

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT TO UMC FOR 2006/07

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. Committee members and attending officers continue to work with colleagues throughout the University to ensure that the procedures, as contained in the Code of Practice on Investigations on Human Beings, 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 changes in legislation, e.g. the recently introduced Human Tissue Act.

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 is being revised again by a sub-committee established by the Committee. This is to ensure that it is fully up to date with changes to internal procedures as well as changes in the external environment that impinge on it. The membership of this sub-committee comprises Professor T Bedford, Professor J Blackie, Mrs McArthur, Dr Campbell, Ms McKean and Ms Wilson. Dr Smith, the Vice-Convener of the UEC, was previously a member but, following his resignation from the Committee has been replaced by the Convener, Mrs Condie. The last edition of the Code of Practice (issued in June 2005) introduced new procedures, principally management and sponsorship approval procedures. The Committee has monitored the effectiveness of these new procedures and is satisfied that they are working well. The single point of entry, through Research & Innovation, is helpful to investigators and ensures that full consideration is given to all aspects involved, i.e. sponsorship, management approval, ethical approval and insurance cover. Further refinements are being made to these procedures in the light of experience of operating them, and will be included as part of the revisions to the Code of Practice. Research & Innovation now have a much greater level of information on studies involving humans conducted by University staff and students, some of which progress to the University Ethics Committee for ethical consideration, and others which are dealt with by the relevant Departmental Ethics Committees.
- **Student projects and professional practice:** dialogue is continuing, both within the Committee itself, and with staff in various departments throughout the University, regarding the types of student projects that require ethical approval and those which could be considered to be 'professional practice', i.e. part of the training requirements where the students are learning specific skills for that profession rather than undertaking a project as such. Whilst the Committee had previously issued guidance to staff on this matter, some departments have sought reassurance from the Committee in order to ensure that they are complying with the policy. In some areas it is not always clear cut when a specific type of activity requires ethical approval and when it does not. The information built up as part of this process is being used to inform the next edition of the Code of Practice.
- **Supervision of student projects:** the Committee has made it clear that while students might be undertaking the main investigator role in their various student projects (whether at

undergraduate or postgraduate level) the student's supervisor must be named as the Chief Investigator for the project. This is to ensure that the student's supervisor is responsible for the actions of the students when they are conducting these studies and must ensure that the students comply with all relevant regulations and guidelines. It also ensures that the students receive adequate supervision when conducting such studies, that they are fully aware of all the risks and the ethical considerations their project poses, and they are trained in the techniques that will be used as part of the project. Additionally, should there be a complaint arising from the study, there needs to be a member of staff who is in a position to take responsibility for dealing with such instances. For many students the project is the final part of their studies and once they have completed it they graduate and leave the University. The member of staff provides the continuity needed in such instances. This view does not appear to be shared by all staff and the Committee has been challenged on this. However, the Committee is clear that, while the project does provide the student with an invaluable learning experience, this cannot be achieved without adequate supervision from relevant staff.

Indeed, the Committee has experienced two specific instances which have reinforced its position in this matter. In the first instance the Committee Convener received a letter from a senior member of staff at Glasgow Royal Infirmary which raised this very issue. This letter was addressed to all three Universities in Glasgow and emphasised the need for students to be adequately supervised at all times when conducting research in the NHS. The University Ethics Committee has informed the NHS of its position, namely that students can not be named as Chief Investigators in any studies and that the student's supervisor is ultimately responsible for any study conducted by students whether in the University or elsewhere. It also asked that if any Strathclyde students were causing concern then the NHS should contact the Committee, via the Convener or secretary, who would take action as appropriate. In the second instance the Committee was asked to consider establishing a policy which would introduce sanctions against students who undertook data collection for projects involving humans without ethical approval. The Committee did not accept that it needed to produce a separate policy on this matter, but considered this to be a failure on the part of the department, and particularly the student's supervisor, to fully inform the students what was required of them and the necessary steps they had to undertake. The Committee continues to remind staff of this.

- **Training:** a number of training events have been held during the year. A training seminar for postgraduate students was held on 3 July 2006 and a training seminar for supervisors was held on 11 October 2006. Additionally the Convener, Vice-Convener and other members and Attending Officers of the Committee have taken part in various training events throughout the University. Some of these have been formal training events for staff or students organised by Faculties or departments, while others have been less formal and more akin to awareness raising events in order to ensure that staff and students know how and when to seek ethical approval.
- **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. These include events run by the Association of Research Ethics Committees (AREC), UK Council for Graduate Education, Keele University and King's College London. Additionally, the University's Data Protection Officer recently addressed the Committee on the provisions of the Data Protection Act and what staff and students needed to do in order to comply with this Act, particularly when processing personal data.

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 61 protocols in 2005/06. This compares with 65 in the previous year (2004/05). To date the Committee has considered 35 protocols in 2006/07 (the comparative figure for this point in session 2005/06 was 45 protocols). This would seem to indicate that the Committee should expect to receive approximately 60-70 projects for consideration and approval each year. A summary of the

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protocols approved by the Committee in session 2005/06 and to date in 2006/07 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 Departmental Ethics Committees on the activities they have undertaken during the previous year and the number of projects that they have considered and approved. In addition to all academic departments some non-academic departments have established DEC's, including Information Resources Directorate, Centre for Academic Practice and Learning Enhancement, and the Centre for Lifelong Learning. 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 so far have been received from 33 departments (out of a possible 39), which represents an 85% return rate. The remaining few departments have received reminders. The returns received show that the DEC's have dealt with 433 applications this year. 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 is currently revising the Code of Practice which will be re-issued once it is finalised. UMC may wish to note the following in particular,

- **Ethical approval for collaborative studies:** as part of the revisions to the Code of Practice some further consideration has been given to collaborative studies and which body should give ethical approval. Under the current procedures all studies involving humans as subjects conducted by the staff or students of the University must be approved by either the University Ethics Committee or the Departmental Ethics Committee in addition to any other external ethics committee. This was agreed following discussions with the University Insurers, who took the view that the University needed to know what its staff and students were doing and, at that time, this was possibly the most effective way of ensuring that this happened, as well as ensuring that the University was satisfied that the staff and students were conducting studies that the University wished to be involved in. However, given the introduction of the management approval and sponsorship procedures and the fact that other institutions now also have their own ethical committees and procedures in place, the Committee is not convinced that this 'double' approval is still necessary and is currently considering when a single approval would be sufficient. For example, for joint courses the Committee considers that the administering institution should be responsible for giving ethical approval to student projects. The staff in both institutions will be fully aware of the types of studies the students are undertaking as part of the course and as long as ethical approval is secured from an appropriate ethics committee then it does not always have to be from this University's ethics committee. Further advice will be given to departments once the Committee has fully considered this matter and once the Insurers have confirmed that any changes in procedures would not affect the insurance cover provided.

- **Revisions to University procedures and forms:** during the course of the year the Ethics Committee's application form has been revised to make it clearer what information is required by the Committee. The revised form is now available on the Ethics Committee web site for all investigators to use. The Committee has also recently developed an additional form that investigators who are undertaking studies involving the NHS are asked to complete in addition to the COREC form. The Committee already accepts the COREC form, rather than ask investigators to complete the University application form as well. However, the COREC form is not user friendly and it is not always easy to identify the particular role the University staff and/or students will undertake in the study being submitted for approval. The summary form produced by the Committee will pick out this information so that the Committee can readily identify what it is being asked to consider.

During the year discussions have been held with staff in Safety Services regarding the taking of blood samples. As a result of these discussions the University's Health and Safety Policy has been amended to make clear that anyone taking blood samples must be properly trained in such procedures and must have ethical approval. UMC approved this amendment at its meeting on 13 February 2007.

- **AREC and UK University Research Ethics Committees:** the Association of Research Ethics Committees (AREC) is an independent self-regulatory body for research ethics committees that works to ensure the protection and safety of the community by promoting good quality research and a high standard of ethical review for research involving human subjects. Originally this Association worked primarily with the NHS and the independent sector. However, in the past few years the University sector has become more involved and in the past year the AREC changed its articles of association to include University Research Ethics Committees (UREC's). The AREC Council is now made up of two sub-committees, one for LREC's (NHS Committees) and one for UREC's (University committees). There are ten members of the Council, four of whom are from the University sector. The University has been a member of AREC since 2002 and has found this a particularly useful link. AREC organises regular conferences and seminars on a variety of topics relating to research and ethical approval. It also provides a useful training programme for members of ethics committees and has led to a number of useful contacts being established. The Committee welcomes the change to the AREC constitution and is confident that this will help ensure that all ethics committees operate to a consistently high standard throughout the UK.
- **Insurance cover:** following discussions at the Committee and as part of the revisions to the Code of Practice further information has been provided to the Committee regarding insurance cover. It is the intention that the revised Code of Practice will have a complete section providing information on the range of insurance policies that the University has in place, the conditions and exclusions that apply and information on claims.

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:

- **Human Tissue Act:** the Human Tissue (Scotland) Act 2006 was recently introduced which has a direct bearing on some of the work carried out in the University. It also clarifies which elements of the Human Tissue Act 2004 apply to Scotland. The Human Tissue (Scotland) Act does not cover the storage and use of tissue removed from living individuals (except for transplantation) but focuses on the use of material removed from bodies after death. It sets out the need to obtain authorisation for the use of such material and who can give such authorisation. It also makes clear that it is an offence within the UK to have human tissue or

cells for DNA analysis without consent of the donor (except in certain specified circumstances). Advice has been sought on the implications of this legislation for the University and this will be reflected in the next edition of the Code of Practice.

- **Other Ethical Frameworks:** last year the Committee reported that the ESRC had developed its own ethical framework which all bodies it awards funds to have to comply with. It is known that other Research Councils are thinking of developing their own ethical frameworks and some professional bodies already have their ethical framework in place (e.g. the British Psychological Society). Whilst most of these are very similar in their nature and, so far, the University's own procedures fit with these other frameworks, the Committee has concerns that researchers are being asked to comply with too many other rules imposed by external bodies. Deputy Principal Ferguson has already raised this matter at Universities Scotland. The Committee was also pleased to note that UREC, through AREC, has raised these concerns directly with some of the bodies concerned. Whilst no conclusions have been reached so far, at least the various bodies are considering this matter further. It is hoped that a more consistent approach across these different bodies can be achieved.
- **NHS:** links with the NHS have been maintained through the year. Ms Frew and Ms McKean (Research & Innovation) and Dr Campbell 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.

Mrs Condie and Dr Campbell met with Ms A Torrie, OREC Manager, NHS Greater Glasgow and Clyde in January to discuss areas of common interest between the University and the NHS in the ethics application and approval process. This was a particularly useful meeting that helped clarify a number of issues. Mrs Condie is keen to establish a regular series of meetings between University ethics committee conveners and NHS REC representatives in Glasgow.

- **Links with other Universities in Glasgow:** as a direct result of membership of the Glasgow Research Governance Group (mentioned above) the University representatives on this group arrange to meet separately to discuss matters of mutual concern to the Universities. Representatives from Strathclyde, Glasgow and Glasgow Caledonian meet on a regular basis to discuss developments in matters relating to research governance, ethical approval and related matters. This is proving to be another useful source of information.

.2 Internal Environment

The Committee would like to draw attention to the following matters:

- **Procedures used in specific studies:** recently the committee received a protocol for consideration that involved muscle biopsy procedures. One of the external members of the Committee raised concerns about the procedures described in the protocol, as they were considered to be out of date with recent changes in legislation governing such procedures. The researchers in this department immediately suspended all muscle biopsy procedures until further notice. External advice has been provided and three members of the University Ethics Committee, Mrs Condie, Dr Gray and Dr Bunney, have visited the department to discuss these procedures in detail and to see for themselves the facilities where these procedures will be conducted. This visit took place on 4 April 2007. It was agreed that the researchers should seek further advice and assistance from relevant staff in the NHS and contact names have been provided. The Committee will monitor this situation and will only allow the department to commence muscle biopsy procedures again when it is satisfied that the procedures being used fully comply with the new regulations governing this area.

- **Charging for ethical review:** last year the Committee raised the possibility of charging for ethical review. It is known that some external bodies, particularly the NHS, are considering charging for ethical review of projects. To date there have been no further discussions of this matter but the Committee will continue to keep this under review.

5. UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

The current membership of the Committee is listed in Annex 1. Mrs Condie became Convener of the Committee on 1 August 2006, in succession to Professor Foot, and is settling into the role. During the year Dr K Smith was appointed as Vice-Convener of the Committee. However, Dr Smith has recently resigned from the Committee and a new Vice-Convener is currently being sought.

A number of new internal members have been recruited to the Committee with Professor T Bedford, Dr A Agapiou and Dr S Kelly joining the Committee on 1 August 2006. It is the intention that further new internal members will be sought to replace those who will be leaving in the summer. An advert will appear in Prism shortly.

Last year the Committee sought authority from UMC to advertise externally for new lay members. The Committee advertised in the local press (Glasgow Herald) in August last year which proved to be a useful exercise. The Committee has now recruited two new lay members who have joined the Committee. They are Mr D Blyth, a lawyer with McLay, Murray and Spens, and Mrs M Whitehead, a former Head Teacher and currently an independent assessor for the Office of Commissioner for Public Appointments in Scotland and a member of the Board of Management of Central College of Commerce.

The Committee would like to pay tribute to Dr Derek Nonhebel, who was appointed as one of the first lay members of the Committee when it was established in 2003 and who left the Committee at the end of March 2007. Dr Nonhebel was a valued member of the Committee.

A number of members of staff regularly attend meetings of the Committee, these include staff from Research and Innovation, Finance Office (for Insurance advice), and the Centre for Academic Practice and Learning Enhancement, in addition to secretarial support for the Committee. Ms Frew and Ms McKean, Research & Innovation, share responsibility and normally will take it in turns to attend the meetings. However, Ms Frew is currently on maternity leave and Ms McKean is providing all the necessary input from R&I during this period. Also during the year Mrs McArthur temporarily undertook additional duties elsewhere in the University and Dr Campbell was recruited to act as secretary to the Committee for the period from June 2006 to May 2007. During this time Dr Campbell has provided excellent support for both the Committee and the sub-committee established to review the Code of Practice. The Committee has benefited from this additional support, particularly as the demands placed on it are more time-consuming, there are now higher expectations about the role and performance of the Committee, there is a need for rigour, and more due diligence needs to be conducted before applications can be approved.

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
13 April 2007

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 current membership of the Committee (as at 16 April 2007) is as follows:

- Ms Elizabeth Condie, National Centre for Training and Education in Prosthetics and Orthotics (Convener of the Committee)
- Dr Andrew Agapiou, Architecture
- Professor Tim Bedford, Management Science
- Professor John Blackie, Law School
- Mr Douglas Blyth, Lay member - Lawyer
- Dr James Bunney, former Chief Pharmacist, Glasgow Royal Infirmary
- Professor Donald Christie, Childhood and Primary Studies
- Dr Carolyn Converse, SIPBS (Pharmaceutical Science)
- Dr Harry Gray, Consultant, Glasgow Royal Infirmary (Student Health Service)
- Mr Andrew Hosie, Scottish Institute for Residential Childcare
- Dr Steve Kelly, Psychology
- Professor Effie MacLellan, Educational Studies
- Dr Niamh NicDaeid, Forensic Science Unit, Pure & Applied Chemistry
- Reverend Brendan Slevin, University Chaplain
- Mr Charles Turner, Lay member – former member of staff
- Mrs Maire Whitehead, Lay member – former Head Teacher

In Attendance

Ms Lynda Frew, Research and Innovation
Ms Louise McKean, Research and Innovation
Dr Christine Sinclair, Centre for Academic Practice and Learning Enhancement
Ms Zoe Wilson, Finance Office (Insurance Adviser)
Dr Fiona Campbell, secretary to the Committee (June 2006 – May 2007)
Mrs G McArthur, Secretary to the Committee.