Sandwell and West Birmingham Hospitals NHS
NHS Trust

RESEARCH & DEVELOPMENT POLICY

PROFILE	
REFERENCE NUMBER:	ORG/047
VERSION:	4
STATUS:	Approved
ACCOUNTABLE DIRECTOR:	Medical Director
AUTHOR:	R&D Director/Manager
DATE OF LAST REVIEW/ ORIGIN DATE:	October 2005
DATE OF THIS REVIEW:	June 2007
APPROVED BY:	Governance Board
DATE OF APPROVAL	December 2007/ Reviewed April 2013
IMPLEMENTATION DATE:	January 2008
DATE NEXT REVIEW DUE:	April 2014
REVIEW BODY:	Governance Board
CATEGORISATION:	Organisational
DATE OF EQUALITY IMPACT ASSESSMENT:	August 2007
APPLICATION:	Trust-Wide
PRINCIPAL TARGET AUDIENCE:	All persons undertaking research activity within the Trust
ASSOCIATED TRUST DOCUMENTS:	Equality Policy Statement, Health & Safety Policy, Misconduct & Fraud Procedure, Procedure for Safety Reporting in Research, Managing Intellectual Property Policy.

Research & Development Policy

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1.0 Introduction

1.1 To ensure that Sandwell and West Birmingham Hospitals NHS Trust ('the Trust') supports good quality research that can complement clinical services by helping to improve patient care, strengthen teaching within the Trust and generally attract, recruit and retain high quality staff.

1.2 To ensure that the public has confidence in the work carried out at the site, the Trust is required to introduce effective systems of Research Governance. This document sets out the Trust policy on matters relating to research and development, including the management of research and the promotion of research and development within the organisation. The document also defines the roles and responsibilities of those involved in research and sets the parameters for the undertaking of research in accordance with requirements determined by the Department of Health and other applicable regulatory bodies.

2.0 Objectives

2.1 To promote research of high quality by setting standards and procedures for research and development within the Trust.

2.2 To define and communicate standards of conduct in research and development within the Trust.

2.3 To define roles and responsibilities of individuals who work in the Trust and for the Trust to ensure that their research follows good practice guidelines.

2.4 To outline how research and development is managed within the Trust.

3.0 Scope

3.1 This policy applies to anyone involved in research and development activity undertaken within the Trust.

4.0 Definitions

4.1 Research

The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This definition includes studies that aim to generate hypotheses as well as studies that aim to test them. (Research Governance Framework for Health & Social Care, Second Edition, 2005).

4.2 Clinical Audit

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery. (Principles for Best Practice in Clinical Audit, NICE 2002).

4.3 Research Governance

A core standard for health care organisations, research governance encompasses a range of principles, requirements and standards set to improve research and safeguard the public by increasing ethical awareness and scientific quality, promoting good practice and preventing misconduct. (Research Governance Framework for Health & Social Care, Second Edition, 2005).

4.4 R&D Department

The Trust department responsible for the administration and approval of research on behalf of the Trust.

4.5 Chief Investigator (CI)

The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, 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. (Research Governance Framework for Health & Social Care, Second Edition, 2005).

4.6 Principal Investigator (PI)

The leader responsible for a team of individuals conducting a study at a site. (Research Governance Framework for Health & Social Care, Second Edition, 2005).

4.7 Researcher

An investigator who is neither the Chief nor the Principal Investigator, sometimes referred to as a co-investigator.

4.8 Contract Commercial Research

Research that is sponsored and funded by commercial companies and directed towards product licensing and commercial exploitation. (Guidance to Facilitate the Conduct of Commercially Funded Research in the NHS, National R&D Costing Initiative, 2005).

4.9 Collaborative Commercial Research

Research that is supported by industry but in which the balance of benefit arising from its conduct is judged to lie in the public sector. Such research is usually investigator-led, is of strategic value to the NHS and is not carried out directly in support of product licensing. (Guidance to Facilitate the Conduct of Commercially Funded Research in the NHS, National R&D Costing Initiative, 2005).

4.10 Educational Research

Research that is undertaken by students in pursuit of a recognised educational qualification.

4.11 Research Protocol/Proposal

A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study. (Standard Operating Procedures for Research Ethics Committees, Version 3.3, April 2007).

4.12 Clinical Trial

Any investigation in human subjects, other than a non-interventional trial, intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products, identify any adverse reactions to one or more such products, or to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining their safety or efficacy. (The Medicines for Human Use (Clinical Trials) Regulations, 2004)

4.13 Multi-Site Study

A study that the Chief Investigator proposes should be conducted at more than one site in the UK. (Standard Operating Procedures for Research Ethics Committees, Version 3.3, April 2007).

4.14 Sponsor

An organisation or institution responsible for securing the arrangements to initiate, manage and finance a study. (Research Governance Framework for Health & Social Care, Second Edition, 2005).

4.15 Clinical Supervisor

Either a consultant or manager of equivalent seniority who will take on the responsibilities of the Principal Investigator if the proposed Principal Investigator is not a consultant or equivalent senior manager.

4.16 National Research Ethics Service (NRES)

The organisation responsible for the provision of robust ethical review of proposed research studies in order to protect the safety, dignity and well being of research participants as well as to ensure the promotion and facilitation of ethical research within the NHS.

4.17 Genetically Modified Organisms (GMOs)/Genetically Modified Micro-Organisms (GMMs)

Genetic modification in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination or both. (The Genetically Modified Organisms (Contained Use) Regulations 2000).

4.18 Intellectual Property

The novel or previously undescribed tangible output of any intellectual activity can legitimately be described as intellectual property. It has an owner it can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written work, designs and images.

Products of creativity and innovation which can be given legal recognition of ownership as Intellectual Property Rights through patents, copyright, design rights, trademarks or know-how. (The Management of Intellectual property & Related Matters: An Introductory Handbook, 1998)

4.19 Misconduct and Fraud

Fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It also includes intentional, unauthorised use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings or devices used in or produced by the conduct of research. (Medical Research Council, 1997).

5.0 Roles and responsibilities

5.1 Chief Executive

The Chief Executive has ultimate responsibility to ensure that research conducted within the Trust is done so in accord with good practice and all applicable regulatory guidelines.

5.2 Research & Development Committee

Research within the Trust will be supervised by the R&D Committee, which has an approved constitution and is chaired by the Director of R&D. Membership of the committee shall include at least one Medical Director, the Director of Nursing (or nominated representative) and a Lay Representative. The Director of R&D will also sit on the Trust Strategic Development Board.

5.3 Director of R&D

The Director of R&D, so appointed by the Trust Board, is responsible for the overall strategic direction of research and development within the Trust. The Director of R&D will report to the Medical Director on research matters and will work with the Trust Director of Governance Development to ensure that the Trust's research governance responsibilities are met.

5.4 R&D Manager

The R&D Manager will ensure that policies, systems and procedures are implemented under the guidance of the Director of R&D to ensure that Government research priorities are observed and that researchers follow Trust procedures and observe proper research governance.

5.5 R&D Department

The R&D Department is responsible for the review and administration of all research undertaken within the Trust.

5.6 Principal Investigator

a) A Principal Investigator should be a consultant or equivalent senior manager within the Trust. Where this is not the case, the research should be supervised by a Clinical Supervisor who should be a consultant or senior management equivalent who is prepared to accept the responsibilities of Principal Investigator for the study.

b) The Principal Investigator is responsible to the Director of R&D and the Medical Director for the proper conduct of the study.

c) The Principal Investigator will be held responsible for the overall conduct and management of the study and should conduct the study in accordance with applicable regulatory guidelines and the responsibilities of Principal Investigator as outlined in the Principal Investigator's Statement, which should be signed before the research commences.

d) It is the Principal Investigator's responsibility to consult with the R&D Department and the R&D Finance lead prior to commencing any research to ensure that all costs to the Trust are accounted for and appropriate arrangements to recover these costs are in place.

e) Prior to undertaking a Clinical Trial, the Principal Investigator must demonstrate an awareness of research governance issues and must provide a copy of a recent certificate of Good Clinical Practice training.

5.7 Researchers

It is the responsibility of all persons involved in research activity to ensure that their conduct is in line with current Trust policy and all other applicable regulatory requirements.

6.0 Trust Approval of Research Projects

6.1 All research undertaken within the Trust will need formal approval of the Director of R&D prior to commencement. This includes:

a) Research involving patients, or samples of blood and/or tissue from patients, or patient records or questionnaires;

b) Research involving people who are not patients; including patient's relatives, staff and healthy volunteers;

c) Research initiated by those in the Trust, or carried out on behalf of others, or carried out by employees of the Trust in other places;

d) Research at the Trust conducted by external organisations or their representatives;

e) Research that is conducted for educational purposes

6.1.1 Individuals wishing to undertake research at the Trust should register their research with the R&D Department in accordance with R&D Trust Approval Process, a copy of which is appended to this document (see Appendix 1). The R&D Department will review projects to ensure compliance with research governance. Undertaking research without authorisation from the Director of R&D is not permitted.

6.1.2 The R&D Department will advise whether the proposed investigation constitutes a research or audit project. If the project is an audit, the investigator must ensure that it is registered with the Clinical Effectiveness Department.

6.2 Justification of Research

Principal Investigators are required to ensure that their work does not unnecessarily duplicate other work. Existing sources of evidence are to be considered carefully before the decision to undertake a new piece of research is taken.

6.3 Peer Review

In accordance with the NHS Research Governance Framework for Health and Social Care (version 2, April 2005), all studies are subject to scientific review by an independent expert in the relevant field. The arrangements for peer review should be proportionate to the scale and perceived risk of the proposed study. Appropriate evidence of peer review should be submitted to the R&D Department. Where no evidence of Peer Review is readily available, the Principal Investigator should ensure that the study is reviewed using the Trust Peer Review form which can be obtained from the R&D Department.

6.4 Ethical Approval

Where required, research will be subject to the scrutiny of an Independent Research Ethics Committee. It is the Principal Investigator's responsibility to liaise with the National Research Ethics Service (NRES) regarding the requirement for ethical review. The contact details for the Local Research Ethics Committee are available on the Trust R&D intranet pages.

6.5 Commercial Research

6.5.1 A commercial study is one in which the Principal Investigator does not have complete freedom to use the data gathered during the study and the results are assumed to be primarily for the benefit of the sponsoring commercial company.

6.5.2 The Trust has a full cost charging policy in respect of commercial research. Income from commercial research must be calculated to recover as a minimum the 'full costs' incurred by the Trust in undertaking work of a commercial nature. This includes staffing costs, additional patient treatment costs and any incidental payments such as travel expenses. In addition to the above, the Trust R&D Department charge a set-up fee and levy on all commercial fees. All costs are subject to VAT.

6.5.3 It is the responsibility of the Principal Investigator to ensure that appropriate arrangements are in place to collect income from commercial organisations and to ensure that this income is treated in accordance with NHS and Trust financial regulations. The service costs associated with commercial work must be reimbursed to the relevant service departments.

6.5.4 No commercial study should commence prior to a Clinical Trials Agreement (CTA) being agreed between the Trust and the Sponsor. CTAs should be handled by the Trust R&D Department and will be signed by the Director of R&D before trial commencement.

6.6 Sponsorship

All research undertaken within the NHS must have a Sponsor. Written evidence of such will be requested for research being conducted within the Trust and sponsored by an external organisation. Where no external sponsor has been identified, the Trust will accept sponsorship

responsibilities in certain circumstances. The Chief or Principal Investigator can apply to the R&D Department for Trust sponsorship by completing the relevant Sponsorship Request form.

6.7 The Use of Patients in Research

6.7.1 It is the Principal Investigator's responsibility to ensure that all patients involved in research (in any capacity) give their informed consent to participate. Care should be taken to produce patient information in accordance with NRES guidelines. Researchers should observe best practice and allow an adequate period of reflection before consent is taken. The Department of Health's Good Practice in Consent Implementation Guide describes principles of good practice.

6.7.2 Research involving persons not able to provide fully informed consent in the usual way should be carefully considered and an alternative subject group found whenever possible.

6.7.3 Research on human subjects using medicinal products will be subject to the Medicines for Human Use (Clinical Trials) Act 2004. It is the Principal Investigator's responsibility to ensure that any clinical trial is conducted in accordance with these and any other applicable regulations and guidelines.

6.7.4 Research using pregnant or breastfeeding women should be avoided if possible. Where the research can only be undertaken on this specific subject group, the results should be of direct benefit to groups represented by the participants (pregnant or breastfeeding women, embryo, foetus or child).

6.7.5 It is Trust policy to discourage the use of payments to healthy volunteers taking part in research. Exceptions will be made for the payment of expenses in relation to travel, time and inconvenience incurred by participants. The level of payment made should be appropriate and not at a level that could be construed as an inducement. Details of any such proposed payments should be disclosed to the R&D Department and agreed by the Director of R&D before being discussed with volunteers.

6.7.6 Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research. It is the Principal Investigator's responsibility to make every effort to ensure that consumers are involved in the development and execution of studies.

6.8 Use of Tissue or Organs in Research

6.8.1 The use of human tissue in research is subject to the provisions of The Human Tissue Act 2004.

6.8.2 In accordance with The Human Tissue Act 2004, consent is required for activities relating to the removal, storage and use of human organs and other tissue; any such activity is referred to as a 'Scheduled Purpose.' Research in connection with disorders or the functioning of the human body

is defined as a Scheduled Purpose. Samples obtained from the living may not require consent provided they are anonymised and used for ethically approved research only.

6.8.3 According to The Human Tissue Act 2004, consent from the deceased person, a person nominated by them, or a 'qualifying person' (usually family members) will be needed to carry out any research or public health monitoring on tissue from the deceased. Principal Investigators proposing to conduct research using the tissue or organs of the deceased should also seek special permission of the Director of R&D. The Trust also requires that the Principal Investigator report the findings of the work to relatives of the deceased.

6.8.4 Where research involves Relevant Material (described as material other than gametes which consists of or includes human cells) samples must only be stored for the duration approved by a Research Ethics Committee. When the approved storage time lapses, any remaining material must be destroyed and cannot be kept for future studies unless an appropriate license issued by the Human Tissue Authority is in place.

6.8.5 Researchers must not sell for profit human samples that have been collected for research purposes within the Trust.

6.8.6 It is the Principal Investigator's responsibility to ensure that human material is suitably stored, that appropriate records are kept to enable the identification of samples and their uses within research programmes and to ensure that arrangements are in place for the respectful disposal of the material upon completion of the research.

6.9 Use of Animals, Human Embryos, GMOs, X-Rays, or Radioactive Isotopes.

6.9.1 It is Trust policy to avoid research on animals. Where the use of alternatives (cells, tissues, computers, bacteria or plants) is not an appropriate substitute, investigators must request special permission from the Director of R&D prior to seeking a license for animal testing.

6.9.2 The use of human embryos for research purposes will be subject to the special permission of the Human Fertilisation and Embryology Authority. Research approved in this area will be governed by The Human Fertilisation and Embryology Act 1990. It is the Principal Investigator's responsibility to ensure that research is conducted in strict accordance with the legislation.

6.9.3 The use of genetically modified organisms (GMO) for research purposes within the Trust is subject to special permission from the Director of R&D. Research involving GMO material will be regulated by The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 (SI 2005/2466). It is the Principal Investigator's responsibility to ensure that this legislation is observed at all times.

6.9.4 Research on human subjects involving the use of x-rays or radioactive isotopes will be subject to the regulations set out in The Ionising Radiation

(Medical Exposure) (Amendment) Regulations 2006. It is the Principal Investigator's responsibility to ensure that this and other relevant regulations are adhered to at all times. The latest guidance is detailed in the document entitled 'Approval for Research Involving Ionising Radiation' (2006).

6.9.5 The Principal Investigator must ensure that human subjects are fully informed about the risks associated with exposure to radiation. Full written consent must be secured before any procedure is carried out.

6.10 No Local Investigator Research

6.10.1 A Research Ethics Committee may consider that studies involving routine or low risk procedures do not require Site Specific Assessment (SSA exempt). However, this exemption applies to ethical review only and Trust R&D approval must still be sought from each participating site.

6.10.2 If a study is declared to be SSA exempt, there is no requirement to appoint a Principal Investigator at individual sites. Instead, a Local Collaborator should be identified who will have the same responsibilities for the research as a Principal Investigator would.

7.0 Principles of Confidentiality and Data Protection in Research

7.1 Any information of a personal nature obtained for, or as a result of research in the Trust, should be regarded as confidential and treated in accordance with the Caldicott Principles.

7.2 The Principal Investigator should ensure that appropriate consent is obtained for the use of data and to ensure that any data collected is processed in a fair and lawful manner and in accordance with the Data Protection Act 1998.

7.3 Principal Investigators involved in multi-centre studies are responsible for implementing procedures to ensure that patient information is anonymised before leaving the Trust premises as appropriate.

8.0 Health and Safety in Research

8.1 All employees have responsibilities for health and safety at work. It is a condition of every contract of employment (and honorary contract) that employees adhere to Trust Health & Safety Policies. This includes undertaking work as a part of a research study.

8.2 All researchers have the responsibility to act reasonably with regard to health and safety in the workplace, taking reasonable care and precaution for their own safety and the safety of others that are affected by their work. The Principal Investigator is responsible for ensuring that any hazards are identified and mitigated before a study commences. Additionally the

Principal Investigator should ensure that other researchers are appropriately trained/qualified and briefed about the research before participating in the study.

8.3 Where appropriate, external researchers should hold an NHS honorary contract before commencing work on any study conducted at the Trust. It is the Principal Investigator's responsibility to arrange for these contracts to be issued by the Trust R&D Department.

8.4 All investigators are responsible for ensuring that they are aware of any safety reporting requirements of the work they are undertaking. The Principal Investigator is responsible for safety reporting in accordance with the Trust Procedure for Safety Reporting in Research and the safety reporting requirements of the appropriate regulatory bodies.

9.0 Archiving

9.1 Essential study documents should be stored in a suitable environment to ensure that they are maintained in a legible condition and are retrievable upon the request of a regulatory authority.

9.2 Sufficient suitable space should be secured for the purpose of archiving study documentation. The facility should be secure and provide adequate protection from physical damage.

9.3 In accordance with Article 17 of Directive 2005/28/EC the essential documents relating to a trial shall be retained for at least five years after the date of completion and shall be retained for a longer period where deemed necessary in accordance with other applicable requirements or an agreement between the Sponsor and the Principal Investigator.

9.4 The Principal Investigator shall retain responsibility for the retained documents and should make the Sponsor aware of the storage arrangements. If the Principal Investigator becomes unable to uphold their responsibilities for the essential documentation, arrangements for a transfer of responsibility to a suitable individual should be made and the Sponsor should be notified of the same.

9.5 The medical records of trial subjects shall be retained in accordance with national legislation and in accordance with the time permitted by the Trust.

10.0 Destruction of Study Documentation

10.1 Most NHS records are destroyed as soon as practicable after the expiry of the relevant retention period. Such records are likely to contain sensitive or confidential information and it is therefore vital that confidentiality is safeguarded at each stage.

10.2 In order to protect confidentiality, the method used to destroy records must be fully effective and ensure complete illegibility; normally this would involve shredding or incineration.

10.3 Record destruction can be done on site or via an approved contractor. It is recommended that a brief description be kept of that which has been destroyed, when and by whom. Where a contractor is used, they should be required to sign a confidentiality undertaking and provide written certification as proof of destruction.

10.4 As the destruction of records is an irreversible act, it is vital to consider any options before making this decision. Where research is being sponsored by an external organisation it is important for researchers to confirm that study documentation is no longer required by the sponsor prior to arrangements for destruction being made.

10.5 Document destruction should be conducted in line with any current Trust Policy which governs the same.

11.0 Increasing Awareness of Research

11.1 It is Trust policy to make information on appropriately approved research widely available. With the exception of commercial research, all research studies undertaken within the Trust will be submitted to a National register.

11.2 It is the Principal Investigator's responsibility to ensure that all findings of their research, including publications are reported back to the R&D Department in order that Trust records of publications may be kept up to date and accurate. Wherever practical, the Principal Investigator should also ensure that research participants are informed of the outcomes of the study they have participated in.

12.0 Links with Clinical Effectiveness

The R&D Department is committed to raising the standards of research in the Trust and will work closely with the Clinical Effectiveness Department to ensure that good practice is shared where appropriate.

13.0 Fraud and Scientific Misconduct

Scientific misconduct or alleged scientific misconduct of investigators will be formally investigated in accordance with the Trust Fraud & Misconduct in Research procedure.

14.0 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 are assessed in accordance with the Equality initial screening toolkit, the results for which are monitored centrally.

15.0 Review

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

16.0 Training and awareness

16.1 The Trust R&D Policy will be circulated to all Trust consultants and will be made available to all Trust members via the R&D Intranet pages.

16.2 The Trust is committed to the principle of training for researchers as appropriate. Applications for assistance toward training costs should be made in writing to the Director of R&D. Cases will be considered on an individual basis and in relation to budgetary constraints.

17.0 Monitoring

17.1 Ultimately, the monitoring of compliance against this policy will be the responsibility of the Director of R&D.

17.2 Details of research activity within the Trust will be held on a database which will be maintained and updated by the R&D Department.

17.3 It is the responsibility of the Principal Investigator to keep accurate records relating to research and to inform the R&D Department of any study amendments. Routine audits will be undertaken by the R&D Department to ensure compliance with the principles of research governance; the Principal Investigator should ensure that these records are available for inspection as appropriate.

17.4 Routine monitoring of research studies will be conducted annually and upon completion of each study by the R&D Department. It is the Principal Investigator's responsibility to ensure that the required reports on the

progress or outcomes of research are produced on time and to an acceptable standard.

18.0 Discipline

It is the responsibility of all researchers undertaking work on Trust premises to observe and co-operate fully with the guidelines detailed within this policy. Failure to comply with Trust policy may result in the following action being taken against the investigator:

- Removal of authorisation for work to be carried out in the Trust
- Removal of the investigator from the project
- Future work may be subject to special monitoring
- Withdrawal of Trust funding for the programme
- Action taken under the Trust Fraud & Misconduct in Research Procedures

19.0 References

Approval for Research involving ionising radiation: R&D Forum (2006)

Data Protection Act (1998)

Department of Health, Good Practice in Consent Implementation Guide: Consent to Examination or Treatment (2001)

Directive 2005/28/EC

Equality Policy Statement (SWBH Trust)

Guidance to Facilitate the Conduct of Commercially Funded Research in the National Health Service (National R&D Costing Initiative, 2005)

Health & Safety Policy (SWBH Trust)

Misconduct & Fraud Procedure (SWBH Trust)

MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct (Medical Research Council, 1997)

NHS Research Governance Framework for Health and Social Care (version 2, April 2005)

Principles for Best Practice in Clinical Audit (NICE, 2002)

Procedure for Safety Reporting in Research (SWBH Trust) Standard Operating Procedures for Research Ethics Committees (Version 3.3, April 2007)

The Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831)

The Human Fertilisation & Embryology Act 1990

The Human Tissue Act 2004

The Ionising Radiation (Medical Exposure) Regulations 2000 (Amendment 2006)

The Management of Intellectual property & Related Matters: An Introductory Handbook for R&D managers & advisers in NHS trusts & independent providers of NHS services (1998)

The Medicines for Human Use (Clinical Trials) Act 2004

20.0 Bibliography

Department of Health Memorandum for House of Lords Committee on Animals in Scientific Procedures (June 2001)

Draft Additional Protocol to the Convention on Human Right and Biomedicine, on Biomedical Research (2001).

ICH Harmonised Tripartite Guideline for Good Clinical Practice

MRC Guidelines for Good Clinical Practice in Clinical Trials

Managing Intellectual Property Policy (SWBH Trust)

The Human Tissue Act 2004: an Assessment of the Act and its Implications for the Specialities of Clinical and Laboratory Genetics. Joint Committee on Medical Genetics (2007)

The Protection and Use of Patient Information: Department of Health Guidance

Research & Development for a First Class Service: Department of Health

Medical Research Council Operational and Ethical Guidelines: Human Tissue and Biological Samples for Use in Research

Best Research for Best Health: Department of Health (2005)

Guidelines on the Practice of Ethical Committees on Medical Research Involving Human Subjects. 4th Edition, Royal College of Physicians

21.0 Further enquiries

Further information relating to this policy can be obtained from the R&D Manager

Sandwell and West Birmingham Hospitals NHS
NHS Trust

RESEARCH APPROVAL PROCESS

Projects that require Trust R&D approval

All research involving NHS staff or patients, their organs, tissue or data taking place within Sandwell & West Birmingham NHS Trust must have approval from the R&D Department. This includes multi-centre projects, research with no local investigator, student projects and local single site projects. Research that has not had prior approval from the Trust R&D Department is not permitted.

Projects that require approval of an Independent Ethics Committee

In addition to Trust R&D Approval, all research that involves staff or patients, their organs, tissue or data will require prior written approval from a Research Ethics Committee. Ethical and R&D approval may be sought in conjunction, however the Trust will not issue a formal letter of approval until it has written confirmation that ethical approval has been issued for the study to be undertaken on SWBH premises.

1.0 Applying for Ethical Committee Approval

(i) Check the NRES website for information on how to submit your application.

There are different procedures depending on whether your study is Multicentre or a single site, so you should read the instructions carefully

(ii) Complete the NRES Application Form.

You will need to complete the standard NRES application form online; the NRES Form is arranged as follows:
A & B: To be completed by Chief Investigator; details of the proposed research, proposed research sites and details of any samples intended to be used for the purposes of the research.
SSI: Locality Assessment.

Guidance for completing this form is available on the NRES website http://www.nres.npsa.nhs.uk/ or from the Local Ethics Committee (check R&D intranet site for information).

(iii)Return the appropriate sections to the Ethics Committee selected to review your application

Include the protocol and any additional information/annexes as requested.

Note: Written ethical approval for single center studies will be sent to the Principal Investigator from the REC reviewing the application. A copy of this letter should be forwarded as soon as possible to the R&D Office. Failure to do so will delay in the issue of R&D approval.

In the case of multi-centre studies where Site Specific Approval (SSA) is required, Principal Investigators will not be notified directly by the Main REC that the site has been approved as suitable to participate in the study. Instead, the Chief Investigator will receive notification as each site is approved. Principal Investigators should liaise closely with Chief Investigators in multi center studies to ensure that they are sent a copy of the SSA for this site. A copy of this notification should be forwarded to the R&D Office as soon as possible to prevent delays in the commencement of the study.

2.0 Applying for R&D Approval

(i) Secure adequate funding for your study

In line with the new National Health Research Strategy 'Best Research for Best Health' the Department of Health has begun the process of withdrawing the R&D budget previously allocated to research active NHS Trusts to support research activities. It is expected that individuals wishing to undertake research within the NHS will proactively seek and secure sufficient funding to sustain their study. As a result, the Trust R&D Department can only approve those studies for which the investigator can provide evidence of adequate resources.

(ii) Complete the R&D Paperwork

There are a number of documents you will be required to submit for R&D Approval. For a comprehensive list, please refer to the Applicant's Checklist included at page 3 of this document.

(iii) The R&D Department will then check the project for compliance with Research governance standards, including but not limited to:

a) Whether researchers hold substantive/honorary contracts with the Trust
b) Adequacy of funding arrangements for the proposed study.
c) Sponsorship arrangements
d) Indemnity arrangements
e) Risk Assessment
f) Suitability of Investigators/facilities

3.0 R&D Approval

Once financial review, research governance checks and ethical approval have been secured the project will be reviewed by the R&D Director for formal approval. A letter will then be issued to the Principal Investigator giving R&D approval for the project to commence within the Trust. Projects must not proceed without receipt of a formal letter of approval from the R&D Department. All research undertaken within the Trust must be conducted in accordance with SWBH Trust R&D Policy.

For further information regarding any of the above please contact the R&D Department either by email r&d@swbh.nhs.uk or telephone (0121) 507 4091.

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Applicants Checklist

The following checklist is for your reference. It outlines the documentation you will need to submit to the R&D Department in order to receive approval to conduct your study within the SWBH NHS Trust or the Sandwell PCTs as applicable. Failure to submit the required documentation will result in the approval of your project being delayed.

Documentation Required	Student Project	Commercial Study	Non-Commercial Study	PCT
Site Specific Information Form (SSI)	X	X	X	X
Approved Protocol	X	X	X	X
Approved Patient Consent Form	X	X	X	X
Approved Patient Information Sheet	X	X	X	X
Ethics Application Form Parts A & B	X	X	X	X
Signed MREC Approval Letter	X	X	X	X
Signed LREC Approval Letter	X	X	X	X
Substantive/Honorary Contract	X	X	X	X
Clinical Trials Agreement		X	X	
Letter of Sponsorship	X		X	X
Principal Investigator Agreement		X	X	
Peer Review			X	X
Trial Authorisation certificate		X	X	X
GCP Training Certificate (for Clinical Trials only)		X	X	X
Researchers' CVs	X	X	X	X

Guidance Notes:

Site Specific Information Form (SSI) – This can be downloaded from the NRES website at http://www.nres.npsa.nhs.uk/ This form is to be used to apply for Site Specific Approval and R&D Approval therefore you will need to submit a copy of this form to

both R&D and Ethics. All researchers should ensure that, where service departments are involved in their study (i.e. Pharmacy, Pathology, Radiology, Histopathology, Haematology, Imaging etc) the Authorisations section (Q39) of the SSI Form is signed off by the head of the participating department indicating their willingness to contribute to the study prior to submission to R&D, this is not a requirement for Ethics submission. In addition to submitting a signed hardcopy of the SSI form, researchers are also required to email a copy of the locked REC application & SSI form as an xml file to r&d@swbh.nhs.uk

Approved Protocol/Patient Consent Form/Patient Information Sheet – For all studies a copy of each of these documents must be submitted. This should be a copy of the Final Version. For Commercial Trials a copy of the Investigators Brochure is also required.

Ethics Application Forms – For all studies a signed hardcopy of the NHS Research Ethics Committee Application form must be submitted (Parts A & B). In addition, researchers are required to a copy of the locked parts A & B forms as xml files to r&d@swbh.nhs.uk

Signed MREC/LREC Approval Letter – Whilst you can make a parallel submission for R&D and Ethical approval, prior to formal R&D Approval being granted you will be required to provide a copy of the appropriate Ethics Approval Letter(s).

Substantive/Honorary Contracts – All those undertaking research involving 'NHS staff or patients, their organs, tissue or data' must hold either a substantive or honorary contract with the Trust. If you do not currently hold a contract, please contact us and arrange for one to be issued.

Clinical Trials Agreement (CTA) – SWBH NHS Trust accepts the unmodified 'NHS-ABPI-BIA model Clinical Trial Agreement 2006-England' for use in Commercial and Non-Commercial trials being sponsored by an external body.

Letter of Sponsorship - All research in the NHS must now have a sponsor. If your study is sponsored by an external organisation, you will be asked to supply written evidence that the organisation has agreed to sponsor your study. If you require the Trust to act as sponsor for your study, please check with the Research Department.

Principal Investigator Agreement – It is the responsibility of the Principal Investigator to ensure that any study that they conduct is undertaken in accordance with NHS Policies on Research Governance and with any national policies and laws that regulate research in the UK. Prior to R&D Approval being granted you will be asked to read the guidance and sign a declaration that you agree to undertake the responsibilities outlined.

Peer Review – Appropriate evidence of independent peer review should be submitted to the R&D Department. Where such evidence is not readily available, the PI should ensure appropriate review is undertaken using the Trust R&D peer review form available upon request.

Trial Authorisation Certificate – For all trials involving medicines you will need to obtain a Trial Authorisation Certificate from the MHRA.

GCP Training Certificate – For Clinical Trials, the Principal Investigator must produce evidence of recently accredited Good Clinical Practice Training (within last 2 years).

Researchers' CV – A signed & dated summary CV for those involved in the research will be required. If required a template is available upon request from the R&D office.

Appendix 2

Sandwell and West Birmingham Hospitals NHS
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EQUALITY IMPACT ASSESSMENT FOR TRUST-WIDE POLICIES

POLICY TITLE:	Research and Development Policy
ACCOUNTABLE DIRECTOR:	Director of R&D
AUTHOR:	R&D Manager
DATE:	14 August 2007

1. Public service organisations are required to take concerted action to identify and eliminate inequality. Undertaking equality impact assessment in relation to all relevant policies provides the means for doing this.

2. This checklist should be completed to determine if the proposed policy is relevant to the Trust's General Duty under race, gender and disability equality.

HECK	**YES**	**NO**
Will the proposed policy involve or have consequences for the patients or staff of the Trust on racial grounds in the context of their gender, disability, sexuality, age, religion and language? • If yes, please explain, identifying those likely to be affected.		✓
Is there any reason to believe that people from the different equality strands, taking into account of interaction between strands, could be affected differently, by the proposed policy • If yes, please state reason and those likely to be affected.		✓
Is there evidence to suggest that any part of the proposed policy could discriminate unlawfully, directly or indirectly? • If yes, please specify • If no, please explain		✓
Is there any evidence that some people may have different expectations of the policy in question due to their race, gender, disability, sexuality, age, religion and language? • If yes, please specify • If no, please explain		✓
Is the proposed policy likely to affect relations between some people due to their race, gender, disability, sexuality, age, religion and language, for example if is seen as favouring a particular group or denying opportunities for another? • If yes, please state reason and those likely to be affected.		✓

3. If any of the questions are answered ‘yes’ then the proposed policy is likely to be relevant to the Trust’s legal duties in relation to race, gender and disability. The author should consult with the Director of Human Resources to develop a more detailed assessment of the impact of the policy and, where appropriate, design monitoring and reporting systems.

4. A copy of the completed form must accompany the policy when it is presented to the relevant body for approval.

Appendix 3

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POLICY IMPLEMENTATION PLAN

POLICY TITLE:	Research & Development Policy
ACCOUNTABLE DIRECTOR:	Director R&D
POLICY AUTHOR:	R&D Director/Manager
APPROVED BY:	Governance Board
DATE OF APPROVAL	

KEY TASKS	ISSUES IDENTIFIED	ACTION TAKEN/PLANNED	LEAD	TIMESCALE
Co-ordination of implementation The implementation plan will be co-ordinated by the R&D Manager under the guidance of the Director R&D.	Time commitment required to produce the policy to requisite standard and the need to circulate to appropriate staff for review and comment.	Research into associated guidelines and directives undertaken in July and August to enable policy to be written and circulated for comment in September.	R&D Manager	July-September 2007
Engaging staff The R&D Department & Committee, Researchers and their Participants will be directly affected by the policy along with Service Departments, Finance Department, and the Trust's research partners including HEIs & Pharmaceutical Companies. The R&D Department & Committee are responsible for implementing the policy.	Ensuring that all relevant parties receive copy of policy or are notified of policy revision & advised where copies of policy can be obtained.	Raise awareness of R&D policies and procedures	R&D Manager	October – December 2007
Involving service users and carers R&D Committee membership includes a lay member who can provide service-user perspective	Research involvement raises a number of complex issues for potential participants and their carers to consider	Researchers are encouraged to involve service users in research development & execution where possible. Additionally, all research participants are given information regarding implications and applicable arrangements of the research.	Chief/Principal Investigator responsibility	Ongoing Commitment
Communication All research undertaken within the Trust, regardless of type/complexity, is subject to R&D approval & must be undertaken in compliance with the R&D policy and associated guidelines.	Ensuring all relevant persons are aware of the requirements of the R&D policy	Ensure R&D policy is made widely available via intranet, issue a copy of the revised policy to all Trust consultants and stipulate in standard communications to researchers that R&D approvals are subject to continued compliance with Trust R&D policies & procedures.	R&D Manager	December 2007
Training Specific training requirements include a certificate of Good Clinical Practice for Principal Investigators involved in Clinical Trials. In general terms some researchers may require training sessions to gain understanding of	Securing the time and resources required to provide adequate training.	Provision of online GCP training for Principal Investigators of Clinical Trials and general training sessions as provided through Trust membership of the Birmingham Research Training Collaborative	R&D Manager	Ongoing Commitment

KEY TASKS	**ISSUES IDENTIFIED**	**ACTION TAKEN/PLANNED**	**LEAD**	**TIMESCALE**
other regulatory requirements and best research practice				
Resources Changes in funding mechanisms for R&D.	The staged withdrawal of Budget 1 monies will impact at Trust level	Slow down and eventual cessation of Own Account studies in Trust research portfolio	R&D Director	Immediate slow down and total cessation by April 2009
Securing and sustaining change As this is a revision of existing policy barriers to policy implementation are unlikely to be encountered.	The need to ensure the continued success of the policy	To maintain awareness of the policy and its content standard R&D correspondence will be amended to include reference to the same	R&D Manager	Ongoing Commitment
Evaluation As this is a revision to an existing policy no major changes in practice are anticipated				