Recording of Research Information in BDCFT Patient Medical Records

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Amendment Summary:	**General:** Changes to the trust name: BDCFT Updated all the regulatory documents with correct dates. Changed West Yorkshire CLRN to Yorkshire and Humber CRN. **Section 4.2**: A temporary change to reflect the S1 problems, more updates to be released on a new version. **Section 4.6**: added roles of chief investigator/ lead clinical support officer and research nurse within the list of support staff. **Section 5.2**:SystmOne procedure updated **Section 6.1**: Consultation process updated with correct stakeholder names. Updated references Updated definitions

CONTENTS

1. Introduction

This standard operative procedure (SOP) has been produced in accordance with Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, The UK policy framework for health and social care research (2018) and ICH GCP Guidelines. This SOP will outline the procedure for recording research information in patient medical notes/records and is to be used in conjunction with the Records Management Policy (October 2017).

1.1 Background

It is important that Bradford District Care Foundation Trust (BDCFT) has a system in place to identify a research participant (patient / carer) in their electronic medical records in order to enable treating clinicians and therapists to be aware of the patient's participation in a research project and to assist the process of audit, monitoring and investigations into research misconduct.

This is especially important for those participating in Randomised Controlled Trials involving Investigational Medicinal Products[1].

Currently the BDCFT has one system for recording patient information through SystmOne, which also holds the mental health and learning disability records.

1.2 Purpose

The purpose of this procedure is to support high quality research and to ensure that research in the Trust is managed in accordance with the requirements of the Department of Health.

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

1.3 Type of Procedural Document

This is a procedural document describing the "how"; and gives guidance about how Investigator/ Lead Clinical Studies Officer/ Research Nurse s, research support and Trust staff are to record research information in patient records. It provides a step-by-step guide, which someone not familiar with the work 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.

2. Duties

2.1 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.

1 As defined By ICH GCP: eg. Drugs and comparators including placebo; complementary medicines/nutritional supplements claiming medical benefits; maggots, leeches etc

2.2 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 to ensure that patient information comply with statutory and Trust's rules on records management.

2.3 Research & Development Director

It is the responsibility of the R&D Director, supported by the Head of the R&D & the Senior Clinical Studies Officer to ensure all relevant staffs are aware of the Procedure, and to facilitate compliance with its contents.

2.4 Head of research / Senior Clinical Studies Officer

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

3. Records Manager

3.1 Researchers, Clinical Studies Officers and Research Support Staff

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

- Chief Investigator/ Lead Clinical Studies Officer/ Research Nurses
- Principal Investigator/ Lead Clinical Studies Officer/ Research Nurses
- Other Investigator/ Lead Clinical Studies Officer/ Research Nurses
- 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.

It is anticipated that this group will be the most likely to be noting involvement in research, and that their knowledge of this procedure should be current and evidenced by the completion of the training log for this SOP held within the BDCFT R&D Office.

3.2 Managers

It is the responsibility of all line managers to ensure that staffs participating in research within their areas of responsibility are aware of this procedure and that they follow the procedure.

3.3 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 if immediate changes to the procedure are required or note for consideration at the next review of the procedure.

3.4 Procedural Document Authors

It is the responsibility of procedural document authors to action the 'Procedure for the Development and Management of Procedural Documents' and ensure all procedural documents for which they have responsibility are developed, reviewed, authorised, ratified and implemented in accordance with the requirements of the procedure, and that they have been put onto the R&D Department web-site.

4. Procedure

4.1 General overview:

Recording in case notes: **general**

Details of any research study should be placed inside the journal notes of any participant following the completion of the consent process applicable to that study[2] using the quick note facility

For in-depth clinical trials or If the participant is not a BDCFT patient a new record can be should be created within the R&D module

Procedural Overview

[Note in the following, the 'Investigator/ Lead Clinical Studies Officer/ Research Nurse 'refers to the delegated individuals as noted on the study delegation log]

The Investigator/ Lead Clinical Studies Officer/ Research Nurse identifies a patient who is eligible to be entered on to a research study.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse receives informed consent from the participant/carer in accordance with the approved study protocol.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse files a copy of the signed consent form, and associated participant information sheet in the participant's medical notes.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse documents the date of consent and any other research information for the visit in the participant's medical notes.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse completes the study recruitment log in the Study Site File.

2 See individual study protocols for details.

NOTE: if a potential participant is approached, but declines entry to the study, then the date of approach, and reasons for non-participation (if given) should be entered in the study recruitment log, and in the clinical notes, as applicable.

Once consented, at each visit:

The Investigator/ Lead Clinical Studies Officer/ Research Nurse confirms the willingness of the participant to continue in the study. The Investigator/ Lead Clinical Studies Officer/ Research Nurse documents the continued willingness to participate, and all other relevant research information, as required by the protocol and Case Report Form (CRF) in the participant's medical notes until study completion or early withdrawal.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse documents the date of completion/withdrawal in the participant's medical notes, with reason for withdrawal if available.

If the study involves interventions, drugs or devices:

The Investigator/ Lead Clinical Studies Officer/ Research Nurse inserts an Alert within the records indicating:

- date of consent,
- study drugs taken/devices used,
- link to the main research information pages so appropriate contacts can be quickly found
- Inform the GPs of the participants in a CTIMP and advise them to update their SystmOne record, where alerts will be visible to others.
- Create a drug trial participation card, the card must include the contact details of the Central Team, drug dosage and details of the study. A blank template of the card could be found here: Z:\R&D\Research projects\patient card.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse files the Patient Information Sheet, signed Consent Form, drug schedule and any other study specific information is placed in the research section of the record.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse updates the research section at every visit, including comments on the visit (drug administration, concomitant medications, adverse events, advice given etc) until completion of the study.

If a visit log is used for the study, the Investigator/ Lead Clinical Studies Officer/ Research Nurse completes the visit log every time contact is made with the research participant until their completion of the study. The visit log may be filed in the study Site File.

In the event of death, the medical records are archived and dealt with according to Trust policy.

4.2 Recording on SystmOne

All contact with registered patients should be completed on SystmOne this can easily be done using the quick note facility.

The Investigator/ Lead Clinical Studies Officer/ Research Nurse will follow the same procedure for record keeping as above, except documents of informed consent and information etc will be uploaded onto the document repository.

Information concerning patients assessments will be placed in the journal notes in SystmOne (if they are part of the patient's treatment or care) as well in the research folder created for the patient.

A specific guide to recording in SystmOne can be found in appendix 1 and at

Z:\R&D\How to guides\adding patients to sys1 v2 Dec 18.docx

5. Consultation, Approval and Ratification Process

5.1 Consultation Process

Stakeholder	Level of involvement
Stakeholder	**Level of involvement**
Information governance Heads of Service	Consultation
Research & Development Director Head of research Senior Clinical Studies Officer	Development
Research Forum Research Executive Group	Approval and ratification

6. Review of the Procedural Document

This document will be reviewed every 2 years or when deemed necessary as a result of statutory or operational change in line with Trust policy

7. Dissemination of the Procedural Document

This document will be held in the R&D office. It will also 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.

8. Training and support for the implementation of the Procedure

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

- Procedural documents
- Guidance available on the intranet and internet web sites
- Access to training e.g.

- Good Clinical Practice
- Introduction to Health and Social care research courses
- Circulation of research courses available via the ‘Comprehensive Local Research Network’

9. 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 NIHR RSS	Audit		As outlined by procedures and assessment of project – See RSS	BDCFT Head of Research / CRNResearch Monitor

10. References

Department of Health, *Best Research for Best Health (2018)*
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/568772/dh_4127152_v2.pdf

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

EU Directive 2001/20/EC
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF

International Committee on Harmonisation Good Clinical Practice Guidelines (1996),
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Mental Capacity Act (2005)
http://www.opsi.gov.uk/Acts/acts2005/pdf/ukpga_20050009_en.pdf

Medicines for Human Use Regulations (2017)
http://www.legislation.gov.uk/uksi/2017/715/made

National Institute for Health Research, Co-ordinated System for Obtaining NHS Permissions (NIHR, CSP), Operating Guidelines (2011)
http https://www.nihr.ac.uk/02-documents/policy-and-standards/Faster-easier-clinical-research/Research-Support-Service/RSS%20framework%20docs/Overview%20of%20NIHR%20RSS%20Framework.pdf

National Institute for Health Research, *Research in the NHS - HR Good Practice Resource Pack (2012)*
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

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/

Associated Documentation

i. Trust R&D policy

Available on the R&D websites

Research Passport Procedure:
Guidance available on the intranet web site:
http://connect.bdct.local/ourorganisation/ourservices/randd/Documents/RD%20SOP05%20Research%20Passport%20Procedure%20FINAL%202018.pdf

NIHR link: 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 Project Monitoring and Audit
Guidance available from R&D office, SOP 7 Access link:

NIHR link:

i. Recording of Adverse Events
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

Trust Data Protection Policies: see intranet

Guidance on Research Finance (SOP2)

ii. BDCFT Capacity and Capability Statement
Available from R&D office and intranet site

Records Management Policy: Procedural and Advice Guide
Available on intranet

11. Definitions

Glossary of Definitions and terms used in Research

APBI	Association of the British Pharmaceutical Industry
Chief Investigator (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/ Lead Clinical Studies Officer/ Research Nurse. 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 aims to measure care against criteria and assess the impact of the implementation of change.
Comprehensive Research Network (CRN)	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 Trusts work with the Yorkshire and Humber CRN.
Co-ordinated System for obtaining NHS Permissions (CSP)	The method by which NIHR Portfolio projects are processed for Trust Research Governance Approval. The process is mediated by the Comprehensive Research Networks (CRNs)
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
ICH-GCP	International Committee on Harmonisation Good Clinical Practice Guideline.
Intellectual Property (IP)	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.)*
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 (REC), 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 Yorkshire and Humber Comprehensive 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.
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 BDCFT. http://www.nyren.co.uk

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.
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' (UK Policy Framework For Health And Social Care Research (2018). 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 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 UK Policy Framework For Health And Social Care Research (2018); • 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; • An individual who is authorised to do so has given written permission on behalf of the NHS organisation.

Research Ethics Committee (REC)	Performs independent review of all NHS based research to ensure compliance with ethical standards.
UK Policy Framework For Health And Social Care Research (2018)	UK Policy Framework For Health And Social Care Research (2018), 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 offices 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.

Appendix:

Drug trial participation card template: