

Memorandum of Understanding for Collaborative Research



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

1. Denotes the principles of research conduct and research governance between Airedale NHS Trust and Bradford District Care



You and Your Care

This document has been approved and ratified. Circumstances may arise where staff become aware that changes in national policy or statutory or other guidance (e.g. National Institute for Health and Care Excellence (NICE) guidance and Employment Law) may affect the contents of this document. It is the duty of the staff member concerned to ensure that the document author is made aware of such changes so that the matter can be dealt with through the document review process.

NOTE: All approved and ratified policies and procedures remain extant until notification of an amended policy or procedure via Trust-wide notification, e.g. through the weekly e-Update publication or global e-mail and posting on the Intranet (Connect).

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Contents

1	Definitions.....	6
2	Background	7
3	Scope	7
4	Observance of the Memorandum	8
5	Guidance	8
6	Principles	8
7	Chief or Principal Investigator.....	9
8	Approval	9
9	Ethics.....	10
10	Research Governance and NHS Permission.....	10
11	Commercial Research	11
12	Consent and Confidentiality.....	11
13	Data.....	11
14	Data Exchange	12
15	Scientific Misconduct	12
16	Intellectual Property	12
17	Equality.....	12
18	Accruals and Performance metrics (Portfolio studies)	13
19	Adverse Events.....	13
20	Notices:.....	13

Memorandum of Understanding for Collaborative Research

AIREDALE NHS FOUNDATION TRUST

And

BRADFORD DISTRICT CARE TRUST

This agreement was made on 10/02/2015

Parties:

**1) Airedale NHS Foundation Trust
Skipton Road, Steeton
Keighley, BD20 6TD**

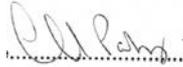
**2) Bradford District Care Trust
New Mill, Victoria Road
Saltaire, BD18 3LD**

Signed on behalf of the participating Trusts:

Airedale NHS Foundation Trust

Name: Carole Paley

Position Head of Research and Innovation

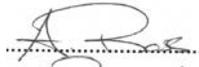
Signature: 

Date: 03/03/2015

Bradford District Care Trust

Name: Angela Ross

Position: Head of Research and Development

Signature: 

Date: 10/02/2015

MEMORANDUM OF UNDERSTANDING

FOR COLLABORATIVE RESEARCH

1 DEFINITIONS

1.1. Where collaborative research is being undertaken the partnership will be referred to as the 'Airedale and Bradford Research Partnership'.

1.2. The following words and phrases have the following meanings:

"Trust" means either Airedale NHS Foundation Trust (ANHSfT) or Bradford District Care Trust (BDCT) and "Trusts" refers to both.

"Lead Trust" means the party designated as lead for a particular study and will be the party responsible for providing NHS approval and negotiations between participating organisations. The Lead Trust will be the organisation where the Chief (CI), or Principal Investigator (PI), is based.

"Partner Trust" means the party who is not leading on a study, but is providing support, such as, identifying patients, recruitment or follow up.

"Memorandum of Understanding (MOU)" means this arrangement comprising its clauses and guidelines and appendices attached to it.

"Clinical Trial" means an investigation involving human subjects to be conducted by investigators at either Trust.

"Participant" means a person recruited to participate in a Clinical Trial.

"Confidential Information" means any and all information, data and material of any nature which is Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998) and relates to any participant associated with an NHS Organisation or his or her treatment or medical history, or other information.

"ICH GCP" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive.

"Intellectual Property (IP)" means patents, trademarks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, and all rights or forms of protection of a similar nature whether or not any of them are registered and including applications for registration of any of them.

“Investigational Medicinal Product” means the study drug or control material as defined in a study’s Protocol.

“Clinical Trials of Investigational Medicinal Products (CTIMPS)” refers to a clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004; that is: an investigation in human subjects, other than a non-interventional trial, intended:

- 1.1.1. To discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products,
- 1.1.2. To identify any adverse reactions, or
- 1.1.3. To study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of the products.

<http://www.mhra.gov.uk/home/groups/is-insp/documents/websiteresources/con051910.pdf>

“Investigator” means the person(s) (PI or CI) who will take primary responsibility for the conduct of a collaborative clinical trial within the Trust.

“Protocol” means the description of a Clinical Trial signed by the Investigator that has received a favourable opinion from the relevant research ethics committee.

“Regulatory Authority” includes, but is not limited to, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency and the General Medical Council.

“Sponsor” means any organisation sponsoring any Clinical Trial under the Medicines for Human Use (Clinical Trials) Regulations 2004 or the Research Governance Framework.

“Staff” means all employees or visiting researchers of a party who participate in research. This includes individuals on Honorary Contracts or with letters of access to permit them to conduct research-related activities within either Trust.

- 1.3. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.
- 1.4. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.

2 BACKGROUND

- 2.1. This Memorandum of Understanding (MOU) has been developed in conjunction with Bradford District Care Trust with the intention of thereby providing a framework for the conduct of collaborative research across Airedale NHS Foundation Trust (ANHSfT) and Bradford District Care Trust (BDCT).

3 SCOPE

- 3.1. This MOU sets out the standards of work and conduct required of those engaged, in whatever capacity, in any collaborative research between ANHSfT and BDCT.

- 3.2. This MOU is effective for any research involving human participants, whether as NHS patients or relatives of patients, healthy volunteers, or members of staff. It applies whether the research requires direct contact, or the use of tissue, organ or fluid samples, whether it requires the use of questionnaires or observational information, or access to confidential information.
- 3.3. This MOU applies to both commercial and non-commercial research and whether adopted onto the NIHR portfolio or not. In relation to commercial research, the terms of the relevant Clinical Research Agreement and its Protocol takes precedence in case of any conflict between the terms of the MOU on the one hand and the Agreement/Protocol on the other.
- 3.4. This MOU will be reviewed annually or as otherwise required in accordance with any legislative or regulatory changes.

4 OBSERVANCE OF THE MEMORANDUM

- 4.1. Researchers engaged in collaborative research between ANHSfT and BDCT must familiarise themselves with the provisions of the MOU and ensure that they are observed.
- 4.2. Researchers and members of the Research Team in each Trust must follow the local policies pertaining to research at that Trust whilst carrying out research on the premises or under the auspices of that Trust. When engaged in research as employees of either Trust, but working within another healthcare or educational institution, the research policies of that other institution shall be paramount if there is any conflict between any part of them and the research policies of the researcher's employing Trust.

5 GUIDANCE

- 5.1. Researchers must make themselves familiar with the latest version of the Declaration of Helsinki and all subsequent revisions. They should keep abreast of developments in the Research Governance Framework that sets out roles and responsibilities for different parties involved in research.
- 5.2. Good Clinical Practice guidance for researchers is available from a variety of sources, for example the Medical Research Council, the General Medical Council and the Royal Medical Colleges.

6 PRINCIPLES

- 6.1. Researchers must work within their own competencies, based on knowledge, experience and expertise. There is a statutory obligation on the one who delegates a task to ensure that the one to whom it is delegated has the competence to carry it out and also that it has been carried out properly.
- 6.2. All research must meet ethical standards and ensure that the dignity, rights, safety and well being of participants are given priority at all times.
- 6.3. Researchers must take steps to ensure that their research does not unnecessarily duplicate research previously carried out elsewhere.

- 6.4. Researchers must open their work to critical review through the accepted scientific and professional channels. Every effort must be made to ensure that the results of research are published or disseminated in other ways, subject to the terms of any relevant Clinical Research or Confidentiality Agreement. Details of the data, methods of collection and analysis, and the outcomes must be open to external scrutiny.
- 6.5. Once established, findings must be made available to those participating in the research (including relatives of deceased patients who have consented to the use of organs or tissue in the research) and to all those who could benefit from the work in an understandable format, through publication and/or other appropriate means.

7 CHIEF OR PRINCIPAL INVESTIGATOR

- 7.1. For each research study there should be designated a Chief Investigator who is responsible for the overall conduct of the research. Individual organisations may have specific criteria for a researcher's eligibility to be a Chief Investigator; Researchers must respect these requirements.
- 7.2. In the case of multi-centre studies, the Principal Investigator is the person who is responsible for the research at a research site. If the research is conducted by a team of researchers at a trial research site, the Principal Investigator is the leader responsible for that team. The Principal Investigator may also be the Chief Investigator.
- 7.3. In the case of University studies the Research Supervisor will act as Chief Investigator for research undertaken for academic qualifications and will also undertake the responsibilities of sponsor.
- 7.4. Any research requiring the collaboration of the NHS or social care services in England must have an organisation willing and able to take on the responsibilities of research sponsor as defined in the Research Governance Framework for Health & Social Care and, in the case of clinical trials involving medicines, as defined in the Medicines for Human Use Clinical Trials Regulations 2004. See MHRA link:
<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/FAQs/>

8 APPROVAL

- 8.1. For each collaborative study, one Trust will be designated as the "Lead Trust", according to the conditions set out in section 10.1.
- 8.2. Researchers must seek all necessary approvals before they can start their research. For collaborative research, R&D approval must be sought at whichever Trust is designated as the Lead for that particular study. The partner Trust will accept R&D approval issued by the lead site.
- 8.3. Clinical trials involving medicines are regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004 which implements Directive 2001/20/EC.

Clinical trials which come under the 2004 Regulations must be authorised by the Medicines & Healthcare Products Regulatory Agency (MHRA).

- 8.4. University-based researchers undertaking research which involves collaboration across both Trusts should be aware that access to resources in the NHS will require prior R&D approval from the Lead Trust.

9 ETHICS

- 9.1. All research involving human participants must be assessed by an appropriate Research Ethics Committee (REC). If the study involves patients of the NHS, their relatives, or resources of the NHS, then the study must be submitted to the appropriate REC. [Full details can be found on the HRA website.](#)
- 9.2. Ethics approval generally applies to specific, individual projects rather than to a type of activity or broad programme of research. It will normally be time-limited and must be renewed if the research is to continue after the expiry of the approval.

10 RESEARCH GOVERNANCE AND NHS PERMISSION

- 10.1. Research governance processes will be carried out at either ANHSfT or BDCT, whichever is the Lead Trust. The location of the Chief or Principal Investigator will determine which is the Lead Trust for that study. The location of the CI will take precedence over the location of the PI when determining the lead Trust.
- 10.2. The Lead Trust Research Governance Office will undertake the following for both Trust sites:
 - 10.2.1. The Lead Trust will ensure that liaison is maintained with the Partner Trust, the local study team, and the Local Clinical Research Network (LCRN)
 - 10.2.2. Perform document checks and obtain assurance of both Trusts' approval of the documentation
 - 10.2.3. Coordinate and receive the feasibility and expressions of interest from both sites
 - 10.2.4. Coordinate contracts and agreements
 - 10.2.5. Agree recruitment targets for the collaborative partnership
 - 10.2.6. Issue the joint NHS permission letter once contracts for both sites have signed
- 10.3. Copies of all relevant documentation will be held by both Trusts.
- 10.4. It is the responsibility of each Trust to ensure that the documentation and checks made on each study fulfil the local requirements of that organisation and, if necessary, contact their local Caldicott Guardian.
- 10.5. Any disputes between the two organisations regarding research approvals should be resolved prior to local NHS permission being granted. Disputes that cannot be resolved will necessitate abandonment of the study by one or both Trusts. The final decision will rest with the respective Heads of Research.
- 10.6. Study amendments should be processed by the Lead Trust, in close communication with the Partner Trust.

11 COMMERCIAL RESEARCH

- 11.1. Commercial research may also be undertaken as collaborative projects and in all cases must be covered by individual Clinical Trial Agreements (CTAs) between the sponsor and each Trust.
- 11.2. Each CTA should contain a financial schedule which has been negotiated between the sponsor and each Trust. The terms of the agreement will relate to the input required from each site and will include staffing, resources and interventions. Each site will identify specific costs to their organisation on the costing spreadsheet.

12 CONSENT AND CONFIDENTIALITY

- 12.1. Informed consent should be obtained from those who agree to participate in a research project. This must be based on a knowledge and understanding of the risks, benefits and alternatives of taking part. The Consent obtained should be in accordance with the Trust's Policy on Consent that deals specifically with research, the 2004 Regulations and should also comply with any arrangements in the Protocol approved by the Research Ethics Committee.
- 12.2. Where participants lack capacity to consent the guidance outlined by the [Health Research Authority](#) and local Trust Policy should be adhered to.
- 12.3. Unless agreed otherwise by an appropriate Research Ethics Committee, consent should be explicit and written.
- 12.4. Information obtained from patients in the course of providing healthcare is confidential. Researchers must abide by the Data Protection Act and other statutory provisions and respect the common law duty of confidence.
- 12.5. Research data and samples must be anonymised if they are to be passed to anyone not bound by a duty of confidence (generally anyone not employed by the relevant Trust or holding an honorary contract), unless explicit consent has been given by the patient.

13 DATA

- 13.1. Data must be stored in a secure and durable form for the length of time specified in the Lead Trust's Policy for the storage and retention of records, or the period specified in the relevant REC approved Clinical Research Agreement/Protocol, whichever is the longer.
- 13.2. The source data, and method of analysis must be recorded and be available for scrutiny if necessary by independent auditors.
- 13.3. Care must be taken to ensure that confidential information is protected from unauthorised access. Care must be taken when disposing of computer systems to ensure that all confidential information is removed.
- 13.4. Use of data must be in accordance with the Trusts' Policies relating to Confidentiality and the processing and use of data and the advice of the Trusts' Caldicott Guardians should be sought and followed.

- 13.5. 'Gift' authorship (where people who did not make a significant contribution to the research are included in the authorship of a paper) will be treated as misconduct and be dealt with under the Lead Trust's Disciplinary Procedure.
- 13.6. It is the responsibility of the Lead Trust to conduct monitoring and audit of collaborative studies, in liaison with the Partner Trust. All monitoring will be conducted in accordance with the Research Governance Framework and regulatory bodies.
- 13.7. Researchers must cooperate with any authorised audits of their research, whether undertaken by Trust, a University, an external funder, a sponsor or regulatory authority.
- 13.8. Researchers may be required to provide annual reports or other research progress reports to the Lead Trust, a University, external sponsor or ethics committee.
- 13.9. Progress reports will be sent to the R&D Department in the Lead Trust and these will be disseminated to the Partner Trust.

14 DATA EXCHANGE

- 14.1. Effective research governance cannot work without exchange and sharing of relevant information between funders, sponsors, research providers and healthcare providers. Data held by researchers relating to research participants will be exchanged with other bodies in appropriate circumstances and subject to the terms of any relevant Clinical Research or Confidentiality Agreement and in accordance with the Data Protection Act 1998.

15 SCIENTIFIC MISCONDUCT

- 15.1. Researchers must, as soon as practicable, report examples and suspicions of misconduct to the relevant Head of Research, the Medical Director or in accordance with the Trust's Whistle Blowing Policy.

16 INTELLECTUAL PROPERTY

- 16.1. Researchers must follow the relevant Trust's policies and procedures with regard to Intellectual Property (IP).
- 16.2. Unless otherwise agreed, IP arising from research will be subject to the policies of the Lead Trust.
- 16.3. If IP is likely to arise as a result of collaborative research outputs there should be a Collaborative Agreement in place regarding revenue sharing and acknowledgements. This may also include an 'agreement to agree' i.e., the points for consideration in the event of a research output becoming commercialised.

17 EQUALITY

- 17.1. Research participants should where possible be reflective of the local diverse communities.

- 17.2. Researchers have the responsibility for ensuring effective communication with participants, in the appropriate language and format.
- 17.3. Where possible, researchers of the same gender as the participants should be offered to take account of religious, cultural and/or personal preference.

18 ACCRUALS AND PERFORMANCE METRICS (PORTFOLIO STUDIES)

- 18.1. For non-commercial studies: Prior to the start of any collaborative research it will be agreed, in consultation with the LCRN, how participant accruals are to be attributed to each organisation. For commercial studies the total number of participants recruited to the study across both sites will be attributed to both organisations.
- 18.2. Approval time shall be attributed to both organisations regardless of which organisation was responsible for the governance checks.
- 18.3. Time to first patient, first visit (FPFV) will be the same for both sites, regardless of where the first participant was recruited.
- 18.4. Recruitment to time and target (RTT) should be measured for both sites combined.

19 ADVERSE EVENTS

- 19.1. Any serious adverse events should be processed in the usual way and also reported to the collaborating Trust for information.

20 NOTICES:

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NOTE: A copy of this MOU should be included with the study documentation for all collaborative projects.