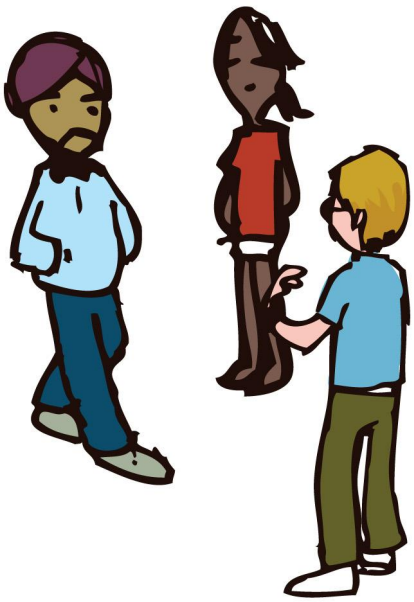
Bradford District NHS
Care Trust

Research and Development Policy

July 2011



You and Your Care

Document details:	Research and Development Policy
Version:	1.0
Persons / committees consulted:	Medical Director R&D Director R&D Strategy group Heads of Service XPLORE- Service user research group Equality and Diversity team and networks Human Resources Deputy Director of Finance West Yorkshire Comprehensive Local Research Network R&D Governance Manager, Bradford Institute for Health Research
Approved by:	Professional Council
Date approved:	24/6/2011
Ratified by:	Service Governance Committee
Date ratified:	8th July 2011
Title of originator / author:	R&D Director and Research Manager/Coordinator
Title of responsible committee / group (or Trust Board):	Service Governance Committee
Title of responsible Director:	Medical Director
Date issued:	July 2011
Review date:	July 2014
Frequency of review:	Every 3 years
Target audience:	All those considering, undertaking, and administering R&D activity within the Trust.
Responsible for dissemination:	R&D Administrator Library Services
Copies available from:	R&D Office Library services BIHR web-site BDCT Intranet
Where is previous copy archived (if applicable)	R&D Office
Amendment Summary:	
Amendment No	Page No. Date

Filename: R&DPolicyFinalDraft7Jun11.doc

Contents

1. Introduction

Research is fundamental to the successful promotion and protection of health and wellbeing and is essential for any organisation aiming to deliver excellence in health and social care. The Department of Health has highlighted the central role of research in delivering both 'health and wealth' for the nation and confirmed that research is part of core NHS business[1]

The National Institute for Health Research (NIHR) has been set up to develop an infrastructure within the NHS to deliver first class government funded research.

BDCT recognises that a culture of research excellence supports the vision and values of the Trust and is committed to building its reputation as a centre of excellence for applied health and social care research. This Research and Development (R&D) policy sets out the Trust's commitment to research and the standards and processes to achieve a high quality and consistent approach to developing, conducting, and governing research across the organisation. The aim is to support the development of high quality research programmes that will benefit service users and carers, staff and local communities. Further, it seeks to ensure that procedures for undertaking research are standardised, consistent, and streamlined, meet all statutory requirements, and protect the safety of services users, staff and researchers involved in research activities.

2. Purpose of Document

2.1. Policy Statement

The policy links directly to the Research Strategy as part of the Trust's overarching strategic vision, values and business plan. The aim is to deliver research that is high quality, inclusive, ensures fair and equal participation, locally relevant, and nationally and internationally significant.

2.2. Purpose of Document

The policy covers all research activity, both commercial and non-commercial involving the Trust including:

- Research involving service users, carers, volunteers and members of staff.
- Research taking place on Trust premises or involving Trust resources, including non-clinical and laboratory based research.
- Research being undertaken as part of an educational qualification.

[1] Department of Health, (2010) The NHS Constitution for England (2009 edition)

Specific objectives of this policy are to:

2.2.1. Build capacity & reputation for excellence in applied health care research

- Encourage and support a culture of high quality research within the Trust.
- Promote service user and carer involvement at all stages of the research process.
- Ensure effective use of NHS R&D support funding for building research capacity.

2.2.2. Deliver research that improves health & well-being and services

- Support & enable individuals in the Trust to carry out research that can lead to improvements in health, quality of services and productivity of the organisation.

2.2.3. Deliver effective research management & governance

- Provide clear guidance for all those involved in research at BDCT including partner organisations.
- Ensure the interests and safety of both researchers and research participants are protected.
- Ensure that procedures for gaining R&D approval, undertaking and monitoring research are standardised, unified, streamlined and compliant with the Department of Health's Governance Framework [2]
- Ensure the Trust derives maximum benefit, including protection of Intellectual Property from research by its staff and/or carried out on its premises.

2.2.4. Support evidence based practice

- Ensure that R&D activities support and contribute to evidence based practice.

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[2] Research Governance Framework for Health and Social Care (2nd Edition, 2005)

3. Definitions

3.1. Type of Procedural Document

This is a policy document describing the structures, systems and processes required to ensure R&D activity is carried out in accordance with national standards and guidance.

3.2. Glossary of terms

ABPI	Association of British Pharmaceutical Industry
Chief Investigators (CI)	The designated lead for a research project, with overall responsibility for the design conduct and reporting of that project if it is at one site. 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.
Commercial Research	Research that is sponsored and funded by a commercial company.
Comprehensive Local Research Network (CLRN)	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. The Trust works with the West Yorkshire CLRN.
Co-ordinated System for obtaining NHS Permissions (CSP)	This is a standardised system by which projects are processed for set up and approval in the NHS. The process is mediated by the Comprehensive Local Research Networks (CLRNs)
Development	The experimental introduction into practice alternative, already proven clinical procedures or methods of care. Development projects are locally focussed with no intention to generalise beyond this local setting.
Funder	Organisation providing funding for a study (through contracts, grants or donations to an authorised member of the employing and/or care organisation). The main funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money.
HEI	Higher Education Institutions, including Universities

ICH GCP	International Committee on Harmonisation Good Clinical Practice Guideline. Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.
Intellectual Property	Intellectual Property is: '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 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.)*
Medicines and Health Care Products Regulatory Agency	A government agency that is responsible for safeguarding the health of the public by ensuring that medicines and medical devices work and are acceptably safe
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[1]. 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	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.
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 service users 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.
Peer Review	The scrutiny of the suitability of protocols in terms of scientific quality, priority, resources, and the suitability of research team to conduct the study by independent peer reviewers within a relevant area of expertise.
Primary Care Research Network	The NIHR topic specific network funded by the Department of Health and is dedicated to expanding clinical research in primary care. It is made up of 8 local networks. Northern and Yorkshire provides local support for BDCT. http://www.nyren.co.uk
Principal Investigator	The local (Trust based) lead in a multi-site project. They will report to the project Chief Investigator.
Research	Research is a process that asks important questions and seeks to answer them through well designed studies and appropriate methodologies. It uses qualitative and quantitative methods, including hypothesis testing. Its aim is to generate new knowledge that may subsequently be useful in improving the effectiveness of health care. 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;
Research Ethics Committee (REC)	Performs independent review of all NHS based research to ensure compliance with ethical standards.

R&D Approval (or NHS permission)	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; • a person authorised to do so has given written permission on behalf of the NHS organisation.
Research Governance Framework	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 Governance Framework for Health and Social Care
Research Support Services (RSS)	An initiative by the NIHR to provide a national framework for NHS research managers 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 offices to provide an effective, streamlined service.
Service Evaluation Project	see 'Development' above
Sponsor	The organisation responsible for securing arrangements to initiate, finance, manage and provide assurance for the quality of a research project. It may be an NHS, HEI or commercial organisation.

4. Duties

4.1. Chief Executive

The overall responsibility for this policy rests with the Chief Executive.

4.2. Medical Director

The Medical Director has overall delegated responsibility for R&D in the Trust.
Duties of the Medical Director include to:

- Provide leadership with regard to the strategic development of R&D aligned to the Trusts' strategic objectives.

- Provide assurance to the Trust Board that research activities and research governance are being carried out in accordance with national guidance on standards of practice and with this policy.
- Check and confirm applications for research comply with national standards and Trust policies on confidentiality, in the role of the Trust's Caldicott Guardian.
- Ensure appropriate approval and ratification of this policy, and its associated procedural documents.

4.3. R&D Director

It is the responsibility of the R&D Director to:

- Lead development, implementation and review of the Trust's Research Strategy.
- Ensure that research activity is linked to the strategic agenda of the Trust and supports improvements in clinical effectiveness.
- Support the development of service user and carer research capacity.
- Act on behalf of the Trust to provide a strategic perspective in the development of an integrated approach to R&D at a local, regional and national level.
- Build and strengthen working relationships with local academic, NHS and voluntary organisations.
- Ensure a high quality of research management and governance and ensure R&D policies, procedures and processes in the Trust meet all statutory requirements.
- Sign, on behalf of the Trust (after appropriate review by the Trust R&D panel):
    - All contracts for commercially sponsored research.
    - All bids or applications requiring commitment of Trust resources.
    - Organisational R&D Approval of research projects.
      This role may also be provided by the Medical Director. For low risk projects, such as some observational or qualitative studies, responsibility for providing organisational R&D Approval may be delegated to the Research Manager/Coordinator (please see the R&D Approval Procedure SOP1 for details).
- Promote and support evidence based practice.
- Ensure that any Intellectual Property generated as a result of R&D activities is appropriately evaluated for exploitation.

4.4. Research Manager/coordinator

The Research Manager has responsibility:

- To support the R&D Director to implement the Trust Research Strategy.
- For the day-to-day management and co-ordination of research activities in the Trust.
- To ensure that standardised processes and procedures, consistent with the NIHR Research Support Services Framework [3] (and any other relevant current regulations and guidance for the conduct of research), are in place and adhered to in the Trust.
- To lead in the provision of expert advice & guidance to researchers and other colleagues aspiring to or participating in research activity.

4.5. Research Strategy group

The Trust's Research Strategy group has responsibility to:

- Advise on and develop the Trust's Research Strategy and review progress made against that strategy.
- Advise on R&D Policies & Procedures and provide an overview of the Trust's research management and governance structures.
- Ensure representation from across all Directorates and groups in the Trust, including:
    - Care groups
    - Service users and carers
    - Support services such as Information Services, Clinical Audit, Finance, as appropriate
    - Researchers

4.6. Human Resources (HR)

The designated HR Manager is responsible for issuing either an honorary contract or a letter of access, as outlined by the NIHR Good Practice Guide and Research Support Services Framework (2010) for all researchers who do not hold a substantial contract with Bradford District Care Trust and require access to service users, staff or facilities to conduct a research project.

[3] National Institute for Health Research In NHS – Research Support Services Framework May 2011

HR also has responsibility for providing support to build research capacity in the Trust. This will be through review of new posts and vacancies for potential to include research and through staff appraisal, and Job Planning processes, in line with the Trust Research Strategy.

4.7. Finance

The Finance Director (or delegated representative) is responsible for ensuring that research in the Trust complies with all national guidance and with the Trust's policies and procedures for the financial monitoring and reporting of research activities. This includes responsibility to:

- Ensure that all proposed research is reviewed and assessed for financial risks and implications to the Trust appropriately and in a timely fashion.
- Check and confirm that all studies are costed and resourced appropriately as guided by the NIHR financial costing template.
- Advise on research contracts with funding organisations, including NIHR and commercial companies.
- Provide specialist financial support and advice to staff applying for research grant applications, including completion of finance forms.
- Support the R&D Director and Manager in monitoring and reporting on funding for research received by the Trust.
- Provide information and advice to support the R&D Director and Manager in business planning and budget setting.

4.8. Researchers

All those involved in research have specific duties, as described in the Research Governance Framework 2nd edition (2005). This includes Chief Investigators; Principal Investigators; other investigators; project Sponsors; project Funders; and those responsible for the care of participants involved in research projects

Please consult the Research Governance Framework for further details of individual responsibilities for these roles.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

4.9. R&D staff

It is the responsibility of all R&D staff, including Clinical Studies Officers, Research Nurses, Research Fellows and Research Assistants, to ensure that their practice is fully commensurate with this research policy, the Research Governance Framework and national legislation and research procedures. They are also responsible for providing advice relevant to their area of research expertise to staff and service users in the Trust.

4.10. Trust Managers

Before agreeing to researchers approaching service users or staff in the service, managers must satisfy themselves that the research has been approved by the Trust, and that those who are not employees of the Trust have been issued with either an honorary contract or a letter of access to the Trust.

Managers should have an awareness of the principles of Good Clinical Practice, as described in the Research Governance Framework for Health and Social Care, 2005

4.11. All Staff

Any member of staff, including individuals holding honorary contracts, participating or considering participating in research must:

- Prioritise their duty of care to the service user above the needs of a research project
- Make themselves aware of this policy and related procedures
- Raise issues of concern with the R&D Director or Manager

4.12. Document Author(s)

The document author(s) are responsible for this document being developed, consulted on, authorised, ratified, and implemented and for ensuring that it has been put onto the relevant websites.

5. R&D Policy

5.1. Scope

The policy is concerned with all R&D activities that involve:

- Service users of the NHS. This includes all potential research participants recruited by virtue of the service user's past or present treatment by the NHS. It includes NHS service users treated under contracts with private and third sector institutions.
- Individuals identified as potential research participants because of their status as relatives or carers of service users of the NHS, as defined above.
- Access to data, organs or other bodily material of past and present NHS service users.
- The use of, or potential access to, NHS premises or facilities.
- NHS staff recruited as research participants by virtue of their professional role.

It may be difficult to differentiate between some service development, service evaluation and research projects. Projects which are **intended to be presented as research** must be compliant with this policy. In case of uncertainty, projects should be referred to the Trust R&D Office for clarification.

5.2. Principles

5.2.1. Building research capacity & reputation

- The Trust, through the R&D office, senior management and research staff, will actively promote and support staff, service users and carers who wish to develop their research skills.
- **Service user and carer** involvement in R&D should be promoted and supported at all stages of the research process. Involvement should include:
    - membership of and input to all Trust R&D groups
    - participation in review of all projects presented to the Trust's R&D Approvals panel
    - membership of research teams applying for grant funding and conducting research projects
    - participation in research training activities
    - Researchers should involve service users and/or carers in the design, process, the conduct of and dissemination of research. Guidance on this is available from Involve[4] or from the R&D Office
    - The results of research should be fed back to participants, and this should be included as part of any project's dissemination strategy
- NHS R&D funding and any investment by the Trust for this purpose should be used strategically to build capacity in key areas, identified and agreed by the Trust Research Strategy group.

5.2.2. Delivering research that improves health & well-being and services

- The R&D office, senior management and HR will support & enable individuals in the Trust to carry out research relating to clinical and managerial practice that can lead to improvements in health, quality of services and productivity.
- Staff, service users and carers will be encouraged and supported to participate in NIHR Portfolio Studies as lead investigators, recruiting sites or participants as appropriate. Participation in these studies, which are recognised to be high quality studies relevant to the needs of the NHS, can deliver increased research capacity for the Trust in addition to the benefits of the research.
- Own account studies – researchers proposing such studies will be encouraged to consider relevance to the Trust's identified strategic

[4] See http://www.invo.org.uk/ for details

research goals, the potential to collaborate with academic partners and to apply for external funding. Own account research should relate to a key service need or aim to develop capacity for later participation in NIHR Portfolio studies.

- Students undertaking research studies as part of their qualification/professional training should consider the relevance of the research to the Trust. Sponsorship of such projects will usually be the responsibility of the University.

5.2.3. Effective research management & governance

- All research falling under the scope of this policy must :
    - Have adequate arrangements and resources to meet the standards set out in the Research Governance Framework, and DH guidance for meeting Patient Care Costs and Excess Treatment Costs[5]. (See Associated documents: SOP2 Guidance on Research Finance)
    - Have explicit written R&D approval prior to commencing. To obtain R&D approval the research must be reviewed in accordance with the R&D approval procedure (see associated documents: R&D notification and approval procedure SOP1)
- All research will require financial review and approval prior to R&D approval
- Sponsorship:
    - The Trust will only act as a sponsor for a research study where there is no other potential sponsor and in line with its Research Capacity statement.
    - The process to gain agreement to act as the sponsoring organisation is described in 'BDCT Guidance for Researchers' (http://172.17.8.92/support/research-and-development/GuidanceforResearchers.php)
    - Researchers proposing to undertake projects that are externally funded or commercially sponsored should involve the Finance Department and R&D staff in negotiations with Funders at the earliest possible opportunity.
    - All commercially sponsored research involving Trust service users in clinical trials must comply with the NHS/ABPI model Clinical Trial Agreement, the International Committee on Harmonisation Good

[5] Department of Health, Guidance on funding excess treatment costs related to non-commercial research studies and applying for a subvention (2009)

Department of Health, responsibilities for Responsibilities for meeting Patient Care Costs associated with Research and Development in the (1997)

Clinical Practice Guidelines and the EU Directive 2001/20/EC. A copy of the model Clinical Trial Agreement can be obtained from the R&D Office.

- All research in the Trust should be conducted in accordance with the most recent national regulations and guidance. These include, for example:
    - Research Governance Framework for Health and Social Care, (2005)
    - Medicines for Human Use Regulations (Clinical Trials) (2005)
    - International Committee on Harmonisation Good Clinical Practice. (1996)
    - Mental Capacity Act (2005)
    - NIHR Research Support Services framework (May 2011)
- The Trust will fully support the WYCLRN in the implementation of the National systems for project approval (NIHR CSP) and monitoring. In addition, support will be offered to legitimate bodies' local monitoring arrangements as appropriate, such as:
    - West Yorkshire Comprehensive Local Research Network
    - Mental Health Research Network
    - Primary Care Research network
    - Medicines & Healthcare Products Regulatory Agency
    - Commercial organisation
- The Trust will ensure that information held about staff or service users is treated in accordance with:
    - The Data Protection Act (1998)
    - NHS Records Code of Practice
    - Protection and use of Patient Information HSC 2000/009
    - Data Protection Act 1998 Guidance LASSL(2000)2
    - Section 60 of the Health and Social Care Act 2001
    - A Manual for Caldicott Guardians
    - The requirements of the Information Governance Toolkit in relation to Trust records including medical records
- The Trust will review and respond to National Guidance for R&D activity, ensuring 'best fit' with local arrangements as necessary. Such guidance would include, for example:
    - Guidance on the issue of Honorary Research Contracts as described in National Institute for Health Research, Research in the NHS - HR Good Practice Resource Pack
    - Department of Health, HSC 1998/106: Policy framework for the management of Intellectual Property within the NHS arising from research & development

    - NIHR Research support Services framework and standard operative procedures
- The Trust will ensure compliance with all required regulation by supporting associated reporting and inspection requirements. Such reporting will include:
    - Care Quality Commission
    - Quality Accounts
    - Medicines & Healthcare Products Regulatory Agency
    - Department of Health
- Procedures and guidance outlining the management and governance of research in the Trust, including the procedure to gain R&D approval, R&D Finance guidance, sponsorship, exploitation of Intellectual Property, and Adverse Incident Reporting are described in the associated documents to this policy (p.21).

5.2.4. Evidence based practice

- R&D activities should support and contribute to evidence based practice.
- Training in critical appraisal skills and access to up-to-date evidence should be available to staff, service users and carers as appropriate.

5.2.5. Intellectual Property

- Intellectual Property (IP) is governed by the Trust's IP Policy, developed jointly by the West Yorkshire Mental Health Research Network. This provides guidelines for the ownership and copyright of published work or research carried out by employees of the Trust. It is designed to:
    - Encourage innovation by staff with regard to research and publication.
    - Maximise the sharing of good practice.
    - Ensure the receipt of income and ownership rights equivalent to the proportion of time and money invested by the Trust.
- The IP Policy is currently being updated to reflect changes since the Trust discontinued its membership of the Consortium.
- The R&D Department will facilitate discussions between researchers who believe their project has related IP issues and the Trust lead for IP to achieve an equitable outcome for all parties.

6. Document Development

The process of development, consultation, approval and ratification of this policy is set out in the Document Summary Sheet.

This policy has been developed to ensure Bradford District Care Trust and partners can participate in R&D that is compliant with national guidance and legislation.

The policy will be reviewed in three years unless national guidance or legislation requires an earlier review. It will be reviewed by consultation with stakeholders along with the results of any monitoring of the compliance and effectiveness of this policy.

7. Equality & Diversity

All R&D activities, Policies and Procedures and the R&D strategy must be compliant with the requirements of the Trust's Equality and Diversity Policy. It is recognised that research can play an integral role in delivering and monitoring the goals of Equality and Diversity and human rights, helping the Trust to meet its legislative duties and ensuring equitable outcomes for all of its staff and service users.

8. Equality Analysis

For a detailed account of the equality analysis screening please refer to Appendix A.

9. Training Needs Analysis.

The R&D department will provide support to individuals as and when required. This will be using a variety of means including:

- Procedural documents
- Guidance available on the intranet and internet web sites
- Access to training e.g.
    - Good Clinical Practice Training
    - Introduction to health and social research courses
    - Circulation of research courses available via the Comprehensive Local Research Network

The Trust is committed to high quality targeted training and effective communication to support this policy. The Trust recognizes that training capacity can fluctuate and will depend on resources available. As such based on an assessment of capacity and risk, the training needs analysis will identify the high priority groups for training.

Issues relating to capacity to meet training needs for the high priority groups will be escalated by the policy lead to the relevant Director for action to mitigate the risk and inclusion on the appropriate risk register.

For a detailed account of training numbers, costs and action plan please refer to Appendix B

10. Consultation, Approval and Ratification Process

This document has been circulated to the Research Strategy group and stake holders for review and comments, before presentation to the Professionals Council for approval.

The document will be ratified by the Service Governance Committee on behalf of the Trust Board.

The table below lists the stakeholders who have been consulted in the preparation of this policy and the individuals or committees responsible for approval and ratification.

Stakeholder	**Level of involvement**
Research Manager R&D Director R&D Strategy Group	Development
R&D Strategy Group Research Governance Lead, BIHR Comprehensive Local Research Network Bradford Institute for Health Research Service users and carer research group- XPLORE Human Resources Dept Equality and Diversity team & networks Finance Dept Heads of Service	Consultation
Professional Council	Approval
Service Governance Committee on behalf of Bradford District Care Trust Board	Ratification

11. Review of the Procedural Document

This document will be reviewed in the first year of implementation by the Research Strategy Group, the R&D team and key stakeholders, then every 3 years or when deemed necessary as a result of statutory or operational change in line with Trust policy.

12. Dissemination and Implementation of the policy

All researchers, clinicians and service leads will be briefed on the policy and will be responsible for ensuring all employees in their team are aware of their role and responsibilities laid out within this policy when conducting research. A circular will be sent out to all staff informing them of how to access this policy and other relevant research documents and procedures. This document will be held in the R&D office and in the library services across the Trust. It will be available on the intranet and internet once ratified.

13. Monitoring Compliance and effectiveness of the Policy

13.1. Process for Monitoring Compliance

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 RSS	Evidence of appropriate documents within site files and master files e.g. All projects are registered and approved by the Trust Ethics and trust approval letters	e.g. Audit and monitoring of research file records	As outlined by NIHR RSS procedures and assessment plan of project:	BDCT and BIHR research governance managers
R&D Dept and Research governance office are compliant to NIHR standards and procedures	Inspection and monitoring By NIHR and CLRN	Audit of governance records	As outlined by the NIHR	NIHR identified: Involvement Research manager BDCT

13.2. Framework for monitoring R&D Office activities in compliance to the R&D policy

Policy Lead	R&D Director
Topic	Monitoring the R&D Policy to report and review R&D activities
Data Collection method	Various e.g. routine activity reporting, service governance report and annual report minutes of meetings within the R&D structure. There is an expectation, as a minimum, there will be a financial year end report of finance, activity and progress
Frequency of Activity	Various according to the individual work stream plans or meeting schedule. There is an expectation that all work plans and terms of reference for meetings will detail the frequency of their reporting. Service governance committee will receive a 6 monthly review report. The Board will be provided with an annual report using the Department of Health Annual Report as a framework
Review Body	Service Governance Committee

13.3. Process for Monitoring Effectiveness

R&D structures will be used to report the effectiveness of R&D to the Trusts' Clinical Governance Structures.

13.4. Standards/Key Performance Indicators

The measures and targets that will assist the Trusts to assess and demonstrate its performance are set out within the following:

- Research Governance Framework for Health and Social Care
- NHS Litigation Authority Risk Management Standards for Mental Health and Learning Disabilities Trusts
- NIHR Research Support Services
- Quality accounts
- BDCT Research Strategy goals

14. References

Department of Health, (2010) The NHS Constitution for England (2009 edition) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613

Department of Health (2010) Equity and excellence: Liberating the NHS

Department of Health, *Best Research for Best Health* (2009)

http://www.dh.gov.uk/en/Researchanddevelopment/Researchanddevelopmentstrategy/DH_4127109

Department of Health, Guidance on funding excess treatment costs related to non-commercial research studies and applying for a subvention (2009)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097628

Department of Health, HSC 1998/106: Policy framework for the management of Intellectual Property within the NHS arising from research & development http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004971

Department of Health, responsibilities for Responsibilities for meeting Patient Care Costs associated with Research and Development in the (1997)

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthserviceguidelines/DH_4018353?IdcService=GET_FILE&dID=14533&Rendition=Web

EU Directive 2001/20/EC

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF

HMSO, Data protection Act (1998)

http://www.legislation.gov.uk/ukpga/1998/29/contents

http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Recordsmanagement/DH_4000489

International Committee on Harmonisation Good Clinical Practice Guidelines (1996), http://www.ich.org/LOB/media/MEDIA482.pdf

Mental Capacity Act (2005)[6]

http://www.opsi.gov.uk/Acts/acts2005/pdf/ukpga_20050009_en.pdf

Medicines for Human Use Regulations (2005)

http://www.gov.im/lib/docs/dhss/health/sd905.pdf

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

http://www.nihr.ac.uk/files/pdfs/Summary%20for%20Higher%20Education%20Institutions%20and%20the%20NHS.pdf

National Institute for Health Research In NHS – Research Support Services Framework (May 2011)
http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx

Research Governance Framework for Health and Social Care (2nd Edition, 2005)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

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[6] [1] It should be noted that the Mental Capacity Act refers to people over the age of 16 years.

15. List of Associated Documents

15.1. R&D Notification and Approval Procedure :SOP1

15.2. Research Passport Procedure –

- guidance available on the intranet web site and NHIR link:

http://wwwnihr.ac.uk/systems/pages/systems_research_passports.aspx

15.3. Research Project Monitoring and Audit

Guidance available from R&D office. NIHR SOP :PO8
Access link:
http://www.nihr.ac.uk/files/nihr%20rss%20documents/annex4/nihr%20framework-annex4-p08-oversee%20study-may11.doc

15.4. Recording of Adverse Events

- guidance available from R&D office and intranet site

15.5. Recording of research in service users records keeping and site file management

- guidance available from R&D office and intranet site

15.6. Trust Data Protection Policies: see intranet

15.7. Guidance on Research Finance

- see Sop 2 attached to this document – available on intranet site

15.8. Model Clinical Trial Agreement -

Clinical Trial Agreement For Pharmaceutical Industry Sponsored Research in NHS Trusts. Access link:

http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/A-Z/DH_4002073#_1

15.9. BDCT Capacity and Capability Statement

- available from R&D office and intranet site

Appendix A

Equality Impact Assessment Screening for Relevance

Name of Policy: Angela Ross Manager / Lead: Research Manager	0 = Not applicable	2 = Some evidence of Equality or differential adverse impact
Service: Research and Development Date: June 2011	1 = No current evidence of equality or differential adverse impact	3 = Substantial evidence of Equality or differential adverse impact

Does this activity or policy have the potential to remove or minimise disadvantage, tackle prejudice, and promote understanding	Age	Disability	Gender Reassignment	Race	Religion or Belief	Sex	Sexual Orientation	Pregnancy and maternity
	1	1	1	1	1	1	1	1

Positive Action Required

Continue to monitor on 6 monthly basis

Does this activity or policy have the potential to advance participation of minority groups in which the level of participation is disproportionately low	Age	Disability	Gender Reassign ment	Race	Religion or Belief	Sex	Sexual Orientation	Pregnancy and maternity
	1	1	1	1	1	1	1	1
Positive Action Required Continue to monitor 6 monthly to ensure inclusion of minority groups								
Does this activity or policy foster good **relations** between persons who share a protected characteristic and those who do not	Age	Disability	Gender Reassign ment	Race	Religion or Belief	Sex	Sexual Orientation	Pregnancy and maternity
	1	1	1	1	1	1	1	1
Total Score	3	3	3	3	3	3	3	3
Positive Action Required Continue to monitor 6 monthly to ensure good relationships with all potential stakeholders								

Equality Impact Assessment Action Plan

Service: Research and Development Name of Strategy Screened: Research and Development	Date completed: June 2011		Action Plan Review Date:	
Equality group(s): ☐ Age ☐ Disability ☐ Gender Re-assignment ☐ Pregnancy & Maternity ☐ Religion or Belief ☐ Sex ☐ Sexual Orientation ☐ Race	Accountable Lead: R&D Director Contact details for person completing this plan: Angela Ross			
Prioritised Action	Outcomes	Timescale	Responsibility	RAG
Involvement and consultation: Information on How to participate in research available on website	To ensure continued engagement of stakeholders Promote service user and carer involvement in all stages of research process	On-going	Research manager and RSG Knowledge information manager	Green
To ensure findings and publications from research are fed back to service users and carers .via monitoring process and communication strategy	Openness and feedback of research	ongoing	Research manager	amber

Equality Impact Assessment Initial Screening Form

Area	Response
Service Area	Research and Development
Function or Policy	Research and development Policy
Manager / Author	R&D Director and R&D manager
Directorate	Medical
Date	June 2011
Review date	June 2012
Purpose of Policy	to deliver research that is high quality, inclusive, ensures fair and equal participation, locally relevant, and nationally and internationally significant.
Associated frameworks e.g. national targets NSF's	Research Governance Framework for Health and Social Care (2nd Edition, 2005) National Institute for Health Research In NHS – Research Support Services Framework (May 2011)
Who does it affect	Staff ,Service users and carers who are participating in research activity
Consultation process Start Date: End Date:	 Jan 2011 June 24th 2011
Clearly state who has been involved and where there is service user, carer and community sector involvement	Consultation as described in development part of this document including the following groups X-plore service user and carer research group Research Strategy Group (includes Service user representative) Equality and diversity networks and community groups

For completion of the following table, please see the screening guidance notes

Equality Group	Positive Impact	Negative Impact	Rational for response
Age	X		All research undertaken will be to promote excellent healthcare and of benefit to service user and care . All potential participants will be encouraged to participate according to protocol
Disability	x		Contact R&D on 1 to 1 basis as appropriate
Gender Re-Assignment	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Pregnancy & Maternity	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care . All potential participants will be encouraged to participate according to protocol
Race	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Religion or Belief	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care . All potential participants will be encouraged to participate according to protocol.
Sex	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol
Sexual Orientation	x		All research undertaken will be to promote excellent healthcare and of benefit to service user and care. All potential participants will be encouraged to participate according to protocol

Equality Impact Assessment Screening Sign Off		Yes
Are you satisfied that the conclusions of the EqIA Screening are accurate?		Yes
Completed by Manager		
Head of Dept / Senior Manager approved		
Quality Approved by:	Policy Group	
	Equality & Diversity	
EqIA Action Plan completed		Yes
EqIA Report completed		

If you would like to comment on this initial Equality Impact Assessment (EqIA) please contact the Equality & Diversity Team

Telephone: 01274 228298

Email: Equality&Diversity_Team@bdct.nhs.uk

Post: Bradford District Care Trust

Equality & Diversity Department

Appendix B

Training Needs Analysis (TNA)

		Training Course:	Training Course:
	Trust Staff Numbers	Number of staff who should be trained (without resource constraints) within the lifetime of the policy/agreed timescale.	Target number of staff who can & will be trained based on the training resources & capacity available during the lifetime of the policy/agreed period.
Refresher Period			
Staff Group			
Non Executive	8		
Executive Director	6		
Management			
Manager Clinical / Care			
Senior Manager band 7 & 8	90		10
Manager band 5 & 6	95		15
Team Leader band 3 & 4	40		
Manager Non Clinical / Care			
Senior Manager band 7 & 8	62		
Manager band 5 & 6	43		
Team Leader band 3& 4	9		

Consultant / Doctor	67		12
SHO	24		
Specialist Registrar	13		4
Modern Matron inc in management	5		
Inpatient / Nursing Home – Registered	126		
Inpatient / Nursing Home – Non Registered	123		
Inpatient / Nursing Home - AHP	3		
Community – Registered	252		
Community – Non Registered	743		
Community - AHP	279		
Admin & Clerical	332		
Ancillary	234		
TOTALS:	2554		

Guidance Notes

Please note the staff numbers provided are approximate and could change at regular intervals

For detailed action plan in regard of how this will be delivered and monitored please refer to the action plan template (found in the training policy)

Staff Numbers (Trust) are available by category from Training & Development. Contact: Vanessa McPhail 01274 228373 / Vanessa.mcphail@bdct.nhs.uk

Manager Clinical / Care

- Senior Manager band 7 & 8
  Includes Matrons, Ward Managers, Team Manager, Managers responsible for Care / Clinical Services, Assistant Directors, Heads of Service
  Manager band 5 & 6
  Includes Assistant Ward / Unit Managers, Managers responsible for Care / Clinical Services
  Supervisory / Team Leader band 3 & 4

Manager Non Clinical / Care

- Senior Manager band 7 & 8
  Includes Assistant Directors / Service Managers
- Manager band 5 & 6
- Supervisory / Team Leader band 3 & 4

Medical - Consultant

SHO
Specialist Registrars

Nursing / Care (Non team leader / managerial role)

- Inpatient / Nursing Home – Registered
- Inc all registered staff not in a management or team leader capacity
- Inpatient / Nursing Home – Non Registered
- Inc all un registered staff not in a management or team leader capacity e.g. HCA / Nursing Assistant
- Inpatient / Nursing Home – AHP
- Inc all psychological therapy staff, OT, Speech & Language, Physiotherapy etc
- Community – Registered
- Inc all registered staff not in a management or team leader capacity
- Community – Non Registered
- Inc all un registered staff not in a management or team leader capacity e.g. HCA / Nursing Assistant/ CSW / SCSW / Care Assistant etc
- Community - AHP
- Inc all psychological therapy staff, OT, Speech & Language, Physiotherapy etc

Admin & Clerical / Support Services / Ancillary

Includes:

All Clerical, Secretarial and Administration staff working in a non managerial / team leader role, all Finance / Human Resources / Informatics working in a non managerial / team leader role

Ancillary

Includes all staff working within Estates, Hotel Services, Catering & Support Services in a non managerial / team leader role / coordinator / supervisor role

TRAINING ACTION PLAN

Responsible Director: Plan Update:

Name of Training	Delivery Frequency (per month/ year)	Length of sessions	Numbers to be trained per session	Job titles of Trainer's identified to deliver	Staff Groups to attend	Current training & delivery method	Refresher frequency (e.g. 1, 2 or 3 years)	Training attendance records held by:	Action required	Residual Risks and Action (Identify any Gaps in provision / resource implications etc)	Date of Review/ Completion	Risk to Trust
Good clinical practice	As outlined by RDS: Ongoing	1 day	10-20 With area cluster	Local or trust sites as identified by CLRN	All those involved in research	By CLRN o	Every 2 years	R&D office and investigator/ researchers files	On request of starting research ensure all staff involved in research are notified that must undertake training prior to commencement of study	Backfill for staff	Annually	

Responsible Officer to Monitor Training: Research Governance Manager: Research Manager/Coordinator

Costs

Based on the above information, please give an approximate cost to the delivery of training, below;-

Cost of delivering the Target number of staff who can & will be trained based on the training resources & capacity available during the lifetime of the policy/agreed period:-

Cost Of Training days x 7.5 hours @ £18 ph (cost of staff time diverted from paid duties to be trained)	Sub Total	Nil
Cost of Backfill days x 7.5 hours @£10 ph	Sub Total	Nil
Cost of Admin	Sub total	Nil
Additional Costs: materials etc	Sub Total	Nil
	Total	

Cost of delivering the number of staff who should be trained (without resource constraints) within the lifetime of the policy/agreed timescale:-

Cost Of Training days x 7.5 hours @ £18 ph (cost of staff time diverted from paid duties to be trained)	Sub Total	
Cost of Backfill days x 7.5 hours @£10 ph	Sub Total	
Cost of Admin	Sub total	
Additional Costs: materials etc	Sub Total	
	Total	Nil

Appendix C Compliance Checklist

Procedural Document Development Checklist

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?		
	Is it clear whether the document is a guideline, policy, protocol or standard?		
2.	**Rationale**		
	Are reasons for development of the document stated?		
3.	**Development Process**		
	Is the method described in brief?		
	Are people involved in the development identified?		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?		
	Is there evidence of consultation with stakeholders and users?		
	Have the requirements of the following been taken into account where applicable: Mental Health Act Mental Capacity Act Care Programme Approach (CPA)Guidance		
4.	**Content**		
	Is the objective of the document clear?		
	Is the target population clear and unambiguous?		
	Are the intended outcomes described?		
	Are the statements clear and unambiguous?		

5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?		
	Are key references cited?		
	Are the references cited in full?		
	Are supporting documents referenced?		
6.	**Approval**		
	Does the document identify which committee/group will approve it?		
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?		
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?		
	Does the plan include the necessary training/support to ensure compliance?		
	Is the Training Needs Analysis completed		
8.	**Document Control**		
	Does the document identify where it will be held?		
	Have archiving arrangements for superseded documents been addressed?		
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?		
	Is there a plan to review or audit compliance with the document?		
	Does the above plan include the minimum NHSLA monitoring requirements (if applicable)		

10.	**Review Date**		
	Is the review date identified?		
	Is the frequency of review identified? If so is it acceptable?		
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?		

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name		Date	
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name		Date	
Signature			

SOP1 R&D Approvals procedure

R&DApprovalProced
ureFinalDraft7Jun11.

SOP2 R&D at BDCT: Guidance on Research Finance

R&DResearchGuidan
ceFinanceFinalDraft7.

RSS 1 R&D Capability statement

NIHRRSSFramework
Annex3-RDOCS_v1c-