

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT TO UMC FOR 2007/08

1. EXECUTIVE SUMMARY

The University Ethics Committee continues to meet on a monthly basis to consider submissions made to it, to monitor various activities and to continue to develop University policy. During 2007/08 the Code of Practice on Investigations involving Human Beings was revised and approved by UMC, Senate and Court. It will replace the current Code of Practice on the web site and members of staff and students will be informed of its availability shortly. Training events will be organised to support the launch of this revised Code of Practice to ensure that staff and students know what is required. There have been changes in the membership of the Committee, which widens the pool of expertise available to the Committee. Additionally, members are encouraged to attend relevant external training events and to share the knowledge obtained at these events with colleagues on the Committee and in the wider University.

2. OPERATION OF THE COMMITTEE

Whilst the University Ethics Committee does not have targets as such, there have been various initiatives that have been viewed as being essential for it to achieve. During the reporting period the Committee has undertaken the following:

i. Policy Development: Revised Code of Practice

The Code of Practice on Investigations involving Human Beings was revised by a sub-group of the Committee comprising Professor T Bedford, Professor J Blackie, Mrs E Condie, Mrs G McArthur, Ms L McKean and Ms Z Wilson. The Code was finalised and has been approved by UMC, Senate and Court. It will shortly be placed on the University web site and members of staff will be informed of its availability. The Code has been significantly revised in order to make it more user-friendly and accessible; and to reflect changes externally, mainly relating to changes in legislation and to guidance issued by the NHS and the Research Councils. The Committee has also revised the procedures to try and make them less burdensome and easier for staff and students to follow. The Committee has agreed that staff may seek generic approval for certain types of investigations and Departmental Ethics Committees may seek delegated authority to consider and approve certain investigations that would normally have to be considered at the University Ethics Committee. It is hoped that this will lead to a more efficient process reducing the burden on applicants as well as Departmental and the University Ethics Committees.

For investigations that have a significant involvement with the NHS the University Ethics Committee has agreed that the NHS Ethics Committee will normally take priority and will provide the formal ethics approval. The University Ethics Committee (or the relevant Departmental Ethics Committee) will still receive a copy of any such application to ensure that it is consonant with University policy and is ethically acceptable, but the primary ethical approval route will be through the NHS Ethics Committee. Where the NHS is involved and the main part of the work is being conducted by a member of staff at the University, then the University Ethics Committee will also ethically review the investigation (as well as the NHS REC) in order to be satisfied that it is acceptable to the University. A similar approach was agreed last year with joint investigations, where it was accepted that seeking ethical approval from two different bodies was not always necessary and that an agreement should be taken at the outset as to which body would take the lead for each study and would, therefore, take primary responsibility for ethical approval.

The application form used by the Ethics Committee has been updated to make sure that it captures all relevant information. Guidance notes on how to complete the form have been developed to accompany it. Two new forms have also been developed: one that can be used to seek generic approval for a series of investigations and/or teaching exercises involving human participants; and another that Departmental Ethics Committees can use to seek delegated authority for certain procedures or categories of studies. The University Ethics Committee will delegate authority to DEC's where it is deemed appropriate. It is hoped that this will help streamline the ethical approval process within the University.

ii. Investigations requiring Ethical Approval: Research and Service Evaluation

A number of investigators in the University have raised issues regarding the types of investigations that require ethical approval and those that might not. Discussions with the NHS have highlighted that the NHS does not require ethical review for any study that could be defined as a service evaluation or an audit of an existing service. Some of the investigations carried out within the University fall into the definition of service evaluations i.e. they are conducted solely to define or assess a particular service provided, usually measured against a professional standard. There is no new knowledge as such. It is acknowledged that even these types of studies have an ethical dimension and can involve a certain degree of risk and need to be carefully constructed before commencing. However, the Committee was of the view that these types of studies did not need formal ethical approval. Rather it is the responsibility of the staff involved and the Head of Department to identify and address all factors, including risk and insurance cover, and to manage the study.

iii. Children as Participants

During the course of the year, and as part of the revisions to the Code of Practice, a significant part of the deliberations have centred around the involvement of children in investigations and the need for consent from the children and possibly also parental consent. Professor Blackie from the Law School, has been particularly helpful to the Committee in developing the advice for investigators which is now captured clearly and succinctly in the revised Code of Practice. In Scotland individuals over the age of 16 years can consent for themselves. Also, under the legislation in Scotland, children aged 12 or over who are deemed to have sufficient maturity and understanding can consent, although it is deemed good practice to seek parental assent as well. For all other children parental consent must be sought and it is good practice to make sure that the child is happy to take part in whatever is proposed.

One related aspect is that of meeting legislative requirements through Disclosure Scotland procedures. Where the participants are under 18 years old or are deemed to be 'vulnerable' then all investigators must be checked through Disclosure Scotland procedures before the investigation can commence. This has caused some difficulties in some investigations carried out. One particular difficulty relates to investigations that might involve access to pupils in a number of different schools. Each school/Local Authority requires a separate Disclosure Scotland check to be carried out before the investigation can commence. This is a time consuming exercise and can quite often delay the start of the project. However, investigators working in this area know that they have to allow time for these checks to be carried out.

iv. Data Protection and Use of Data

The University's Data protection Officer addressed a meeting of the University Ethics Committee last year. This proved to be a useful session and addressed a number of issues. One matter that has been further considered by the Committee since then is the use of data obtained in one investigation being used in a subsequent, related investigation. Under the terms of the Data Protection Act this is allowed as long as the

data is fully anonymised and no individual can be identified from the data provided. From the ethical point of view it has always been accepted that individuals must consent to their data being used in each investigation and investigators have been encouraged to seek further consent from individuals to use the data in any subsequent study. However, in light of the Data Protection advice and from guidance being issued by other bodies, (some of the Social Science Research Councils and professional bodies) it is now becoming more acceptable that data can be used in subsequent studies as long as it is fully anonymised. The University Ethics Committee decided that it would be good practice for investigators to seek consent from participants at the outset to use the data obtained in the investigation they have agreed to take part in and, potentially, any subsequent related investigation, bearing in mind the need to maintain anonymity. Individual participants can then agree to this, or not, from the start. This does not apply to any investigation that involves medical notes as, under the NHS guidance, this data can only be used for the investigation that the individual consented to.

v. Training

The programme of training and awareness raising sessions in Faculties and departments throughout the University has continued, although time and resource limitations have meant that it has not been possible to respond to every request. The substantial commitment involved in developing the new Code of Practice and related documents during the past year has reduced the time available for training on the part of the Convener, other key members and officers.

Additionally, Dr Sinclair of CAPLE, is assisting the Committee to develop generic training materials. As an interim measure a Research Ethics module has been developed and is available on WebCT. This provides some basic information for investigators to access. It is the intention to develop further training materials.

vi. Approval of Protocols

The Committee considered and approved a total of 50 protocols in session 2006/07. This compares with 61 the previous session (2005/06). To date in session 2007/08 the Committee has considered 58 protocols (the comparative figure for this point in the session last year was 35). As awareness of the ethics procedures rises within the University more applications have come forward for approval. Some of the applications received this year relate to seeking generic approval for teaching activities (e.g. in Sports Science) and so approval for these activities is now in place for three years. A summary of the protocols approved in session 2006/07 and to date in session 2007/08 is attached for information in Annex 2.

vii. Monitoring of Protocols

The Committee also monitors the progress of every protocol that it approves, except for the generic protocols that are monitored by the relevant Departmental Ethics Committee. This monitoring is undertaken annually, in July/August each year. The number of projects being monitored by the Committee continues to grow each year, as not all projects are completed within the year of approval. Last year 113 monitoring forms were issued and the information obtained was reported to the Committee.

viii. Monitoring of Departmental Ethics Committees

The University Ethics Committee monitors the activities of all Departmental Ethics Committees (DEC) on an annual basis. The DEC's are required to provide an annual report to the Committee in February each year (the report is for the previous calendar year) so that the Committee has information on the number and range of projects approved by the DEC's and any issues emerging from these. DEC's are also encouraged to raise any other issues that they might have with the University Ethics Committee. In this way the University Ethics Committee can keep abreast of the

concerns that DEC's and staff in departments have. This year 39 forms were issued to departments – this includes three to CAS departments: Information Resources Directorate, Centre for Academic Practice and Learning Enhancement, and Centre for Lifelong Learning. To date 34 forms have been returned, representing a return rate of 87%, a reminder has been issued to the remaining departments.

3. CHALLENGES AND FUTURE ISSUES

i. Revised Code of Practice: Training

In light of the revised Code of Practice being approved and issued a number of actions now require to be taken. The most important of these is training and awareness-raising for staff and students. The revised Code of Practice and accompanying application forms will be placed on the secretariat web site. Access to these documents has been improved and linkages between the Code and the forms, and the Code and other sources of useful information are being developed. Detailed guidance notes have been produced to accompany the forms which should help applicants understand what information is required by the Committee in order for it to take a decision. As previously mentioned it is also the intention to develop web-based training materials that will assist investigators develop projects and understand the issues that they require to address before they start their investigations.

The Committee believes that the revised Code of Practice should streamline the current procedures. Staff are already familiar with the procedures in place and the revisions should help improve the efficiency of the whole process. The revised procedures also allow for more activities to be delegated to departmental level where this is considered appropriate. The Committee wishes to encourage DEC's to be more active and to take more responsibility as, in many instances, this is where the greatest level of professional expertise in that particular area lies. However, the University Ethics Committee will need to be satisfied that it is appropriate for the DEC to undertake such activities and it will continue to monitor the DEC's activities on an annual basis.

ii. Professional Practice and Procedures: Keeping up to date

One challenge facing the Committee and members of staff in departments is keeping up to date with developments, not just in terms of the legislation but also professional standards and practice. During the year an instance was raised where the practice being followed by departmental staff was not the most up to date. This involved the use of rectal probes. Advice was sought from the NHS and the department has now adjusted its procedures to ensure that it fully complies with the standard expected for such procedures. The revised Code of Practice makes it clear that it is the responsibility of staff to keep up to date with the professional standards required in their area. Where the Committee becomes aware that this might not be the case it will work with staff to ensure that any corrective action necessary is fully implemented.

iii. External Environment

It is essential for the University Ethics Committee, and for staff in departments to keep abreast of relevant developments. The University is a member of the Association of Research Ethics Committees (AREC), which is an independent self-regulatory body for research committees predominantly (but not exclusively) aimed at the NHS. It has recently established a sub-committee, the University Research Ethics Committees (UREC), which is aimed at the higher education sector and the ethical issues that such institutions face. Given the nature of higher education this body covers a much wider range of issues than the AREC and is proving to be very helpful to Universities. In light of the feedback obtained from the various AREC/UREC events attended it is becoming apparent that Strathclyde is at the forefront of dealing with ethical matters in the higher

education sector. Indeed colleagues in other institutions are now consulting staff here on various ethical matters.

Links with the NHS are being maintained, largely through the Glasgow Research Governance Group. Various developments have taken place relating to procedures involving the NHS. One recent development was the launch of the Research Passport scheme. This is for University staff who conduct research in an NHS environment that could impact on patient care. All University staff involved in such research must obtain the relevant clearance from the NHS authority involved and be issued with a 'Research Passport' before they can start the investigation.

4. UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

The current membership of the Committee is listed in Annex 1. Mrs Condie continues as Convener and four Vice-Conveners have been appointed. Previously only one Vice-Convener had been appointed. However, due to the volume of work involved and the need to ensure coverage it was decided that it would be better if each Faculty had one member who was either the Convener or a Vice-Convener. The following members of the Committee are now Vice-Conveners: Professor T Bedford, Dr S Kelly, Professor E MacLellan and Dr N NicDaeid. The Vice-Conveners are expected to assist the Convener in dealing with the various tasks arising from the meetings, to chair the meetings in the Conveners absence, and to assist with policy development and training events. The Vice-Conveners were appointed in November 2007 and this arrangement will be reviewed in one year's time.

Dr C Converse completed her period of membership of the Committee in July and Dr K Smith had resigned from the Committee in March.

Two new members of the Committee joined in August 2007: these being Dr P Riches, SIPBS and now Bioengineering, and Dr J Tettey, SIPBS. Unfortunately Dr Tettey subsequently moved to another job and a replacement had to be found. Dr J Johnson, SIPBS, joined the Committee on 1 March 2008.

5. RISK MANAGEMENT

The Risk Management schedule for the Committee is attached at Annex 3. The Committee continues to monitor and manage these matters as appropriate.

Gwen McArthur
Secretary to the Ethics Committee
23 April 2008.

ETHICS COMMITTEE

MEMBERSHIP 2007/08

Name	Category/Faculty	Date Appointed	Membership ends
Convener			
Ms E Condie	National Centre	01.09.03	31.07.09
Internal Members			
Dr A Agapiou	Architecture	01.08.06	31.07.09
Professor T Bedford	Management Science	01.08.06	31.07.09
Professor J Blackie	Law School	01.05.05	31.07.08
Prof D Christie	Childhood & Primary Studies	01.09.05	31.07.08
Mr A Hosie	Social Work	01.09.03	31.07.09
Dr J Johnston	SIPBS	01.03.08	31.07.10
Dr S Kelly	Psychology	01.08.06	31.07.09
Prof E Maclellan	Educational Studies	01.09.03	31.07.10
Dr N NicDaeid	Forensic Science	01.09.03	31.07.09
Dr P Riches	Bioengineering	01.08.07	31.07.10
Rev B Slevin	Chaplaincy	01.07.04	31.07.10
External Members			
Dr J Bunney	Chief Pharmacist (Retired)	01.11.04	31.07.10
Dr H Gray	Student Health Service Consultant, GRI (retired)	01.10.00	31.07.09
Lay Members			
Mr D Blyth	Lay	01.11.06	31.07.09
Mr C W Turner	Lay	01.10.04	31.07.08
Mrs M Whitehead	Lay	01.04.07	31.07.09

GMcA
4.04.08