



Research Ethics Policy and Procedures

May 2003

Contents

RESEARCH ETHICS POLICY AND PROCEDURES

Background	4
Definition of Research	6
1 RESPONSIBILITIES	
1.1 Researcher	7
1.2 University	7
1.3 School Research Committee	8
1.4 Responsibility to Participants	8
1.5 Integrity of the Researcher	9
1.6 Responsibilities of Data Collectors and Data Transcribers	10
1.7 Responsibilities of Research Supervisors, Research Project Directors/Managers	10
2 GUIDING PRINCIPLES	
2.1 Beneficence and Non-Maleficence	10
2.2 Informed Consent	11
2.3 Participants in a Research Study have the Right to give their Informed Consent before Participating	11
2.4 Where Third Parties are Affected by the Research, Informal Consent should be Obtained	12
2.5 The Consent of Vulnerable Participants or their Representatives' Consent should be Actively Sought by Researchers	12
2.6 Research Based on Human Tissue or Collections of Human Material	12
2.7 Difficult Issues requiring Specialist Advice and Special Measures	14
2.8 Stored Organs and Tissue	15
3 CONFIDENTIALITY	16
4 DATA PROTECTION ACT 1998	17
APPENDIX 1	18
APPENDIX 2	20
APPENDIX 3	21
APPENDIX 4	22

APPENDIX 5	23
APPENDIX 6	25
REFERENCES	29
ACKNOWLEDGEMENT	29
GLOSSARY	30

A RESEARCH ETHICS POLICY AND PROCEDURES

Background

It is important that research and development occurs within a quality research environment and adheres to professional and moral processes constituting externally recognised best practice.

Since World War II, a moral imperative to operate within an acceptable code of ethics, in addition to any legal constraints, has been central to the work of all agencies involved in research, consultancy and other related activities with people, animals and other living subjects, including the environment.

The Nuremburg Code (1947) and the Declaration of Helsinki (1964 plus modifications made in 1975, 1983, 1989, 1996 and 2000) provide the early benchmark for later guidance developed by organisations such as the United Nations International Covenant on Civil and Political Rights, Article 7 (1966), the World Health Organisation, International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993). On a national level, individual countries have developed their own Codes of Conduct for medical research; in the UK these include the Medical Research Council (Responsibility in Investigations on Human Subjects, revised 1992), the British Medical Association Code (1993), the British Psychological Society Ethical Guidelines and the British Sociological Association Statement of Ethical Practice. More recently, Universities engaged in research, consultancy and related activities with human and animal subjects have also drawn up their own ethical guidelines and regulations. It is important to note that the latest revision of the Declaration of Helsinki 2000 has further emphasised informed consent (Paras 21 –6) and Paragraph 20 states that “subjects must be volunteers and informed participants in the research project”.

Within Bournemouth University, most Schools operate School Research Committees and they have established their own procedures for obtaining ethical approval for embarking on a proposed research project or consultancy reflecting the concerns, needs and restrictions of their particular discipline. These procedures are usually guided by external agencies such as the relevant professional body or the National Health Service and related organisations.. There is an additional requirement relating to fieldwork or clinical trials directly involving NHS sites, patients, staff or records whereby the approval of the relevant Local Research Ethics Committee (LREC) must be obtained before commencing any such work. In addition the University has a responsibility to work within the Department of Health and Social Care Research Governance Framework (DOH 2001), providing a quality research culture and ensuring that staff and students are aware of their responsibilities regarding research in health and social care settings. The Department of Health Research Governance framework lays out five domains for the conduct and governance of research:

- Ethics
- Science

- Information
- Health safety and employment
- Finance and intellectual property

In 2001, the University Research Committee recommended that an overarching University Ethical Advisory Group be established. It has been agreed that this body will offer advice, information and guidance rather than acting as a legislative or judicial body. The University Ethical Advisory Group is guided by commonly agreed standards such as those laid down in the Declaration of Helsinki and by the belief that all educational research should be carried out within an ethic of respect for persons and living beings in general, knowledge, justice and quality. The principles developed by the Committee apply to staff and students within the University and they aim to provide clear guidelines to protect the interests of human, animal and other living subjects including the environment.

Against this context therefore, the policy and procedures outlined in the following pages should be considered as a part of the research process at all levels of research activity and output including undergraduate, postgraduate, postdoctoral and members of staff across the University.

DEFINITION OF RESEARCH

The definition of ‘Research’ embraced by Bournemouth University is deliberately wide-ranging. The definition reflects the spread of disciplines and related research activity that exists within the University.

We understand ‘Research’ (for the purposes of this policy) to mean a systematic investigation, generated by a particular hypothesis or question, which involves testing and evaluation and which results in the development of or contribution to the general body of knowledge. Research in this sense has many facets which can include:

1. **Basic Research:** experimental or theoretical work undertaken to acquire new knowledge with no particular application or use in view.
2. **Scholarship:** work which is intended to expand the boundaries of knowledge and across disciplines through the analysis, synthesis and interpretation of ideas and information. (Boyer’s definition of scholarship (1990) includes the scholarship of discovery; the scholarship of integration; the scholarship of application; and the scholarship of teaching). Scholarship is founded on a rigorous and documented methodology and includes forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases.
3. **Strategic Research:** work which is intended to generate new knowledge which might provide for future application.
4. **Applied Research:** work which is undertaken to develop or test existing knowledge and which is primarily directed towards either specific practical objectives or towards the evaluation of policies or practices.

Activities which may be equivalent to research when particular conditions are met include:

5. **Consultancy:** which involves the development of existing knowledge and the application of analytical and investigative skills to the resolution of problems presented by a client, usually in an industrial, commercial or professional context; and
6. **Professional practice and Practice Development:** some of which overlaps with consultancy when conducted at an advanced level. In certain subject areas and professions the theorisation and effectiveness of professional practice are advanced by academic staff who practice and participate in it.

1. RESPONSIBILITIES

1.1 Researcher

The first responsibility for ethical conduct rests with the researcher, who should:

- consider ethical implications of all projects, including funding source and conduct all research in accordance with ethical principles. The checklist (Appendix 2) is a good starting point for this process.
- seek expert advice where appropriate.
- consult relevant documents from professional bodies at <http://ris.bournemouth.ac.uk>. and also Appendix 5)
- be aware of, and operate in accordance with the University's policies and procedures and professional requirements.
- develop and maintain awareness of relevant discipline and professional ethical issues.

The researcher has responsibility for ensuring that appropriate ethical approval is sought. If researchers are unsure or in doubt as to what is appropriate they should consult RIS and seek advice. The flowchart on Appendix 3 and Checklist on Appendix 2 gives a general indication.

1.2 University

The University is responsible for:

- developing, operating and reviewing policies and guidelines which prevent unethical practices, and which are consistent with recognised standards and best practice in the disciplines (a)
- providing appropriate guidance (b)
- supporting researchers who are undertaking research, which is ethically sound through implementation of guidance and appropriate supervision (c).

University Research Committee (a)



University Ethics Advisory Group (b)



School Research Committee (c)



Researcher(s)

1.3 School Research Committee

The School Research Committee has responsibility for:

- making researchers, staff and supervisors aware of ethical guidance
- providing specialist advice or advising where advice can be sought
- overseeing implementation of ethical policies and best practice.

The ultimate responsibility for the care of human participants rests with the researcher. However, in discharging it's duty, the University has established and the University Ethics Advisory Group to develop policy, provide advice and it has empowered School Research Committees to implement the ethics policy at School level. Where NHS sites, records, staff, patients, carers or other vulnerable groups are involved, decisions are delegated to local Research Ethics Committees and in the case of Social Services, Association of Directors of Social Services (ADSS).

1.4 Responsibility to Participants

- a) In all circumstances, researchers must consider the ethical implications of their research and the physiological, psychological, social, political and economic consequences of it for the participants. Every effort must be made to assure the protection of Research participants against physical, mental, emotional or social injury. No harm must come to them as a result of being involved in the study.
- b) The researcher is responsible for obtained informed and freely given consent from each individual who is to be a subject of study or be personally involved in a study. The researcher should explain as fully as possible and in meaningful terms to the participants what the research is about, who is undertaking and financing it and why it is being undertaken. He or she must make explicit the subject's right to refuse to participate or to withdraw at any stage of the project, and this right must be respected. When it is not possible to obtain informed consent, i.e. vulnerable groups e.g. unconscious patients, specialist advice must be obtained and approval gained from an appropriate Local Research Ethics Committee.
- c) If the participant, for any reason, is unable to appreciate the implications of participation, informed consent must be obtained from parents or legal guardian, in the case of children. An agreed consent form should be signed in all cases. A template for an information sheet and consent form is given in Appendix4.
- d) If the participants are being accessed as patients or information is being abstracted from medical records, then the guidelines issued by the MRC (MRC Ethics Series and DOH Research Governance Framework 2001) should be followed.
- e) If the nature of the research is such that fully informed participants before the study would invalidate results, then whatever explanation is possible

should be given to the participants. There must be provision for appropriate explanation and debriefing to the participants on completion of the study.

- f) An investigator should seek the opinion of experienced colleagues whenever their research requires or is likely to involve:
- psychological or physiological stress, or
 - encroachment on privacy
- Under the new national research governance guidance please note that an investigator will not be permitted to proceed where research requires or is likely to involve deception or covert data collection.
- g) All participants in all studies must be informed of the nature of the study and their consent obtained. There may be occasions where investigations compare standard interventions (or care or education) with new or other interventions to be tested. In these cases all participants must be informed of the nature of the study and debriefing or an option to receive the new intervention should normally follow participation as a matter of course.
- h) Explanations to participants should include information as to how their names came to the knowledge of the researcher. Researchers should identify themselves and the organisation responsible for the study and provide participants a written note giving this information, together with a brief statement concerning the nature of the study.
- i) The nature of any assurance of confidentiality or anonymity, or restrictions on the use of information, must be made clear to the participants and strictly adhered to.
- j) The researcher should be aware that the use of records can present particular problems in relation to confidentiality.

1.5 Integrity of the Researcher

Please also see *B Procedure for Investigation and Resolving Scientific Misconduct*.

- a) Given the stage of the researchers career, or in the case of students, the Supervisor's career, they must possess knowledge and skills compatible with the demands of the investigation to be undertaken and must recognise and not overstep the boundaries of their research competence. Researchers should not accept work they are not qualified to carry out or to supervise.
- b) The researcher has the responsibility, to publish or make otherwise available the results of the research, displaying or making available schedules or other research tools and reporting all relevant data, including negative evidence. Limitations about the validity of the conclusions and the extent to which they can be generalised should be stated.

- c) Reporting of results must be truthful and accurate.
- d) As is common practice in any publication, acknowledgements should be made of the contributions of others, but permission must be obtained before names are cited or quotations or acknowledgements made apart from those in already published works, which are governed by copyright.
- e) The researcher should be aware that they have some responsibility for the use made of the research and should not ignore its misuse.
- f) The researcher is responsible for adherence to the code of ethics by members of their team and by any students working under their guidance.

1.6 Responsibilities of Data Collectors and Data Transcribers

- a) Researchers have an obligation to make clear to their employers or sponsors that they cannot undertake work outside their research competence and to decline work where limitations of competence or facilities in terms of money, time, personnel or equipment are such as to make the achievement of the research aims impossible.
- b) The researcher must make clear to his or her employer or sponsor that 'solutions' to problems cannot be guaranteed and should make explicit the limitations of the proposed research.
- c) The terms under which research is being carried out should be stated in a clear way with as much detail as possible, to avoid misunderstanding.

1.7 Responsibilities of Research Supervisors, Research Project Directors/Managers

The research supervisor(s) for each student are responsible for ensuring students are aware of the implementation of procedures and guidelines above. Project managers and directors are responsible for ensuring that research teams are aware of, and implement guidance.

2. GUIDING PRINCIPLES

Research should be undertaken in accordance with commonly agreed standards of good practice, such as those laid down in the Declaration of Helsinki.

- Beneficence – 'do positive good'
- Non-Maleficence – 'do no harm'
- Informed consent
- Confidentiality/Anonymity
- Veracity 'truth telling'

2.1 Beneficence and Non-Maleficence

- Concerns risk(s), harm and hazards, and includes emotional and mental distress, damage to financial and social standing as well as physical harm.
- The research should be scientifically sound and the purpose should be to contribute to knowledge
- The research should be undertaken and supervised by those who are appropriately qualified and experienced.
- The importance of the objective should be in proportion to the inherent risk to the participants. Concern for the interests of the participants must always prevail over the interests of science and society.
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others
- Research should not be undertaken where the hazards involved are not believed to be predictable
- Adequate facilities and procedures should be in place to deal with any potential hazards.

2.2 Informed Consent

Ethically, informed consent is part of the principle of respect for autonomy. Rights of self-determination and “not to be harmed” are implicit in the European Convention on Human Rights which is now given further effect in the UK in the Human Rights Act 1998 which came into force in October 2000. Furthermore, the Department of Health makes clear that the primary consideration in any research within health and social care is preserving the dignity, rights, safety and well-being of participants and that informed consent is at the heart of ethical research (DOH 2001 Paras 2.2.1 and 2.2.3). In addition, the British Sociological Society and the British Psychological Society also draw attention to informed consent issues within research.

- Each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort participation may entail
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern
- Consent should be required in writing and records of consent should be maintained.
- Potential participants must be informed that they are free to withdraw consent to participation at any time.
- There should be a procedure for making complaints and participants should be made aware of this.
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice, in any way, their academic progress.

- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines.
- Specialist advice and appropriate LREC approval sought where consent cannot be obtained.

In addition, where participants are vulnerable, for example children, the frail elderly and when the participants' capacity to consent is in doubt, specialist advice should be obtained. (Please see resources listed DOH 2001; Fennel 2001, British Medical Association 2001)

2.3 Participants in a Research Study have the right to give their Informed Consent before Participating.

- a) Participants should understand the purpose and nature of the study, what participation in the study requires, and what benefits are intended to result from the study (see Section 2 for special guidance on vulnerable participants and section 3 below for exceptional circumstances).
- b) Voluntary informed consent, in writing, should usually be obtained from any participant who is able to give such consent (see Appendix 4)
- c) It is the researcher's responsibility to seek ongoing consent during the course of a study.
- d) Consent may be implied by the completion and return of many social survey questionnaires, removing the need for written consent.
- e) Individual consent may be unnecessary for some research activities, such as community research, which may be quite unintrusive, for example studies involving observation of public behaviour. However researchers need to consider the privacy of individuals and groups involved, the right of privacy must be respected and researchers need to ensure that the research does not run counter to the Human Rights Act 1998, Article 8 (Right to respect for private and family life).

2.4 Where Third Parties are Affected by the Research, Informal Consent should be Obtained

- a) When third parties, for example, spouses, teacher or health care professionals, are directly involved in the care, education or treatment of the potential participants, consent should also be obtained from them.
- b) Informal consent should involve sharing of information about the project.
- c) If the proposed research is likely to interfere with the treatment or care being provided by a third party, it is necessary that they be fully informed and sign a consent to participate.
- d) In certain situations, the affiliation of participants to particular organisations or special groups such as educational institutions, business organisations,

or hospitals, may necessitate the granting of permission to conduct the research project and any relevant policies or guidelines should be followed.

2.5 The Consent of Vulnerable Participants or their Representatives' Consent should be Actively Sought by Researchers.

If the involvement of children in a research study is justified, then parents or other legal guardians have the right to be informed and to give their consent for inclusion of the child in the study.

2.6 Research Based on Human Tissue, or Collections of Human Material

Samples of human tissue may be obtained from volunteers, from patients or from people who have died. This type of research has a contribution to make in developing therapy, or adding to scientific knowledge. Human material also has an important role in diagnosis, medical training or in public health for example by the examination of historical collections. The purpose of this type of research can be described as *therapeutic*.

Human tissue and remains can also be used in a research context for *non-therapeutic* purposes. Human material can be used for forensic purposes, with examination made of human remains to establish cause of sudden death, unnatural or violent death e.g. war crimes. In addition this type of research may aim to identify previously unidentifiable collections.

Human material in this present document refers to biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails¹ and substances extracted from such material such as DNA (MRC 2001). It can be distinguished into four groupings

- Research on new collections and research using reused samples
- Material obtained from living donors and material taken from people who have died
- Human material donated solely or partly for research and material left over following diagnosis and treatment
- Unclaimed and unidentified organs and tissue (includes bones)

General Guiding principles (From DOH 2002 Human Bodies, Human Choices, The Law on Human Organs and Tissue in England and Wales)

- Research should only go ahead if the potential benefit outweighs risk to donors of the samples
- The Human Body and its parts should be treated with respect and should be treated as gifts
- Samples of biological material obtained for use in research should be treated as gifts. Donors' wishes should be respected when using the material.

¹ The use of human sperm, eggs or embryos is subject to the Human Fertilisation and Embryology Act(1990) and must be approved by the Human Fertilisation and Embryology Authority

- The human body and its parts shall not give rise to financial gain (though it is legitimate for suppliers to levy an administrative and/or handling charge for material that has been acquired and stored in an ethical manner)
- Informed consent is required from the donor or next of kin , if the donor has died whenever a new sample is taken wholly or partly for use in research
- Patients should always be informed when material left over following diagnosis or treatment might be used for research
- All research using samples must be approved by an appropriate research ethics committee
- Researchers should treat all personal and medical information as confidential
- Research participants have a right to know individual research results that affect their interests, but should be able to choose whether to exercise that right. Researchers should decide at the beginning of a project what information about the results of laboratory tests done should be made available to participants and agree these plans with a ethics committee
- Deception should never be used
- Records of storage and use should be properly maintained and where necessary, linked to (or unlinked from) relevant patient information systems
- All research using samples of human material, organs or tissue must be approved by a properly constituted research ethics committee
- Researchers should treat all personal and clinical information relating to research participants as confidential
- Where possible research participants, if they wish, should be able to know individual research results that affect their interests

NB: Please also see (a) *DoH Use of Human Organs and Tissue: A draft Interim Statement for Consultation by the Department of Health* and (b) *NHS Retained Organs Commission: A Consultation Document on Unclaimed and Unidentifiable Organs and Tissue, a Possible Regulatory Framework*

2.7 Difficult Issues Requiring Specialist Advice and Special Measures

There are a number of situations which raise additional ethical issues which need careful consideration. In addition there are often different circumstances surrounding the collection of the material and the historical and legal context of the time. This has resulted in different standards guiding past practice. A further complicating feature is that it may not always be possible to know when unidentifiable material was collected.

- Samples, which have been stored for a long time may have a useful role for research, which was not, or could not be envisaged at the time the samples were collected.
- Using material for studies not specifically foreseen at the time raises difficult ethical issues.

- It is often either not possible or practical to return to donors or next of kin for new consent
- Information obtained from research using biological samples, if disclosed, can have implications for the individual donor, but also for their relatives and may lead to discrimination in other aspects of their lives
- The value of many samples is dependent upon related personal or clinical information, respect for confidentiality is therefore very important.
- Historical collections, archived or museum collections and war graves raise a number of complex issues

In the cases above academic staff and students are advised to seek specialist guidance using the sources listed in here and ensure adherence to the three ethical principles of the Belmont Report 1979: Respect for persons, beneficence and justice.

The Retained Organs Commission have consulted the academic, healthcare and wider community about a new possible regulatory framework for collections of human material which take account of the historical and legislative framework. For example “ before 1948 it would be unlikely for there to be any record of organs being retained to enable relative or families to be traced. No consent required for retention or post mortem and between 1948 and 1961 there was no requirement to gain consent for organ retention following either coroners or hospital post mortems” (Section 23). The Commission will report their findings later this year 2002 and will take into account forensic cases.

Academic staff engaged in forensic archaeology should also consult the guidance from “Historic Scotland”.

Academic staff and students whose work involves the use of human tissue, organs or waste should in addition to the Bournemouth University Research Governance Framework, Research Ethics policy and procedures consult the following additional guidance:

- Medical Research Council Human Tissue and biological samples for use in research: operational and Ethical Guidelines. MRC Ethics Guidance www.mrc.ac.uk
- Retained Organs Commission February 2002 www.nhs.uk/retainedorgans//index.htm
- Nuffield Council on Bioethics Bedford Square London Human Tissue and Ethical and Legal Issues April 1995.

- The Royal College of Pathologists (1999) Consensus Statement of Recommended Policies for Uses of Human Tissue in Research Education and Quality Control www.rcpath.org
- Genetic Research – Human Genome HUGO Ethics Committee www.ornl.gov/TechResources/Human-Genome/publicat/hgn/v9n3/16hugo.html
- United Nations Human Rights Home page www.unhchr.ch

2.8 Stored Organs and Tissue

The following approach, which also forms part of the draft interim statement, may offer a basis for new legislation or a regulatory framework established as a result:

- **“Valid consent may previously have been given** to a particular use or uses, in which case it is lawful to use the organ or tissue as already authorised (but see third bullet point below);
- **Where the donor is identifiable** and unambiguous consent has not been obtained for the storage or use (or different use) of tissue, consideration should be given as to whether it is possible (or, depending on the nature of the research, necessary) to seek consent from the person concerned (or, if he or she is no longer alive or cannot be reasonably traced, from a relative). It is important to test assumptions about such prospects and not take for granted that organs or tissue obtained from a certain date are likely to have been “abandoned”. However, logistic possibilities may sometimes have to be balanced against other factors, such as the potential distress to those who might be contacted. These are issues on which research ethics committees may be able to advise;
- **Where the identity of the donor is apparently unknown, or he or she cannot reasonably be traced (including where the tissue is simply too old for this to happen)**, there is, by definition no prospect of obtaining contemporary consent. It is possible that a form of consent was in fact given at some time in the past (maybe orally), even if there is now no satisfactory evidence of this: and, indeed, the antiquity of some samples is such that their removal and storage would have been subject to a rather different legal and ethical framework. It would therefore be wrong to conclude that the use of unidentifiable tissue is necessarily unethical. But equally such tissue should not be used without careful consideration. The following principles should apply²:
- Tissue sample from established collections may be used for research provided that this has been approved by a local or multi-centre research ethics committee and there is potential harm to the donors;
- If there is suitable tissue for which valid consent has been given or could be obtained, this should normally be used in preference to that for which the parameters of consent are inadequately recorded;

² These draw in part on MRC guidance and that of other bodies (eg Royal College of Physicians)

- Researchers should satisfy themselves that there is no evidence of samples having been obtained in an unethical manner, nor any cultural objections to their use or ethical concerns about the propriety of a collection as a whole” (DOH 2002 pp 16-17 paragraph 33).

3. CONFIDENTIALITY

- a) When personal identifiers are used in a study, researchers should explain why this is necessary and how confidentiality would be protected.
- b) Procedures for protecting the confidentiality of participants should be followed and include:
 - securing individual confidentiality statements from all research personnel;
 - coding data with numbers instead of names to protect the identity of participants
 - using codes for identification of participants when transcribing audiotapes, and destroying the tapes on completion of transcription.
 - storing data with any identifying information in a locked file to which only one or two persons have access;
 - using pseudonyms for participants, agencies and geographical settings in the publishing of reports;
 - disposing of information that can reveal the identity of participants or places carefully (e.g. burning or shredding rather than disposal in wastebaskets).

4. DATA PROTECTION ACT 1998

1. The collection and storage of research data by researchers must comply with the data protection act of 1998. Researchers should follow the University's Data Protection Policy and Guidelines
2. Researchers should be aware of the risks to anonymity, privacy and confidentiality posed by all kinds of personal information storage and processing, including computer and paper files, e-mail records, audio and videotapes, or any other information which directly identifies an individual.
3. Participants must be informed of the kinds of personal information which will be collected, what will be done with it, and to whom it will be disclosed. 'Consent to process' may need to be obtained where information collected from individuals is to be used later for research purposes.
4. Measures to prevent accidental breaches of confidentiality should be taken (see section Informed Consent below) and in cases where confidentiality is threatened, relevant records should be destroyed.
5. Provisions for data security at the end of a project must be made. Where the researcher leaves the University, this responsibility should usually rest with the relevant School.
6. Currently the policy for keeping research data, research transcripts, videos and other related electronic data – tapes and videos should be kept for a two year period after completion of the research study and hard copies of transcripts and analysis for a period of five years.

APPENDIX 1

WHAT IS AN LREC?

- 1991 - DOH required each health authority in England and Wales to set up LREC's.
- LREC has authority to review and approve research proposals involving patients and healthy volunteers within NHS.
- Mixture of lay & professional people.
- Researchers are DENIED access to NHS patients without approval to LREC

All research proposals which involve/affect patients should be submitted to LREC (includes some audit projects) using the form provided by the LREC.

THE ROLE OF RESEARCH ETHICS COMMITTEES

1. A Research Ethics Committee is convened to provide the independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for research studies comply with recognised ethical standards;
2. The purpose of a Research Ethics Committee in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants. It shares this role and responsibility with others as described in the *Research Governance Framework for Health and Social Care*.
3. We are responsible for acting primarily in the interest of potential research participants and concerned communities, but should also take into account the interests, needs and safety of researchers who are trying to undertake research of good quality. However, the goals of research, while important, should always be secondary to the dignity, rights, safety and well-being of the research participants;
4. Take into consideration the principle of justice. This requires that the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture and ethnic considerations. In this context the contribution of previous research participants should also be recalled.

- 5 We should provide independent, competent and timely review of the ethics of proposed studies. Although operating within the Governance Framework determined by the Department of Health, in our decision-making, we need to have independence from political, institutional, profession-related or market influences. We need similarly to demonstrate competence and efficiency in our work, and to avoid unnecessary delay;
6. We should have due regard for the requirements of relevant regulatory agencies and of applicable laws, in common with all those involved in research in the NHS and Social Care environments. It is **not** for an Ethics Committee to interpret regulations or laws, but we may indicate in our advice to the researcher and host institution where we believe further consideration needs to be given to such matters.

THE REMIT OF AN NHS RESEARCH ETHICS COMMITTEE

NHS Research Ethics Committees COREC 2001 Paragraph 3.1 COREC 2001 states:

“Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- a. Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user’s past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
- b. Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above
- c. Access to data, organs or other bodily material or past and present NHS patients
- d. Fetal material and IVF involving NHS patients
- e. The recently dead in NHS premises
- f. The use of, or potential access to, NHS premises or facilities
- g. NHS staff recruited as research participants by virtue of their professional role

APPENDIX 2

ETHICS CHECKLIST

Why consider ethical issues?

It is important to demonstrate good scientific practice (objectivity, integrity, honesty, co-operation) as well as to consider specific issues if the study involves participation of humans, or data sources involving the “social world”

Areas for particular attention that you should discuss with your supervisor and seek advice are shown in the table below

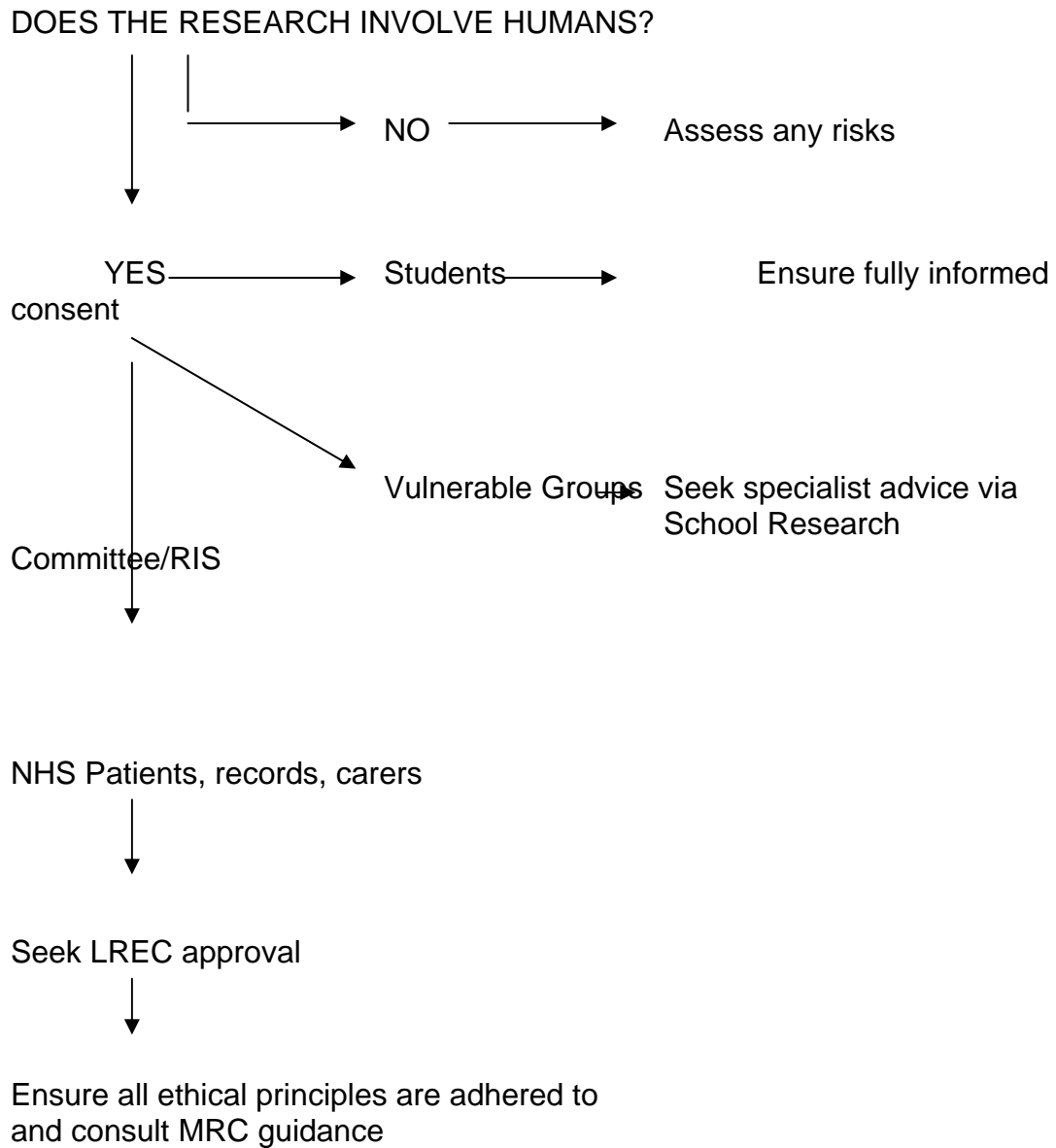
A range of resource material is available from RIS.

Access to data, organisational or personal	Requires formal access?/consent?/data protection
Human fluids, tissue, organs, remains	Seek specialist advice, eg MRC www.mrc.ac.uk
Access to vulnerable groups	Seek specialist advice - IHCS
All NHS sites (hospital or community) staff, patients and their records, carers	Seek specialist advice and approval via Local Research Ethics Committees
Research with students/healthy volunteers	Informed consent?/minimise harm and inconvenience
Access to voluntary sector	Seek LREC approval
Studies involving some kind of deception or covert fieldwork	Seek guidance from: British Psychological Society www.bps.org.uk British Sociological Association www.britisoc.org.uk/about.ethic/htm
Being in ownership of sensitive data as a result of data collection e.g. crime, fraud	Seek advice from relevant sector and discuss and devise a plan to protect yourself and integrity of the work

N.B. All persons/participants should be informed about research and have an opportunity to consent.

APPENDIX 3

FLOWCHART



APPENDIX 4

TEMPLATE FOR INFORMATION SHEET AND INFORMED CONSENT

The following issues should be addressed in an informed consent:

- Title of the study
- Purpose of the study
- Why participant was selected
- Description of procedures, purpose, length of time required and how participants will be involved.
- Discomforts, inconveniences expected
- Risks, if any
- Benefits, if any
- Withholding standard care/treatment or an alternative, if any
- Compensation to be expected, if any
- How confidentiality, anonymity and privacy will be maintained
- Right of participant to refuse to participate or withdraw at any time for any reason
- Sources for information and assurances that researcher will provide further and ongoing information (e.g. name and contact phone number of the researcher)
- Signature of the researcher and the participant or the participant's representative
- Signature of the witnesses where appropriate

APPENDIX 5

USEFUL WEBSITES

Multi-Centre REC (MREC) are downloadable from their website and meeting dates and contact information for MRECS are also available.

www.doh.gov.uk/research/rd3/nhsrandd/rgimpplan.htm Research Governance Implementation Plan

<http://onlineethics.org/> Online Ethics Centre for Engineering and Science, (American)

www.mrc.ac.uk/index/public_interest/ethics_best_practice.htm MRC site

www.britsoc.org.uk/about/ethic.htm British Sociological Association Statement of Ethical Practice

<http://jme.bmjournals.com/> Online Journal of Medical Ethics

http://ourworld.compuserve.com/homepages/Bulletin_of_Medical_Ethics/homepage.htm Provides an independent source of news and views on a wide range of issues in health care ethics. The Bulletin is published 10 times a year.

www.kcl.ac.uk/depsta/law/research/cmle/ Centre of Medical Law and Ethics at Kings College London

www.nuffieldbioethics.org/home/index.asp Independent body established by the Trustees of the Nuffield Foundation in 1991 to consider ethical issues arising from developments in medicine and biology

<http://www.ibe.org.uk/> Institute of Business Ethics (IBE) set up to emphasise the essentially ethical nature of wealth creation and to encourage the highest standards of behaviour by companies and to publicise the best ethical practice. IBE has created a Code of Business Ethics and holds consultations and conferences, publishes research and identifies effective actions which business organisations can take.

www.presswise.org.uk PressWise Trust. Established in 1993. Media Ethics charity.

<http://members.netscapeonline.co.uk/coneres> Consumers for Ethics in Research. Publicises views of people taking part in health research. Promotes informed debate about research.

www.users.globalnet.co.uk/~foodeth/aboutus.htm Food Ethics Council. Independent Council for ethical standards in food and agriculture. Established in 1998 as a result of widespread public concern over recent developments in the agriculture and food industries, some of which appear to infringe widely held ethical principles.

www.ccsr.cse.dmu.ac.uk/index.html Centre for Computing and Social Responsibility. Addresses the social and ethical impacts of information and communication technologies through research, consultancy and education.

www.bmj.com/misc/cope/ Committee on Publication Ethics. The COPE Report 1998.

www.ori.hhs.gov The Office of Research Integrity (ORI), (American)

APPENDIX 6

LOCAL NHS RESEARCH ETHICS COMMITTEES

Anna Jenkins (Administrator)
Bath LREC
Royal United Hospital (Forbes Fraser)
Coombe Park
Bath BA1 3NG
01225 825725

Mrs N. Nathoo
UBHT Ethics Committee Secretary
United Bristol Healthcare LREC
Trust Headquarters
Marlborough Street
Bristol BS1 3NU
0117 928 3613

Mrs Sue Bowman
Southmead LREC Secretary
Southmead Health Services NHS Trust
Southmead Hospital
Westbury-on-Trym
Bristol BS10 5NT
Tel: 0117 9505050

Mrs Ann-Marie Burrows
Weston Research Ethics Committee Secretary
Weston Area Health Trust
Weston General Hospital
Grange Road
Weston-super-Mare BS23 4TQ
Tel: 01934 636363 (ext 3343)

Mrs Kathleen Matthews
Research Ethics Committee Secretary
Frenchay Healthcare NHS Trust Headquarters
Beckspool Road
Frenchay
Bristol
BS16 1JE
Tel: 0117 9701070 (ext 3507)

Mrs Carmen Thomas
Ethics Committee Co-ordinator/Secretary
Clinical Directorates Office
Cornwall LREC
Royal Cornwall Hospital

Truro TR1 3LJ
01872 74242

Mrs Sandy Chivers (Manager)
North & East Devon LREC
Department of Medical Affairs
Royal Devon and Exeter Hospital (Wonsford)
Barrack Road
Exeter EX2 5DW
01392 402369

Mrs Rachel Hanson
East Dorset LREC Secretary
Poole Hospital NHS Trust
Longfleet Road
Poole BH15 2JB
01202 448201

Mrs Debbie McDermott
Ethics Committee Secretary
West Dorset LREC
West Dorset General Hospitals NHS Headquarters
Dorset County Hospital
Old School of Nursing
Princes Street
Dorchester DT1 1TS
01305 254640

Mrs Hazel Moynihan
Clerk to East and West Gloucestershire Research Ethics
Gloucestershire Health Authority
Victoria Warehouse
The Docks
Gloucester GL1 2EL
Tel: 01452 318864

Sandra Tapping
North & Mid Hampshire LREC
Harness House
Aldermaston Road
Basingstoke RG24 9NB
01256 312248

Sandra Jenkinson (Administrator)
Isle of Wight, Portsmouth & South East Hampshire LREC
Department of Public Health
Finchdean House
Milton Road
Portsmouth PO3 6DP
02392 835139

Clair Wright
Southampton & South West Hampshire LREC
Trust Management Offices, Mailpoint 18
General Hospital
Tremona Road
Southampton SO16 6YD
02380 794912

Sue Luscombe
Plymouth LREC Secretary
South and West Devon Health Authority
The Lescaze Offices
Chinner's Bridge
Dartington TQ9 6JE
Tel: 01803 861876

Miss Sarah Parsons
Secretary
Torbay LREC
South Devon Healthcare Trust
Hengrave house
Torbay Hospital
Lawes Bridge
Torquay TQ2 7AA
Tel: 01803 614567

Sally Chandler
Ethics Committee Secretary
Postgraduate Centre
East Somerset NHS Trust
Yeovil District Hospital
Higher Kingston
Yeovil BA21 4AT
01935 475122 x2559

Mrs Elisa Stanbury
West Somerset Ethics Committee Secretary
Research and Development Support Unit
Taunton and Somerset Hospital
Musgrove Park
Taunton TA1 5DA
Tel: 01823 342799

Kirsten Peck (Administrator)
Salisbury LREC
Wiltshire Health Authority

Southgate House
Pans Lane
Devizes SN10 5EQ
01380 728899
Chair: Sally Tomlin

Kirsten Peck (Administrator)
Swindon LREC
Wiltshire Health Authority
Southgate House
Pans Lane
Devizes SN10 5EQ
01380 728899
Chair: Godfrey Fowler

Paul Williamson
South West Multicentre Research Ethics Committee
The Lescaze Offices
Shinners Bridge
Dartington TQ9 6JF
Tel: 01803 861947
Website: <http://dialspace.dial.pipex.com/mrec/>

Sarah Edwards
Lecturer in Ethics in Medicine
Centre for Ethics in Medicine
University of Bristol
73 St Michael's Hill
Bristol BS2 8EG
0117 928 9843; fax 0117 927 9814

The R & D Directorate contracts with the University of Bristol to provide the NHS with access to high quality advice with respect to the ethical issues inherent in research design, with the aim of improving the quality of research and the ethical scrutiny of research in the south and west. While Dr Ashcroft is happy to discuss issues with researchers, members of research ethics committees, NHS staff or researchers who wish to make enquiries about specific issues relating to research ethics should contact the chair of the relevant LREC in the first instance.

REFERENCES

- British Medical Association (2001) *Consent, Rights and Choices in Health Care for Children and Young People*. London, BMJ Books
- British Medical Association Code in *Medical Ethics To-day*, 1993
- British Psychological Society (<http://www.bps.org.uk/index.cfm>)
- British Sociological Society (BSA) (<http://www.le.ac.uk/so/bsa/bsa.html>)
- BSA Statement of Ethical Practice (<http://www.britisoc.org.uk/about/ethic.htm>)
- Declaration of Helsinki (<http://ohsr.od.nih.gov/helsinki.php3>)
- Department of Health Research Governance Framework Draft 2nd Edition
<http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance.htm>
- DoH (2001) *Reference Guide to Consent for Examination or Treatment*. London, Department of Health (<http://www.doh.gov.uk/consent>)
- DOH (2002) document *Human Bodies, Human Choices*, The Law on Human Organs and Tissue in England and Wales, A summary Consultation Report (<http://www.doh.gov.uk/tissue>)
- Fennel, P. (2001) Informed consent and clinical research in psychiatry. In *Informed Consent in Medical Research* (eds. L Doyal & S Tobias), pp. 182-92. London, BMJ Books
- Medical Research Council – Responsibility in Investigations on Human Subjects
British Medical Journal 2 178-179
- Royal College of Paediatrics and Child Health: Ethics Advisory Committee 2000, Guidelines for the ethical conduct of medical research involving children. *Archives of Disease in Childhood*, 82, pp. 177 - 82.
- The Belmont Report, The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, Department of Health and Human Services, April 18, 1979
- The Human Rights Act 1998
(<http://www.hmso.gov.uk/acts/1998/19980042.htm>)
- The Nuremburg Code (<http://ohsr.od.nih.gov/nuremburg.php3>)
- The Scientific Integrity Committee of the Midwest Nursing Research Society 2002 *Guidelines for Scientific Integrity* 2nd Edition
- The Treatment of Human Remains in Archaeology: Historic Scotland Operational Policy Paper 5 – Dorset House Library Ref 930.102 852 H15
- United Nations International Covenant on Civil and Political Rights, Article 7
(<http://www.redress.org/uniccpr.html>)
- World Health Organisation – International Ethical Guidelines for Biomedical Research Involving Human Subjects
(http://www.cioms.ch/frame_1993_texts_of_guidelines.htm)

ACKNOWLEDGEMENT

- University of Teesside Policy Procedures and Guidance Notes for Research Ethics 5th Edition May 2000
- Sheffield Hallam University Research Ethics Policies and Procedures
- University of Sunderland Ethics Committee Code of Practice, 1st Edition June 1994
- Oxford Brookes University Ethical Standards for Research Involving Human Participants Code of Practice March 2000

GLOSSARY

ADSS	Association of Directors of Social Services
BPS	British Psychological Society
BSA	British Sociological Association
DOH	Department of Health
MRC	Medical Research Council
NHS	National Health Service
RIS	Research, Innovation and Strategy Office