies.
CRN Yorkshire and Humber	The local body established to oversee the governance of NIHR Portfolio Projects locally, and to facilitate the local development of, and recruitment to, such projects.
CTA	Clinical Trial Agreement, detailing responsibilities for all parties involved in the Trial.

Dementia and Neurodegenerative Disease Network (DeNDRoN)	Topic specific research network supporting Research projects in this disease group.
Development	Can be defined as work directed towards introducing an innovation or the improvement of a service or process, often based on findings of research. An important element of development is the dissemination and implementation of research findings. Development Projects are locally focused with no intention to generalize beyond this local setting.
EUDRaCT	European Database of Randomised Controlled Trials. Registration is compulsory for all UK Randomised Controlled Trials.
Funder	The organisation providing finance for a project. (NOTE this is not necessarily the same as the project Sponsor)
HEI	Higher Education Institutions' including Universities
HRA	Health Research Authority
ICH-GCP	International Committee on Harmonisation Good Clinical Practice Guideline.
Intellectual Property (IP)	Intellectual property is defined as: 'The novel or previously undescribed tangible output of any intellectual activity ---. It has an owner, it can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images.' (*Department of Health. 1998.)*
Intellectual property rights	These are defined as: '--- the legally protected rights which enable owners of items of intellectual property (IP) to exert monopoly control over the exploitation of these rights, usually with commercial gain in mind. They give the right to stop others exploiting this property, sometimes for a fixed period, sometimes indefinitely.' (*Department of Health. 1998.)*
Integrated Research Applications Service (IRAS)	Single entry point system for all research related applications. Automatically prepares the forms for projects to be completed and forwarded to a variety of research related regulatory bodies for approval or registration. Includes Research Ethics Committees (RECs), NHS Research and Development, National Patient Safety Agency, Medicines and Healthcare Products Regulatory Authority (MHRA).

IRCTN	International Randomised Controlled Trial Number. Unique identifier required for all randomised controlled trials.
Mental Capacity Act (2005)	The Mental Capacity Act (2005), implemented in 2007, is a framework to protect people who may lack capacity to make some decisions themselves about such things as their property and affairs, health care treatment, where they live, and their personal care. The Act also sets out a framework for the approval and regulation of research, and introduces safeguards and controls for the inclusion in research of those people who lack capacity to consent to participate.
Mental Health Research Network (MHRN)	The NIHR's Topic Specific Network supporting mental health research. This does not currently cover all of England and West Yorkshire's link is through the West Yorkshire Comprehensive Local Research Network.
MHRA	Medicines and Healthcare Products Regulatory Agency.
MRC	Medical Research Council
National Institute for Health Research (NIHR)	A virtual institute created following the Best Research for Best Health strategy. The goal of the NIHR is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public.
National Institute for Health Research Portfolio Studies	Research projects fitting the criteria for entry onto the NIHR portfolio. These are often multi-site, multi-organisational projects attracting funding resulting from National competition e.g. from DH funding sources. Recruitment to such studies is a focus of the recent DH Strategy 'Best Research For Best Health'.
'Own Account' Projects	Research projects sponsored locally and having a local focus, with support coming exclusively or largely from within the Trust.
Principal Investigator (PI)	The local (Trust based) lead in a multi-site project. They will report to the project Chief Investigator. They have responsibility for ensuring compliance with local monitoring and audit procedures.
SAE	Statement of Activities
SOE	Schedule of Events

Research	This is another word for 'enquiry'. It is a systematic and rigorous process of investigation that is undertaken to discover facts or relationships and reach conclusions using scientifically sound methods. The Department of Health has defined research as: 'The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods' (*Department of Health. 2005. 'Research Governance Framework for Health and Social Care' London, Department of Health*). The criteria used by the R & D Department to define research are as follows: Projects should provide new knowledge; Projects should be designed to be generalisable beyond the particular setting of the project; There should be an intention to publish the results of the project in a peer reviewed journal.
R&D Authorisation (Confirmation of Capacity and Capability)	A process of checks and reviews by an NHS organisation to ensure that any research involving human participants their tissue or data have : • adequate arrangements and resources to meet the standards set out in the RGF; • an identified sponsor has taken on responsibility for the study; • the study has received ethical approval (where required); • there is a clinical trial authorisation in place for a clinical trial of a medicine; • the allocation of responsibilities is agreed and documented; • appropriate contractual arrangements are in place; • legislation relating to the research is followed within the organisation;
Research Ethics Committee (REC)	Performs independent review of all NHS based research to ensure compliance with ethical standards and protect the rights, safety, dignity and well-being of research participants
Research Governance Framework (RGF)	The Research Governance Framework for Health and Social Care is the key document revised in 2005, outlining the necessary regulation for research within the NHS.

Research Support Services (RSS) Framework	An initiative by the NIHR Research Support Services to provide a national framework for NHS Head of Research to offer a consistent professional service, using a risk approach to managing projects and governance. Within the framework there are a number of standards and procedures guiding the management of research governance in order for NHS R&D Department to provide an effective, streamlined service.
Service Evaluation Project	This is a wider process than audit in that it not only records what changes occur but also what led to the changes. It assesses the effectiveness of an intervention, service, or organisation. See also 'Development' above.
Sponsor	The organisation providing assurance for the quality of a research project. It may be an NHS organisation, HEI or commercial organisation.

Appendix 1: Research Governance Checklist For Researchers

The checklist below is a tool to help you focus on key research governance requirements when planning and conducting NHS research. Not all sections will apply and will depend on the type of study you wish to undertake. **This is your aide-mémoire and <u>does not</u> form part of your R&D application**. Further guidance is available on the R&D section of Connect.

Check	✓
Nominated Sponsor	
Does your research study have a Sponsor as defined in the Research Governance Framework for Health & Social Care and The Medicines for Human Use (Clinical Trial) Regulations 2004?	
The Sponsor is the organisation that is responsible for the initiation, management and/or financing (or arranging the financing) of a study.	
Applicants are required to acquire a signature on the Sponsor's Declaration page of their IRAS Application form prior to submission.	
Peer review	
Has an appropriate process of scientific critique demonstrated that your research proposal is worthwhile and of high scientific quality?	
The sponsor of the research is responsible for the assessment of the scientific quality of the proposed research. The research proposal must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for review should be commensurate with the scale of the research and the potential risks or burdens involved for participants. For example minimum requirement would be one clinical and one academic expert	
The REC expects to receive a protocol that has already been subjected to scientific critique	
A copy of any available comments or scientific critique reports from referees or review committees should be enclosed with the application.	
The REC system recognises that <u>*student research*</u> has an educational and training value and that proposals (especially from undergraduates) will not normally be of the same scientific merit or importance as those submitted by professional researchers. However, research proposals from students should be reviewed at least by the academic supervisor. The REC expects the academic supervisor to provide assurance that the proposal has identified a valid research question and is suitably designed, taking into account the limitations of time and resources.	
Data Protection	
Do you understand the project issues that may arise due to the General Data Protection Regulation 2018and other legal provisions and guidance on handling information? And, have you put in place appropriate counter-measures that are in accordance with Trust policy to ensure that the project does not breach any of the principles outlined in the General Data Protection Regulation 2018 If you're not sure, seek advice from your Data Protection Officer	
Do you know how to comply with the NHS rules on patient confidentiality? If you're not sure, seek advice from the Trust's Caldicott Guardian and/or Information Governance Department.	
Health & Safety	
Do you understand the project issues that may arise due to the Health & Safety Act and relevant national regulations in respect of yourself and other participants? If you're not sure, seek advice from the Trust's Health & Safety Advisor.	
Writing a Protocol: Risk Assessment, Study Management & Monitoring	

Have you undertaken and documented a risk assessment?	
Have you used the outcome of your risk assessment to inform the development of your protocol with regard to appropriate study management & monitoring arrangements in accordance with the principles of good clinical practice (GCP)?	
Are there adequate arrangements in place to deal with new information if it becomes available which may affect individuals continued participation in the study, scientific direction as well as safety information?	
Is there a project management group?	
Has a steering committee been convened?	
Patient & Public Involvement	
Have you identified a role for a participant, carer, service user or member of the general public in your research?	
Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of the research	
Support Departments	
Agreement should be sought from relevant support departments regarding the additional resources required to undertake the research study. These tests and/or assessments and/or procedures should be clearly defined in the Site-Specific Information (SSI) Form.	
Have you received written confirmation from the Funder confirming the award/grant and their terms and conditions	
Written Agreements	
For all funded work, is there written agreement with your collaborators confirming acceptance of their agreed role and responsibilities and allocation of resources and that they have read and agree to adhere to the protocol?	
A clinical trial agreement or clinical study agreement or sponsorship agreement is a contract between the Trust and the Sponsor and as such should be signed off by the Sponsor and the Trust's designated authority to sign research contracts usually the Director of R&D. Sometimes the investigator is required to sign the agreement as well. You must not sign any written agreement you receive directly from the Sponsor, but FIRST forward it to the R&D Department for review first.	
Contracts of Employment	
Do all members of the research team working on Trust premises have either a substantive or honorary contract of employment or a Letter of Access issued by the Trust, including yourself, confirming the contractual terms and accountability.	
The Research Passport process should be completed by anyone who is not employed by the Trust but who wishes to engage with Trust staff or patients in research.	
Intellectual Property	
Your study may be sensitive to intellectual property rights. Contact the R&D Department for advice.	
Ethics Approval	
Do you have a favourable opinion of an appropriate Research Ethics Committee?	
Clinical Trial Involving a Medicine	
Does the trial require authorisation by the MHRA (Medicine and Healthcare Products Regulatory Agency)?	
Trials which fall under the Medicines for Human Use (Clinical Trial) Regulations 2004 must have a Clinical Trials Authorisation (CTA) , issued by the MHRA.	
Are you aware of your legal duties? The Medicines for Human Use (Clinical Trial) Regulations 2004 came into force on 1st May 2004.	
Are you GCP trained within the last two years? Are all other study personnel carrying out procedures in the protocol GCP trained? When did you last attend a refresher course?	

R&D Authorisation	
Do you have the explicit written permission to proceed from each NHS organisation participating in your research?	
Pulling of Patients' Records	
Will you require access to patients' records? If you are the individual who will be accessing medical records on Trust premises (in accordance with explicit written patient consent) and you are not employed by the Trust, you may require a Letter of Access. Please contact the R&D Department .	
The Foundation Trust has a dedicated Medical Records Clerk for the pulling of case notes at the Foundation Trust for research purposes. If you require this support, please contact R&D Department .	
Informed Consent	
Are you and others in the research team who are responsible for obtaining consent equipped with the knowledge of the current Law and guidance pertaining to obtaining valid informed consent?	
Reporting Adverse Events	
Have you ensured that all those involved with the care of the participant are familiar with the Trust's policy and procedure for reporting adverse events?	
Have you also ensured that all study personnel know the arrangements for reporting serious adverse events within agreed timelines to the Sponsor and the main Research Ethics Committee? This procedure should be clearly described in the protocol.	
Research involving medicines is regulated under the Medicines for Human Use (Clinical Trial) Regulations 2004 which came into force on 1st May 2004 and you must adhere to their specific requirements with regard to recording and reporting adverse events.	
Monitoring	
You should ensure that requests for reports on the progress and outcomes of the work required by those with a legitimate interest (such as the sponsor, the funder(s), the Trust) are produced on time and to an acceptable standard and that all data and documentation associated with the study are available for audit on request	
Finance	
You should liaise closely with your Finance Manager to ensure that research grants and income are managed in accordance with the Trust's Standing Orders and Standing Financial Instructions.	
Protocol Amendments	
Have Applied to the HRA for any amendments to the Protocol and passed these on to all Participating Sites	
Dissemination	
Do you have a dissemination strategy? Do you intend to publish the results of your study in professional peer reviewed journals?	
Have you made arrangements to ensure that the established findings will be made available in an understandable format, i.e, in lay person's terms, to the participants and to all those who could benefit from the work?	
Industry Sponsored Research	
Have you sent the Clinical Trials Agreement (CTA) and indemnity document(s) to the R&D Department for review and agreement?	
The Clinical Trials Agreement is between the Sponsor and the Trust, and not between you (the investigator) and the Sponsor and should be based on the model agreements without modification as published with guidance at http://www.ukcrc.org/regulation-governance/model-agreements/mnca/	
Has the Sponsor completed the Industry Costing Template in order to calculate the research costs (including Trust overheads and pharmacy fees)? Go to the UKCRN	

website at https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm	

Appendix 2: Local Impact Summary

BDCFT Local Impact Summary Form

R&D Department
Osprey House
Lynfield Mount Hospital
Bradford BD9 6DP

Tel: 01274 228618
research@bdct.nhs.uk

Date:
Project Title: «Research_Title»
BDCFT Ref: «RD_No»
Service Director/Manager:
Proposed start date: «Local_Start_Date»
Proposed end date: «Local_End_Date»
Service Area impacted:

Chief Investigator: «Chief_Investigator»
PI/Local Lead: «Principal_Investigator»
Sponsor: «Sponsor_Organisation_»
Funder: «Funder_Organisation»
NIHR Adopted: «Portfolio_Study»
CSP/NIHR/IRAS no: «CSPIRAS_No»
Peer Review:
Agreed number of participants at BDCFT:
Recruitment Period: «Local_Start_Date» - «Local_End_Date»
Risk level: high/low

Lay Summary of Study and Impact on BDCFT Services

Before issuing this approval request, the R&D Department have confirmed the following:

1. The Project has a named sponsor
2. The Project has gained favourable ethical approval which includes the approval of patient information sheets, consent forms and all recruitment materials
3. The scientific quality of the protocol has been assessed and is considered to be of good quality (including Peer review)
4. Appropriate indemnity is in place
5. Where appropriate, authorisation from MHRA for clinical trials of investigational medicinal products (CTIMPs) has been given
6. Where appropriate, the requirement for honorary contracts has been established
7. Where appropriate, the requirement for a formal financial review has been established
8. Where appropriate, authorisation from the Caldicott guardian has been received/requested

If you would like to see the study protocol or any other documentation such as participant information sheets or consent forms please contact the Research nd Development Team on 01274 228618 or email research@bdct.nhs.uk

Appendix 3 : Pharmacy Directorate Clinical Trial Charges Scale of Charges as at 17th January 2013 (excl VAT)

* The charges listed below are in line with the Standard Industry Costing Template costing(V2 October 2012).. These will be revised in line with any amendments to the national agreements. Invoices will be charged at the rate agreed for the individual study (as per the national Standard Industry Costing fees) in force at the time the agreement has been made.
These fees will be reviewed twice a year, or when the industry costings change. A copy of any revised charges will be forwarded to the CRA at the earliest opportunity.*

1. Set up fee and Close Down Fees

Pharmaceutical services have been divided into three categories, reflecting the complexity of services required for different types of studies, the definitions used here are as per the Industry Costing Template:

Study Type A:
dispensary based study with no aseptic compounding required (single site only)**:**
£902.66

Study Type B:
only aseptic compounding and no dispensing activity (single site only) :
£1203.55

Study Type C:
requires both dispensary and aseptic handling (single site only)
£1805.32

Additional site fee
This is payable for each additional trust site participating in the study
£300.89

The following activities are included in the set-up and Close Down Fees (irrespective of if the study has recruited patients or not):

- Review protocol
- Feasibility assessment
- Communication with the sponsor
- Participation in mandatory local review and approval processes
- Attendance at meetings & liaison with PI, Research Nurse, CRA
- Write bespoke prescribing guide
- Write & approve bespoke dispensary SOPs, worksheets & associated documentation
- Set up dispensing & stock control software systems and documentation
- Set-up electronic prescribing and pharmacy systems , where applicable
- Set up supply systems
- Train all relevant Pharmacy staff, as required
- Review contract including pharmacy costing
- Close down

2. <u>Trial Management/Maintenance activities</u>

Minimum charge per annum (or part thereof)
£185.00

The following activities are included in IMP Management Activities:

- IMP receipt, ordering and returning (whether using manual or IVR/IWR systems)
- On-site or within Trust storage temperature reporting and includes excursion reporting (not independently chargeable).
- Provision of non-standard (i.e. bespoke company format) temperature reports will be chargeable as these such reports are not routinely provided by the NHS.

Note: this excludes dedicated time with the CRA – this is chargeable separately

3. <u>Dispensing fees</u>

The following activities are included in the Dispensing Fee:

The following activities are included in the dispensing fee:
• Prescription screening
• Dispensing & labelling
• Routine stock accountability
• Aseptic compounding incl. essential pre- and post-dose set-up and clean-down (charged in addition to dispensing fee)
• Dedicated consumables (costed per dose)
• Randomisation of new participants if agreed as a pharmacy role

- **Dispensing fee**

A dispensing fee is also applicable for any IMP or other drug compounded aseptically in addition to the compounding fee **£24.26** (per drug (IMP or other agent) per visit.

Additional Dispensing Fee for Controlled Drugs:

£9.70 (per item dispensed)

Aseptic compounding fee (per item prepared per visit)

£8.22 IMP specific consumables charged per dose **(**additional charges will be made if preparation time is above 60 minutes at a rate of £58.22 per hour)

Use of IVR/IWR system for dispensing by Pharmacy (additional time) £9.70

Individual patient drug accountability time
Only where specifically requested or required, **£14.55** (per drug per visit)

Posting/arranging IMP delivery to patient **£14.55** (per delivery) **PLUS** courier /postal costs.
Only where specifically requested or required.

4. Variable costs

- **Drug storage Fee**

Storage space over 0.5m2 approx. (= one shelf 0.3m deep x 1.5m long – including returns) regardless of temperature requirements (per site charge as required)

£50 per month

Note: one off equipment charges will apply for IMP requiring refrigeration (see below)

Note*: the dimensions used for calculating storage area requirements and fees where refrigerators are used will be based on the external dimensions of the refrigerator and NOT the actual shelf space as the former takes up considerably greater space*

- Waste disposal as hazardous waste per 50L container (per site charge as required)

£25 per 50L container OR £50 per patient per trial

(the per patient charge is more practical than calculating the volume of waste likely to be generated for each IMP).

- Waste disposal storage pending collection or disposal of all unused/unwanted/expired medicines originally supplied by Sponsor per month or part thereof (per site charge as required). Chargeable only if not collected within 1 month of the first request to collect.

£50 per month (over 1 month)

- **Items requiring refrigeration**:

Provision of dedicated fridge by sponsor **No charge**

or

□□Fridge provided by pharmacy:

□□IMP occupies up to one shelf @ **£200 one off charge**

□□IMP occupies between one and two shelves @ **£400 one off charge**

□□IMP occupies two to three shelves (entire fridge) @ **£600 one off charge**

□□IMP occupies more than one fridge – proportionate charges @ **£200 per shelf**

Note: the dimensions used for calculating storage requirements and monthly fees where refrigerators are used will be based on the external dimensions of the refrigerator and NOT the actual shelf space as the former takes up considerably greater space.

5. Other Pharmacy Services

The following activities will be included in the MCTA and invoiced to the Sponsor as incurred through the course of the study at the Industry Costing Template Rate or as otherwise indicated:

- Re-labelling and releasing of IMP batch
- CRA-requested dedicated Pharmacy staff time to support monitoring visits. Chargeable as additional to standard/routine service provision of basic access, hospitality, documentation provision and query response (Usual staff hourly rate)Dedicated audit time with CRA or other Sponsor affiliate (minimum charge 2 hours)
- Extending working hours (Usual staff rate + 50%)
- Out-of-hours working (Usual staff rate + 100%)

- Revision of relevant SOPs or IMP documentation as a result of a substantial protocol amendment (Usual staff hourly rate)
- Non-standard reporting of or additional company requested stock or temperature checks (Usual staff hourly rate)
- IMP specific consumables (total cost)
- Courier/ posting costs for IMPs (third party costs as required e.g. per patient)
- Equipment purchase for specific IMP requirements in storage space or conditions (total cost)

Staff charges will be based on the NIHR CRN Industry Costing Template standard rate of **£58.22** per hour for each staff member implicated.

5. Methods of Payment

The method of payment will be agreed between the pharmacy department and the sponsor as part of the CTA.

Approved 16th January 2013

2) BDCFT Pharmacy Costing Template:
To be completed by the Trial Pharmacist or Head of Pharmacy Services

Study Title		**BDCFT Reference**
Activity	**Comments**	**Cost**
Set up Fee: **State study Type** • Study Type A • Study Type B • Study Type C		
Additional site fee		
2. Trial management activities		
3.Dispensing Fees • additional dispensing fees for controlled drugs • Aseptic compound • Use of IVR/IWR system for dispensing • Individual patient accountability time • Posting /arranging IMO delivery to patient •		
4. Variable costs • drug storage • Waste disposal • Items requiring refrigeration		
Other pharmacy services: please state		
Total costing		

For industry studies the method of payment will be agreed between the pharmacy department an the sponsor as part of the CTA

Signature of designated officer

Name Designation
Date

Appendix 4: Student Research Guidance

Before you embark on any research or any postgraduate project on BDCFT site consider the following:

- **Do you have the time to design the project obtain ethical and organisational approval and then conduct the study?**

If you are considering undertaking primary research, you will need to allow for time to negotiate the feasibility of conducting your project proposal and to obtain the appropriate ethical approval and organisational permission. This is likely to take up to 60 days for ethical permission to be granted, followed by a similar period for post-ethical approval by the Trust.

Whilst we do not seek to prevent primary research at this level, the nature of the timescales to achieve the required ethical and organisational approval make many research projects, aiming to be completed in a single year unrealistic.

Discussions with local universities have resulted in many undergraduate students opting for literature based studies (e.g. Systematic reviews), or work that does not include patients, or staff directly, so removing the need for such approvals processes. For Masters students we recommend you undertake a service development/evaluation or audit for your projects. These do not require the same level of review, and so can be started more quickly.

- **Do you have the research support to conduct the research project you have proposed?**

Many students have not undertaken a research or development project before therefore by undertaking a service development, evaluation or audit project research skills can be developed for future research projects. Also, from the initial study findings there will be the option to explore future possibilities of a substantial piece of collaborative research within your chosen topic.

Evaluation and service development projects are required to be authorised by the head of services. Please check with R&D Department.

If you are wishing to undertake primary research please ensure that the academic institution will sponsor and provide you with the appropriate support.

- **Will the outcome of your project be of benefit to the service users, carers, staff, your department or the Trust?**

All projects taking place with the BDCFT must be able to demonstrate that they are of good quality, worthwhile and show some benefit to the service and its service users or staff. You will be expected to present your findings to the department and forward a report to the R&D Department for dissemination. Where possible we encourage publishing your work in a peer-reviewed journal.

- **Has the proposal been discussed and approved by the site line manager and or head of service?**

All projects that take place within BDCFT need to demonstrate that the site manager has agreed for the study to take place within their department ,and any overheads or extra costs for staff time or resources have been calculated and agreed to be supported by the department.

- **Does your project proposal fall within the category of research as defined by the NHS?**

The definitions for different types of projects are to be found here

http://www.hra-decisiontools.org.uk/research/

If your project does fall within then category of research:-

- Discuss your proposal to both your academic supervisor and line manager, and contact the R&D Department as soon as possible. Only those projects that can demonstrate that they are worthwhile and feasible (as outlined above) within the timeframe will be considered.
- Obtain peer reviews or supervisor reviews and approval by the academic institution you are registered with.
- Ensure that the Higher Education Institution (HEI) to which you are registered will complete the IRAS (ethical approval application) form section D, that states that they will sponsor and will be responsible for the conduct of your study.
- You will need to apply for NHS ethical approval in addition to the above by completing an application IRAS form online; https://www.myresearchproject.org.uk/
- You will need to apply for HRA approval as outlined above
- You will have to be able to demonstrate adequate arrangements for indemnifying their research. If you are NHS staff it is likely that you will be covered by NHS indemnities, assuming your project is related to your usual work/training in some way.
- If you are a student employed by another organisation, who wishes to conduct research that is on BDCFT site and involves BDCFT service users or staff, you will have to obtain access through the research passport system prior to research activity. To obtain access please follow the guidance and complete the appropriate forms on the following link:

  https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm

  And then forward your application to the R&D Department: research@bdct.nhs.uk

For further information please contact the R&D Department: research@bdct.nhs.uk

Tel no: 01274 363208