UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT TO UMG FOR 2005/06

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. In June 2005 the revised Code of Practice on Investigations on Human Beings (3rd edition) was issued. Since then the Committee and attending officers have worked with colleagues throughout the University to ensure that these procedures become well known and established within the system. Training and awareness raising sessions have been held with various departments and groups of staff and students, and will continue to be held throughout the coming session. Additionally attention has been paid to the external environment and the changing requirements that have been developed by various external bodies including the Research Councils and, more recently, the Scottish Executive.

2. OPERATION OF THE COMMITTEE DURING THE PREVIOUS YEAR

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:

- Policy development: the Code of Practice on Investigations on Human Beings was revised by the Committee in order to take account of new external requirements and to introduce new internal procedures, specifically the need for management approval and consideration of sponsorship before any project could be forwarded to the Committee for ethical scrutiny. The revised Code of Practice was approved by Court in June 2005 and issued thereafter. The single point of entry, via R & C Services, has helped streamline the process and ensures that management approval, ethical approval and the provision of insurance cover for each project is all now dealt with through one process. It also means that R & C Services now have a much greater level of information on studies involving humans, some of which progress to the University Ethics Committee for consideration, and others which are dealt with by the relevant Departmental Ethics Committees.
- Student Projects: following a series of discussions at its meetings, and following dialogue with staff in various departments throughout the University, the Committee issued further guidance in March 2006 to staff and students regarding the types of student projects that required ethical approval and those which could be considered to be 'professional practice', i.e. part of the training requirements where the students were learning specific skills for that profession rather than undertaking a project as such. It also reaffirmed which types of projects could be approved by Departmental Ethics Committees and which had to be forwarded to the University Ethics Committee for consideration and approval.
- Training: a formal training seminar was held on 30 November 2005 which was open to all members of staff to attend. The Convener of the Ethics Committee chaired this event which discussed the Code of Practice, the new procedures, and what was expected of staff and students when conducting investigations on humans. This was attended by 26 members of staff from throughout the University.
- Awareness Raising: other events have been organised throughout the year to raise awareness of the new procedures. Some of these events were: i) the Convener of the Committee presented a seminar to the Faculty of Education in September 2005, which was particularly well attended by staff from all departments in the Faculty; ii) the Convener and Ms Frew (R&C Services) gave a seminar to staff in the National Centre; iii) Ms Frew and Ms McKean (R&C Services) have attended various meetings at both Faculty and Departmental level to discuss the new procedures e.g. the Law, Arts and Social Sciences Research Committee, the School of Social Work Department meeting; iv) Ms Frew and Ms McKean have held various presentations for staff and

- students to discuss the new procedures e.g. the Bioengineering Unit, the Department of Marketing. Additionally, Ms Frew, Mrs McArthur and the Convener of the Committee have provided advice to staff and students throughout the year as the occasion has arisen.
- Training of the Committee members: members of the Committee have continued to participate in a range of training events and seminars organised by external bodies in order to keep up to date with developments. One of the most useful training events has been the seminars run by King's College, London which are specifically aimed at University Ethics Committees and where colleagues from other Universities meet to discuss ethical issues in a University context.

In addition to the above initiatives the Committee has continued to consider and approve protocols and to monitor those protocols and also the activities of the Departmental Ethics Committees.

- **Approval of Protocols**: the Committee considered and approved a total of 65 protocols in 2004/05. This compares with 37 in the previous year (2003/04). To date the Committee has considered 46 protocols in 2005/06 (the comparative figure for this point in session 2004/05 was 33 protocols). This shows that raised awareness of the procedures has led to more protocols coming forward to the Committee for consideration and approval. A summary of the protocols approved by the Committee in session 2004/05 and to date in 2005/06 is attached at Annex 2 (this is restricted information under the Freedom of Information Act).
- Monitoring of Protocols: the Committee monitors all the protocols that it approves. This monitoring is undertaken annually, with the information being sought in July/August each year. The Committee now has complete information on all the protocols that it has approved which shows when the project started, provides information on any unusual events that occurred or any other information the Committee needs to know which occurred during the project, and when the project will end/has ended. The number of projects that the Committee monitors each year continues to grow, as not all projects are completed within the year and the Committee continues to monitor them all until completion.
- Monitoring of Departmental Ethics Committees: the Committee seeks an annual report from all academic departments on the activities of the Departmental Ethics Committees. Additionally, the Centre for Lifelong Learning has established a Departmental Ethics Committee and both the Centre for Academic Practice and Learning Enhancement (CAPLE) and the Information Resources Directorate (IRD) are considering establishing their own DEC's. This information is sought in February each year and is for the previous calendar year. The Committee was particularly heartened this year by the improvement in the return rate from the departments. Responses were received from 28 departments (out of a possible 45), which represented a 62% return rate. A follow-up request for information was issued and further responses received. Only some 9 departments have still to respond. These are currently being followed-up.

Whilst not all departments have established a Departmental Ethics Committee, they have established some independent group to ethically review relevant projects. The University Ethics Committee would continue to urge departments to establish a separate Departmental ethics Committee.

3. NEW INITIATIVES AND ACHIEVEMENTS

During the year the Committee has debated and further refined the University policy and procedures for investigations involving human beings. As mentioned above the Committee issued further guidance regarding student projects and when these required ethical approval.

Disclosure Scotland Policy and Procedure: in 2005 Court approved the University's Disclosure Scotland Policy and Procedure which had been prepared in light of the Protection of Children (Scotland) Act 2003. This meant that all staff and students who conduct projects/investigations involving children and young people under 18 years of age must be checked through the relevant

disclosure procedures. This has had a significant impact on students, both undergraduate and postgraduate, who are involved in such investigations. Whilst students on some courses are always checked through these procedures prior to admission to the course (e.g. the B.Ed or the BA in Social Work) others will now have to be checked should they wish to undertake studies involving children under 18. The Code of Practice will be amended at its next revision, but all staff have been advised accordingly. This has had an impact on a number of studies and has meant that more staff and students now have to be checked before they can undertake certain projects.

Informed Consent: the Committee has also revisited the matter of informed consent, particularly in relation to children in residential homes. How informed consent is sought from these children and whether or not consent is also sought from their parents/guardians is a matter currently under debate at the Committee. It is known that for some of these children it would not be appropriate to seek informed consent from their parent/guardian and so the Committee has to be sure that other safeguards are in place to protect the children. Further advice is being sought from the Children's Commissioner for Scotland, and from colleagues at Glasgow University who also work in this area, to establish best practice and to ensure that the University is meeting this.

Confidentiality of business: this relates primarily to commercially sensitive aspects of particular projects and to intellectual property rights. Whilst there is no attempt to censor the committee members or to limit their activities, the Committee has to be able to reassure researchers that any commercially sensitive aspects of their projects will be respected and will be treated in confidence. The Committee spent some time debating this matter and has agreed that each of the external and lay members of the Committee (i.e. those that are not members of staff of the University) will be asked to sign a simple declaration that they will respect the confidential nature of such matters when they arise in the business of the Committee.

4. STRATEGIC CHALLENGES AND FUTURE ISSUES

.1 External Environment

The Committee has continued to monitor the external environment and would comment particularly on the following matters:

Research Councils: the Committee was rather concerned that the ESRC developed its own ethical framework which all bodies it awards funds to now have to comply with. Whilst the University's policies and procedures do meet the ESRC framework requirements, the University now has to ensure that its policies and procedures meet a range of different frameworks established by a variety of external funding bodies and Research Councils. The Senior Officer, Deputy Principal Professor Ferguson, has raised the Committee's concerns on this matter at Universities Scotland. Whilst it is acknowledged that it is difficult to prevent external bodies from imposing their own requirements on the University, it is hoped that some commonality can be achieved, at least between the Research Councils, in order to minimise the number of different frameworks the University has to comply with.

NHS: links with the NHS have been maintained through the year. Both Ms Frew (R&C Services) and Ms McArthur, secretary to the Committee, have continued to represent the University at the Glasgow Research Governance Group. This continues to be a useful forum in providing contact with colleagues in the NHS and in the expanding links the University now has with the NHS. It also provides the University with early warning of changes being made to the system of management scrutiny and ethical review operating in the NHS which affect the University either directly or indirectly. The most recent examples of this have been the discussions regarding the implementation of the new legislation on the storage of human cells and tissue (effective from 6 April 2006); and the recent revisions made to the Research Governance Framework for Health and Community Care (revised framework issued in March 2006). The full implications of these changes have been

discussed and the Committee is now considering how these impact on University policy and procedures.

Warner Report: the Department of Health commissioned the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees (the Warner Report) which was published in June 2005. The University was invited to comment on this report and the response was prepared by Professor Foot, following discussion at the Committee. Generally the Committee welcomed the content and spirit of this report. It was acknowledged that there had been some attempt to reduce bureaucracy, and the Committee provided some specific comments that could lighten the load even further if accepted. More recently the Chief Scientists Office has established a Scottish Ethics Advisory Group to look at this report in detail and specifically from the Scottish perspective. Further consultation is currently underway, with responses having to be received by 21 April. Once further information has been received the Committee will adjust its procedures if necessary.

.2 Internal Environment

Charging for ethical review: it is known that some external bodies, particularly the NHS, are considering charging for ethical review of projects. Whilst the University currently enjoys a special relationship with the NHS it is unlikely that charges will be introduced, at least at this point in time. However, it does raise the issue that the University may have to meet such charges in the future.

It also raises the question of whether the University should be including charges for ethical scrutiny, particularly for those projects that seek external funding. Now that full economic costing applies to all University activities it is considered that some consideration needs to be given to a realistic cost to be included in grant applications being made to external funders. The Senior Officer and Convener of the Committee will be meeting to discuss this matter but, in the meantime, it would be helpful if UMG could give some early consideration to this matter also.

Membership of the Committee: two of the longest serving members of the Committee, Professors Foot and Furman, will be completing their period of membership at the end of this session. The Committee has given some early consideration to matters of succession planning and has made specific recommendations – see below. The Committee is also aware that it needs to attract new lay members, and has made recommendations also set out below. It is aware that it needs to ensure a balance of representation from across the wider community in its membership. Induction training will be provided to all new members when they start.

5. UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

The current membership of the Committee is listed in Annex 1. Professor Hugh Foot has continued to chair the Committee, but has intimated that he will be retiring at the end of this session. The Committee has considered this matter and now

RECOMMENDS to the University Management Group that Mrs E Condie, the current Vice-Convener of the Committee, be appointed Convener of the University Ethics Committee with effect from 1 August 2006.

The Committee has also considered the matter of succession planning, as other members of the Committee near the end of their period of membership, and particularly the recruitment of lay members. These matters are currently under debate, but the Committee would also

RECOMMEND to the University Management Group that it be permitted to advertise externally for new lay members.

Some consideration is being given to the appointment of a Vice-Convener for the Committee. A recommendation on this matter will be brought to UMG in the near future.

The Committee has added to the number of people who regularly attend its meetings. It was agreed that a representative should be invited from the Centre for Academic Practice and Learning Enhancement in order to assist with the delivery of the necessary training for both staff and students. The Attending Officers are:

Dr Christine Sinclair, Centre for Academic Practice and Learning Enhancement Ms Lynda Frew, Research and Consultancy Services Ms Louise McKean, Research and Consultancy Services Ms Zoe Wilson, Finance Office, - for insurance matters Mrs Gwen McArthur, secretary to the Committee.

6. 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 Committee 25 April 2006

Annex 1

UNIVERSITY ETHICS COMMITTEE

1. Remit

The remit of the University Ethics Committee is

- to consider general ethical issues relating to the teaching and research of the University which involves investigations on human beings;
- to provide impartial advice to participants and researchers and to protect the dignity, rights, safety and well-being of all actual and potential participants;
- to approve studies submitted for ethical review and to monitor such studies as appropriate, and receive reports on their outcomes;
- to devise and submit for approval by Court a University Code of Practice on investigations on human beings, to keep the Code under review and to recommend such modifications as from time to time are deemed necessary;
- as a matter of routine in the case of investigations which may interfere with normal human function, to consider the ethical implications of individual proposals for investigations on human beings and to advise whether or not these are acceptable;
- to be available to give advice to staff and students of the University who undertake or who participate in such investigations on the ethical considerations involved;
- to liaise with external bodies, such as relevant NHS Ethics Committees, on ethical matters as appropriate;
- to meet on a monthly basis and to report annually to the University Management Group.

2. Composition of the University Ethics Committee

The composition of the University Ethics Committee is such that it comprises a pool of up to 18 members representing a broad range of experience and expertise (including a lawyer, a medically qualified person, and a chaplain) from members of staff within the University, from external members (i.e. who are not employees of the University), and from lay members (i.e. members who are independent of the University and have no previous experience in carrying out research involving human participants). There is a quorum of seven for each meeting.

Up to 12 internal members – one of whom shall be Convener

Up to 3 external members

Up to 3 lay members.

A Vice-Convener will be appointed from amongst the members of the Committee, this should normally be a lay member.

Members of the Committee will normally be appointed by the University Management Group for three years at a time, and may be reappointed for a second term of three years.

Additionally, at the Convener's discretion, the Committee

- may co-opt up to two further members to discuss particular submissions
- seek expert advice and guidance from named members of staff or other independent experts on a range of matters as and when required.

3. Membership of the University Ethics Committee

The membership of the University Ethics Committee is (as at 26 April 2006):

- Professor Hugh Foot, Psychology (Convener)
- Professor John Blackie, Law School
- Dr James Bunney, former Chief Pharmacist, Glasgow Royal Infirmary
- Dr David Carus, Mechanical Engineering
- Professor Donald Christie, Childhood and Primary Studies
- Ms Elizabeth Condie, National Centre for Training and Education in Prosthetics and Orthotics (Vice-Convener of the Committee)
- Dr Carolyn Converse, Pharmaceutical Science
- Professor Brian Furman, Physiology and Pharmacology
- Dr Harry Gray, Consultant, Glasgow Royal Infirmary (Student Health Service)
- Mr Andrew Hosie, Scottish Institute for Residential Childcare
- Professor Effie MacLellan, Educational Studies
- Dr Niamh NicDaeid, Forensic Science Unit, Pure & Applied Chemistry
- Dr Derek Nonhebel, Lay member Former member of staff
- Reverend Brendan Slevin, University Chaplain
- Dr Kevin Smith, Bioscience
- Mr Charles Turner, Lay member former member of staff

In Attendance

Ms Lynda Frew, Research and Consultancy Services
Ms Louise McKean, Research and Consultancy Services
Dr Christine Sinclair, Centre for Academic Practice and Learning Enhancement
Ms Zoe Wilson, Finance Office (Insurance Adviser)
Mrs G McArthur, Secretary to the Committee.

4. Induction and Training

New members of the University Ethics Committee must attend an induction session, preferably prior to taking up appointment. All members of the Committee will be encouraged to attend relevant training and other events as deemed appropriate.

5. Declaration of Interests

All members of the University Ethics Committee, and anyone asked to provide expert advice to the University Ethics Committee, who have an interest which may affect their consideration of a particular proposal are required to declare that interest and, if necessary, should temporarily withdraw from the meeting for consideration of that proposal.

DEPARTMENTAL ETHICS COMMITTEES

The Composition of the Departmental Ethics Committees is such that they shall comprise a minimum of two members of staff from the Department concerned and may also include either a member of staff from another department or an external member. The quorum for DEC's is two, and it is essential that no member of staff can make a judgement on a protocol that they have submitted to the DEC for consideration. One of the members of the DEC may act as secretary to the DEC or an independent secretary may be appointed.

DEC's shall meet as often as required to consider submissions made to them. Investigators who have submitted proposals for consideration shall be informed of the DEC's decision by the secretary to the DEC. DEC's are required to report annually to the University Ethics Committee on their operations.