

## Research & Development Policy

Issue Date	Review Date	Version
June 2020	June 2025	8

### Purpose

To ensure the safety, well-being and rights of all participants taking part in research projects conducted by the Trust and that the research conducted produces reliable and good quality data.

### Who should read this document?

This policy and associated procedures is targeted at all personnel involved in research activity within the Trust.

### Key Messages

Researchers must ensure the safety, well-being and rights of research participants and staff.  
 Researchers must ensure the production of verifiable good quality data from research projects.  
 Researchers must comply with the relevant National Legislation regarding research and the collection of data, the DoH UK Policy Framework for Health and Social Care Research (2017), the research study protocol, Trust policies and Standard Operating Procedures (SOPs).

### Core accountabilities

<b>Owner</b>	Dr Chris Rollinson, Research Governance Manager
<b>Review</b>	Dr. Gary Minto, Associate Medical Director RD&I Corinna Mossop, RD&I Manager Ben Hyams, RD&I Lead Research Nurse Elinor Pegg, RD&I Operations Manager Dr Helen Neilens Research Advisor and Trust Innovation Lead
<b>Ratification</b>	Dr Phil Hughes, Medical Director Dr Paul McArdle, Deputy Medical Director
<b>Dissemination (Raising Awareness)</b>	Dr Chris Rollinson, Research Governance Manager
<b>Compliance</b>	RD&I research governance team

### Links to other policies and procedures

Trust Management of Intellectual Property Policy  
 Trust Information Governance Policy  
 Trust Data Protection SOP Documents  
 Trust Confidential Information  
 Trust Information Security Policy

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Trust Research SOPs

<https://www.plymouthhospitals.nhs.uk/research-sops>

### Version History

2	September 2006	Incorporates the additional requirements of the Medicines for Human Use (Clinical Trials) Amended Regulations 2006 which came into force on the 29 <sup>th</sup> of August 2006  Data protection checks are now only required for UHP sponsored studies  Further clarifies the process for researchers applying to UHP for their studies to be sponsored by the Trust.
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3	March 2008	Outlines revised R&D structure Clarifies current practice with regard to governance risk assessment Details change in procedure for obtaining honorary contracts New procedure following the disbanding of the National Research Register R&D will not audit commercial studies; external reports are to be requested by R&D
4	March 2010	Policy completely re-written
5	April 2011	Revised R&D Committee Terms of reference & structure. New R&D Director.
6	June 2012	Updated and Terms of Reference for The Genetic Modification Safety Committee (GMSC) added. Clarification of the role of Clinical Research Nurse / Midwife as a member of the clinical care team.
7	January 2016	Reviewed and updated
7.1	August 2016	Minor amendment CLRN replaced with CRN
8	October 2019	Complete revision

*The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.*

**An electronic version of this document is available on Trust Documents.  
Larger text, Braille and Audio versions can be made available upon request.**

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## 1 Introduction

- 1.1 This policy aims to promote good research practice in the Trust, enhance the ethical and scientific quality of research, to safeguard the rights and interests of patients, standardise the management and approval of all research activity carried out within the Trust, maximise research productivity, minimise all avoidable negative impact on clinical services and ensure that all research activity is in accordance with the UK Policy Framework for Health and Social Care (2017) and other legislation relevant to clinical research.
- 1.2 The Policy also ensures that research is inclusive of all protected characteristics e.g. disability, race, gender, age, religion and belief, pregnancy and maternity, sexual orientation and marriage and civil partnership.
- 1.3 The Trust wishes to encourage and support employees to conduct research which is consistent with the Trust Research Strategy. The Trust is committed to supporting staff to deliver research to time and target as required by the National Institute for Health Research (NIHR).

## 2 Purpose and Scope

- 2.1 The Trust and individual researchers have a statutory responsibility to ensure that all research involving the Trust, or Trust patients, is conducted in accordance with the UK Policy for Health and Social Care Research (2017). Trust compliance with this requirement is monitored by the Care Quality Commission.  
<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
- 2.2 This policy is applicable to all research involving Trust premises or staff, NHS patients to whom the Trust has a duty of care, patient material, or patient data, conducted by Trust employees, independent contractors and other non-employees. The policy is of particular relevance to clinical research activity, but applies equally to all research.

## 3 Definitions

- 3.1 **Definition of research:** the Health Research Authority defines research as ‘the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods’<sup>1</sup>. Broadly speaking, a piece of research has all of the following characteristics:
  - It follows an established method of data collection and analysis;

- It is designed to elicit information that will be applicable to, and of interest, to people outside the immediate research context/organisation;
- It will be publicly disseminated (e.g. *via* conference presentation or publication).

**3.2 Many different types of research are conducted in the NHS.** Any project or investigation that (a) meets this definition and (b) involves any of the people, material or facilities listed below is regarded as a research study, and is subject to the provisions of this policy document:

- (a) NHS patients (i.e. people recruited to the study by virtue of their past or present treatment or care by this Trust or any other NHS organisation);
- (b) Tissue, blood, foetal, *In vitro* fertilisation (IVF) material or any other material removed from NHS patients both past and present and the recently dead in NHS premises;
- (c) Data collected from past or present NHS patients, including all information stored in the patient's health records;
- (d) The use of NHS premises or facilities;
- (e) NHS staff.

**3.3 Common types of NHS research include:**

- (a) Research on tissue samples and other laboratory-based research;
- (b) Imaging and technology research involving, for example, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) or ultrasound technology;
- (c) Clinical trials of interventions, including drugs, surgery, radiotherapy, behaviour change, and screening;
- (d) 'Health services' research examining service delivery, health economics and social science studies;
- (e) Clinical research, meaning research that directly involves inpatients or outpatients and often affects patient care;
- (f) Population-based or epidemiological research, such as retrospective research using data from medical records or databases;
- (g) Behavioural and health psychology research;
- (h) Secondary research, meaning secondary analysis of existing research data or literature, including reviews and meta-analyses.

**3.4 Clinical Audit, Local Service Development and Evaluation, and Clinical Case Studies.**

There are a number of activities that, although similar to research in some aspects and sometimes referred to as 'research', nevertheless are not classed as research by the

Department of Health and therefore are not subject to the provisions in this Research Policy. The most common of these activities are:

#### 3.4.1 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 [i.e. a standard that has already been set] and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.”<sup>2</sup> Those conducting clinical audit activity should obtain the necessary authorisation from the relevant Trust officers and refer to the Clinical Audit Policy.

#### 3.4.2 Service Evaluation

Service Evaluation in itself is not a research activity. However, the evaluation of a service development may in some cases be considered a research activity. Generally speaking, a small scale evaluation carried out for the purposes of local service monitoring or appraisal is not a research activity. When planning to conduct a local service evaluation activity the necessary authorisation should be obtained from the relevant Trust officers in the Clinical Audit team.

#### 3.4.3 Clinical case studies

Clinical case studies and case reports are not classed as research. However, in all instances (a) the patient’s informed, written consent must be obtained and the consent documented in the patient’s health record, and (b) the case report must be anonymised.

## 4 Duties

4.1 **Role of Director of Research, Development & Innovation.** The Director of RD&I will be an Associate Medical Director reporting to the Medical Director and their deputy for all matters related to RD&I in UHP. The Director of RD&I strategically manages UHP RD&I Department to meet the requirements of the Trusts Strategic research plan.

4.2 **Responsibilities - Research, Development & Innovation Department.** UHP RD&I are responsible for facilitating research within UHP by:

- developing and establishing streamlined systems for the management of research involving UHP, this includes systems to ensure that UHP can meet the responsibilities of a research sponsor under the Medicines for Human Use (Clinical

Trials) Regulations, Medical Device Regulations and the UK Policy Framework for Health and Social Care Research (2017)

- developing the UHP RD&I approval process to meet the requirements of the Department of Health
- developing and establishing a robust system for the performance management of studies, to include NIHR key performance indicators
- supporting Principal Investigators to achieve a successful study delivery by:
  - assistance with robust feasibility
  - where possible research nurse and or administrative support
- maintaining a record of all research being conducted within the UHP, including student research
- ensuring, where necessary, that an appropriate Research Ethics Committee has approved the research
- assessing applications for UHP to act as research sponsor to individual studies
- arranging for written agreements to be put in place for all research involving an external partner, funder and/or sponsor, including agreement with universities or other employers in relation to student supervision
- in relation to both commercial and non-commercial research:
  - Costing of research studies
  - Negotiating contracts
  - Developing and establishing systems to ensure financial probity
- in relation to non-commercial research:
  - Costing of research studies
  - Ensuring Research Governance compliance
- supporting Chief Investigators running single centre and multicentre studies
- providing training in research methodology and governance
- monitoring and audit of research
- permitting and assisting with any monitoring, auditing or inspection required by relevant authorities
- developing the UHP RD&I strategy in consultation with the public, patients and researchers
- promoting strategies for patient and public involvement in research
- promoting the dissemination of research findings
- assisting with the identification and management of intellectual property arising from research or innovation

- compiling and submitting reports as required to the Department of Health (e.g. annual report on RCF expenditure)
- preparing and submitting an annual business plan and annual report for Clinical Research Network (CRN) South West Peninsula SWP- CRN
- taking action in accordance with the UHP policy and standard operating procedures on receipt of any report of suspected research misconduct
- taking action in accordance with the research related Adverse Event (AE) reporting standard operating procedure
- providing an annual report to the Trust Board

#### 4.3 Responsibilities - Management

Heads of Service Lines are responsible for establishing systems at directorate level to comply with the Trust's RD&I approval process and research governance.

Managers can assist in meeting these responsibilities by:

- Ensuring adequate line management of researchers
- Allowing access to appropriate training

#### 4.4 Responsibilities – Researchers

All research staff, including those holding an Honorary Contracts or Letters of Access have a responsibility of being familiar with the principles of Good Clinical Practice (GCP) described in the UK Policy Framework for Health and Social Care (2017).

Researchers who do not hold a substantive employment contract with UHP and who interact with research participants in a way that has direct bearing on the quality of their care must hold a UHP Honorary Contract.

Researchers are responsible for ensuring that:

- the research is conducted in accordance with:
  - the UK Policy Framework for Health and Social Care (2017)
  - the current version of the Trust and regulatory approved protocol
  - the relevant national legislation
- care professionals are informed of a subject's participation in research (where applicable)
- the integrity and confidentiality of clinical and other records and data generated by the research is protected in accordance with data protection legislation and the Caldicott Principles

- any failures in conducting the study in accordance with the above are reported as appropriate
- key performance indicators are reported according to national or local policy
- all adverse events are recorded and reported in accordance with the UHP Research Related Adverse Event Reporting standard operating procedures
- suspected misconduct is reported in accordance with the UHP Policy and standard operating procedures

#### **4.5 Responsibilities - Chief Investigator (CI)**

For a Clinical Trial of an Investigational Medicinal Product (CTIMP), 'a drug study' the CI must be a medically qualified doctor or dentist and the Trust requires they are a Hospital Consultant with a substantive employment contract or Honorary Contract with the Trust. Medically qualified doctors who are an Associate specialist grade may be considered as CIs, but only after a review by the R&D Office as to their suitability.

For all other studies the Chief Investigator must be a senior individual. For Trainee led research a student or junior staff member may act as the CI provided the student has a designated supervisor with appropriate experience, expertise and training within the Trust.

The CI has overall responsibility for the conduct of the research and is accountable for it to their employer, and, through them, to the sponsor(s) of the research. The CI is also directly accountable to the care organisation(s) where the research takes place (or through which the research team has access to participants, their organs, tissue or data). If the research is taking place at more than one site, the CI takes on personal responsibility for the design, management and reporting of the study, and co-ordinating the Principal Investigators (PIs).

#### **4.6 Responsibilities - Principal Investigator (PI)**

The PI and the CI may be the same person. In this case the CI must assume the PI responsibilities detailed in this policy in addition to the CI responsibilities. The PI must be a senior individual, with appropriate experience and expertise.

For trainee led research the student may act as the PI provided the student has a designated supervisor with appropriate experience, expertise and training.

For CTIMPs the PI must be a Hospital Consultant or in some cases an associate specialist, unless the CI is a consultant in the Trust in which case with the CI's supervision a registrar may undertake the PI role.

The PI is responsible for the conduct of the study at UHP and must ensure that the RD&I Department is involved in arranging agreements relating to the UHPs responsibilities in conducting research involving an external partners, funders and/or sponsors.

In relation to commercial research the PI must:

- refer all commercial research to the Feasibility team in RD&I Office at the earliest opportunity prior to the research commencing. Please forward study details to [plh-tr.rd-feasibility@nhs.net](mailto:plh-tr.rd-feasibility@nhs.net)
- ensure that commercial research is performed under a written agreement between the UHP and the commercial company. This agreement must be signed by the Associate Director of Finance in the Trust

## **5 Main Body of Policy**

### **5.1 Requirements for Trust Confirmation of Capacity and Capability**

5.1.1 All research taking place within the Trust must have confirmation of Capacity and Capability from the Trust RD&I department before any research activity begins. The Trust will only extend NHS indemnity cover to its employees taking part in research studies that have been registered and received confirmation from the RD&I department.

5.1.2 Formal confirmation must be sought for both CRN Portfolio and non-portfolio projects (own-account / student led)

5.1.3 The Trust will not accept liability for research that has not been registered and formal confirmation issued.

### **5.2 Research Sponsorship**

5.2.1 All research must have an identified sponsor. The sponsor is the organisation / institution that takes overall responsibility for the initiation, financing, management and monitoring of a study.

5.2.2 The Trust (UHP) will consider acting as sponsor where the CI holds a substantive employment contract or Honorary Contract with the Trust. For commercially initiated research, the commercial company would be expected to act as research sponsor. For educational studies or studies leading to an educational qualification the educational establishment would in most cases act as the study sponsor. Evidence of research sponsorship will be required before Trust RD&I confirmation of Capacity and Capability is issued.

### 5.3 Health Research Authority (HRA) and Research Ethics Committee (REC) Review

5.3.1 The Health Research Authority (HRA) Approval is a single approval process for all types of project based research undertaken in the NHS in England. HRA approval brings together the pre-existing independent, National Research Ethics Service, with a single, national governance and legislative compliance assessment. HRA approval, replaces the need for local checks of legal compliance and related matters by each participating organisation.

5.3.2 The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. Research involving patients, service users, care professionals or volunteers, or their organs, tissue or data must be reviewed independently to ensure it meets ethical standards. Secondary to this is the need to ensure data quality and integrity derived from all studies.

5.3.3 For all research which falls within the remit of the Governance Arrangements for Research Ethics Committees (GafREC) paragraph 3.1, review from a recognised NHS Research Ethics Committee (REC) is required (see GafREC guidance at: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/>)

5.3.4 Applications for HRA Approval must use the application form in IRAS, enabled by selecting HRA Approval in question 4 in the project filter on IRAS. In addition to completing the HRA form in IRAS, the application to the HRA should also include the Organisation Information Document (OID) which should be used to provide information on participating NHS/HSC organisations in the UK (for single site studies where the site is the Sponsor an OID is not required). There are commercial and non-commercial versions available. An outline OID for each site type should be completed as part of a submission. For non-commercial studies it should be accompanied by a completed Schedule of Events or Schedule of Events Cost Attribution Template (SoECAT). The two documents allow the sponsor to make clear what activities will be undertaken locally and the cost type for each activity. The forms are intended to capture all information around study activities being undertaken at a local level (See <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>)

5.3.5 Applications for HRA / REC approval are processed *via* the Integrated Research Application System (IRAS) at <https://www.myresearchproject.org.uk/>

5.3.6 For Higher Education Institutions projects which do not require review by the NHS research ethics committee, an alternative REC review will usually be required. This will be provided by an appropriate University ethics committee. Most universities have established research ethics committees as part of their internal governance arrangements. These research ethics committees are not part of the National Research Ethics Service. Where research meets the criteria for requiring ethical review within the governance arrangements of the National Research Ethics Service, University internal ethics committees are not required to conduct a further review. However, all students and researchers employed by universities must check their university's internal policies as internal ethics committees in Universities often have an extended governance role.

5.3.7 For university student research studies, HRA approval should be sought for any educational study led from England that:

- requires review by an NHS Research Ethics Committee (REC)
- is taking place in an NHS organisation involving NHS staff/ resource/ time
- is applying for support from the NIHR Clinical Research Network.

Students will need to liaise with educational sponsors and Trust's RD&I office prior to submission of their projects.

## 5.4 **Consent**

5.4.1 All studies must demonstrate appropriate arrangements regarding consent. Informed consent is the process by which a participant voluntarily confirms willingness to participate in a particular study, having been informed of all aspects of the study that are relevant to their decision to participate. This should be documented by means of a written, signed and dated consent form saved in the investigator site file and a notification recorded in their medical records (see also 5.4.2.). Copies of the consent forms should also be saved in medical notes if the project is a Clinical Trial of an Investigational Medicinal Product (CTIMP, a drug study).

5.4.2 Researchers should always aim to inform people fully and obtain appropriate prospective consent. There may be rare occasions where this not possible which will either be covered by an application the HRA Confidential Advisory Group (CAG) or there will be a clearly defined process for seeking the consent or an opinion from either a consultee, guardian or professional consultee or guardian described in the study protocol that has received a positive ethical opinion. For example, in the case

of urgent public health studies with explicitly verbal consent/assent arrangements, the consent should always be documented in the medical notes.

## 5.5 Finance

### 5.5.1 Financial Probity

5.5.1.1 Financial probity and compliance with the law and with the rules set out by HM Treasury for the use of public funds are as important in research as in any other area. There must be transparency and accountability of all research income and expenditure.

5.5.1.2 The Attributing the Costs of Health and Social Care Research and Development (AcoRD, DH, 2012) provides a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS in a transparent, robust and consistent manner.

5.5.1.3 There should be written agreements for all research taking place in the Trust. These agreements are only valid if signed by one of the authorised signatories for research (Associate Director of Finance or deputy) or delegated authority. An exception to this rule, is the Organisation Information Document (OID), completed as part of the Health Research Authority approval which can form an agreement for non-commercial projects. The study sponsor may accept confirmation by email from a delegated individual. For UHP the delegated individual would be the Research Manager or the Research Operations Manager.

5.5.1.4 When considering a study, the Manager of RD&I and finance accountant must be satisfied that all costs for the research are fully covered. For all commercial research within the Trust there is also a non-refundable RD&I set up fee.

5.5.1.5 Trust staff should provide financial and progress reports to funders and to the Trust annually or as reasonably requested.

### 5.5.2 Commercial / Industry Funded Research

5.5.2.1 The Trust recognises the contribution industry-sponsored research can make to the provision of high-quality patient care. The Trust is responsible for effective governance arrangements for any industry-sponsored research to ensure that:

5.5.2.1.1 All research is fully costed, and that the costs are properly recovered

5.5.2.1.2 The interests and safety of patients participating in research are protected in all eventualities

5.5.2.1.3 Any regulatory, ethical and financial approvals are obtained

5.5.2.1.4 Any risks (liabilities) are properly considered and minimized

5.5.2.2 The Trust presents a professional approach in its dealings with industry. All industry-sponsored research activity must be negotiated and authorised by the Trust's RD&I department. Only protocols and studies registered with the RD&I department will be covered by the appropriate insurance or NHS indemnity arrangements. All industry-sponsored research should be fully costed. The full cost of a research study should include the direct staff costs, costs for any contracted service, relevant indirect costs (e.g. for finance, research administration, personnel and property service infrastructure).

## **5.6 Conducting Clinical Trials of Investigational Medicinal Products (CTIMPs, [Drug Studies])**

5.6.1 There is strict legal framework within which clinical trials of investigational medicinal products (CTIMPs) must be conducted. The EU Clinical Trials Directives and GCP Directives (transposed in UK Law through the Medicines for Human Use (Clinical Trials) Regulations 2004) and subsequent amendments, state that clinical trials must be carried out according to the principles of International Conference on Harmonisation – Good Clinical Practice Good Clinical Practice (ICH GCP). ICH GCP is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting CTIMPs that involve the participation of human subjects. Compliance with ICH GCP provides assurance that the rights, safety and well-being of trial subjects are protected and that the results of CTIMPs are credible and accurate.

5.6.2 The legislation states it is against the law to start or conduct, or to recruit participants to a clinical trial involving a medicinal product until there is a favourable opinion from an ethics committee and a clinical trials authorisation from the licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

## **5.7 Research Management and Governance Training**

5.7.1 Researchers are required to dedicate adequate time to complete training as requested by the RD&I department and sponsors, and as per regulatory requirements. Training may include, but is not limited to: policy and procedures;

research study-specific, information governance, research governance; and ICH GCP Training.

5.7.2 The Trust RD&I department will have oversight of training and provide support to new researchers as required.

5.7.3 All staff working on research studies in the Trust should be working to the standards of UK Policy Framework for Health and Social Care Research (2017) which incorporates the principles of ICH GCP and for CTIMPs, as described in UK law in the Medicines for Human Use (Clinical Trials) Regulations 2004. The standards of GCP described in these two documents are the same but are legally binding for CTIMPs and form the basis of audit or inspection. ICH GCP training is available through online training and the National Institute for Healthcare Research Clinical Research Network (NIHR CRN) <https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>. NIHR research training is also available as a face to face course within the Trust, details of courses can be located here <https://www.plymouthhospitals.nhs.uk/research-courses-events>

5.7.4 For all Trust sponsored research projects, the CI and research team (including university employed researchers working on Trust projects) will be required to have completed research training covering the principles of GCP every 2 years. Courses can be found as indicated above.

## 5.8 **Use of Patient Data**

Personal information means information of any type about individuals, living or deceased, held in any form by the Trust or its employees or independent contractors. This includes written and electronic records, opinions, images, recordings, and information obtained from samples. Identifiable information is information from which the individual to whom the information pertains might be identified by a person viewing the information (e.g. unique ID number, date of birth, telephone number). Researchers should refer to the NHS Confidentiality Code of Practice (2003). Anonymised data are data prepared from personal information, but from which the individual cannot be re-identified (e.g. age, height, Body Mass Index). Linked anonymised data (also referred to as pseudonymised data) are anonymous to the people who receive and hold it but contain information or codes that would allow others (e.g. the Chief Investigator) to identify people from it. Linked data are typically used where it may be necessary to refer back to an original data source for further information or verification. Confidential information is any

information obtained by a person on the understanding that they will not disclose it to others, or obtained in circumstances where it is expected that they will not disclose it.

5.8.1 Data and information collected in the course of research must be recorded, handled and stored in a way that allows accurate reporting, interpretation and verification to ensure data integrity. The appropriate use and protection of patient data should be paramount and particular attention must be given to systems for ensuring confidentiality of personal information.

5.8.2 The handling of personal information in research must be compliant with Trust policies in relation to the Data Protection Act 2018 and the General Data Protection Regulation (GDPR). Any data/confidentiality breaches must be reported using the Trust's incident reporting system (DATIX).

5.8.3 Data collection must take note of the DoH "National Opt Out Programme". Details of the scheme can be viewed at <https://digital.nhs.uk/services/national-data-opt-out> or <https://www.hra.nhs.uk/about-us/news-updates/national-data-opt-out/>. This allows patients to opt out of their data being used for secondary purposes which includes research. However, if a patient is approached and consents to take part in a study this would take precedent over their opt out for the period of the study.

5.8.4 Emergency research taking place usually in the Emergency Dept (ED) or the Intensive Care Unit (ICU), must be approved by a REC and HRA and normally involves the use on legal or professional guardians or consultees and often with retrospective consent. If gaining explicit consent looks likely to be impossible or impractical, as in for example large registry studies, an application to have the need for consent put aside can be made to the Confidentiality and Advisory Group (CAG) under Section 251 of the NHS Act 2006. Requests for this use are made through the Confidentiality and Advisory Group (CAG). <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/>.

If data is to be used for research without consent, then evidence of approval from CAG must be provided as part of the submission to the RD&I department before confirmation of capacity and capability will be granted.

5.8.5 All raw research data should be handled on Trust premises where possible. Data should only leave the Trust following the prior agreement of the RD&I

Department. Under no circumstances can healthcare records be removed from the Trust premises.

5.8.6 Data collected in the course of the project must be retained for an appropriate period as stipulated by the project sponsor and/ or funder to support monitoring by regulatory and other authorities.

5.8.7 When research projects become inactive, files should be archived in a secure, locked storage environment in accordance with the guidelines of the sponsor and the RD&I department should be informed of any changes to archiving arrangements.

5.8.8 Safe and secure storage, retention and destruction of research data, and logging of this in a study site file, (what was destroyed, by whom and when) is the responsibility of the Chief Investigator, or data custodian if different. The key that links subjects to data should be stored securely and separately.

5.8.9 Data loss must be reported and acted upon promptly with completion of the appropriate documentation. Refer to the Trust Reporting of accidents, incidents and near miss situations – including serious incidents policy (DATIX).

5.8.10 The use of existing personal information for research purposes:

5.8.10.1 The Data Protection Act 2018 and GDPR requires that when people give information they should be told what it will be used for and to whom it will be passed. The Trust is a research-active organisation and it is possible that researchers may want to access and process a patient's personal information at a later date for research purposes. This later processing may be unlawful without the patient's further consent. There are three routes to processing these data lawfully; these are set out below.

(1) The preferred route is for researchers to obtain consent from each individual patient whose data they wish to access or process. This consent must be obtained on a study-by-study basis, i.e. for each individual study.

(2) The Health Research Authority Confidentiality Advisory Group (CAG) have advised that a person from within the patient's clinical care team would legitimately be able to access identifiable information without consent in order to prepare a fully anonymised data set. This means undertaking the minimum necessary data processing required to extract and immediately anonymise the information. This person must be a member of the patient's clinical care team –

i.e. a person directly involved in the diagnosis, care and treatment of an individual: people external to this team are not permitted to process data, regardless of their contractual status with the NHS organisation and regardless of the data protection registration status of the organisation or database involved. If it is not clear whether or not a researcher is a member of the patient's clinical care team, advice should be sought from the Trust's Caldicott Guardian.

(3) When it is neither reasonably practicable to gain each individual's consent nor for a member of the patient's clinical care team to process the information, then the researcher is required to gain permission for their activity from the Health Research Authority Confidentiality Advisory Group (CAG) ('Section 251 approval').

## 5.9 Health, Safety and Employment/Honorary Status

5.9.1 The safety of research participants and research staff must be given priority at all times. Health and Safety Regulations and Trust policies or employing organisation's Health and Safety policies must be strictly observed during the course of the research. This is particularly important if the research involves the use of potentially dangerous or harmful equipment, substances or organisms.

5.9.2 Appropriate employment arrangements must also be in place for research staff. For NHS staff, evidence of their employment status will be required. Researchers not employed by any NHS organisation who interact with research participants in a way that has a direct bearing on the quality of their care will be issued honorary research contracts *via* the Trust HR department.

5.9.3 For non-NHS staff where their research does not have a bearing on the quality of patient care, a Letter of Access (LoA) should be issued. It is the responsibility of the Chief Investigator or Principal Investigator at each site, to work with the RD&I department to ensure staff have the necessary contracts or Letters of Access in place before staff begin research work within the Trust.

5.9.4 When an honorary contract is not required a LoA may be provided. The RD&I department will process applications for research passports and LoAs in accordance with the NIHR Research in the NHS–HR good practice resource pack (<https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx> ) and local Standard Operating Procedure (SOP) <https://www.plymouthhospitals.nhs.uk/research-sops>.

## 5.10 Monitoring compliance and effectiveness

5.10.1 Organisations and individuals involved in research are expected to be able to demonstrate compliance with the requirements of the UK Policy Framework for Health and Social Care Research (2017) and applicable national regulation. It is a statutory requirement that CTIMPs are conducted in accordance to the Medicines for Human Use (Clinical Trials) Regulations 2004, which includes with the principles of ICH GCP. Working to current regulation and GCP principles involves meeting stringent criteria in respect of study documentation, safety monitoring and reporting, data capture and management, study monitoring, training of study personnel and study conduct in general. If a study has a commercial sponsor, the commercial company (or a delegated Clinical Research Organisation) would conduct and monitor the CTIMP in accordance with ICH GCP guidelines.

5.10.2 For studies for which UHP is a recruiting site, the RD&I department will conduct an initial Risk Assessment based on the research application. This risk assessment will determine if there is a need for any extra monitoring / oversight of a hosted research study. With regards to monitoring and auditing, the UK Policy Framework for Health and Social Care Research (2017) states that:

“Organisations remain responsible, including through monitoring and training, for ensuring that the research activities are conducted in accordance with their applicable legal obligations” (UK Policy Framework for Health and Social Care Research, 2017, p. 24)

5.10.3 For Trust sponsored projects, the RD&I department will carry out monitoring and audits to ensure compliance with the UK Policy Framework for Health and Social Care Research (2017). See Trust research SOPs <https://www.plymouthhospitals.nhs.uk/research-sops/1-qa-2858/>.

## 5.11 **Care Professionals' Responsibilities**

5.11.1 Trust staff will retain responsibility for the care of their patients or service users, when they are participating in research.

5.11.2 Before approaching patients, service users, carers or staff for participation in research, Trust staff must ensure that the relevant permissions are in place for the Trust. Advice should be sought from the RD&I department.

## 5.12 **Involvement of Service Users and the Public in Research**

5.12.1 Participants or their representatives will be involved wherever possible in the design, conduct, analysis and reporting of research, including literature reviews and direct research delivery.

5.12.2 Once established, findings must be made available *via* the Chief Investigator to those participating in the research and to all those who could benefit, through publication and/or other appropriate means.

### 5.13 **Intellectual Property**

5.13.1 NHS organisations are required to manage the Intellectual Property (IP) arising from their activities. Ideas arising out of routine work as well as research may lead to improvements in patient care through new innovations and financial benefits to the inventor or the NHS.

5.13.2 The Trust Lead on Innovation (based in the RD&I Dept) is responsible for leading with advice on IP within the Trust.

### 5.14 **Study Agreements/Contracts**

5.14.1 Before a research study can start, sponsors and host institutions must ensure that the appropriate agreements in place which set out the responsibilities of the parties involved in the research.

5.14.2 Commercial Studies: For commercial CTIMPs the Trust expects that commercial companies will use the OID and national model Clinical Trial Agreement (mCTA or CRO mCTA) for pharmaceutical companies working with the NHS. Model agreements can be found *via*: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/model-agreements/>

5.14.3 Non-commercial Studies: For non-commercial studies clinical trials or investigations a mNCA should be used, in addition to the OID. For other non-commercial studies, partners may use the OID or the model Non-Commercial Agreement as suggested by the Health Research Authority.

### 5.15 **Indemnity**

5.15.1 NHS indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust.<sup>4</sup> The Trust only accepts liability for research activity that has received confirmation of capacity and capability by the RD&I Department.

5.15.2 For commercial CTIMP studies, commercial companies will provide cover for negligent and non-negligent harm under the standard Clinical Trial Compensation Guidelines recommended by the Association of the British Pharmaceutical Industry. This should be clearly outlined in the Clinical Trial Agreement, patient information sheet and consent form supplied to study participants.

## 5.16 Research Misconduct and Fraud

5.16.1 The Trust is committed to maintaining the integrity and probity of research undertaken in the Trust and will thoroughly investigate any allegations of misconduct in research made against employees of the Trust including those with Honorary Contracts.

5.16.2 The UK Research Integrity Office is an independent body that provides expert advice and guidance about the conduct of research. The NHS Counter Fraud Authority (NHSCFA) became a Special Health Authority on 1 November 2017. This organisation (which was previously known as NHS Protect) is tasked to lead the fight against fraud, bribery and corruption in the NHS. The Trust has a Local Counter Fraud Specialist and if research fraud is suspected please consult the Trust research SOP (QA6 Suspected Research Fraud) before taking any action <https://www.plymouthhospitals.nhs.uk/research-sops/1-qa-2858/>.

5.16.3 Research misconduct is addressed through a number of mechanisms and disciplinary action may be taken.

## 5.17 Dissemination of Results and Information

5.17.1 All Clinical Trials (CTIMPs) must be registered on the EudraCT Database (European Union Drug Regulating Authorities Clinical Trials Database). Furthermore, all interventional studies must be registered on a publicly accessible register as a condition of the favourable ethical opinion. Recognised registries that currently meet ICMJE (International Committee of Medical Journal Editors) criteria are the International Standard Randomized Controlled Trial Number registry ([www.isrctn.org](http://www.isrctn.org)) and the US National Institute of Health registry (<http://clinicaltrials.gov/>). All the databases/registries require that the study results are uploaded within 12 months of the end of study notification.

5.17.2 Trust researchers are encouraged to publish their work and to make the work open to critical review through the accepted scientific and professional channels. Researchers are advised to follow the guidance of the International Committee of Medical Journal Editors regarding authorship.<sup>3</sup> Authorship credit should be based only on substantial contribution both to the study and to the manuscript. Participation solely in the acquisition of funding, or the collection of data, or the clinical care of research participants does not justify authorship. Instead, following the guidance of the British Medical Journal, a full list of

contributors should be provided at the end of the paper, giving details of who did what in planning, conducting, and reporting the work.

5.17.3 Lay summary findings must be made accessible to those participating in research and to those who could benefit from them.

5.17.4 Findings should be made available in multiple formats, allowing for a variety of audiences to access the outcomes from the research.

5.17.5 All participants should be informed of the outcomes of the research of which they participated in. Research outcomes should be shared with the Trust services involved in the delivery of the project.

## 5.18 **End of Study Notification and Archiving**

5.18.1 It is the responsibility of the Chief Investigator to inform the Trust when a study has ended. The definition of end of trial or study should be included in the study protocol.

5.18.2 For CTIMPs it is a statutory requirement that the MHRA as the Competent Authority, REC and RD&I office are notified of the end of the trial within 90 days or within 15 days if the Trial is terminated early.

5.18.3 For non-CTIMPs, an end of study notification should be sent to the RD&I office and REC within 90 days of the end of the trial or within 15 days if the Trial is terminated early. Advice can be sought from the RD&I department.

5.18.4 Studies will be archived after the study close out letter has been received and finance have confirmed all invoices have been met. Details of the close out and archiving procedures can be located in the Trust SOPs at <https://www.plymouthhospitals.nhs.uk/research-sops/6-study-close-sc-2863/>

## 5.19 **Training**

5.19.1 Any Trust member of staff who is involved in research needs to be aware of their role and responsibilities and receive necessary training, in particular be familiar with the study protocol.

## **6 Overall Responsibility for the Document**

RD&I

## **7 Consultation and Ratification**

The design and process of review and revision of this policy will comply with the development and management of formal documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the RD&I senior management team and ratified by the Medical Director or their deputy.

Non-significant amendments to this document may be made, under delegated authority from the RD&I Director, by the nominated owner. These must be ratified by the Medical Director or their Deputy Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades that are directly affected by the proposed changes.

## **8 Dissemination and Implementation**

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

## **9 Monitoring Compliance and Effectiveness**

### **9.1 Trust Responsibilities:**

9.1.1 The Trust must be made aware of all research undertaken within the organisation, or involving participants' organs, tissue or data obtained through the Trust. All research must be notified to the RD&I department.

9.1.2 The Trust Research Governance Manager oversees the governance processes adopted by the RD&I department on behalf of the Trust and reports to the RD&I Associate Medical Director and the RD&I Research Manager.

The RD&I Associate Medical Director reports to the Trust's Executive board where the Trust Medical Director and Deputy (Trust Executive managers) have responsibility for RD&I. It is the responsibility of the RD&I department to:

- (a) Ensure that research involving participants for whom it is responsible has ethical approval, HRA approval and has provided confirmation before the study starts
- (b) Ensure that non-NHS employed researchers hold honorary NHS contracts, or appropriate Honorary Research Contracts/ Letters of Access
- (c) Permit and assist with any monitoring, audit or inspection as required
- (d) Ensure that all research meets the standards set out in the UK Policy Framework for Health and Social Care Research (2017).
- (e) Ensure that all research is reviewed by service leads to assess local feasibility and any potential risks associated with the conduct of the work within the clinical directorate. This is facilitated by the Trust RD&I department.
- (f) Implement a monitoring and auditing programme to quality assure that all process/protocols and applicable regulatory requirements are adhered to
- (g) To report to the Trusts Quality Assurance Committee (QAC) as requested.

## **10 References and Associated Documentation**

1. Department of Health, 'UK Policy Framework for Health and Social Care Research', 2018, Department of Health, London
2. National Institute of Clinical Excellence, 'Principles for Best Practice in Clinical Audit', 2002, National Institute for Clinical Excellence: London
3. International Committee of Medical Journal Editors, Uniform requirements of manuscripts submitted to biomedical journals. Medical Education, 1999. 33(1): p.6678
4. NHS Executive, NHS Indemnity: Arrangements for Clinical Negligence Claims in the NHS. 1996, NHS Executive: Leeds.

### **Legislation and Policy cross references**

The Medicines for Human Use (Clinical Trials) Regulations 2004

The Human Tissue Act (2004)

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

The Medical Devices Regulations 2002

The Medical Devices (Amendment) Regulations 2005.

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) and associated regulation.

The Mental Capacity Act 2005

Data Protection Act 2018

Section 251 of the NHS Act 2006

UK Policy Framework for Health and Social Care Research (2017)

ICH E6 (R2) Good Clinical Practice (2016)

Trust Policies - G:\DocumentLibrary\UHPT Trust Documents

Trust Research SOPs - <https://www.plymouthhospitals.nhs.uk/research-sops>

Dissemination Plan			
<b>Document Title</b>	Research and Development Policy		
<b>Date Finalised</b>	June 2020		
Previous Documents			
<b>Action to retrieve old copies</b>	Remove previous version on Trust Documents Network share Folder		
Dissemination Plan			
Recipient(s)	When	How	Responsibility
All Trust active staff	As soon as the documented is ratified and placed on the Trust Intranet site	Trust Documents Network share Folder and via 'Vital Signs' staff news letter and e- mail to all research staff	Chris Rollinson

Review Checklist		
<b>Title</b>	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
<b>Rationale</b>	Are reasons for development of the document stated?	Yes
<b>Development Process</b>	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
<b>Content</b>	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
<b>Evidence Base</b>	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
<b>Approval</b>	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Yes
<b>Dissemination &amp; Implementation</b>	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
<b>Document Control</b>	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
<b>Monitoring Compliance &amp; Effectiveness</b>	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
<b>Review Date</b>	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes

<b>Overall Responsibility</b>	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes
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<b>Core Information</b>	
<b>Date</b>	June 2020
<b>Title</b>	Research & Development Policy
<b>What are the aims, objectives &amp; projected outcomes?</b>	To ensure the safety and well being of patients taking part in research projects and the production of verifiable good quality data
<b>Scope of the assessment</b>	
<p>Research is essential to the successful promotion and protection of health and wellbeing, and also to modern, effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants. Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision making processes, clear allocation of responsibilities and robust monitoring arrangements.</p>	
<b>Collecting data</b>	
<b>Race</b>	<p>There is no evidence to suggest that there is an impact on race regarding this policy.</p> <p>Anonymous ethnic data is collected by the MHRA (the national regulator) for drug studies <i>via</i> the Developmental Safety Update Report (DSUR).</p> <p>Consideration needs to be made if the first language of the participant is not English and interpretation services should be offered. Consideration should also be made if information provided is required in a different language.</p>
<b>Religion</b>	<p>There is no evidence to suggest that there is an impact on religion or belief and non-belief regarding this policy.</p>
<b>Disability</b>	<p>There is no evidence to suggest that there is an impact on disability regarding this policy.</p> <p>Consideration needs to be made for participants who declare a disability, learning disability or mental health issue and reasonable adjustments must be made as appropriate (see Trust research SOPs).</p>
<b>Sex</b>	<p>There is no evidence to suggest that there is an impact on sex regarding this policy.</p> <p>The sex of individuals is collected by the MHRA for drug studies <i>via</i> the Developmental Safety Update Report (DSUR).</p>
<b>Gender Identity</b>	<p>There is no evidence to suggest that there is an impact on gender identity regarding this policy.</p>
<b>Sexual Orientation</b>	<p>There is no evidence to suggest that there is an impact on sexual orientation regarding this policy.</p>

<b>Age</b>	<p>There is no evidence to suggest that there is an impact on age regarding this policy.</p> <p>Data on the age range of trial participants is collected by the MHRA for drug studies <i>via</i> the Developmental Safety Update Report (DSUR)</p>
<b>Socio-Economic</b>	<p>There is no evidence to suggest that there is an impact on socio-economical issues regarding this policy.</p> <p>It is recognised that participants from low income families tend to carry a greater disease burden and are therefore more likely to be invited to take part in research. However, where possible the risks and benefits of taking part in research should be borne by society as a whole.</p>
<b>Human Rights</b>	<p>The document has considered that a priority of the research team is the dignity, rights, safety and well-being of participants.</p> <p>Arrangements are in place for the disclosure of relevant information should the participant be under the auspices of the local authority or other agencies</p>
<b>What are the overall trends/patterns in the above data?</b>	No comparative data has been used to date which means that no trends or patterns have been identified

<b>Involving and consulting stakeholders</b>	
<b>Internal involvement and consultation</b>	Prof Simon Rule <i>R&amp;D Director</i> , Dr Lisa Vickers <i>R&amp;D Manager</i> , Corinna Mossop <i>Clinical Trials Manager</i> , Ben Hyams <i>Research Matron</i> and Jo Arthur <i>Information Governance Support Manager</i> .
<b>External involvement and consultation</b>	None.
<b>Impact Assessment</b>	
<b>Specific issues and data gaps that may need to be addressed through consultation or further research</b>	

<p><b>Overall assessment and analysis of the evidence</b></p>	<p>Consideration needs to be made if the first language of the participant is not English and interpretation services should be offered Consideration should also be made if information provided is required in a different language.</p> <p>Consideration needs to be made for participants who declare a disability, learning disability or mental health issue and reasonable adjustments must be made as appropriate.</p> <p>It is recognised that participants from low income families tend carry a greater disease burden and are therefore more likely to be invited to take part in research. However, where possible the risks and benefits of taking part in research should be borne by society as a whole. The document has considered that a priority of the research team is the dignity, rights, safety and well-being of participants.</p> <p>Arrangements are in place for the disclosure of relevant information should the participant be under the auspices of the local authority or other agencies</p> <p>For research to be considered to be ethical it should comply with the following seven principle:</p> <ol style="list-style-type: none"> <li>1. Societal/ Scientific value. Research that will improve health and well being or increase knowledge</li> <li>2. Scientific validity. Use of acceptable scientific principles &amp; methods and competent investigators, to produce reliable and valid data</li> <li>3. Fair subject selection. Selection of subjects so that vulnerable individuals are not targeted for risky research, and the rich and socially powerful not favored for potentially beneficial research</li> <li>4. Favorable risk-benefit ratio. Minimize risks, enhance potential benefits, risks are proportionate to the benefits to the subject or society</li> <li>5. Respect for subjects. Subjects should have their privacy protected, the opportunity to withdraw, their well-being monitored &amp; maintained, be informed of new information concerning research, compensated for injury</li> <li>6. Informed consent. Provide adequate information to subject so that he or she can make voluntary decision</li> </ol> <p>Independent review. Review of the above by individuals unaffiliated with the research (Independent Peer &amp; Ethics review)</p>
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<b>Action Plan</b>				
<b>Action</b>	<b>Owner</b>	<b>Risks</b>	<b>Completion Date</b>	<b>Progress update</b>
Collect and monitor data collected from Datix on incidents and complaints.	Research Governance Manager  & Research teams	Litigation Patient safety Data quality Trust reputation	ongoing	Monthly reports made to the Quality Committee.