Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Conducting Research and Development Operational Policy

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1. Introduction

All research in the NHS must be conducted according to the standards of the Department of Health's Research Governance Framework for Health and Social Care 2nd Edition 2005, (the framework) and other applicable legislation. Everyone involved in undertaking research involving service users, staff, human tissue or data is responsible for knowing and following the principles of good practice relating to ethics, science, information, health & safety and finance as set out in the framework.

2. Purpose of this Operational Policy

This policy sets out the procedures that should be followed when conducting any research and development (R&D) within Avon and Wiltshire Mental Health Partnership NHS Trust (the Trust). It refers to the guidelines that should be followed (Peer review guidelines and monitoring guidelines). The policy has been developed to ensure that all Clinicians and Researchers, and the Trust itself conform to the requirements of Research Governance, Research Ethics and regulatory requirements.

3. Scope

This Policy applies to all research being undertaken within AWP, research undertaken by AWP staff and research requiring access to Trust premises or sites, service users, carers, clinical or Trust data, staff, human tissue or organs, however funded, and to all Trust staff and students.

In summary, Research and Development is working to address a specific question:

- To explore new ideas/hypotheses;
- To develop new services/treatments;
- To determine whether service/treatment is effective;
- To determine how best to deliver service/treatment;
- To determine acceptability of service/treatment.

It includes work that:

- Is externally funded by non-commercial or commercial R&D funders;
- Is sponsored by non-commercial R&D funders independent from the Trust (including Medical Research Council, NHS R&D and Department of Health);
- Is sponsored by the Trust and without external research funding;
- Uses qualitative or quantitative methodology;
- Involves a chief investigator or principal investigator who is a staff member of the Trust, or external to the Trust.

Research being undertaken for undergraduate or postgraduate qualifications also falls under the remit of this policy, though it will be the responsibility of the appropriate University to ensure sufficient scientific quality.

For all the above classes of research, the procedures outlined in the remainder of this Policy should be followed.

4. Research Protocol

Research which is poorly designed is regarded as being unethical, and is also not the best use of staff/clients' time. Therefore, researchers should get advice on methodology at an early stage (and before submission to the Health Research Authority) from the Trust R&D Office and/or the Research Design Service for studies submitting to NIHR.

Researchers should undertake a literature review in the area of research being proposed, to ensure that the work does not unnecessarily duplicate existing work. Similarly, researchers should explore available research registers, and appropriate Clinical Trial Registers (such as the Medical Research Council and National Clinical Trials Database) to ensure the proposed research is not being conducted elsewhere already.

Service users and/or carers should be involved in the research throughout the study, including the design, data collection and analysis stages.

Research shall be submitted to the Trust's Research and Development Office for review and approval of scientific methodology and relevance to the Trust, according to the agreed process, prior to submission to the Health Research Authority. The Trust will assess the proposed research and make a decision on whether the research can proceed, where appropriate making recommendations on research methodology and design.

For externally funded research (both non-commercially and commercially funded) and research which has an external Sponsor, this review will not be an additional hurdle to studies which have already been subject to independent review (by recognised 'partner organisations' of the NHS). It will not unnecessarily duplicate any scientific review undertaken by other outside funding agencies during the process of the grant being awarded. However, final Trust permissions, following a Favourable Ethical Opinion (where appropriate) must still be obtained.

Further information and guidance on the Trust's peer review is available in the Trust Research and Development Peer Review Guidance Notes.

5. Ethical Review

The NHS Research Ethics Committee's (REC) "favourable opinion" is required for all research, as set out in the Governance Arrangements for Research Ethics Committees – A Harmonised Edition (GAfREC; updated April 2012):

- Potential research participants identified from, or because of, their past or present use of the services listed above (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls;
- Potential research participants identified because of their status as relatives or carers of past or present users of these services;
- Collection of tissue (i.e. any material consisting of or including human cells) or information from users of these services; or
- Use of previously collected tissue or information from which individual past or present users of these services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available,
- Xenotransplantation (i.e. putting living cells, tissue or organs from animals into people), which, as a matter of Government policy, is recommended to take place in a controlled research context, carried out with a research protocol approved by a REC within the UK Health Departments' Research Ethics Service;
- Health-related research involving prisoners, for which the National Offender Management Service, Scottish Prison Service and Northern Ireland Prison Service require review by a REC as well as compliance with their own approval procedures; and
- Social care research projects funded by the Department of Health, which must always be reviewed by a REC within the Research Ethics Service for England.

5.1 Exceptions

This document does not apply in England and Wales if research proposals are reviewed by a committee operating in accordance with the Economic and Social Research Council's Framework for Research Ethics, unless:

- The research involves withdrawing standard care; or
- The research involves NHS patients or service users as research participants
- (see paragraph 2.3.2); or
- The research is a social care research project funded by the Department of Health; or
- There is a legal requirement for review by a REC

With these conditions, the Framework for Research Ethics sets out principles, requirements and standards for review by university committees that are compatible with those set out in this document.

This document does not apply to research reviewed by the Ministry of Defence Research Ethics Committee (MoDREC). Where research approved by MoDREC continues within the services for which the UK Health Departments are responsible following transfer of participants into their care, it does not then require separate REC review under this document. MoDREC operates to standards set out separately by the Ministry of Defence which are compatible with those in this document.

REC review is not required for research anywhere in the UK involving previously collected material consisting of or including human cells except where it is required by law, or where the research also involves use of identifiable information about patients or service users, or where consent for research has not been given by the donors or the research is outside the terms of consent for research, or using anonymous material with due consent presents no outstanding issues of research ethics.

REC review is not required for research involving human biological material not consisting of or including cells, except where it is required by law, or where the research also involves use of identifiable information about patients or service users.

Studies involving NHS Staff recruited by virtue of their professional role do not need an NHS REC ethical review unless there is a legal requirement to do so – e.g. carried out under the Mental Health Act.

Healthcare market research may be undertaken in accordance with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), except where otherwise required by law, e.g. if it requires approval under the Mental Capacity Act.

These lists have been taken from the current version of GAfREC, but they are not exhaustive. Where there is doubt, reference should be made to the full document.

From 31 March 2016, HRA Approval is the process for applying for approvals for all study-based research in the NHS led from England. Applications for Ethical Review are made to the Health Research Authority via the IRAS System, and can be accessed at the following links:

- http://www.hra.nhs.uk/ (HRA)
- https://www.myresearchproject.org.uk/ (IRAS)

Advice about completing applications can be obtained from the HRA website.

All relevant legislation and guidance such as the UK Medicines for Human Use (clinical trials) regulations, Good Clinical Practice in Clinical Trials, the Medical Research Council guidance on the use of Personal Information in Medical Research, Data Protection Laws, Human Rights Act,

The Mental Health Act, Mental Capacity Act, and NHS Guidelines on Research Governance shall be adhered to when conducting R&D within the Trust.

6. AWP Research and Development Management Permission

The HRA approval process replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study. NHS R&D Management Permission will be provided by the AWP Research and Development Office.

6.1 Assessment

The NHS Research and Development Management Permission process will:

- Review the feasibility of undertaking the research locally, assess the logistics for the local supporting departments, undertake contract and budget negotiations, ensure compliance with legislation, assess local research team suitability, and issue Letters of Access or Honorary Research Contracts;
- Arrange access to research nurse or other resources or financial support, as appropriate;
- Support the process where research involves NHS patients taking part through private or charity providers.

You should note the following points to avoid unnecessary delays in the review process:

- Contracts: It is strongly recommended that you use the NHS model agreements. Failure to do so is likely to delay your study while a legal review is undertaken, and may incur a charge;
- Finance: For commercially funded research you are recommended to use the Industry Costing Template;
- Research Passports and Honorary Contracts or Letters of Access: The local Research and Development office will determine the necessary contractual arrangements for the research team;
- Radiation: For research involving ionising radiation (e.g. X-rays and CT scans), whether additional or standard practice, the NHS organisation is legally required to assess each individual study.

6.2 Permissions

NHS Research and Development Management Permission will be provided once the following are in place, in accordance with the Research Governance Framework for Health and Social Care (RGF):

- Allocation of adequate arrangements & resources to meet the standards set out in the RGF;
- Ethics approval in place (where required);
- Appropriate contractual arrangements are in place;
- Study Sponsor has taken responsibility for the study;
- Allocation of responsibilities agreed and documented;
- MHRA approval in place (where required);
- IRMER or ARSAC approval (where required);
- Appropriate internal authorisation to conduct the study locally may be required;
- Appropriate insurance or indemnity arrangements are in place.

AWP Research and Development Office Permissions should be obtained for all research in the Trust, irrespective of whether a research ethics review is needed.

Further information on Research and Development approval can be found in the Trust Research and Development Guide, 'Starting Your Project'.

7. Treatment Costs and Service Support Costs for Externally Funded Non-Commercial Research and Development

Treatment costs are the patient care costs which would continue if the patient care service being researched continued to be provided after the R&D stops. When the patient care being researched differs from the normal, standard, treatment for the condition, this is termed excess treatment costs. These costs should be met through normal arrangements for commissioning patient care.

Service Support costs are the additional patient care costs associated with Research and Development, which will end once the Research and Development activity in question stops, even if the same patient care service continues to be provided. This might cover things like extra blood tests, extra in-patient costs, extra staff time for consultations, extra nursing attention. Service Support costs are normally met by the Trust from its Research and Development Support Funding Budget from the NIHR

The principles for meeting patient care costs associated with externally funded non-commercial Research and Development are set out in the Health Service Guidelines (HSG) (97) 32.

The detailed application of these principles and guidance for researchers and NHS Trust are outlined in the documentation under Executive Letter (EL) (97) 77.

NHS England has been working in consultation with Department of Health (DH) and other key stakeholders to develop an NHS England strategic plan on the process and funding of Excess Treatment Costs that delivers DH policy. As a result, NHS England has published new guidance to help clarify the rules and expectations, which can be found at the following site: https://www.england.nhs.uk/wp-content/uploads/2015/11/etc-guidance.pdf

Contact the Research and Development Office for further information or to discuss any queries.

In the case of the costs being associated with external R&D grant proposals originating from Trust staff, notification to the Trust should be prior to submission of the grant to the external non-commercial Funder.

In the case of the costs being associated with external R&D grant proposals being led from other bodies such as a University or other Trust, notification must be prior to formal agreement to participate/collaborate with the research.

The Trust will consider whether the research is eligible (against strict criteria laid down by the Department of Health) for provision of treatment costs or service support, and advise the researcher within 4 weeks of their notification.

For further information on treatment costs and service support contact the R&D Office and consult the relevant documents.

8. Service User and Carer Involvement

AWP recognises the important contribution that its Service Users and Carers have to make in relation to Research and Development in the Trust. For all Research and Development studies sponsored and led by AWP, it will be expected that Service Users and Carers will be involved in the identification of research questions, the development of research studies, assessment of research tools and the collection, analysis, write-up and dissemination of research findings.

This will be encouraged by the Research and Development Office at the early stages of study design, and assessed for studies seeking AWP sponsorship. Although Service User and Carer

involvement in Research and Development will not be a requirement of Trust Research and Development Approval, justification for not seeking such involvement will be sought by the Research and Development Office at the time of the Research and Development review.

AWP does not have any influence over Service User and Carer involvement in relation to studies that it does not sponsor or lead on. However, there is an expectation that such involvement will play an important part in the development of the high quality research adopted in the NIHR portfolio.

9. Research Passports and Honorary Contracts

All researchers applying to carry out research within AWP must have a substantive contract, a license to practice or letter of access with AWP. The National Institute for Health Research has launched a national scheme called Research Passports that sets out best practice for NHS organisations and employers. AWP will use the approved Research Passport Algorithm to ensure that the Trust meets its responsibilities that all researchers have appropriate contractual arrangements undertaking Research.

10. Sponsor

Under Research Governance, all research in the NHS needs to have a formally agreed research governance Sponsor. If this responsibility is to be met by the Trust then this needs to be agreed with the Research and Development Office prior to submission for ethics review or submission of the Research and Development approval form to the Research and Development Office.

11. Research Involving Medicinal Products

Research involving pharmaceutical products, clinical trials or other studies primarily examining efficacy, effectiveness or adverse events of medicinal products for human use need to have the appropriate clinical trial approval from the Medicines and Healthcare Regulatory Authority and must adhere to the Medicines for Human Use (Clinical Trials) Regulations 2004.

12. Indemnity

If the research proposal involves a novel treatment, intervention or clinical procedure, and/or new equipment, device or drug, then appropriate procedures for patient indemnity must be arranged. If a commercial company is supplying a drug or clinical device then the Standard Association of British Pharmaceutical Industry indemnity of the Model NHS: ABPI Clinical Trial Agreement must be obtained (contact the Research and Development Office for advice).

13. Intellectual Property Rights (IPR)

IPR is any data, information, equipment, research tool (such as questionnaires or assessments), product, or research result which as well as being of value to the evidence base, is also potentially commercially exploitable.

The Trust-agreed policy on Intellectual Property Rights shall be observed (contact the Research and Development Office for further information or a copy of the policy).

14. Contractual Agreements

The Trust's Research and Development and Finance Departments must be notified of all financial and research agreements with outside agencies, including commercial companies, prior to signing. Where appropriate, the Trust will seek legal advice on the appropriateness of the agreement.

15. Commercial Research

As a minimum, the full costs of commercially funded research should be recovered, including overheads at rates agreed and used on the NIHR Commercial Costing Template.

All commercial and non-commercial contracts for research studies should be sent for approval by the AWP Research and Development Office and for subsequent Trust authorisation by the Trust's Head of Procurement and Contracts, in the AWP Finance Department.

16. Record-Keeping

Records of all service users' informed consent and carers'/relatives' assent, and all appropriate research records should be stored and made available when requested by the Trust and other authorised agents (such as District Auditors).

All adverse events relating to Research and Development being conducted within AWP should be reported to the Research and Development Office of the Trust, as well as the routine Trust procedures for reporting such events. This includes both clinical adverse events and non-clinical adverse events such as issues concerned with gaining consent and record keeping.

Any praise or complaints or Health and Safety issues relating to Research and Development should be handled through the normal Trust mechanisms. The Research and Development Office should also be notified.

17. Storage and Re-Use of Research Data

All data shall be stored according to Ethical Committee and/or recognised good practice guidelines (such as from the Medical Research Council), and the Department of Health guidelines.

Appropriate ethical and Trust approval (and where appropriate informed consent from patient/client) must be obtained for sharing or reuse of data for any purpose other than for which it was originally collected.

The Trust's Policy on Managing Innovation and Intellectual Property Rights (IPR) should also be adhered to in such cases.

No data should be passed to any third parties unless it is first anonymised, except for in exceptional circumstances.

Further information on records retention, storage and disposal can be found in the Trust Records Management Policy.

18. Deviation from Approved Protocol

Any deviation from the approved protocol should be agreed with the HRA, the Sponsor, the Trust and the external Funder (if externally funded).

19. Research Steering Groups

All Research and Development studies should ideally be managed by a formal steering group, which will monitor progress. For clinical trials, it is best practice to constitute an independently led Trial Steering Group, and in some cases an Independent Data Monitoring Committee. For further information on best practice for the conduct of clinical trials, the appropriate Department of Health and Medical Research Council guidance should be referred to.

20. Final Reports of Progress and Research Findings

The Trust will request final reports of progress made and a summary of the research findings according to specified formats. These reports will be used to ensure that the research has been conducted according to the approved protocol and ethical favourable opinion. In addition, the report will facilitate dissemination of any research findings within the Trust and wider.

Where appropriate, the Trust will request a financial reconciliation at the end of the study. This will include when there has been specified Trust Research and Development funding and/or service support used to support a Research and Development study (either externally funded non-commercial or Trust-sponsored).

All publications involving the Trust should acknowledge the Trust appropriately.

All research taking place within the Trust must be subject to a monitoring procedure which includes an annual audit of 10% of studies in line with Department of Health requirements, and a final and annual reporting system.

Further information on monitoring and reporting can be found in the Trust's Procedures for Monitoring Research and Development Projects for Research Governance.

21. Responsibilities

Board Directors, the Research and Development Committee and the Director of Research and Development are responsible for ensuring that all staff know how to access Trust-wide policy from the Board Library and that material changes to Trust-wide policy, and new policies are brought to the attention of all affected staff, and ensuring that this Trust policy, procedures and protocols and associated guidelines are implemented across their operational areas of responsibility.

Individual staff members have a personal duty to work within the provisions of this Trust-wide policy, and their associated procedures, protocols and guidelines.

LDUs have a responsibility to ensure their developments are consistent with the Trust Research and Development Strategy.

Failure to observe and implement policy and their related procedures, protocols and guidelines is addressed through performance management mechanisms, training, or where appropriate, the Trust's Disciplinary Procedures.

22. Monitoring and Audit

The Associate Director of Research and Development will be the responsible person for monitoring this policy, ensuring it remains fit or purpose and that it is implemented appropriately within the Trust, reporting to the Quality and Standards Committee.

23. Standards

- Professional practice standards for all professions to undertake ethical research;
- Research Good Clinical Practice (The Medicines for Human Use (Clinical Trials) regulations (2004);
- Mental Capacity Act (2005);
- The Human Tissue Act (2005);
- Department of Health Research Governance Framework for Health and Social Care.

24. References

- Research Governance Framework (Department of Health, 2nd Edition 2005)
- AWP Policy on Intellectual Property Rights Management

- AWP Records Management Policy
- AWP Recruitment and Selection Policy
- Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials (MRC, 1998)
- Medicines and Healthcare products Regulatory Agency good clinical practice for clinical trials (2016)
- The Medicines for Human Use (clinical trials) regulations (2004)
- Mental Capacity Act (2005)
- The Human Tissue Act (2004)
- 'AWP Research and Development Guidance for Peer Review', available from the Research and Development Office
- 'AWP Research and Development Guidance for Monitoring Research and Development Projects for Research Governance', available from the Research and Development Office

The detailed application of these principles and guidance for researchers ('Non-Commercial External Funded R&D in the NHS: Guidance for Researchers'), and NHS Trust are outlines in the documentation under Executive Letter EL (97) 77.

Version History

Version	Date	Revision description	Editor	Status
1.0	01 Apr 2001	Finalised	TS	Approved
1.1	01 Feb 2005	Revisions to incorporate changes in Research Ethics procedures – approved by R&D Committee	TS	Approved
2.0	27 Feb 2008	AWP Board approval	TS	Approved
3.0	02 Feb 2012	3 year review approved by Quality & Healthcare Governance Committee	MW	Approved
3.1	3 May 2016	3 year review - reviewed by the R&D management group and	Research and development facilitator	Approved
4.0	11 May 2016	3 year review approved by Quality and Standards Committee	Research and development facilitator	Approved
4.1	22 July 2019	Extended until September 2020	HR Director - JF	Approved