Queen Victoria Hospital NHS
NHS Foundation Trust

CODE OF PRACTICE FOR RESEARCHERS

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DISTRIBUTION	NHS Employees and Honorary Contract holders at QVH NHS Foundation Trust, who are involved in R&D
RELATED POLICIES	
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EQUALITY IMPACT ASSESSMENT	091116-2
THIS DOCUMENT REPLACES	CP.2019.3

1. Introduction

This policy sets out standards of work and ethical conduct expected of those employees engaged in research work at the Trust.

2. Scope

The code is effective for any research involving human participants, whether as NHS patients or relatives of patients, healthy volunteers, or members of staff. It includes children, and their parents or carers. It applies whether the research requires direct contact, or the use of tissue, organ or fluid samples, whether taken specifically for research, stored from previous studies, or surplus to clinical requirements, or access to confidential information.

The code supplements other general codes of practice or good practice guidelines for research issued by the Trust.

3. Duties

Employees must familiarise themselves with the provisions of the code and ensure that it is observed.

Employees must follow the policies on research of the Trust and of any other educational or health care institution in which they work.

Employees wishing to conduct research at the Trust can find further information on the Research and Development section of the Trust Intranet and in the first instance contact the R&D manager.

4. 4.1 Guidance

Researchers must make themselves familiar with the latest version of the Declaration of Helsinki[1] and all subsequent revisions. They should keep abreast of developments in the Department of Health's Research Governance Framework[2] that sets out roles and responsibilities for different parties involved in research.

Good practice guidance is available from a variety of sources, for example the Medical Research Council[3], the General Medical Council[4] and the royal medical colleges.

4.2 Principles

Researchers must work within their own competencies, based on knowledge, experience and expertise. If any aspect of the work is delegated you must ensure that the person to whom it is delegated has the competence to carry it out.

All research must meet ethical standards and ensure that the dignity, rights, safety and well being of participants are given priority at all times.

Researchers must take steps to ensure that their research does not unnecessarily duplicate research previously carried out elsewhere.

Every effort must be made to ensure that the results of research are published or disseminated in other ways. Details of the data, methods of collection and analysis, and the outcomes must be open to external scrutiny. Publication details must be passed to the R&D Department.

4.3 Principal Investigator

For each piece of research there should be designated a Principal Investigator who is responsible for the overall conduct of the research. Usually, this should be a consultant level individual.

4.4 Approval

Researchers must seek all necessary approvals before they can start their research, including (but not limited to) Trust Approval, Ethical Approval, HRA Approval and MHRA Approval as appropriate. Researchers should contact the Research and Development Department to confirm what approvals are necessary.

4.5 Ethics

All research involving human participants must be assessed by an appropriate research ethics committee. If the study involves patients of the NHS, their relatives, or resources of the NHS, then the study must be submitted to an NHS-based Research Ethics Committee. Generic ethics approval, which broadly covers the use of discarded tissue for improving wound healing and surgical techniques, is in place at the Trust. However, Trust R&D approval must still be sought before undertaking any such projects to ensure that the project is within the remit of the existing generic ethics approval.

When applying for Research Ethics Approval researchers must follow the guidance issued by the National Research Ethics Service (NRES)[5], and use the national online IRAS application system found at myresearchproject.org.uk.

Ethics approval generally applies to specific, individual projects rather than to a type of activity or broad programme of research. It will normally be time-limited and must be renewed if the research is to continue after the expiry of the approval.

Certain types of research have specific procedures which must be observed. These include the following, amongst others:

A. Gene Therapies and Stem Cell Therapies

If the research involves the production or use of genetically modified organisms then strict national regulations apply. In particular, all gene therapy proposals must be submitted and approved by the MHRA, national Gene Therapy Advisory Committee (GTAC), and by a local Genetic Modification Safety Committee in the organisation where the research will be carried out. HTA approval is also required for procuring cells and tissue.

B. Fetal Tissue The law does not distinguish between fetal tissue and other tissue from the living; fetal tissue is regarded as the mother's tissue. Consequently, fetal tissue is subject to the same consent requirements under the HT Act as all other tissue from the living. However, because of the sensitivity attached to this subject, it is good practice to always obtain consent for the examination of fetal tissue and for its storage or use for all scheduled purposes. It is also good practice to obtain consent

for research on non-fetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is non-identifiable. It should be noted that the reference to fetal tissue within the relevant HTA code of practice does not include stillbirths (babies born dead after 24 weeks gestation), or neonatal deaths (babies or fetuses of any gestational age which are born showing signs of life and die before the age of 28 days). Obtaining consent for the removal, storage or use of the tissue of babies from stillbirths or neonatal deaths should be handled in accordance with provisions for gaining consent for use of the tissue of the deceased. It is recommended that, whenever possible, the consent process for the examination of stillbirths and neonatal deaths involves the mother, and that, where appropriate, both parents are involved.

It is recognised that, in the absence of specific legal requirements, guidance on the use of fetuses and fetal tissue for research has been derived from the 1989 Review of the Guidance on the Research Use of Fetuses and Fetal Material, also known as the Polkinghorne Guidelines. A number of aspects of the Polkinghorne Guidelines are outside the remit of the HTA. However, it should be noted that guidance within the Polkinghorne guidelines which recommended that in the context of giving consent, women should not know the purpose for which the fetus would be used, or whether it would be used at all, is now superseded by HTA guidance on valid consent, which must be based on the person's understanding of what the activity. For guidance on the disposal of fetal tissue, and burial or cremation of stillbirths and neonatal deaths, see the HTA code of practice on Disposal of human tissue.

C. Xenotransplantation

If the research involves xenotransplantation, then specific approval must be sought from the appropriate Ethics committee.

D. *Animal Studies*

If the research involves animal work appropriate licenses from the Home Office should be obtained, and Home Office guidance adhered to.

4.5 Clinical Trials

Researchers working on clinical trials must work to ICH-GCP guidelines, under the Medicines for Human Use (Clinical Trials) Regulations 2004 [13]. They must undertake formal GCP training. The NIHR currently provides free guidance and training in GCP and the taking of consent. For more information, see: https://www.crn.nihr.ac.uk/learning-development/good-clinical-practice/

4.6 Consent and Confidentiality

Consent must be obtained from anyone invited to take part in a research project. This includes children, and their parents or carers. This must be based on a knowledge and understanding of the risks, benefits and alternatives of taking part.

Unless agreed otherwise by an Ethics Committee, consent should be explicit and written. The consent process will be initially scrutinised by the Trust R&D Governance Committee, by examining the relevant Patient Information Sheet and Consent Form.

Information obtained from patients in the course of providing healthcare is

confidential. Researchers must abide by the Data Protection Act and respect the common law duty of confidence.

Research data and samples must be anonymised if they are to be passed to anyone not bound by a duty of confidence (generally anyone not employed by the Queen Victoria Hospital NHS Trust or not holding an honorary contract), unless explicit consent has been given by the patient. Human tissue samples must not be passed to anyone outside of QVH unless a Material Transfer Agreement has been signed (forms are available from the Trust DI). A formal request must be sent to the Trust R&D Governance Committee and valid Ethics approval must be in place. The Trust DI must be informed of all tissue transfers and all tissue being distributed must be recorded by the Trust DI in compliance with the Trust Tissue Bank Ethics Approval

4.7 Use of human tissue, organs, fluids, tissue blocks and histology slides

It is good practice to obtain consent to procure and use discarded tissue for research projects even if the tissue samples are to be anonymised. Patients can consent to their discarded tissue being used when they complete the relevant section of the Trust Consent to Investigation or Treatment Form. Researchers using human tissue under the Trust generic ethics approval must complete a form available from the Trust's Designated Individual, who is responsible for overseeing the use of human tissue, organs, fluids, tissue blocks and histology slides in research, detailing the project the tissue is to be used for. This must be submitted to the Trust R&D Governance Group for approval.

If the project is approved, details for each consented sample, including confirmation of consent, hospital V number, donor date of birth, date of donation, sex and tissue type must be recorded and given to the Trust DI.

Discarded tissue regularly collected during surgery may be sent to the Blond McIndoe Research Foundation. The tissue should be supplied with the following details for each sample; confirmation of consent, hospital V number, donor date of birth, date of donation, sex and tissue type. This information will be recorded by the Trust DI and will form part of an annual report to the Ethics committees which oversees the Trust Research Tissue Bank Approval. Stickers to accompany the tissue samples are available in theatres.

Researchers who wish to use ocular tissue from deceased donors, supplied through the Eye Bank must, for each sample complete the relevant tissue use form supplied by the Trust DI

Outside the Trust Generic Ethics approval human tissue, organs, fluids, tissue blocks and histology slides can only be used for research if the research has been approved by an NHS Research Ethics Committee. Consent would normally be required from the person from whom the sample has been taken unless the Ethics Committee determines otherwise. Reference should be made to the latest GMC and HTA guidance[7].

For tissue, organs, fluids, tissue blocks and histology slides that have previously been stored and archived, if patient details are to be used as part of the research, the sample can only be used for the purpose originally consented by the donor, otherwise further consent is required.

If this is not possible then the sample may be used for research provided that the project has been approved by an NHS Research Ethics Committee and the sample is anonymised to the researcher. There may be occasions when a clinician involved in research may also have access to a secure database that would permit identification of a sample used in research and the identity of the patient whose material is being used. Providing the research material is not identifiable to the researcher (e.g. coded by a laboratory accession number) and the researcher does not seek to link the sample to the patient, it will still be regarded as non-identifiable and the research will be permissible without consent if approved by a recognised research ethics committee.

4.8 Authorship

Researchers should abide by the Vancouver Guidelines[8] for authorship in publications.

'Gift' authorship will be treated as misconduct and be dealt with under the procedures for Fraud and Misconduct in Research.

4.9 Monitoring of research

The Trust R&D Department will monitor studies Sponsored by the hospital, in accordance with the Research Governance Framework, and the relevant Clinical Trials legislation. Researchers must cooperate with any authorised audits of their research, whether undertaken by the Trust, external funder or sponsor, or regulatory authority.

4.10 Progress Reporting

Researchers will be required to provide six-monthly reports of progress with the research via the Trust R&D Department to the R&D Governance Group.

4.11 Scientific Misconduct

Researchers must abide by the policy of the Trust on fraud and misconduct in research[10]. All employees have a duty to report examples and suspicions of misconduct. Allegations of misconduct will be dealt with by the employer concerned even if the allegation relates to work undertaken under the terms of an honorary contract with another organisation.

Researchers must collaborate with any properly constituted investigation of misconduct. Researchers must abide by the policies of the Trust on all other forms of misconduct[11].

Registered Medical Practitioners who are found to have committed serious research misconduct will be reported to the General Medical Council under its Fitness to Practice Procedures.

4.12 Intellectual Property

Researchers must adhere to the Trust policy on Intellectual Property[12].

4.13 External Funding

External funding will be subject to the terms of the Trust's external funding policy (see appendix 1).

5 Training and Awareness

All staff contacting the R&D manager and wishing to conduct research at the Trust will be provided with a copy of this policy. Training for consent for which includes treatment, screening for contagious diseases and the use of discarded tissue will be provided at the doctors' induction. Any specific requirements for consent training involving patients taking part in clinical trials will be specified on a project by project basis by the R&D Governance Group. The persons responsible for taking consent will usually be specified on the individual ethics applications.

6 Equality

The Trust recognises the diversity of the local community and those in its employ. Our aim is, therefore, to provide a safe environment free from discrimination and a place where all individuals are treated fairly, with dignity and appropriately to their need. The Trust recognises that equality impacts on all aspects of its day to day operations and has produced an Equality Policy Statement to reflect this. All policies and procedures are assessed in accordance with the equality impact assessment tool, the results of which are monitored by the Equality and Diversity Group.

7 Data Protection

The Data Protection Act 1998 protects personal data which includes information about staff, patients and carers. The NHS relies on maintaining the confidentiality and integrity of its data to maintain the trust of the community. Unlawful or unfair processing of personal data may result in the Trust being in breach of its data protection obligations.

8 Records Management

Records are created or received in the conduct of the business activities of the Trust and provide evidence and information about these activities. All records are also corporate assets as they hold the corporate knowledge about the Trust. The Trust has a Records Management Policy for dealing with records management. Compliance with and the application of this policy will ensure that the Trust's records are complete, accurate, and provide evidence of and information about the Trust's activities for as long as is required.

9 Review

This policy will be reviewed in three years' time. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

10 Monitoring of policy

All new staff will be made aware of this policy at induction. It will be monitored by the R & D Department, as appropriate, as part of the general monitoring of all research studies Sponsored by the Trust.

11 Discipline

Breaches of this policy will be investigated and may result in the matter being treated as a disciplinary offence under the Trust's disciplinary procedure.

12 References

1 The Declaration of Helsinki, www.ftp.cc.ic.ac.uk/pub/depts/neuropat/HS/humtis10.htm
2 The Research Governance Framework for Health and Social Care (second edition), 2005, www.doh.gov.uk
3 Medical Research Council, www.mrc.ac.uk
4 General Medical Council, www.gmc-uk.org
5 NRES, www.nres.npsa.nhs.uk
6 Advisory Committee on Genetic Testing (ACGT) (Polkinghorne Committee), www.doh.gov.uk/genetics/acgt/publications
7 General Medical Council, Good Practice in Medical Research, Jan 2002, www.gmc-uk.org
8 HTA (The Human Tissue Authority - www.**hta**.gov.uk)
9 The International Committee of Medical Journal Editors of over 400 journals (the 'Vancouver Group') New England Journal of Medicine (1991:324; 424428)
10 QVH Policy for Misconduct and Fraud in Research, version 4
11 QVH Disciplinary Procedure; QVH Drug and Alcohol Abuse Policy
12 QVH Policy for the management of intellectual property arising from research and development, version 3
13 http://www.opsi.gov.uk/si/si2004/20041031.htm

Appendix 1

TREATMENT OF EXTERNAL FUNDING FOR RESEARCH

1 **Duties**

The R&D Dept will draw up and negotiate Clinical Trial Agreements (CTAs) and other research contracts on behalf of the Trust. The Finance Dept will review all CTAs and other research contracts to ensure costings are accurate and overheads are appropriate. The R&D Governance Group (which includes a representative from Finance) will review the financial aspects of a new research project as part of its standard review procedures.

2. **Income**

Where external funding awarded allows for overheads, the Trust will charge 30%. This is to cover the cost of Estates and all corporate services such as Finance, HR, R&D, Library and IT. This percentage will be adjusted if grant guidelines only permit a lower level. It is accepted that not all grant awards make an allowance for overheads, and where researchers can demonstrate that research support costs or overheads are not permitted in bids, the Trust will not charge overheads.

Overhead will be calculated at the rate of 30% of the total cost of all research salaries involved in the award (including on-costs but not salary overheads), and on clinical services such as X-ray and pharmacy. Overheads will not be charged on costs such as consumables or patient transport.

3. **Costing of Research Funding Bids**

Researchers should seek the assistance of the research accountant and R&D Manager when putting together research funding bids. The research accountant will then ensure that the bid includes an element for research support costs or overheads where permitted. The Trust will use the standard NHS costings template for commercial research, where appropriate.

4. **Accounting**

All research income and expenditure must be posted to a research budget. Transactions relating to self-funded projects will be posted to named Research Project budgets. All other transactions will be posted to the Research infrastructure budget. Research transactions which initially fall into departmental budgets will be recharged to the appropriate research budget. All transactions must be subject to normal Trust financial procedures and authorised by the Research budget manager or a delegated authority where appropriate.

5.

Charitable Trust Funds

Donations to charitable trust funds are not covered by this policy.

QVH screening tool to inform a full Equality Impact Assessment (EqIA)

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Disability	No	
	• Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so, can the impact be avoided?**		
6.	**What alternatives are there to achieving the policy/guidance without the impact?**		
7.	**Can we reduce the impact by taking different action?**		

If you have answered yes to questions 1-4 and/or identified a potential discriminatory impact of this service or policy, please **conduct a full equality impact assessment (located within the Corporate Policy folder on intranet)** and refer to the Equality & Diversity Manager.
For guidance in answering the above questions or for the full impact assessment, please contact the Trust Equality & Diversity Manager.