Research Policy

Approved by: Clinical Governance Committee
Date of approval: 13th September 2006
Originator: Medical Director

Introduction

The DoH Research Governance Framework for Health and Social Care states that '*Research is essential to the successful promotion and protection of health …. At the same time research can involve an element of risk…. Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research.'*

Policy Statement

The Pasque Charity recognises the vital contribution research makes to the development and delivery of care in the palliative setting. It is the aim of the charity to encourage relevant research and to ensure that any research carried out within the charity is relevant, appropriate and ethically sound and that this research is done to the highest standard. The charity actively seeks to support individuals, especially those doing professional courses, in initiating research.

The purpose of this policy is to ensure that any staff or students, who wish to undertake research, follow the correct procedures, thereby ensuring that the principles of research governance are not breached and that: -

- all clinical research projects are conducted in accordance with the Department of Health research governance framework.
- any research conducted by the palliative care provider is carried out with appropriate consent and authorisation from any patients involved, and where staff are the subject of a research project, from the staff involved, in line with published guidance on the conduct of research projects.
- before any research is undertaken a research proposal must be prepared and approval obtained from the appropriate Research Ethics Committee. MREC approval must be gained for all multi-centre research projects.
- research projects are appropriate for the provider to be participating in and are properly managed and documented.
- research will be conducted in accordance with the Charity's Research Procedure.

Related Hospice policies/procedures:

Consent
Research Procedure

Responsibility/Accountability

Ultimate Responsibility held by:

Chief Executive

First line responsibility held by:

Medical Director
Director of Nursing

Policy Monitoring and Review

- Annual report on research activities to the Board of Trustees
- Quarterly report on research activities to Clinical Governance Committee (or equivalent)
- Policy review 3 yearly, or when legislation, or Department of Health Guidance requires

Compliance with Statutory Requirements

- Private and Voluntary Health Care (England) Regulations 2001 Part 1 Regulation 9 (1j) and Part III Regulation 24
- Healthcare Commission Core Standard C32

Scope

The policy and accompanying procedure ensures that where research is being conducted within a palliative care organisation the patient, employees and the organisation are safeguarded through the seeking and granting of ethical approval and through informed consent. Where research is being undertaken, a nominated individual within the organisation will take responsibility for the management and documentation of all aspects of the research, providing regular reports on research activities and progress.

Staff training requirements

Training will be provided in the obtaining of informed consent for any research being undertaken, and in the specific requirements of the research protocols.

Audit plan

Adherence to the stated policy will be audited :
All research projects will include an audit and evaluation element.
An audit trail of the paperwork and records from each research project will be followed to ensure adherence with the principles above.

Appendix 1
What's new in the second edition of the *Research Governance Framework for Health and Social Care* (published 2005)

- *Research governance is one of the core standards all organisations should achieve in delivering NHS care.*

The Health and Social Care (Community Health and Standards) Act 2003, Section 45

- Health care organisations have to take standards into account in discharging their duty of quality.

The Human Tissue Act 2004 (to come into force in 2006)

- For tissue from patients, consent is required except in specified circumstances (such as when a research ethics committee (REC) has agreed to the study and the sample is anonymised).
- For post-mortem tissue, consent of person before he/she died, or of the relatives of the deceased, must always be obtained.
- Proposal to REC should describe how material will be disposed of and how findings will be reported to relatives.
- Human Tissue Authority is responsible for regulation from 2005.

The Mental Capacity Act 2005 (to come into force in 2007) provides safeguards for participants who lack capacity to consent to research.

- Researchers will have to respect person's previous wishes and consult someone, such as a carer, who is able to take an independent view.
- There will be legal requirement for review by appropriate body.

The Medicines for Human Use (Clinical Trials) Regulations 2004 transposed Clinical Trials Directive 2001/20/EC into UK law.

- A clinical trial must not start, or seek to recruit participants, until favourable opinion from an ethics committee and authorisation from the Medicines and Healthcare products Regulatory Authority (MHRA) is received.
- The Regulations specify responsibilities of sponsors and investigators in trials of medicines.
- Participants must have interview with a researcher, and be given a contact point for further information about the trial.

Ethical review

- New legislation above requires ethical review before study starts.
- Protocol must not change without ethics/MHRA approval.
- For clinical trials on medicines, the ethics committee must be recognised by the United Kingdom Ethics Committee Authority (UKECA).
- Researchers must keep ethics committees informed of progress.

- Central Office for Research Ethics Committees (COREC) has transferred to the National Patient Safety Agency (NPSA).

Review of research

- Independent expert review of protocols is required.
- All data must be available to inspection and auditing bodies.
- Protocol must not change without formal agreement from those who gave permission (includes MHRA and ethics).

The funder of research:

- ensures quality and value for money, based on research costs and any care or treatment costs;
- makes arrangements for independent expert review;
- ensures funding is conditional on identifying a sponsor;
- provides assistance to any enquiry, audit or investigation of the funded work.

The sponsor:

- is responsible for ensuring expert scientific and ethics reviews are carried out;
- ensures arrangements are in place to be alerted to significant developments;
- ensures arrangements are in place for compensation.

The chief investigator (CI):

- is responsible for the design, management and reporting of the study at all sites;
- is responsible for ensuring that each investigator is aware of legal duties, for clinical trials involving medicines;
- is responsible for ensuring protocol is approved by relevant bodies, conditions are acted upon, and that research follows the agreed protocol except in the case of urgent safety measures.

Organisations providing care:

- must ensure the sponsor has assumed responsibility, research has been reviewed by appropriate bodies, and that an authorised person has given written permission on behalf of the care organisation for the research to begin;
- must arrange for researchers not employed by any NHS organisation to hold an NHS honorary contract;
- must ensure adverse incidents are reported to NPSA.

Misconduct

- New NHS Counter Fraud and Security Management Service has overall responsibility for countering fraud.
- Universities UK are to establish a panel for Research Integrity in Health and Biomedical Sciences to provide advice on maintaining high standards.

Related guidance:

The NHS as an Innovative Organisation: A Framework and Guidance on the Management of Intellectual Property in the NHS (DH, 2002)
National Standards, Local Action (DH, 2004)
Standards for Better Health (DH, 2004)

Appendix 2

It is for the Charity Commission to advise charities what is expected of their trustees. The Charity Commission agrees with the following summary, based on the law and good practice.

It is a basic duty of trustees to ensure, for all their charitable research, that the research falls within the scope of their charity's purpose and its powers, and is an effective way of fulfilling those charitable purposes including the aim of achieving a public benefit. The trustees can also be expected to take reasonable steps to satisfy themselves that the research is well managed and cost-effective, and is of good quality. The trustees of a funding charity have the same overall accountability for the use of its funds as do the trustees of a charity carrying out its own research, if they are funding an individual, or a group of individuals, or a noncharitable body. The trustees of the funding charity need to be confident that the above duties are being carried out properly by the party which is being funded to carry out the research. Where a charity is making a research grant to another charity, such as a university or the NHS in its capacity as trustee of a charity, the trustees can properly translate the monitoring responsibilities to the trustees of the recipient charity. The charity with the monitoring responsibilities is expected to have a written agreement with the recipient making clear who accepts key responsibilities. It is expected to satisfy itself that the recipient is competent, and has the procedures and systems in place, to carry out the responsibilities it is to have under the agreement. Having satisfied itself, the funder is entitled to assume (unless evidence suggests otherwise) that the responsibilities are being discharged properly, provided that there are in place adequate arrangements for reviewing progress.

Taken from: Research governance in health and social care
Notes for charities *31 July 2002*

Appendix 3

Research

STANDARD C32

C32.1 There is a written policy which states whether or not research is carried out in the establishment.

C32.2 Where the policy states that research is carried out within the establishment, there are written procedures that set out the requirements to be met concerning research projects.

C32.3 All clinical research projects are conducted in accordance with the Department of Health research governance framework.

C32.4 Any new interventional procedures to be carried out in the establishment are referred to NICE.

C32.5 All clinical research projects are approved by a Research Ethics Committee.

C32.6 There are documented agreements in place for the allocation of responsibilities between all parties involved.

C32.7 The lead professional for each research project is documented.

C32.8 The responsibilities of the lead professional include:

_ the management of the research project;

_ the monitoring of progress on the project.

C32.9 There are documented agreements in place between the establishment/agency and their personnel and between the establishment/agency and funders about ownership, exploitation and income from any intellectual property that may arise from research conducted on their premises.

C32.10 Records are kept of all research projects, including information about the patients involved, or patients whose data or tissue has been used in the project, for 15 years after the conclusion of the treatment.

C32.11 Lawful consent or authorisation is obtained for the participation of any patient in a research project.

C32.12 The registered person is responsible for ensuring that all research projects undertaken are appropriate for the organisation to be involved in and are properly managed.

Taken from:
Department of Health
Independent
Health Care
National Minimum Standards
Regulations
London: The Stationery Office

Appendix 4

hospice care: hospice research

Research involves the generation and discovery of new knowledge through a systematic process of information gathering and analysis.

There are various types of research, which draw on theories and methods from biomedical sciences, physical sciences, social sciences and the humanities. All members of the multi-disciplinary clinical team may undertake research. Some examples include:

- Clinical research which usually involves health care professionals such as doctors, nurses and therapists. It is usually concerned with determining the efficacy of new treatments or ways to deliver care to patients and their families. It may also be concerned with understanding disease processes.
- Health services research which involves broader issues concerned with identifying and assessing the needs of individuals and groups in society and how services are organised and delivered. Health services research often incorporates health economic evaluations and population level epidemiological analyses.
- Social research which may involve studies which seek to understand the lived experience of illness from the perspective of patients and their carers. It may investigate the process of care and the nature and quality of interactions between service users and health care services.

A definition of research
There are many different definitions and approaches to research but it is generally agreed that it involves a systematic approach to collecting and analysing information to develop new or improved knowledge. The National Council for Hospice and Specialist Palliative Care Services provides one definition:

"Research is the systematic pursuit of knowledge through observation, experiment, and analysis" (1999)

What is researched?

- Communication and decision making
- Symptom relief
- New treatments and technologies
- Bereavement and loss
- Needs of families, friends and carers
- Quality of life
- Improving services, evaluating costs and clinical efficiency
- Support and education of health professionals
- Finding meaning and emotional support
- Role of volunteers

Reference: *Research Governance Framework for Health and Social Care (published 2005)*

How is research conducted?
Some of the approaches used include:

- Clinical trials
- Qualitative methods
- Surveys
- Developing new measures and outcomes
- Cost analyses
- Epidemiological analyses
- Service evaluations and audits

What is research used for?
Research provides information for evidence-based practice in relation to:

- Improving services
- Improving treatment and care
- Helping to commission, plan and evaluate services
- Evaluate cost effectiveness
- Guiding education for the public, service users, carers and health professionals.

Who facilitates research?
Facilitators include:

- Hospices and specialist palliative care units
- University academic departments
- Palliative care academic centres, such as Department of Palliative Care and Policy, Guy's, King's and St. Thomas School of Medicine and Sheffield Palliative Care Studies Group
- National and local charities
- National Council for Hospice and Specialist Palliative Care Services
- NHS Trusts and Research & Development initiatives
- Palliative Care Research Forum
- Royal Society of Medicine: Palliative Care Forum.

Taken from: Help the hospices. Hospice care: hospice research
http://www.helpthehospices.org.uk/hospicecare/index.asp?submenu=4

Appendix 4
The role of Research Ethics Committees

Taken from: -

Governance arrangements for NHS Research Ethics Committees

2 The role of Research Ethics Committees

2.1 Research Ethics Committees are the committees 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.

2.2 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*.

2.3 RECs are responsible for acting primarily in the interest of potential research participants and concerned communities, but they 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 and researchers, while important, should always be secondary to the dignity, rights, safety, and well-being of the research participants.

2.4 RECs also need to 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 in particular age, gender, economic status, culture and ethnic considerations. In this context the contribution of previous research participants should also be recalled.

2.5 RECs 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 their decision-making RECs need to have independence from political, institutional, profession-related or market influences. They need similarly to demonstrate competence and efficiency in their work, and to avoid unnecessary delay.

2.6 In common with all those involved in research in the NHS and Social Care environments, RECs should have due regard for the requirements of relevant regulatory agencies and of applicable laws. It is not for the REC to provide specific interpretation of regulations or laws, but it may indicate in its advice to the researcher and host institution where it believes further consideration needs to be given to such matters.

3 The remit of an NHS REC

3.1 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 of 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.
3.2 If requested to do so, an NHS REC may also provide an opinion on the ethics of similar research studies not involving the categories listed above in section
3.1, carried out for example by private sector companies, the Medical Research Council (or other public sector organisations), charities or universities.

9 The Process of Ethical Review of a Research Protocol

The Review

9.1 All properly submitted and valid applications shall be reviewed in a timely fashion and according to an established review procedure described in the REC's standard operating procedures**.** A valid application is one which has been submitted by an appropriate investigator, is complete, with all the necessary documents attached, and is signed and dated.
9.2 RECs shall meet regularly on scheduled dates that are announced in advance. Meetings should be planned in accordance with the needs of the workload, but RECs must meet the time standards for review.
9.3 REC members should be given enough time in advance of the meeting to review the relevant documents.
9.4 Meetings shall be minuted. There should be an approval procedure for the minutes.
9.5 The applicant (and if appropriate, the sponsor and/or other investigators) shall be invited to be available to elaborate on or clarify specific issues as required by the REC at its meeting. An REC should not cause unnecessary delay by deferring consideration of an application when the necessary further information it requires could have been obtained from the applicant at the first review meeting.
9.6 Independent expert referees may be invited by the Chairman to attend the meeting or to provide written comments, subject to applicable confidentiality agreements.

Elements of the review

9.7 The primary task of an REC lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety for participants, to the informed consent process, documentation, and to the suitability and feasibility of the protocol.
9.8 The Research Governance Framework makes it clear that the sponsor is responsible for ensuring the quality of the science. Paragraphs 2.3.1 and 2.3.2 state that:

- "It is essential that existing sources of evidence, especially systematic reviews, are considered carefully prior to undertaking research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.
- All proposals for health and social care research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality. Arrangements for peer review must be commensurate with the scale of the research."

9.9 Thus, protocols submitted for ethical review should already have had prior critique by experts in the relevant research methodology, who should also comment on the originality of the research. It is not the task of an REC to undertake additional scientific review, nor is it constituted to do so, but it should satisfy itself that the review already undertaken is adequate for the nature of the proposal under consideration.
9.10 If the committee is of the opinion that the prior scientific review commensurate with the scale of the research is not adequate (including adequate statistical analysis), it should require the applicant to re-submit the application having obtained further expert review.
9.11 In addition to considering prior scientific review, RECs need to take into account the potential relevance of applicable laws and regulations. It is not the role of the REC to offer a

legal opinion, but it may advise the applicant and the host NHS body whenever it is of the opinion that further expert legal advice might be helpful to them.

Requirements for a favourable opinion

9.12 Before giving a favourable opinion, the REC should be adequately reassured about the following issues, as applicable:

9.13 *Scientific design and conduct of the study*:

a. the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation where appropriate), and the potential for reaching sound conclusions with the smallest number of research participants

b. the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants, other present and future patients, and the concerned communities

c. the justification for use of control arms in trials, (whether placebo or active comparator), and the randomisation process to be used

d. criteria for prematurely withdrawing research participants

e. criteria for suspending or terminating the research as a whole

f. the adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring committee (DSMC)

g. the adequacy of the research site, including the supporting staff, available facilities, and emergency procedures. For multi-centre research, these locality issues will be considered separately from the ethical review of the research proposal itself

h. the manner in which the results of the research will be reported and published.

9.14 *Recruitment of research participants*

a. the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity) and the justification for any decisions made in this respect

b. the means by which initial contact and recruitment is to be conducted

c. the means by which full information is to be conveyed to potential research participants or their representatives

d. inclusion criteria for research participants

e. exclusion criteria for research participants.

9.15 *Care and protection of research participants*

a. the safety of any intervention to be used in the proposed research

b. the suitability of the investigator(s)'s qualifications and experience for ensuring good conduct of the proposed study

c. any plans to withdraw or withhold standard therapies or clinical management protocols for the purpose of the research, and the justification for such action

d. the health and social care to be provided to research participants during and after the course of the research

e. the adequacy of health and social supervision and psychosocial support for the research participants

f. steps to be taken if research participants voluntarily withdraw during the course of the research

g. the criteria for extended access to, the emergency use of, and/or the compassionate use of study products

h. the arrangements, if appropriate, for informing the research participant's general practitioner, including procedures for seeking the participant's consent to do so

i. a description of any plans to make the study product available to the research participants following the research

j. a description of any financial costs to research participants

k. the rewards and compensations (if any) for research participants (including money, services and/or gifts)
l. whether there is provision in proportion to the risk for compensation/treatment in the case of injury/disability/death of a research participant attributable to participation in the research; the insurance and indemnity arrangements
m. the nature and size of any grants, payments or other reward to be made to any researchers or research hosts
n. circumstances that might be lead to conflicts of interest that may affect the independent judgement of the researcher(s).

9.16 *Protection of research participants' confidentiality*

a. a description of the persons who will have access to personal data of the research participants, including medical records and biological samples
b. the measures taken to ensure the confidentiality and security of personal information concerning research participants
c. the extent to which the information will be anonymised
d. how the data/samples will be obtained, and the purposes for which they will be used
e. how long the data/samples will be kept
f. to which countries, if any, the data/samples will be sent
g. the adequacy of the process for obtaining consent for the above.

9.17 *Informed consent process*

a. a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, the time-frame in which it will occur, and the process for ensuring consent has not been withdrawn
b. the adequacy, completeness and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representatives
c. clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals
d. assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being)
e. the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

9.18 *Community considerations*

a. the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
b. the steps which had been taken to consult with the concerned communities during the course of designing the research
c. the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs
d. a description of the availability and affordability of any successful study product to the concerned communities following the research
e. the manner in which the results of the research will be made available to the research participants and the concerned communities.

Expedited review

9.19 RECs shall establish any procedures necessary for the expedited review of research proposals. These procedures, which should be described in full in the Standard Operating Procedures, should specify the following:

a. the nature of the applications, amendments, and other considerations that will be eligible for expedited review
b. the quorum requirements for expedited review
c. the status of decisions (e.g. whether requiring confirmation by the full REC or not)

Decision-making

9.20 In making decisions on applications for the ethical review of research, an REC should take the following into consideration:
a. a member should withdraw from the meeting for the discussion and decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the Chair prior to the review of the application, and recorded in the minutes
b. an REC should not review an application in which one of its own members is a named researcher; such applications should be submitted to another REC
c. by invitation of the Chair, independent experts or others may take part in the discussion of the proposal at the REC meeting; however, a final decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. the investigator, representatives of the sponsor, independent experts) from the meeting, with the exception of REC administrative staff and approved observers
d. decisions should only be made at meetings where a quorum is present
e. the documents required for a full review of the application shall be complete and the relevant elements mentioned above should be considered before a decision is made
f. written comments from absent members shall be allowed to inform the discussion, but only those members who actually participate in the review by the committee at its meeting shall participate in the decision
g. there should be a pre-determined method for arriving at a decision; it is recommended that decisions be arrived at through consensus where possible. Where a consensus is not achievable, the REC should vote.

9.21 Advice that is not binding may be appended to the decision.
9.22 In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
9.23 An unfavourable opinion on an application should be supported by clearly stated reasons.

10 Submitting an application

10.1 The application shall be submitted by the "principal investigator" who is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. It follows that the applicant should be of adequate qualification and expertise to fulfil this important role.
10.2 Where a potential applicant is inexperienced, there should be an identified supervisor of adequate quality and experience who will counter-sign the application form, and then share the responsibility for the ethical and scientific conduct of the research. A current signed CV of the supervisor should be submitted with the application.
10.3 RECs should ensure that their requirements for submitting an application for review are described in an application procedure that is readily available to prospective applicants.
10.4 Research to be undertaken by students primarily for educational purposes (e.g. as a requirement for a University degree course) shall be considered according to the same ethical and operational standards as are applied to other research.
In such cases the supervisor takes on the role and responsibilities of the sponsor. In reaching its decision, the REC will wish to consider the broader overall benefits gained by such research.

Application requirements

10.5 These shall be published by the REC and shall include the following:
a. the name(s) and address(es) of the REC secretariat to which the application is to be submitted
b. the application form
c. the format for submission
d. any additional documentation
e. the language(s) in which core document(s) are to be submitted
f. the number of copies to be submitted
g. the deadlines for submission of the application in relation to the review dates
h. the means by which the application will be acknowledged, including the communication of the incompleteness of the application
i. the expected time for notification of the decision following review
j. the time frame to be followed in cases where the REC requests supplementary information or changes to the documents from the applicant
k. the fee structure, if any, for reviewing an application
l. the application procedure for amendments to the protocol, the recruitment material, the potential research participant information, and the information or methods used to obtain consent
m. the process for addressing any disputed decisions.

The documentation

10.6 All documentation required for a thorough and complete review of the ethics of proposed research should be submitted by the applicant. This may include, but is not limited to:
a. signed and dated application form
b. the protocol of the proposed research (clearly identified and dated),together with supporting documents and references, and details of any previous scientific peer review
c. a summary, synopsis or diagram ("flowchart") of the protocol in nontechnical language
d. a description of the ethical considerations involved in the research
e. diary cards and other questionnaires intended for research participants
f. when the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with the summary of the clinical experience with the study product to date (e.g. recent investigators brochure, published data, a summary of the product's characteristics)
g. the applicant(s)'s current curriculum vitae (updated, signed and dated).
h. material to be used (including advertisements) for the recruitment of potential research participants
i. a full description of the process to obtain and document consent
j. written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages

Governance arrangements for NHS Research Ethics Committees
July 2001