Memorandum of Understanding
on Joint Working for Effective Research Governance
between
The University of Birmingham (the “University”)
and
University Hospital Birmingham NHS Trust (the “Trust”)

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## Signatures

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1. Principles

The University of Birmingham (the “University”) and University Hospital Birmingham NHS Trust (the “Trust”), collectively referred to as the “Parties”, agree to work collaboratively to ensure high standards of research management, administration and governance. This agreement does not over-ride the existing policies of either Party as expressed in previously existing policy statements, codes of conduct or guidance applying to either Party’s employees. The Parties both recognise that all clinical and medical research involving the two organisations will adhere to the standards set out in the latest version of the World Medical Association’s Declaration of Helsinki where appropriate.

Except where expressly stated otherwise, this Memorandum of Understanding is a supplement to other agreements affecting the relationship between the University and the Trust. It has been developed in response to the Department of Health’s Research Governance Framework for Health and Social Care (RGF) which stresses the importance of clear agreements that allocate responsibilities appropriately among organisations and individuals involved in research in the NHS. It also builds on recommendations for good practice from a number of recent committees and reports including:

- the report of the Follett committee
- the Nuffield Trust’s report on University Clinical Partnership
- and the Joint Medical Advisory Committee’s Good practice in NHS/academic links.

The memorandum is based on the model developed by a working party for the Department of Health/NHS R&D Forum. It covers in broad terms arrangements that are needed to ensure effective and efficient governance of research affecting both organisations. It incorporates more specific agreements where these have already been developed and indicates where additional such agreements will need to be developed in the future. This is an organic document and will be added to on an on-going basis and reviewed at least annually.

1.1 Scope

The agreement applies to any research that involves both organisations through sharing of personnel, equipment, facilities, information or other resources. This includes, but is not restricted to, any research involving human participants, whether as NHS patients or relatives of patients, healthy volunteers, or members of staff. 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,

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1 The Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects, 52nd WMA General Assembly, Edinburgh, October 2000.
5 Good practice in NHS/academic links, HEFCE, 1999.
or surplus to clinical requirements, or if the researchers require access to confidential personal information.

It is intended that this document shall be updated when necessary to take account of new developments and arising legislation such as the Human Tissues Act 2004, when such relevant Acts or Regulations are published.

It is recognised that although the majority of research covered by this agreement will involve the School of Medicine at the University, a significant proportion of research in the Trust involves collaboration with other Schools and Departments in the University including the School of Health Sciences, and the School of Sports and Exercise Sciences.

1.2 Confidentiality Status

This is not a confidential agreement. Its existence should be publicised internally and copies made freely available on request to either organisation.
2. Managing Human Resources

1. Reference is made to the joint working arrangements established by the Parties in the light of the Follett report governing accountability and management of senior staff jointly appointed between the University and the Trust.

2. The Parties agree to share information regarding their employment policies and procedures.

2.1 Honorary Attachments

1. In accordance with Department of Health requirements as set out in the Research Governance Framework, anyone who is not employed by the Trust but who requires access to patients of the Trust or their relatives, or organs, tissues or information about patients or relatives must hold an honorary attachment with the Trust or work under the direct supervision of an identified person who holds an Honorary Contract. In the latter case it is the responsibility of the honorary contract holder to ensure that those under their supervision adhere to the principles of this agreement and relevant policies and guidance. Researchers who interact with individuals in a way that has direct bearing on the quality of their care must hold a NHS honorary contract\(^7\). Researchers who do not hold honorary contracts with the Trust may only have access to fully anonymised information about patients, unless patients have given explicit consent otherwise. This applies to all categories of staff including doctors, nurses, allied health professionals, scientists, managers and technical staff. The University will ensure that all its employees are aware of these requirements.

2. Both Parties will ensure that the procedures for obtaining honorary attachments are known to each other and that applications for honorary attachments will be processed within 2 weeks of receiving the complete necessary documentation.

3. Either Party may decide not to issue an honorary attachment in which case the reasons for the refusal will be made clear to the applicant and the other Party. Both Parties will act reasonably in making such a decision and an appeal process will be developed between the Parties.

4. The Parties will develop a joint database of all those employed by one of the Parties but holding honorary attachments with the other. Access to the database with authorisation to amend records will be governed by a clear set of procedure that are in line with the Data Protection policies of the parties.

5. The Parties will draw up and make available to each other their criteria and procedures for obtaining honorary attachments.

2.2 Code of Practice

1. Researchers working in the Trust, either employed by the Trust or holding an honorary attachment with the Trust, must abide by the “Code of Practice for Research” given in

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\(^7\) DH, Research Governance Framework, Edition 2 para 3.10.3
Appendix 1 A. The Parties will ensure that all of their relevant employees, whether or not they are currently engaged in research, are aware of the Code of Practice. The parties will also regard failure to abide by the Code as a disciplinary matter.

2 Researchers working in the University, either employed by the University or holding an honorary attachment with the University, must abide by the “Code of Conduct for Research” given in Appendix 1 B. The Parties will ensure that all of their relevant employees, and all Heads of Schools whether or not the School is are currently engaged in clinical research, are aware of the Code of Conduct and will regard failure to abide by the Code as a disciplinary matter.

3 It is the intention of the Parties to work towards a common Code of Practice for clinical research.

2.3 Scientific Misconduct

1 The Trust and the University currently have complementary policies for dealing with Scientific Misconduct. In cases of alleged misconduct initial investigation will be carried out by the organisation in which the allegations were first made. However, the employer of the person accused will complete the investigation and deal with any subsequent disciplinary action.

2 The Parties will work to develop a joint policy on scientific misconduct by the end of 2004.
3. Research Activity

3.1 Research Authorisation

1 No research governed by this agreement can take place involving either the Trust or the University until all of the required approvals and authorisations have been provided in writing.

2 For the majority of research covered by this agreement, formal, explicit approval by an NHS Research Ethics Committee is required before the research can begin. The circumstances under which ethics committee approval is needed are set down by the Central Office of the Research Ethics Committees (COREC). These guidelines, conditions and procedures will be followed by the Parties and their employees.

3 Formal and explicit approval by the Trust’s Associate Medical Director for Research and Development is required before research involving any of the following can begin:

- employees of the Trust as researchers or research subjects (except where such Trust employees are submitted as subjects through another Trust)
- access to resources, facilities or services of the Trust
- access to patients for which the Trust has responsibility, their relatives or carers - this includes access to confidential information, tissues, organs or fluids (whether taken specifically for research, taken from material that is surplus to clinical requirements, or archived material)

4 Formal and explicit approval by the University is required before research linked with the University and involving patients of the Trust, or tissues or records associated with patients of the Trust can begin. These approvals must follow the internal systems of the School(s) involved and be signed by an authorised signatory of the University in accordance with the University’s financial regulations. This applies to projects in which the staff member is the PI or a collaborator.

5 Confirmation that appropriate insurance cover is in place is required before a clinical research project involving employees of either Party can begin. See Section 7.6 for further details.

6 The Trust and University will ensure that their employees are aware of and adhere to the requirements and procedures for obtaining approval to start their research.

7 Certain types of research require specific assessment and approval procedures as set down in National guidelines. These include research involving genetically modified organisms (including gene therapy), foetuses or foetal tissue, and xenotransplantation. The Parties will ensure that researchers intending to undertake research falling into these categories are aware of, and follow, the national procedures and relevant University and Trust guidelines.

3.2 Principal Investigators

1 It is a requirement of the Trust that all research involving its resources or patients must have a designated Principal Investigator (“PI”) who is employed by the Trust or holds an honorary
attachment with the Trust. The PI would usually have to be of consultant status or equivalent.

2. The PI has specific duties and responsibilities under research governance.

3. Before the Trust will approve the study, the PI must sign a declaration that they will adhere to the research governance policies of the Trust.

### 3.3 Sponsor

1. UK legislation translating the EU Directive on Clinical Trials (2001) into UK law requires there to be a sponsor for all clinical trials after May 2004.

2. The Department of Health has further stipulated that from April 2004, no research may continue in the NHS that does not have a sponsor.

3. The Trust will consider on a case-by-case basis taking on the role of Sponsor for a specific research study and will make this explicit in the research approval letter.

4. The University will consider the feasibility of taking on the role of Sponsor as a matter of urgency.

5. The Trust and University will each provide the other with any written confirmation that an external organisation has accepted the role of sponsor for each piece of research.

6. If there is no confirmation that an external organisation is willing to take on the role of sponsor for a specific piece of research then the Trust and University may agree between them, as part of the formal approval process, that either one of them may take on the role, or the organisations may take on the role jointly. In the first instance the employing organisation of the lead or Principal Investigator may be expected to accept the role of sponsor.

7. If no external organisation is willing to take on the role of sponsor and neither the Trust nor the University agree to take on the role, then the research must not take place.

### 3.4 Monitoring

1. The Parties will give each other such assistance as is needed for monitoring and auditing research activity to ensure it is carried out to acceptable quality standards.

2. Researchers may be required to provide brief annual reports (following a specified template which has been developed by the Trust’s Research and Development Office and agreed by the University) for each research project, indicating progress with the research. Researchers will be advised of any such requirement prior to the commencement of the project. Copies will be provided to each Party.

### 3.5 Risk management and incident reporting

1. All research involving the Trust is covered by the Trust’s policy on reporting research-related serious adverse events. The Parties will ensure that their employees are aware of, and abide by, this policy.
2. Reporting of adverse events, adverse drug reactions, and suspected unexpected serious adverse reactions (SUSARS) will conform with UK legislation following the EU Directive on clinical trials (2001).

3. The Trust and the University will work to develop a joint approach to risk management and a joint protocol for incident reporting.
4. Resources and Facilities

4.1 Research Facilities

1. Specific arrangements exist for researchers to access dedicated clinical research facilities in the Trust or University, these include the Institute for Clinical Research, and the Wellcome Trust Clinical Research Facility. (include web-links)

4.2 Libraries

1. All researchers and clinicians have free access to the libraries at the Queen Elizabeth Hospital and Selly Oak Hospital, lending rights are restricted to those holding honorary attachments with the Trust.

2. Access to the Barnes Library in the Medical School is restricted to registered users which includes all consultants from the Trust and others holding honorary appointments with the University.
5. Information

5.1 General
1. Wherever relevant to the work or responsibilities of the other Party and subject to legal restrictions on data protection and confidentiality the Parties shall make available to each other relevant information needed to ensure proper governance of research. This will include information about
   - Research funding applications and awards
   - Research publications and other forms of output
   - Research ethics submissions
   - Research activity
   - Details of research-based postgraduate training (including MDs, PhDs, Mphils etc.) involving the Trust
2. It is the intention of the Parties to provide access to shared and discrete databases held by the Parties detailing the information given above for named individuals in either Party. Such access shall only be granted where this would not conflict with the Data Protection Act 1996.

5.2 Publications
1. The University and Trust currently hold separate databases detailing research outputs, principally publications.
2. The Parties agree, to exchange information on their databases to avoid duplicating effort.
3. The Parties are committed to co-ordinate their procedures for collecting information about publications from their respective employees to provide ease of access to relevant information to both Parties.

5.3 Ethics submissions
1. The Trust will be primarily responsible for collecting information about submissions made to the South Birmingham Research Ethics Committee. This information will be freely exchanged with the University as requested.

5.4 Educational and Training Research Projects (including PhDs and MDs)
1. The University will maintain a database of all students whose work involves the Trust and who in addition are registered for research-based higher degrees. Information on the database about research that could involve the Trust will be made available to the Trust on request.
2. All University Supervisors shall comply with the University Code of Practice on the Supervision and Monitoring Progress of Research Students, section 2. The Trust shall consider and agree with relevant Schools whether in any particular case, additional accreditation is required.
5.5 Public Access to Information

1. Information about all research activity covered by this agreement should be in the public domain. The Trust will work with the University to ensure that provision of this information is done in such a way as to avoid breaches of confidentiality and the Data Protection Act, protects intellectual property and complies with the Freedom of Information Act 2000.
6. Finances

6.1 Research awards
1. Each party will ensure that legitimate costs claimed by both parties are incorporated into all research grant applications.
2. Before signing off research grant applications relevant to this agreement, the University must be satisfied that the Trust has had an opportunity to include its legitimate costs, and vice versa.

6.2 Costing of Research
1. The parties will work to develop a compatible approach to identifying full economic costs of research following the recommendations set out in relevant guidance documents including the financial regulations of both Parties, the Government’s PICTF (“Pharmaceutical Industry Competitiveness Task Force) report and recommendations from the review of the dual support system.

6.3 Contracts
1. The Parties will initiate a compatible approach to dealing with contracts for research in April 2004. Neither Party will sign a contract that commits services or resources provided by the other, without the prior written agreement of the other Party.
2. The Trust intends to adopt the national model contract for commercially sponsored research endorsed by the Department of Health and the ABPI. The Trust and University shall work together to develop an effective working arrangement for this model contract.
7. Access to Patients, patient material and information

7.1 Confidentiality

1. Information obtained by the Trust for the purpose of providing healthcare is governed by the Data Protection Act 1998 and by the common law of confidentiality.

2. Researchers have no right of access to patient-identifiable information unless given explicit consent from the patient. The Trust agrees to facilitate the obtaining of such explicit consent.

3. Completely anonymised, unlinked data may be used for research without explicit consent from patients provided this has been approved by an NHS ethics committee and by the Trust.

4. The Parties will agree a formal mechanism to enable the transfer of confidential information between themselves when appropriate with due regard to the requirements for consent.

7.2 Consent

1. Researchers must obtain written informed consent from patients before involving them in research. They must ensure that the consent process is documented in the patient records.

7.3 Use of Human Tissue, Fluids and Organs

1. The use of human tissue, fluids and organs from patients under the care or previously under the care of the Trust, whether obtained specifically for research, obtained from material that is surplus to clinical requirements, obtained from archived sources within the Trust or University, or obtained at Post Mortem, is governed by similar Trust and University policies.

2. The Parties must ensure that their employees are aware of and abide by these policies.

3. The Parties will ensure that any human tissue, fluids and organs taken, stored or used for research is only done with the explicit consent of the patient.

4. The Parties will agree a formal mechanism to enable the transfer of tissues and samples between themselves and ensure that tissue samples are not exported from the Trust unless with the consent of the patient. Unless the procedure identified at 7.1.4 above has been followed the material will be anonymised and the key linking the material to the original patient will be retained in the Trust.

5. The Parties will develop a common policy on handling human tissue for research, to ensure that such research, whether undertaken by University or Trust employees, is subject to proper governance procedures in line with National recommendations and any relevant local policies over and above these recommendations.

7.4 Patient Records

1. Access to patient records for research purposes is only permitted when

   • the patient has given explicit consent for that use
• Ethics Committee and Trust for the research has been given

2. Researchers who are not employed by the Trust must hold an honorary attachment to have direct access to patient records.

3. Researchers who do not hold honorary attachments may only be given access to anonymised, unlinked data by which it would be impossible to trace back to the original patient - unless the relevant patient has given consent otherwise or such access has been approved by the National Patient Information Advisory Group (PIAG).

4. Queries about accessing patient records or patient information for research should be addressed to the Trust’s R&D office or the Trust’s Caldicott Guardian.

7.5 **Data Protection**

1. The Parties will ensure that:

   • their employees abide by the Data Protection Act 1998 for storing and processing personal data, and to each Party’s Data Protection Policies
   • if personal data is stored on a computer, access to the computer must be password protected.
   • paper-based records will be stored in secure, locked cabinets.
   • before a computer is disposed of, or passed to someone else, all personal information stored on the computer has first been removed.

7.6 **Liability, Insurance and Indemnity**

1. The Trust is required to obtain an indemnity from commercial sponsors, to cover claims for non-negligent harm, for all commercially sponsored research. The research will not be allowed to take place without such an indemnity. This is irrespective of any indemnities arranged between the sponsor and the University, although the University would anticipate the commercial sponsor placing the University in a similar position to the Trust. For the avoidance of doubt the University is not a commercial sponsor for the purposes of this Memorandum of Understanding.

2. Both Parties will also seek indemnities wherever possible from non-commercial research sponsors, but may allow the research to take place without such indemnities provided it is clear to those taking part in the research that they would only be able to make claims for negligence.

3. The Trust is legally not allowed to take out insurance cover against claims of compensation for non-negligent harm. Therefore any research for which the Trust is acting as sponsor will not be covered for non-negligent harm.

4. Research for which the University is acting as sponsor will not be covered for non-negligent harm unless the University has provided an explicit indemnity to the Trust. The Trust will not allow statements in the patient information leaflet and consent forms that claim otherwise. The University shall consult with its insurers on a case-by-case basis on appropriate insurance for the research.
5. The Parties will agree in respect of each research project the terms of insurance and Indemnities appropriate to the research.

7.7 **Clinical Research outside NHS premises**

1. Clinical research having direct contact with patients of the Trust can only take place on Trust premises or in areas specifically agreed with the Trust. A list of areas outside the Trust where such research can take place is listed in Appendix 3.

2. The University will ensure that no clinical research involving direct contact with patients of the Trust takes place on its premises outside the areas designated above. The list can be updated at any time by mutual consent and agreement in writing.
8. Health and Safety

8.1 Occupational Health
1. Existing arrangements for co-operative working between occupational health departments extend to include all activities covered by the MOU.
2. The parties will ensure that all laboratories have regular risk assessments to confirm with the COSHH regulations.
3. Appropriate containment procedures must be followed for research involving micro-organisms.
4. The Parties will ensure that all employees are aware of and will abide by codes of practice, guidelines and policies on Health and Safety of both Parties. Responsibility for adherence to any such codes or guidelines lies with the PI and the institutional leads for Health and Safety.

8.2 Pharmaceuticals
1. All medicines used for research must be stored and dispensed through the Trust’s Pharmacy or through alternative arrangements explicitly agreed with the Trust’s Head of Pharmacy Services.
2. Clinical Trials involving medicines that fall under within the scope of the EU Directive on Clinical Trials (2001) must be registered by the sponsor with the Medicines and Healthcare Products Regulatory Authority (MHRA).

8.3 Medical Devices
1. All medical devices must used for research must either be CE-marked or labelled “exclusively for research”.

8.4 Radiation Protection
1. The parties will ensure that ARSAC and IRMER guidelines and any institutional regulations are followed as appropriate.
9. Implementation

1. A joint University/Trust research governance working group shall be established to oversee the implementation and review of this agreement.

2. The committee will ensure that a report is produced in April each year detailing progress with establishing the working arrangements and making recommendations for change as necessary. This report will be submitted via the Joint Liaison Committee to the University Council and Trust Board.

3. Research and Enterprise Services at the University and the R&D Offices at the Trust have the prime responsibility for ensuring that governance arrangements for research involving the Parties are agreed and followed. The Trust and University facilitate close working between the offices.
Appendix 1 Codes of Conduct for Researchers

A : University Hospital Birmingham NHS Trust (the “Institution”)

Code of Conduct for Research Involving Human Participants

1 Scope

1.1 This code sets out standards of work and ethical conduct expected of those engaged in clinical work in the Institution, whether directly employed by the Institution or holding an honorary position.

1.2 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 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 requires access to confidential personal information.

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

2 Observance of the code

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

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

3 Breach of the code

3.1 Breaches of this code may lead to disciplinary action by the Institution.

4 Advice

4.1 If you have any doubts or questions about the applicability of the code or the provisions contained within it you should contact the Trust’s R&D Manager.

5 Guidance

5.1 Researchers must make themselves familiar with the latest version of the Declaration of Helsinki and all subsequent revisions. They should keep abreast of developments.
with the Department of Health’s Research Governance Framework which 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, the General Medical Council and the Royal medical colleges.

6 Principles

6.1 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.

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

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

6.4 Every effort must be made to ensure that the results of research are published or disseminated in other ways, subject to the protection of intellectual property rights. Details of the data, methods of collection and analysis, and the outcomes must be open to external scrutiny.

7 Principal Investigator

7.1 For each piece of research there should be designated a Principal Investigator who is responsible for the overall conduct of the research. The PI must hold a substantive or honorary contract with the Trust and would usually be expected to be of consultant status or equivalent.

8 Approval

8.1 Researchers must seek all necessary approvals before they can start their research.

8.2 Research should be aware that access to resources of either Party is likely to require explicit approval by a senior manager authorised to give it, usually this will be the Research and Development Director for the Trust, or the appropriate Head of School for the University. If in doubt about who can authorise the research, contact the Research and Development Office in the Trust or University, or the Medical Director for the Trust or the relevant School’s Finance Officer in the University.

9 Ethics

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9 Copies of these documents are available from the R&D Office and from various web-sites including the Trust’s R&D website (www.uhb.nhs.uk/about/research).
9.1 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.

9.2 Researchers must follow the guidance issued by the Central Office of the Research Ethics Committees (COREC), based in London.

9.3 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.

9.4 Certain types of research are subject to specific ethical regulation these include:

**Foetal Tissue**

9.4.1 If the research requires the use of foetal tissue then you must abide by the guidance and procedures set out by the Polkinghorne Committee.

**Genetic Modification**

9.4.2 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 national Gene Therapy Advisory Committee (GTAC), and by a local Genetic Modification Safety Committee in the organisation where the research will be carried out.

**Xenotransplantation**

9.4.3 Research involving xeno-transplantation is subject to guidance issued by the Department of Health. Research must be submitted to the UK Xenotransplantation Interim Regulatory Authority (UKXIRA) for approval.

10 **Consent and Confidentiality**

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

10.2 Unless agreed otherwise by an ethics committee, consent should be explicit and written.

10.3 Researchers must be aware that under UK law no one can give consent on behalf of anyone else even if the individuals are incapable of giving consent themselves. The only exception are parents and guardians who can give consent for their children under the age of 16, unless the child is capable of understanding the issue, and can give consent themselves.

10.4 Information obtained from patients in the course of providing healthcare is confidential. Researchers must abide by the Data Protection Act 1998 and respect the common law duty of confidence.

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10.5 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 Trust or holding an honorary contract), unless explicit consent has been given by the patient.

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

11.1 Researchers must make themselves aware of, and follow, the Institution’s full policy on the use of human tissue, organs, fluids, tissue blocks and histology slides in research.

11.2 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 and consent has been given by the person from whom the sample has been taken unless the Ethics Committee has agreed that consent is not required. Researchers must be aware of the terms set out in the Human Tissue Act (2004)=.

11.3 For tissue, organs, fluids, tissue blocks and histology slides that have previously been stored and archived, every effort must be made to obtain consent from the person from whom the sample has been taken. If this is not possible then the sample may be used for research provided that this has been approved by an NHS Research Ethics Committee, the sample is anonymised and the link to the original patient is broken so that it is impossible to trace the sample back to the person.

12 Data

12.1 Data must be stored in a secure and durable form for a period of at least 15 years.

12.2 The raw source, and method of analysis must be recorded and be available for scrutiny if necessary by independent auditors.

12.3 Care must be taken to ensure that confidential information is protected from unauthorised access. Care must be taken when disposing of computer systems to ensure that all confidential information is removed.

12.4 Authorship

12.4.1 Researchers should abide by the Vancouver Guidelines for authorship in publications (copies available from the R&D offices).

12.4.2 ‘Gift’ authorship, where someone is named as an author although they have made no material contribution to the design or conduct of the study or to the production of the publication, will be treated as misconduct and be dealt with under the procedures for Scientific Misconduct.

12.5 Monitoring
12.5.1 Researchers must cooperate with any authorised audits of their research, whether undertaken by the University, NHS Trust, external funder or sponsor or regulatory authority.

12.6 **Progress Reporting**

12.6.1 Researchers may be required to provide annual or other reports of progress with the research to the University, NHS Trust, external sponsor or ethics committee.

13 **Scientific Misconduct**

13.1 Researchers must abide by the policies of the University and Trust on scientific misconduct.

13.2 All employees have a duty to report examples and suspicions of misconduct.

13.3 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.

13.4 Researchers must collaborate with any properly constituted investigation of misconduct.

13.5 Researchers must abide by policies of the Trust or University on all other forms of misconduct.

14 **Intellectual Property**

14.1 Researchers should make themselves aware of the University and Trust policies on management of intellectual property (ideas and inventions, patents, designs and copyright).
B : The University of Birmingham

1. Principles

1.1 Statement of Guiding Principles

This Code of Conduct ("the Code") prescribes standards of work performance and ethical conduct expected of all persons engaged in research in The University of Birmingham ("the University") based upon the following guiding principles:-

   a. Research involves, inter alia, the pursuit of truth in furtherance of the advancement of knowledge.

   b. Research workers should, in all aspects of their research-
      
      i. demonstrate integrity and professionalism,

   ii. observe fairness and equity,

   iii. avoid, or declare, conflicts of interest,

   iv. ensure the safety of those associated with the research,

   v. observe all legal and ethical requirements laid down by the University or other bodies properly laying down such requirements.

   c. Research methods and results should, subject to appropriate confidentiality in relation to personal or commercially protected information, be open to scrutiny and debate.

1.2 Observance of the Code

Teaching staff, research workers and research students must familiarise themselves with the Code and ensure that its provisions are observed. Heads of School have a general responsibility to seek to ensure general compliance with the Code in their Schools. The University will draw attention to the Code of Conduct in its induction processes for newly appointed researchers and research students. Supervisors of students involved in research will seek to ensure compliance with the Code on the part of students.

1.3 Breach of the Code

Failure to comply with the provisions of the Code may be grounds for a disciplinary action.

1.4 Advice

Where a research worker is in doubt about the applicability of provisions of the Code, or about the appropriate course of action to be adopted in relation to it, advice should be sought from a member of the Joint Ethics and Research Governance Committee of the Council and Senate. A member of the Joint Ethics and Research Governance Committee should provide this advice on a confidential basis.

2. Specific Requirements

2.1 Research Data

   a. Research data must be recorded in a durable and auditable form, with appropriate references so that it can readily be recovered.

   b. Research data must be retained intact normally for a period of at least five years from the date of any publication which is based upon it.

   c. It is the duty of the principal investigator in any research project to comply with the Data Protection Act, and to ensure that copyright is not breached.
Specific arrangements should be made to protect the security of research data where there is a contractual requirement to do so.

A research unit, department or School must establish procedures for retention of research data in a form which would enable retrieval by a third party, subject to any limitation imposed by the confidentiality of personal data.

Research workers must comply with these retention procedures.

Research data related to publications should be available for discussion with other research workers, except where confidentiality provisions prevail.

Confidentiality provisions relating to publications may apply in circumstances where the University or the research worker has made or given confidentiality undertakings to third parties or confidentiality is required to protect intellectual property rights. It is the obligation of the research worker to enquire as to whether confidentiality provisions apply and of the head of unit, department or School to inform research workers of the obligations with respect to these provisions.

### 2.2 Publications

A publication must contain appropriate reference to the contributions made by all participants who have made what might reasonably be regarded as a significant contribution to the relevant research.

Any person who has participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research should be given the opportunity to be included as an author of a publication derived from that research.

Any person who has not participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research should not be included as an author of a publication derived from that research.

In addition to meeting the requirements of paragraph 2.2(b), an author must ensure that the work of research students, research staff and support staff is recognised in a publication derived from research to which they have made a significant contribution as defined in 2.2(a) above.

A publication which is substantially similar to another publication derived from the same research must contain appropriate reference to the other publication.

A research worker who submits substantially similar work to more than one publisher should disclose that fact to the publishers at the time of submission.

### 2.3 Supervision of Research Programmes/Projects

Each research unit, department or School must adopt guidelines for supervision of research programmes/projects in accordance with any requirements which may be prescribed from time to time by the Academic Board.

A supervisor of research programmes/projects must observe and undertake the responsibilities set out in these guidelines.

A person must decline appointment as a supervisor of a research programme/project unless that person expects to be able to discharge the responsibilities set out in the guidelines.

### 2.4 Conflict of Interest

A research worker must make full disclosure of any personal potential or actual conflict of interest in research. Conflict of interest means any personal or close family affiliation or financial involvement with any organisation sponsoring or providing financial support for a project undertaken by a research worker. Financial involvement includes direct personal financial interest, provision of
personal benefits (such as travel and accommodation) and provision of material or facilities for personal use. (For the avoidance of doubt, the provision of sponsored studentships, or elements of travel/accommodation for a students, should be excluded from this definition.)

b. A disclosure of a personal conflict of interest in research must be made to the Head of School as soon as reasonably practicable.

c. A research worker must comply with a direction made by the Head of School in relation to a personal conflict of interest in research. Heads of School may seek advice from the Registrar and Secretary in cases of doubt.

3. Additional Requirements

3.1 Any special standards of work performance and ethical conduct imposed by law or by the University in relation to particular categories of research are deemed to be included in this code in its application to persons engaged in that research in the University.

3.2 In the case of work involving animals, there is a general requirement for research workers to demonstrate that they have considered seriously the use of alternative methods of research before the use of animals is proposed, and that the likely costs to animals have been weighed against the improvement in knowledge and understanding of the living world. The Named Veterinary Surgeon has an explicit duty to advise research workers about welfare issues in relation to the use of animals for research purposes, which may also raise ethical concerns.

3.3 It shall be the duty of the Director of Biomedical Services Unit to bring forward to the sub-committee on ethics in animal research, through the Certificate Holder, any matters raising issues of ethical concern. In such cases Home Office licensees (or potential licensees) shall have the opportunity to make a submission to the sub-committee, in writing, or, exceptionally, orally.

3.4 Schools in which research workers undertake non-clinical research where human beings are the subject of physical or other tests must submit protocols on ethical, health and safety procedures for approval by the Joint Ethics and Research Governance Committee. Such protocols must involve the establishment of School Ethics Sub-Committees to approve all investigations involving human subjects. Such School Ethics Sub-Committees shall comprise at least the Head of School, two members of staff, the School Safety Officer, two members external to the School, and one female and one male student member of the School.

4. Misconduct

4.1 Misconduct in research is constituted by a failure to comply with the provisions of the Code and, without limiting the generality of the foregoing provisions, includes:-

a. the fabrication or falsification of research data,

b. the use of another person’s ideas, work or research data without appropriate acknowledgement,

c. misleading ascription of authorship to a publication.

4.2 Members and employees of the University have a duty to report misconduct in the prosecution of research, where they have good reason to believe it is occurring, to the Head of School or some other person in authority. In the first instance, the person to report to will normally be a head of department, head of School or Dean. The procedures and protections set out in the University's Code of Corporate Governance in relation to Public Interest Disclosure ('Whistleblowing') shall apply as appropriate in the area of the conduct of research.

4.3 It will be the responsibility of the University, using its normal procedures, to investigate allegations or complaints about misconduct in research or scientific or scholarly fraud. At an appropriate stage, the University will inform relevant sponsors of a particular research project of allegations of scientific fraud.

This code was approved by the Senate on 24 March 1999 and by the Council on 31 March 1999

Last updated July 2002
Appendix 2 Existing Policies

This memorandum of understanding also incorporates the following policies.

University of Birmingham Policies
Policy on managing Intellectual Property
Policy on Dealing with Scientific Misconduct
Research code of practice
Data protection policy
Code of practice on use of computing facilities
Race Equality Policy

University Hospital Birmingham Policies
General Policy on Research Governance
Policy on Principal Investigators
Policy on Reporting Adverse Events
Policy on obtaining, storing, using and disposing of human tissue for research
Policy on Dealing with Scientific Misconduct

Joint Policies
Appendix 3  Non-NHS locations where clinical research is permitted.

The areas of the University where clinical research involving direct contact with patients of the Trust presently encompass

- The Clinical Investigation Unit
- The Wellcome Trust Clinical Research Facility

Proposals for further areas to be included in the memorandum of Understanding will be considered in the first instance by the Joint Research Governance Committee for approval by the Chief Executive officer of the Trust.