The Royal Wolverhampton NHS Trust

OP30 Research Governance Policy

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Appendices

1.0 Policy Statement (Purpose / Objectives of the policy)

The Royal Wolverhampton NHS Trust (RWT) recognises the importance of research. Research involves risk, both financial and the safety and wellbeing of the research participants. To minimise and prevent such risks, robust governance arrangement are essential.

RWT must comply with the UK Policy Framework for Health and Social Care Research (2020) when participating in research. Research Governance6is one of the core standards for health care requiring health care organisations to have systems to ensure the principles and requirements of the framework are consistently applied. Health care organisations must take this standard into account in discharging their duty of quality under Health and Social Care Act 2012.

The purpose of research governance is to enhance the culture, systems and working practices to ensure that patient safety, probity, quality assurance and quality improvement are central components of all research activities.

This policy is based on the UK Policy Framework for Health and Social Care Research, 2020. This policy will aim to minimise RWT's liability and maximise benefit from research activities and promote RWT's reputation as a credible research site.

Research Governance applies to all research with human participants, their organs, tissue or data performed within the RWT. Research activity can be undertaken directly by Trust employees or by external personnel irrespective of whether the subjects of the research are patients, families/carers, or Trust staff.

This document dictates the standards to be implemented across the Trust and the lines of accountability for the implementation of these standards.

The 19 principles which are the benchmark for good practice that the management and conduct of all health and social care research in the UK are expected to meet are as follows.

- *Safety* – The safety and well-being of the individual prevail over the interests of science and society.
- *Competence* – All those involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.
- *Scientific and Ethical Conduct* – Research projects are scientifically sound and guided by ethical principles in all their aspects.
- *Patient, Service User and Public Involvement* – Patient, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.
- *Integrity, Quality and Transparency* – Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

- *Protocol* – The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents.
- *Legality* – The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.
- *Benefits and Risks* – Before commencing any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated.
- *Approval* – A research project is started only if HRA approval and any other relevant approval has been granted.
- *Information about the Research* – Information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).
- *Accessible Findings* – Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e., legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.
- *Choice* – Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.
- *Insurance and Indemnity* – Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.
- *Respect for Privacy* – All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.
- *Compliance* – Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

The following principles also apply to interventional research i.e. where a change in treatment, care or other services is made for the purpose of research:

- *Justified Intervention* – The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

- *Ongoing Provision of Treatment* – The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g., continuing or changing the treatment, care or other services that were introduced for the purposes of the research).
- *Integrity of the Care Record* – All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and such a way and for such a time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected.
- *Duty of Care* – The duty of care owed by the health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

Research Governance comprises the systems that provide the regulation of research and the way it is conducted in health and social care settings by setting standards, ensuring that arrangements are in place to monitor projects to maintain research quality and provide safeguards to the public.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

2.1 Research

Research can be identified as the attempt to derive generalised new knowledge by addressing clearly defined questions with systematic and rigorous methods.

2.2 Non-Research

2.2.1 Many other activities are not research even though they use similar methodologies. In that case, they do not require assessment by a research ethics committee or formal approval within the UK Policy Framework for Health and Social Care Research.

2.2.2 In practice the boundaries between research and other activities may not always be clear.

2.2.3 The other activities include clinical audit, local developments of existing research, introducing clinical innovations/investigations, service evaluations, Case Studies and Case Reports, consensus methods, patient or staff surveys, data management, and analysis and quality assurance programmes.

2.2.4 The R&D Directorate has guidance on how to categorise a project and will provide access to further resources. Further information can also

be found via the following link: http://www.hra-decisiontools.org.uk/research/.

2.3 Research Sponsor

The individual, organisation or partnership that takes on overall responsibility to set up, run and report a research project. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research.

2.4 Chief Investigator (CI)

The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; if the study involves researchers at more than one site, the CI is the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site. For clinical trials involving medicines, the CI must be an authorised health professional.

2.5 Principal Investigator (PI)

Person responsible for the conduct of the research at an individual site. If a study is conducted by a team of individuals at a site, the investigator leading the team is called the PI. For clinical trials involving medicines, the PI must be an authorised health professional.

2.6 Researchers/Co-Investigators

Members of the research team other than the CI or the PI. For clinical trials involving medicines, an investigator must be an authorised health professional.

2.7 Funder

Organisation providing funding for a study (through contracts, grants or donations to an authorised member of the employing and, or care organisation). The main funder typically has a key role in scientific quality assurance and is normally the sponsor in the case of commercial research.

2.8 Research Site

Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care and, or the employer members of the research team (HRA 2017). Health and social care organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a study.

2.9 Research Passport

The Research Passport System provides a mechanism for Higher Education (HE) employers to share pre-engagement information about a researcher with relevant NHS organisations in which that researcher will be conducting their research activity. The Research Passport System provides clear guidance on the relevant checks required: a robust process for HE employers to document and evidence the checks which have been undertaken; and clear principles that enable NHS organisations to have a

record of and rely on those checks for the duration of the Research Passport.

2.10 Research ethics committee (REC)

Committee established to provide participants, researchers, funders, sponsors, employers, care organisations and professionals with an independent opinion on the extent to which proposals for a study comply with recognised ethical standards. There are other committees involved in research; depending on the study requirements, approval may need to also be sought from other bodies such as the MHRA, HTA, GTAC, CAG, etc.

2.11 International Conference on Harmonisation – Good Clinical Practice (ICH-GCP)

Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. These standards give assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study. Section E6 of ICH defines principles of Good Clinical Practice (referred to as ICH-GCP or just GCP). Research teams on CTIMPS in the UK must follow GCP requirements as detailed in MfHU (CT) Statutory Instruments; all non-CTIMP studies conducted within the NHS adhere to GCP according to UK Policy Framework for Health and Social Care Research.

2.12 Suspected Unexpected Serious Adverse Reaction (SUSAR)

A Serious Adverse Reaction (SAR) – which is unexpected (i.e., its nature and severity is not consistent with the known information about that product from the Investigator's Brochure or the SmPC) and suspected, as it is not possible to be certain of causal relationship with the Investigational Medicinal Product.

2.13 National Institute for Health and Care Research (NIHR) Portfolio

The NIHR Portfolio contains high-quality clinical research studies across a range of over 26 specialty groups that are eligible for consideration for research support from the Clinical Research Network in England. Portfolio adoption can provide management of current studies, feasibility of future studies, and support with staffing. Activity data of studies and recruitment from the NIHR portfolio is used to inform NHS infrastructure allocation and supports the performance management of each of the Clinical Research Networks.

2.14 Health Research Authority

The HRA protects and promotes the interests of patients and the public in health and social care by ensuring research is ethically reviewed and approved. The HRA promotes transparency in research and oversees a range of committees and services. It co-ordinates and standardises research regulatory practice and provides independent recommendations of identifiable patient information where it is not always practical to obtain consent for research and non-research projects.

2.15 Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK, underpinned by science and research. They make sure that the products they regulate work properly and are acceptable safe. The MHRA advises on the designs of clinical trials to ensure patient involvement and patient safety and advise on the evidence of safety and impact that the developers will need to demonstrate for each product. The agency monitors trends in data which enable the identification of safety concerns; they are investigated and a decision is made on the best course of action which could lead to products being withdrawn from the market.

3.0 Accountabilities

3.1 The Department of Health (DH) statement of strategy 2021 - 2023 sets out the direction of NHS Research and Development (R&D). This has resulted in a number of infrastructure changes and system improvements to support research including the setting up of the NIHR. The NIHR report directly to the DH and have assisted in the revision of research funding mechanisms and the streamlining of research governance.

3.2 The Trust Board MUST be aware of all research being undertaken within the organisation. The Trust Board is responsible for obtaining assurance that the adequate arrangements and resources for any research meet the standards set out in the UK Policy Framework for Health and Social Care Research.

3.3 The Research & Development Directorate Manager (Group Lead) and the Clinical Director Report directly to the Managing Director for R&D as executive lead for all strategic and operational R&D activity. All R&D staff are accountable to the R&D Directorate Manager (Group Lead) but may be responsible to a designated line manager.

3.4 It is the responsibility of the R&D Directorate Manager to ensure that the Policy and procedures are implemented, reviewed and updated.

3.5 This policy will be reviewed in light of changing research governance needs, amendments to national terms, conditions and legislation.

3.6 This policy applies to any member of staff involved in research at RWT.

4.0 Policy Detail

The purpose of this policy is to instruct the reader in the appropriate procedures regarding the conduct of research within the Trust. Ensure all research undertaken by RWT complies with statutory legislation and guidance.

- Provide a framework for the development of a robust research governance process across RWT and its partner organisations.

- Clearly define accountability and responsibility for Research Governance.
- To ensure any incidents, hazards or risks arising from Research Governance are identified and managed in accordance with Trust policies.
- To promote good practice across RWT.
- To enhance ethical and scientific standards and quality.

The policy applies to all research activity where:

- RWT is a lead organisation,
- RWT is a participating site in research,
- participants are a patient, care giver, volunteer or member of staff,
- the use of patient tissue, organs or data is required,
- research is taking place on RWT premises,
- research is involving RWT resources,
- research is non-clinical or laboratory based, and
- research is being undertaken as part of an educational qualification.

4.1 Management of Research Governance

4.1.1 The Trust Board has established a Research and Development (R&D) Directorate for the management of research and development activities. The R&D Directorate is led by a Managing Director of R&D along with a Clinical Director of R&D, who is accountable to the Board through the Chief Medical Officer.

4.1.2 Both the R&D Managing Director and Clinical Director have established lines of accountability to the Management and Trust Boards and links with clinical governance, risk management, the Divisions, the Trust Peer Review Committee, external researchers, and the Clinical Research Network (CRN).

4.1.3 The R&D Directorate will facilitate all research within RWT. The Directorate has an operational responsibility for research governance within the Trust as follows.

4.1.3.1 Working towards achieving the UK Policy Framework for Health and Social Care Research.

4.1.3.2 Promoting a quality research centre within RWT.

4.1.3.3 Ensuring researchers have seen a copy of this policy and understand their responsibilities.

4.1.3.4 Ensuring the research is properly designed and that it is well managed, monitored and reported.

4.1.4 R&D is managed on a day-to-day basis by the R&D operational management team. R&D quality assurance will be managed proactively through the R&D Governance Group (Appendix 1):

4.1.5. The Trust Board will be kept informed of all significant developments, risks and progress. Quarterly reports on R&D activity are provided the Trust Management Committee and the Trust Board.

4.1.6 Intellectual Property (IP) – It is a requirement of the UK Policy Framework for Health and Social Care Research that employers should ensure agreement with their partners (e.g., funders, sponsors, collaborators, commercial partners, network members, integrated board etc) and employees about accountability and division of responsibilities, including arrangements for any intellectual property arising from research. Arrangements have been put into place via Trust policy OP22 which covers the ownership, exploitation and income from any IP that may arise from research.

4.1.7 All financial information about NIHR Portfolio adopted research activity, compliance with research governance, and IP will be reported by the R&D Directorate as per the DH requirements to the NIHR through the various required mechanisms such as the CRN and the Academic Health Science Network (AHSN) as appropriate.

4.1.8 The R&D Directorate will produce an Annual Report to the Trust Board to provide in-depth appraisal of all research activity and research governance undertaken by the Trust.

4.1.9 The R&D Directorate will keep a database detailing all projects registered in RWT.

4.1.10 For each research study, a senior individual will be designated as the PI who will be responsible for the conduct of the research and is accountable to RWT and Sponsor for the research at RWT. Written agreement with research partners will document the allocation of responsibilities through the Organisation Information Document (OID) and contracts.

4.1.11 Sponsor for Own Account Research

4.1.11.1 RWT will act as Sponsor for research generated within the Trust (“Own Account Research”) that does not have external sponsorship after review and agreement of each project on an individual basis.

4.1.11.2 Sponsorship responsibilities include ensuring:

- The scientific quality of the research,
- That the research has received all appropriate research body approvals,
- The research is conducted to high quality standards,
- That there are appropriate financial and non-financial resources, and
- Appropriate levels of project management, risk analysis, mentoring, monitoring and assessment.

4.1.12 RWT has a duty to investigate complaints by patients, members of the public, staff or anyone else concerning any research project conducted within RWT. RWT's PALS service will investigate complaints alongside the R&D Directorate on behalf of the Trust and report the findings to the Chief Medical Officer and Chief Nursing Officer.

4.1.13 Any employee of the Trust who suspects that research data collected within the Trust may be fraudulent or suspects misconduct during a research project must report this through the R&D Directorate and their line manager.

4.1.14 The R&D Directorate will report all incidents where an investigation has been conducted and has resulted in fraud or misconduct (as defined by the MHRA) to the sponsor who will then send a notification to the MHRA as appropriate. This report will also be sent to the R&D Governance Group for actioning. If the incident is of a financial nature or if any concerns relating to potential financial fraud or bribery are identified, the Local Counter Fraud Specialist must also be notified. The contact details can be found on the counter fraud intranet pages.

4.1.15 All researchers within RWT will familiarise themselves with the UK Policy Framework for Health and Social Care Research and must receive appropriate training in line with the R&D Directorate SOPS.

4.1.16 **Requirements for Trust Confirmation of Capacity and Capability**

All research taking place within RWT must have Confirmation of Capacity and Capability before the commencement of any research activity. The only official notification of Confirmation of Capacity and Capability will be a letter and Local Assessment Checklist signed by the R&D Directorate Manager or delegated representative to the local research team, and an email to the sponsor and copy to R&D Quality Assurance Team and Finance

where appropriate. Researchers must contact the Project Management Team within the R&D Directorate who will provide guidance on the submission in line with R&D SOPs (see Appendix 2).

4.1.17 **Requirements for Health Research Authority (HRA) approval**

All project-based research taking place in the NHS in England and Wales requires approval from the HRA. HRA approval consists of the assessment of governance and legal compliance by HRA staff, and the independent ethical opinion by a Research Ethics Committee (REC) under one application. It applies where the NHS organisation has a duty of care to participants, either as patients or service users or NHS staff and volunteers. Researchers for projects where RWT will be acting as sponsor must contact the Sponsorship Team within the R&D Directorate who will provide guidance on the submission for approval.

4.1.18 **Requirements for Research Ethics Committee (REC) Approval**

The DH requires that research involving patients, service users, care professionals or volunteers, or their organs, tissue or data is reviewed independently to ensure it meets ethical standards. For all research which falls within the remit of the Governance Arrangements for Research Ethics Committee (GafREC) paragraph 3.1, there must be review from an NHS Research Ethics Committee (REC). Researchers for projects where the Trust will be acting as sponsor must contact the Sponsorship Team within the R&D Directorate who will provide guidance on the submission for approval. Researchers for projects where the Trust will be acting as Sponsor must contact the Sponsorship Team within the R&D Directorate who will provide guidance on the submission for approval.

4.1.19 **Requirements for MHRA Approval**

Research on medicinal products which fall in the category of Clinical Trials on Investigational Medicinal Products (CTIMPS) that take place within RWT must have MHRA approval before the commencement of any research activity. Researchers for projects where RWT will be acting as sponsor must contact the Sponsorship Team within the R&D Directorate who will provide guidance on the submission for approval in line with R&D SOPs.

4.1.20 **Other Approvals**

Research may require approval or licenses from other legal bodies before the research can commence, e.g. Human Tissue Authority for the use of human tissue or Confidentiality Advisory Group for use of patient data without consent.

4.1.19 **Agreement of Responsibilities**

For all research projects, the R&D Directorate will review all agreements connected to individual projects (investigator, financial, pharmacy, indemnity and any other agreements usually contained into one template), and will be responsible for obtaining the signature of the Chief Financial Officer on each of these documents (as well as those of the investigator and Clinical Director of Pharmacy as appropriate).

4.2 Ethics

"The dignity, rights, safety and well-being of participants must be the primary consideration in any research study" (DH 2001). All research performed within RWT must be in line with the "Ethical Principles for Medical Research Involving Human Subjects" stated in the declaration of Helsinki, 1964 updated 2000, and the Human Tissue Act 1998 (WMA, HMSO, 1998).

4.2.1 All research projects performed within RWT will (where applicable in accordance with HRA requirements) have received full ethics approval before Trust confirmation is given. Evidence of full ethics, HRA approval and Trust confirmation must be available for each research study prior to any study procedures being performed on subjects.

4.2.2 All research subjects must be fully informed about the research study and be given the opportunity to ask questions, have answers provided to those questions, and have adequate time to consider participation in the research prior to giving written consent to participate, in line with the research prior to Obtaining Informed Consent for Clinical Trials (CP22 now integrated into CP06 as attachment 6) and the R&D Standard Operating Procedure. Consent must also be sought in the way agreed during the ethical review as per the approved protocol requirements. Particular attention will be given to the involvement of children, emergency consent and vulnerable adults.

4.2.3 Protection of subject data must be a priority and all researchers must be aware of their legal and ethical duties in respect to this.

4.2.4 All research must respect the diversity of human culture and conditions and take account of ethnicity, gender, disability, age and sexual orientation in its design, undertaking and reporting.

4.3 Science

4.3.1 Every protocol must be subjected to review by relevant experts who are able to offer independent advice on its quality. It is the research sponsor's responsibility to ensure adequate peer review is in place

where is proportional to the scale of the research.

4.3.2 For RWT sponsored research where the research is externally funded by a large funding body, for example from a research council or a charity, or commercial funding such as a drug company grant scheme, it is expected that peer review would have been undertaken as part of the application for funding process.

4.3.3 For RWT sponsored research that does not have funding from large funding bodies or commercially provided funding through drug company grant schemes, or if the investigators request review prior to funding applications, the R&D Directorate will arrange peer review through the Trust Research Peer Review Group.

4.3.4 For externally sponsored projects, it is the responsibility of the sponsor to arrange peer review.

4.3.5 For projects done by students, the peer review processes of the University MUST be involved prior to seeking Trust confirmation.

4.3.6 It is the responsibility of the PI to ensure sufficient support with the conduct of the research, if they believe that support is needed, in order to maintain high quality standards. The R&D Directorate will assess the level of support required and, where possible, assist with the management, training and mentorship needs for the successful delivery and completion of the research project.

4.4 Information

4.4.1 During the course of a research study, the research subjects have the right of access to the information being collected or written as described under the Data Protection Act (2018). This right can also extend at the end of the research study to a summary of the findings (positive, negative or inconclusive) in a language easily understood by the public. The protocol must describe the research dissemination strategy which addresses different media and writing styles for different audiences.

4.4.1 The R&D Directorate maintains information on all research being undertaken within the organisation. The information is available to anyone wishing to access it, on request, with the exception of projects where there is intellectual property.

4.4.2 It is the responsibility of researchers to submit research findings for publication in peer reviewed journals or to disseminate findings through presentation and other methods.

4.4.3 In order for RWT to satisfy sponsor reporting requirements, it is the responsibility of the researcher to inform the R&D Directorate of the outcome of their research, including publications and presentations of research findings, and how they have altered clinical practice.

4.4.4 Whenever possible, RWT will endeavour to involve consumers of health care in the design, conduct, analysis and reporting of research.

4.4.5 It is the responsibility of the sponsor to notify the Trust of the outcome of the study and provide code break information so the Trust can inform the patients.

4.5 Health, Safety and Employment

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

4.5.2 The handling of personal information in research must be compliant with RWT policies in relation to the General Data Protection Regulation (2016) and any data or confidentiality breaches must be reported following RWT policy.

4.5.3 RWT has a duty to ensure the security of systems used in research for data collection, storage and transfer of data.

4.5.4 All uses of identifiable patient data for research purposes and defined as personal data in line with GDPR must be reviewed by the Trust's IG team or delegate and, or a Data Protection Impact Assessment is produced in line with current SOPs for externally sponsored and Trust sponsored research.

4.5.5 The safety of research participants and research staff must be given priority at all times. Health and Safety Regulations and RWT Policies must be strictly observed during the course of research. This is particularly important if the research involves the use of potentially dangerous or harmful equipment, substances or organisms.

4.5.6 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 must hold an NHS honorary research contract or Letter of Access. It is the responsibility of the CI or PI at each site, to ensure staff have the necessary contracts or letters of access in place before the staff begin research work within RWT.

4.5.7 Indemnity Arrangements for indemnity and insurance will be in place for the protection of research subjects and staff. All research studies will have a nominated sponsor.

4.5.7.1 The Trust provides standard NHS indemnity to compensate anyone harmed by negligence by its employees. The Trust does not provide compensation for non-negligent harm.

4.5.7.2 NHS indemnity may be extended to research partners, e.g.,

academic researchers, who are not directly employed by the NHS through honorary research contracts where appropriate (i.e., where the researcher has a direct bearing on the care of RWT patients).

4.5.8 The expertise of specific support services will be sought in line with the protocol to ensure that the health and safety of participants and staff and their data are of the highest consideration. These services are Medical Physics in relation to radiation and associated clinical regulations, Pharmacy, Radiology, Pathology, Information Governance and IT Department.

4.5.9 Where a protocol requires the use of a substance or an action that may result in potential harm to researchers, the sponsor will give training and competence established before the researcher is allowed to participate.

4.5.10 The R&D Directorate will have systems put in place to assess, monitor, prevent and handle any potential health and safety issues arising from the research project. The R&D Directorate will receive and review copies of all reported Suspected Unexpected Serious Adverse Reactions (SUSARs).

4.5.11 There are legal requirements for clinical trials of investigational medicinal products (CTIMPS) regarding safety monitoring and reporting. For CTIMPS where RWT acts as sponsor, the responsibility for monitoring safety will be delegated to the CI. For multiple sites, this will be the responsibility of the CI to review safety data across all sites. This will involve review of all Serious Adverse Events (SAEs) through an established committee such as a Safety Monitoring Committee that would be set up with the help of the R&D Directorate as required. The R&D Directorate will ensure appropriate reporting procedures and timelines are met as per the legal requirements (e.g., notification to the MHRA) outlined in the R&D Safety Reporting SOPs.

4.6 Monitoring and Audit of Research

Organisations and individuals involved in research are expected to be able to demonstrate compliance with the UK Policy Framework for Health and Social Care Research and the requirements in legislation and regulations described within the framework.

It is also a statutory requirement that clinical trials involving medicinal products (CTIMP) are conducted in accordance with the principles of Good Clinical Practice (GCP). 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 to GCP provides assurance that the rights, safety and well-being of trial subjects are protected and that the results of clinical trial are credible and accurate.

Working to 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.

For externally sponsored research, it would be expected that the external sponsor would conduct and monitor the study in accordance with GCP guidelines.

If RWT acts as Research Sponsor for a study, then the Trust will conduct and monitor the study in accordance with GCP guidelines. The roles and responsibilities of the sponsor and CI will be outlined in the Investigator's Responsibilities Form which forms part of the Sponsorship approval process.

The R&D Directorate will also conduct audits to assess adherence to study Protocols, Trust Policies, and R&D Standard Operating Procedures to assure reliability of the Quality Control Systems.

4.7 Finance and Intellectual property

4.7.1 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.

4.7.2 When considering issuing Trust confirmation of capacity and capability for a research project, the R&D Directorate must be able to satisfy itself that all costs for research are fully covered. The R&D Directorate will only give confirmation for the research study once the study has been costed appropriately taking into account the Attributing the Costs of Health & Social Care Research & Development (AcoRD), and adequate sources of funding and other resources have been secured.

For Trust sponsored research, the R&D Directorate must be able to satisfy itself that all costs for research are fully covered. For research which has received grant funding, the Trust, through the R&D Directorate will be the grant holder and manage the grant funding.

4.7.3 NHS Guidance, HSG(97)32 is clear that funding for commercially contracted research (funded and sponsored by a commercial company) must cover the full costs incurred, including appropriate Trust overheads. For all commercial research within the Trust there will also be a non-refundable R&D fee and other support service fees, where applicable.

4.7.4 The R&D Directorate will keep detailed financial information on all projects relating to remuneration and expenditure linked to studies and participants. This information will support the corporate overview of the R&D financial activity within corporate financial systems.

4.7.5 The Trust R&D Management Accountant will have access to view and report from the R&D Directorate Financial Management systems and internal audits will be undertaken periodically to ensure robust financial accountability.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the implementation revenue resources of this policy require additional	No
3	Does the implementation of this policy require additional manpower	No
4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments	

6.0 Equality Impact Assessment

The initial screening of this policy has not identified any adverse/negative impact and therefore a full equality analysis is not required. The completed general screening proforma has been submitted.

7.0 Maintenance

It is the responsibility of the R&D Director and R&D Directorate Manager to ensure that the policy and procedures are implemented. The R&D Governance Group will recommend any changes/amendments and updates.

8.0 Communication and Training

8.1 Directors and Managers are responsible for ensuring that all staff involved in research are made aware of this policy. Staff with specific roles relating to this policy will have appropriate training through the R&D Directorate.

8.2 Research undertaken in the Trust is the responsibility of the PI. The PI is accountable for each member of their team who must be qualified by education, training and experience for their delegated role.

8.3 The R&D Directorate will ensure that all researchers have received the mandatory research training before commencing research in the Trust as per the statutory requirements and R&D Standard Operating Procedures. Upon completion, the researcher will receive a certificate of attendance which lasts for a specific period of time. Refresher training will be required when this time lapses.

8.4 A database will be maintained by the R&D Directorate of all

researchers trained.

9.0 Audit Process

The R&D Governance team will submit to the R&D Management Group an annual audit plan to ensure assurance and compliance to this policy and the associated standard operating procedures.

Criterion	Lead	Monitoring method	Frequency	Committee / Group
All research to comply with Good Clinical Practice principles	Quality Assurance Manager	Audits of selected active research studies	6 monthly	R&D Governance Group
All Trust sponsored research to be risk assessed prior to approval	Quality Assurance Manager / Project Manager (Trust Sponsored Studies)	Risk Assessment reviews	As required	R&D Governance Group
Incidents reported against R&D activity to be reported appropriately	Quality Assurance Manager	Serious Adverse Event reports/Datix/ Governance Reports	Monthly	R&D Governance Group
All research active staff to have received the appropriate training for their role	Quality Assurance Manager	Training reports	Monthly	R&D Governance Group

10.0 References - Legal, professional or national guidelines

- UK Policy Framework for Health and Social Care Research (UK Health Departments and HRA, 2020): UK Policy Framework for Health and Social Care Research - Health Research Authority (hra.nhs.uk)
- Governance Arrangements for Research Ethics Committees (GafREC) (DH, 2012): https://www.gov.uk/government/publications/health-research-ethics-committees-governance-arrangements
- Declaration of Helsinki (World Medical Association,1964 updated 2000) WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association
- CP06 Attachment 6 (previously CP22) http://intranet.xrwh.nhs.uk/pdf/policies/CP_06_Policy.pdf

Part A - Document Control

Policy number and Policy version: OP30 Version 3.0	**Policy Title** **Research Governance Policy**	**Status:** Final		**Author: R&D Directorate Manager** **Chief Officer Sponsor: Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1.0	01/1998	Y Hague	New Policy
	2.0	11/2014	S Glover	Policy Review following Internal and National Infrastructure change
	2.1	03/2019	S Glover	Policy Review and update
	2.2	02/2022	S Glover	Reviewed by Chief Medical Officer extended to June 2022 – Pending full review
	2.3	08/2022	S Glover	Reviewed by Chief Medical Officer extended to November 2022 – Pending full review
	3.0	October 2022	S Glover	Full review of policy
Intended Recipients: All Trust staff				
Consultation Group / Role Titles and Date: R&D Governance Group 31st August 2022.				
Name and date of Trust level group where reviewed	Trust Policy Group – October 2022			
Name and date of final approval committee	Trust Management Committee – October 2022			
Date of Policy issue	November 2022			

Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	October 2025 every 3 years
Training and Dissemination: to all staff via intranet and available via internet	
Publishing Requirements: Can this document be published on the Trust's public page: **Yes** If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.	
To be read in conjunction with: R&D SOPS, UK Policy Framework for Health and Social Care, CP06 Appendix 6	
Initial Equality Impact Assessment (all policies): Completed Yes **Completed Yes** If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	R&D Governance Group to receive reports.
Document summary/key issues covered. The Royal Wolverhampton NHS Trust (the 'Trust') acknowledges the importance of research to the successful promotion and protection of health and wellbeing. It must be noted that 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. To minimise and prevent such risks a robust governance policy for the management and conduct of research is required. Research Governance comprises the systems that have been developed to provide the regulation of research and the way it is conducted in the health and social care settings thus ensuring maintenance of research quality and providing safeguards to the public	
Key words for intranet searching purposes	Research, clinical trial, governance, quality
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**No (delete as appropriate)**

Part B **Ratification Assurance Statement**

Name of document: OP30 Research Governance Policy

Name of author: Sarah Glover Job Title: R&D Directorate Manager

I, the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: *Sarah Glover*

Date: 08/09/2022

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number OP30 and policy version3.1	**Policy Title Research Governance Policy**	
Reviewing Group	Trust Policy Group	**Date reviewed: October 2022**
Implementation lead: Sarah Glover sarah.glover7@nhs.net		
Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	N/A	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	N/A	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	To all staff via Trustnet and R&D specific pages	Within 1 month of approval.
Financial cost implementation Consider Business case development	N/A	
Other specific Policy issues / actions as required **e.g. Risks of failure to implement, gaps or barriers to implementation**		

Appendix 1

R&D Directorate Governance Group

Terms of Reference

Key Purposes

- To review all internal and external information relevant to the governance responsibilities of the Directorate, Trust's Governance Strategy, Research Governance Policy and Clinical Trial Regulations.
- To consider any issues of non-compliance against internal and external Governance standards and Key Performance Indicators, and devise and monitor action plans to address these.
- To monitor the effectiveness of Risk Management process within the directorate, with the ultimate aim of improving safety for both patients and staff.;
- To identify lessons learned from Governance activities and consider these for wider disseminations if appropriate.
- To provide a two-way channel for the dissemination of Governance information at all levels within the Trust (for example new and/or amended policies).
- To provide assurance reports as required to divisional/ Trust level committees, thereby demonstrating robust accountability arrangements for Governance within the directorate in the management of their operational risks.

Overall KPI

- To identify, prevent and manage all clinical and non-clinical risks in order to ensure that all risks are minimised.

Membership

R&D Directorate Manager

R&D Quality Assurance Manager

R&D Lead Research Nurse

R&D Project Manager

Trust Governance Officer (Quarterly)

Other staff may be co-opted for specific agenda items or projects

Quorum

- The R&D Quality Assurance Manager plus either the R&D Directorate Manager or R&D Lead Research Nurse must be present for the meeting, plus 1 other group member of the membership for the meeting to be declared quorate.

Frequency

- Meetings will be held monthly with a minimum of 10 meetings per year.

Appendix 2

R&D Standard Operating Policy Directory

All Research & Development Standard Operating Policies can be found by clicking on the following link Standard Operating Procedures (xrwh.nhs.uk)	Standard Operating Title
R&D S01	Preparation, Review and Title of Standard Operating Procedures for Research
R&D S02	Application for Sponsorship of CTIMP's
R&D S03	Delegation of roles and responsibilities
R&D S04	Notification of Serious Breach of GCP or Trial Protocol
R&D S05	Research Related Adverse Event Reporting Procedure
R&D S06	Safety Reporting
R&D S08	Monitoring of Research Studies
R&D S09	Set up and Management of Research Project
R&D S10	Obtaining Consent in Research Study
R&D S11	Archiving of Essential Documentation
R&D S12	Research Training
R&D S16	Research Study Risk Assessment
R&D S17	Research Study Close-out
R&D S18	Clinical Trial External Visits
R&D S19	MHRA Inspection Procedures
R&D S20	Medical Cover for Clinical Trials
R&D S21	Trial Data Management
R&D S22	End of Study Reports
R&D S24	Contracts
R&D S27	Trust (R&D) Approval Submission
R&D S28	Registration, Maintenance and Calibration of Research Equipment
R&D S30	Dry Ice
R&D S36	Information Governance Risk Assessment
R&D S37	Trust Research Peer Review Group
R&D S38	Reviewing Proposals for Classification
R&D S40	Management of Protocol Deviations and Violations
R&D S42	Obtaining a Unique Protocol Number
R&D S43	Registration of Study on Public Database
R&D S44	R&D Study Audits
R&D S46	RWT Assessment, Arrangement and Confirmation of a Research Study
R&D S47	Taxi Bookings for Research
R&D S48	Research Study Patient Experience
R&D S49	Sponsorship of Amendments
R&D S50	Case Report Form (CRF) Design
R&D S51	End of Studies Activities

Appendix 3

Glossary:

ABPI	Association of the British Pharmaceutical Industry
ADR	Adverse Drug Reaction (also known as AR)
AE	Adverse Event
AHSN	Academic Health Science Network
Amendment	A change to the current protocol
AMRC	Association of Medical Research Charities
AR	Adverse Reaction (also known as ADR)
ARSAC	Administration of Radioactive Substances Advisory Committee
ASR	Annual Safety Report
ATMP	Advance Therapy Medicinal Products
BRC	Biomedical Research Centre
BRU	Biomedical Research Unit
C/O	Complains of
CA	Competent Authority
CC	Coordinating Centre
CAG	Confidentiality Advisory Group
CCRN	Comprehensive Clinical Research Network
CCG	Clinical Commissioning Group
CF	Consent Form (also ISF, Informed Consent Form)
CFR	Code of Federal Regulations (US)
CI (i)	Chief Investigator
CI (ii)	Coordinating Investigator
CLRN	Comprehensive Local Research Network
CRA	Clinical Research Associate
CRF (i)	Case Report Forms
CRF (ii)	Clinical Research Facility
CRN	Clinical Research Network
CRO	Clinical Research Organisation or Contract Research Organisation
CSAG	Clinical Studies Advisory Group
CSG	Clinical Studies Group
CTA (i)	Clinical Trials Administrator
CTA (ii)	Clinical Trials Agreement
CTA (iii)	Clinical Trials Associate (similar to CRA)
CTA (iv)	Clinical Trials Authorisation
CTAAC	Clinical Trials Advisory and Award Committee
CTD	Clinical Trial Document
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
CV	Curriculum Vitae
DeNDRoN	Dementias and Neurodegenerative Diseases Research Network
DH	Department of Health (for England)
DIPEx	Database of Individual Patient Experience
DNA	Did not attend
DPA	Data Protection Act
DQ	Data Query
DRN	Diabetes Research Network
DSMB	Data and Safety Monitoring Board
ECMC	Experimental Cancer Medicine Centre
EM	Experimental Medicine
EMA	The European Medicines Agency

EU	European Union
EudraCT	European Clinical Trials Database
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
GAfREC	Governance Arrangements for Research Ethics Committee
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GTAC	Gene Therapy Advisory Committee
HEI	Higher Education Institution
HFEA	Human Fertilisation and Embryological Authority
HRA	Health Research Authority
HRC	Honorary Research Contract
HTA	Human Tissue Act or Human Tissue Authority
HTA	Health Technology Assessment
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH/GCP	international Conference on Harmonisation of Good Clinical Research
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product
IND	Investigational New Drug: sometimes used instead of IMP
Indemnity	Compensation for damage loss or injury
Investigator	Researcher conducting the (clinical) study (CI/PI)
IP	Intellectual Property
IRAS	Integrated Research Application System
IRB	Independent Review Boards
IRMER	Ionising Radiation Medical Exposure Regulations
ISF	Investigator Site File
ISRCTN	International Standard Randomised Control Trial Number
LPMS	Local Project Management System
LRN	Local Research Network
MCA	Mental Capacity Act
mCIA	model Clinical Investigation Agreement
MCRN	Medicines for Children Research Network
mCTA	model Clinical Trial Agreement
MfHTU (CT)	Medicines for Human Use (clinical Trials) Regulations
MHRA	Medicines and Healthcare products Regulatory Agency
MHRN	Mental Health Research Network
mNCA	model Non-Commercial Agreement
MRC	Medical Research Council
NCRN	National Cancer Research Network
ND	Not done
NHS	National Health Service
NHSI	NHS Improvement
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NIHR CRN CC	National Institute for Health Research Clinical Research Network Coordinating Centre
NIHR IS	National Institute of Health Research Information Systems
NIMP (non-IMP)	Non-Investigational Medicinal Product
NK	Not Known
NOCRI	National Office for Clinical Research Infrastructure
OSCHR	The Office for Strategic Coordination of Health Research (UK wide)
PCF	Patient/Participant Consent Form

PCRN	Primary Care Research Network
PI	Principle Investigator
PIAG	Patient Information Advisory Group (now NIGB)
PIC	Participant Identification Centre
PIS	Participant or Patient Information Sheet
PID	Patient Identifiable Data
PM	Project Management
PPI	Patient and Public Involvement
QA	Quality Assurance
QC	Quality Control
QLQ	Quality of Life Questionnaire
R&D	Research and Development
RCT	Randomised Controlled Trial
RDS	Research Design Service
REC	Research Ethics Committee
RfPB	Research for Patient Benefit
RGF	Research Governance Framework
RM&G	Research Management and Governance
RN	Research Nurse
RWT	The Royal Wolverhampton NHS Trust
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
Serious-ADR	Serious Adverse Drug Reaction
SI (i)	Statutory Instruments
SI (ii)	Sub-Investigator
Site	RWT
SLA	Service Level Agreement
SMO	Site Management Organisation
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SRN	Stroke Research Network
SUSAR	Suspected Unexpected Serious Adverse Reaction
TCRN	Topic specific Clinical Research Network
TMF	Trial Master File
Trust	The Royal Wolverhampton NHS Trust
UKCRC	United Kingdom Clinical Research Collaboration
WHO	World Health Organisation
WMA	World Medical Association