Pasque Charity

Research Procedure

Approved by: **Clinical Governance Committee**

Date of approval: **13th September 2006**
Originator: **Medical Director**

Policy area
Research Policy

Aim and Scope of Procedure

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

Staff Responsibilities
Director of Nursing
Medical Director

Method:

- Follow the recommendations in the Department of Health in the Research Governance Framework for Health and Social Care (Published 2005 – or any updated versions)

The process for all research projects undertaken within the Charity follows, four stages:

- Stage 1 – Planning the research and protocol development
- Stage 2 –Submission to Clinical Governance Committee and submission to the relevant Multi-centre Research Ethics Committee for ethical approval
- Stage 3 – Research project undertaken
- Stage 4 – Completion of project and dissemination of results

Stage 1 - Protocol Development

The proposal will include:

- Project protocol
- Research Ethics Committee applications (COREC)
- Information sheets and consent forms
- Researcher's current cv
- Details of external researchers (for honorary contracts)
- Supporting documentation including:
- Associated costs eg. support costs and extra treatment costs
- Details of research funding, if available.
- Formal Risk Assessment.

Planning the research

All research projects, both clinical and non-clinical, should be conceived, designed, and implemented according to the highest standards, including:

• Clear documentation of the rationale for the study and any subsequent modifications. Each key document and any changes should be signed and dated by the researcher responsible to establish the provenance of the study and protect intellectual property rights.

• Adherence to current safety practices, ethical standards, and law.

• Securing all necessary ethical review and regulatory approvals in good time, for example from Local Research Ethics Committees.

• In clinical studies, identifying a health professional who will take overall responsibility for the well-being and interests of patients or healthy volunteers involved and for ensuring that their rights (e.g. in terms of consent and confidentiality) are protected.

• Identifying the individual or group that will take ultimate responsibility for overseeing the scientific and ethical conduct of the study as the scientific plans are put into practice. This is especially important in projects affecting patients or volunteers and in other complex and collaborative programmes.

• Consultation with patients or other beneficiaries/consumers wherever appropriate, especially in clinical and applied research.

• Consultation with statisticians at the planning stage, where relevant. The statistical power of a study should be an early consideration, and researchers should draw on professional statistical advice if needed. This is especially important for studies involving people to avoid unnecessary or unproductive experiments.

• Ensuring, where appropriate, that organisations responsible for the care of any patients involved are aware that the research is being planned.

• Assessment of resources needed (e.g., space, staff, funding, biological resources, facilities, and clinical support) to ensure the study is viable within the available means.

• Economy in the use of resources.

• Regular review of progress so that new findings can be taken into account and the project plan modified accordingly, especially if plans involve any risk to participants

•Agreement in advance on who will be writing any planned publications and the authorisation required to publish

• Acknowledgement of formal or informal contributions to the work, including sponsoring organisations and scientific collaborators.

• A formal risk assessment for submission to the Research Ethics Committee should be carried out on the whole project to include identifying all risks that might occur.

Peer Review
Peer review is a requirement under the research governance framework and is designed to ensure that the research questions, methodology and analysis of a project are appropriate.

Stage 2 - Ethical Approval

It is at this stage that the research project should be brought to the Clinical Governance Committee for their approval on behalf of the trustees and the charity.
All projects approved by the Clinical Governance committee will then be submitted to the relevant Research Ethics Committee (COREC).
Any major changes to the project should be brought back to the Clinical Governance Committee for their approval.

The legal and ethical requirements relating to human participants and personal information should be familiar to each person involved in the study, and they should know to whom to turn for advice.

Risks of research misuse
In progressing their scientific investigations, researchers should actively consider any risks that their research will generate outcomes that could be misused for harmful purposes. Where such risks exist, they should seek advice and take active steps to minimise them.

Standard written protocols
Standard written protocols should be available covering the process of seeking informed consent from patients or volunteers, to ensure clarity and consistency.

Gathering and storing data
• Confidentiality of personal data is essential, including data associated with tissue and biological samples. A Local Research Ethics Committee, Multi-Centre Research Ethics Committee, or other appropriate ethics committee must approve all research involving identifiable personal information or anonymised data. All personal information must be encoded or anonymised as far as is possible and consistent with the needs of the study, and as early as possible after collection; This applies to both paper and electronic records.
• Data should be stored in a way that permits a complete retrospective audit if necessary.
• Data should be stored safely, with appropriate contingency plans.
• Data records should be monitored regularly to ensure their completeness and accuracy.
• Raw (original) data/images should be recorded and retained.

Retaining data
Retention of accurately recorded and retrievable results is essential for research.
• Primary research data (and where possible/relevant specimens, samples, questionnaires, audiotapes, etc) must be retained in their original form within the research establishment that generated them for a minimum of ten years from completion of the project.
• Work that informs national policymaking should be archived.
• Researchers who are leaving the establishment that generated the data and who wish to retain data/copies of data for personal use must get permission from their Head of department to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the consent.
• Publication of the data (including in Masters/Doctoral theses) does not negate the need to retain source data.

Notebooks and electronic records
The following basic policies apply:
• All raw data should be recorded and retained in notebooks or in an electronic notebook dedicated to that purpose.
• Machine print-outs, questionnaires, chart recordings, auto radiographs, etc which cannot be attached to the main record should be retained in a separate ring-binder/folder
• Records in notebooks should be entered as soon as possible after the data are collected. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.
• In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.

Computer-generated data
Special procedures are necessary for electronically generated data.
• Data should be backed-up regularly; duplicate copies should be held on disc in a secure but readily accessible archive.
• Where feasible, a hard copy should be made of particularly important data.
• Copies of relevant software, particularly the version used to process electronic data, must be retained along with the raw data to ensure future access. Software updates must be logged and stored as new formats and media are adopted.
• Special attention should be paid to guaranteeing the security of electronic data.

Stage 3 - Research Project
The researcher can now undertake the research.
Progress Reports
Progress of all research projects will be reported to the Clinical Governance Committee.

Stage 4 – Completion of Project and Dissemination of Results
On completion of the research, the researcher is expected to make public their results.

Reporting the results
Once any issues of confidentiality and ownership have been addressed, research findings should be disseminated so that they can be assessed by scientific peers and more widely. This is essential if scientific knowledge is to be used appropriately and effectively. Accordingly, researchers should publish their data in a timely fashion in a peer-reviewed journal or in other equally reputable publications and/or present their results at scientific meetings.
A copy of the research project should be submitted to the Clinical Governance Committee prior to any external dissemination to ensure the final piece of work meets the Charities requirements on presentation.

Authorship
• Authorship of papers should include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper. Authors should have participated sufficiently in the research to take public responsibility for the content.

Commercial exploitation
• Intellectual property can only be protected adequately if researchers keep thorough, accurate, and contemporaneous research records.
• Researchers who collaborate with industry should take special care to keep detailed records of their research.

References:
1. **Medical Research Council *Ethics* Series Good Research Practice. (**Updated

September 2005)
2. Chesterfield & North Derbyshire Royal Hospital NHS Trust
POLICY FOR REQUESTING PERMISSION TO CONDUCT RESEARCH
3. Research Governance Framework for Health and Social Care 2005