UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT TO UMG FOR SESSION 2004/05

1. OVERVIEW

Session 2004/05 has been another busy session for the Committee, as it continues to meet on a monthly basis and consider protocols coming forward for approval as well as developing policy for the University. The Committee continues to consider how best to comply with relevant legislation and other external requirements, all of which impact on the work of the Ethics Committee. This has led to the introduction of new procedures within the University, which in turn has led to a further revision to the Code of Practice on Investigations on Human Beings. The new procedures are still in the process of being embedded within the University system and the Committee continues to deal with issues raised by the Departments in response to implementing them. Training and awareness raising are issues that the Committee is continuing to address as it tries to assist colleagues in meeting the various responsibilities and requirements placed on them as a result of the new procedures.

2. UNIVERSITY ETHICS COMMITTEE

.1 Membership

There has been some turnover in the membership of the Committee during the session and its current membership is as detailed in Annex 1. Professor H Foot has continued as Convener of the Committee and Mrs G McArthur has continued as secretary to the Committee. In reviewing its composition the Committee confirmed that it needed to ensure that it had members representing a broad range of experience and expertise which, in addition to including lay members, should also include a lawyer, a medically qualified person and a chaplain. The Committee has also considered matters of succession planning and has taken steps to ensure that there is a regular turnover of members without too many leaving at one time. The Committee agreed to appoint Mrs E Condie as Vice-Convener. Although the Committee had previously decided that its Vice-Convener should be a lay member (to be consistent with the Research Governance Framework) it reconsidered this position. Given that all the lay members are new members the Committee decided to appoint Mrs Condie as Vice-Convener in light of her experience in this area.

.2 Operation of the Committee

The Committee continues to meet on a monthly basis where it considers new submissions, receives further information on continuing submissions and considers matters of policy. To date this session the Committee has considered 42 new submissions. A summary of the protocols considered by the Committee is attached at Annex 2 for information. In session 2003/04 the Committee considered a total of 37 protocols – a summary of which is also attached at Annex 2.

.3 Monitoring of Departmental Ethics Committees

The University Ethics Committee is responsible for monitoring the activities of the Departmental Ethics Committees. 2004 was the first year that the Committee conducted this monitoring. The annual reports from the DEC's in 2004 were quite disappointing. The level of response was not as good as it could have been which prompted the Convener to write to Heads of Departments to remind them of their responsibilities in this area and the need to establish separate committees to conduct ethical review of projects. There is increasing pressure from external sources, not least of which is the University's Insurers, to ensure that ethical review does occur for all projects involving human beings.

Session 2005 has brought a much better response from across the University. At the very least departments are now aware that they must conduct ethical review of projects involving humans. Dialogue with departments is continuing to make sure that they recognise the value of establishing a separate committee, preferably with some external representation, to ethically review projects. As departments become more familiar with this process and what is required of them then the data obtained will become more robust and there should be greater consistency in the decision-making process.

.4 Monitoring of Protocols Approved by Committee

The Committee now monitors all protocols that it approves. 2004 was the first year that such monitoring took place and proved a very useful exercise. There was an excellent response from the researchers involved which confirmed that they are acting responsibly and are following University procedures. One or two issues were raised as a result of this exercise and these have been followed-up by the Committee. The main issue to emerge last year regarded the start date of projects. In some instances it appeared that the project had started before ethical approval had been given. However, in following this up with the investigators it was found that this was not the case. The start date given was when the researcher had been recruited to the study whose task it was to conduct the background research, prepare the protocol and then submit it for approval. No recruitment of volunteers or data collection had taken place until after ethical approval had been given. Improved dialogue between the Committee and the researchers should overcome such differences in terminology in the future.

The Committee will be undertaking this task annually, in the summer each year, and expects that the information obtained will be robust and will provide an assurance to the management that researchers are acting responsibly and that any problems identified will be dealt with appropriately by the Committee and the staff concerned.

3. POLICY AND PROCEDURES

.1 Development of New Procedures

New procedures have been developed within the University for investigations involving human beings, particularly where the University is asked to be the sponsor or the co-sponsor. These procedures were approved by Senate in October 2004 and Court in November 2004, and have introduced a new step at the first stage, which now means that all submissions to the Ethics Committee are processed through R&C Services in the first instance. Under these procedures the Senior Officer responsible for research and the Director of Research & Consultancy Services consider each new project in terms of risk to the institution and whether or not the University will act as sponsor. If the project is considered to be high risk it will be forwarded to the Sponsorship Group for decision, otherwise the Senior Officer and Director of R&C Services can consider it. If approved at this stage it will then be passed to the appropriate Ethics Committee (either University Ethics or Departmental Ethics Committee) for ethical review. Only once all management aspects have been fully considered and the risk assessed, will the protocol be passed to the Ethics Committee for ethical review. This is consistent with the Research Governance Framework and mirrors the procedures in place in the NHS. It also ensures that a management risk assessment is undertaken for each project before it is approved, thus enhancing further the University's own risk assessment and governance procedures. Matters of adequate insurance cover for each project are also considered at this early stage and the Ethics Committee informed if cover is confirmed or if there are outstanding issues to be resolved first.

More recently the Committee has discussed these procedures again and is of the view that these may be too cumbersome for many low risk investigations that the University is involved in, particularly student projects. It has, therefore, proposed that the procedures be amended so that for any new investigation that involves human subjects (including research, teaching exercises and student projects) which is within the remit of the UEC, and/or involves the NHS, and/or is externally funded

then the Chief Investigator must follow the procedures as set out above. However, for investigations that are not within the remit of the UEC, do not involve the NHS and have no external funding (this will be particularly relevant to the majority of student projects), then these may be dealt with at the Departmental level. The Head of Department should consider whether the University is an appropriate sponsor for the investigation and the management risk issues, if any, arising from the investigation. If the Head of Department decides the University is an appropriate sponsor and there are no management risk issues, the sponsorship section of the UEC form should be signed and dated by the Head of Department. Where the Head of Department is the Chief Investigator then the Dean should act for the Head of Department. The UEC application form has been amended accordingly. The Departmental Ethics Committee (DEC) will ethically review such projects. Only once the investigation has both management and ethical approval can the project begin.

These procedures have been included in the revised Code of Practice which, it is hoped, will shortly be made available to all staff (on the intranet). In the meantime Ms Frew, of R&C Services, has been working with various departments to ensure that they understand and comply with the new procedures. Additionally the Convener and Ms Frew have attended departmental training sessions to discuss these procedures with staff in departments.

.2 Student Projects

The Committee has been considering the most appropriate way to deal with student projects. Essentially the University is the sponsor for every student project, i.e. the University is responsible for all aspects of the study, including seeking all appropriate approvals, ensuring good practice in conducting the study, monitoring the progress of the study and for reporting the outcomes. The new procedures, as outlined above, apply to all student projects.

It is also possible that generic approval can be sought by departments. This would provide approval for certain procedures to be carried out as part of student projects each year. In this way approval could be sought for a range of projects at one time. However, any student project that involved the NHS, or the criteria set out in the Code of Practice for the University Ethics Committee, or was externally funded would still have to come through R&C Services and the University Ethics Committee.

The Committee is continuing a dialogue with departments, to ensure that they know that all student projects involving investigations on human beings must be ethically reviewed by the appropriate committee, either the University Ethics Committee or the Departmental Ethics Committee, and must comply with these new procedures. Externally a group was set up by the Government to review student projects, principally in relation to the introduction of the new legislation for clinical trials. However, this may well have an impact on all student projects and will require the University to ensure that how it handles student projects is consistent with the findings of this group. The outcomes of this government group are still awaited, and will be considered by the Committee once available. Thereafter any adjustment to University procedures will be made as appropriate, although the Committee is confident that these should be relatively minor.

.3 Revised Code of Practice

The Code of Practice on Investigations on Human Beings has been revised to reflect the introduction of the new procedures (see 3.1 above), the various changes in the requirements of the NHS, and to take account of any perceived omissions in the previous code of practice. It is hoped that this revised Code of Practice will be approved soon and introduced by the start of next session, at latest. It is recognised that this Code of Practice will continue to evolve as the whole area of risk assessment and ethical review continues to develop.

.4 Informed Consent

In continuing its dialogue with departments the Committee has had a number of discussions on the subject of informed consent. The Committee is quite clear what researchers must do in seeking informed consent from volunteers and has provided this information to departments. The Code of Practice also makes this clear. Given the wide range of subjects studied within the University, it is acknowledged that informed consent can be sought in a variety of ways and from a wide range of volunteers. The basis of informed consent is that it is freely given by the volunteer once they are clear what the purpose of the study is, who will be conducting it, what the study involves and how it will affect them. Volunteers must be made aware that they are free to withdraw from the study at any time, without having to give a reason, and that the information will be treated anonymously and confidentially and will only be used in that particular study, unless the researchers ask for consent to use the data in another study. Volunteers should be told how long the data will be retained for and should be informed of the outcomes of the study, unless they decline this information. All of this needs to be built into the informed consent process.

The Committee had a number of discussions with various departments regarding seeking consent from children (under 16 years) and from those taking part in telephone interviews, mail surveys or questionnaires conducted in the street. For the latter exercises the Committee informed the researchers involved in such studies to ensure that they recorded, as appropriate (e.g. ticking a box on a form/questionnaire; giving verbal consent over the telephone, etc), that the volunteer had consented to take part in the study after they had been given the appropriate information about the study. In relation to studies involving children under 16 years of age it was considered good practice that in most cases the consent of the parent or guardian should also be sought. However, in some circumstances this was not always appropriate and the Committee sought advice from the Law School before issuing this to departments so that they were clear what they could do in relation to involving children in such studies. The Code of Practice has been updated to include this information.

4. TRAINING

.1 Training Organised

The University Management Group agreed that a budget be set for this area so that staff and members of the University Ethics Committee could attend relevant training courses and training opportunities could be provided within the University. The Senior Officer with responsibility for research is the budget holder for this. Within the University a training seminar was held on 25 November 2004 for members of the Committee, plus invited interested parties, where there was a discussion of the new University procedures. Ms Alison Palmer from COREC (Central Office for Research Ethics Committees) was invited to this seminar to discuss the legislation for clinical trials and the research governance framework. This proved to be a most useful exercise for all involved.

.2 Training Attended

Members and attending officers of the Ethics Committee have attended a range of training seminars throughout the year. The Convener, secretary of the committee and Ms Mcfarlane of R&C Services attended a training session offered by Professor A Gaw, from the Clinical Trials Unit, Glasgow University. This proved to be a most useful session regarding clinical trials and what was required of institutions and investigators running clinical trials. However, the University does not run many clinical trials and agreement has been reached that the University will most likely run clinical trials in conjunction with the NHS so that responsibility will be shared.

Other members of the Committee have attended various courses organised by the Association of Research Ethics Committees (AREC) and the Bulletin of Medical Ethics (BME). Whilst this tends to concentrate primarily on medically related activities it has provided some useful information and

contacts. Two seminars in particular proved useful: one on informed consent and one on data protection.

.3 Training Required

The Committee is clear that general awareness raising within the University is required in order to ensure that staff and students are aware of the need for ethical review, the new procedures now in place and the responsibilities placed on them. Ms Frew, R&C Services has been working with colleagues in departments to ensure that they are aware of the procedures. Also the Convener and Ms Frew took part in a training seminar organised by the National Centre to discuss ethical approval and the issues this raised. However, it is acknowledged that more training sessions need to be offered to ensure wider coverage of the new procedures.

It is also the intention that the information on the requirements for ethical approval should be included in the information pack for new members of staff and built into the course for the training of academic supervisors of postgraduate research students.

5. EXTERNAL LINKS AND COMPARATORS

.1 The NHS

The University continues to be involved with the Glasgow Research Governance Group, which comprises representatives of the NHS in Glasgow and from each of the three Universities (Glasgow, Glasgow Caledonian and Strathclyde). Ms Frew and Mrs McArthur represent the University on this committee. This has led to reaching agreement on the information required for studies run which involve both the NHS and the University (both staff and students). It has also led to the development of a Memorandum of Agreement for clinical trials, whereby the University will be co-sponsor of such studies with the NHS. This will mean that the University will be responsible for the protocol and seeking all necessary approvals; whilst the NHS will be responsible for the clinical aspects of the study and pharmacovigilance.

The Committee is aware that the Chief Scientists Office now expects researchers in the University to be at least aware of the requirements of the research governance framework and of the standard expected. It is, therefore, imperative to ensure that all staff and students are aware of this. Awareness raising sessions within the University, together with the publication of the revised Code of Practice, is essential.

.2 Other Links

The Convener has contributed to various external training sessions and to the publication of two reports on ethical matters. These being: The Guidelines for minimum standards of ethical approval in psychological research, issued by the British Psychological Society in July 2004; and ‘University Research Ethics Committees: Their role, remit and conduct’ written by Ms S Witherspoon, Deputy Director of the Nuffield Foundation and Professor A Tinker, Kings College London. This latter document was produced following a survey of UK Universities to determine what their current practices were in relation to ethical review.

Additionally two members of the Committee are also member of other ethics committees. Dr K Smith is a member of the NHS Lothian LREC 01 (since 2003); and Dr D Carus is a member of the European Commission’s Ethics Committee that considers proposals for funding. These contacts are invaluable in keeping the Committee up to date with developments elsewhere and ensuring that the Committee follows best practice.

6. RISK ASSESSMENT AND MANAGEMENT

The Committee would comment as follows on the key risks and how they are being managed:

- **Failure of staff and students to follow procedures** – there are a number of checks within the system to pick up on submissions coming forward that have not followed correct procedures. Submissions to UEC must come forward via R&C Services in the first instance. Without confirmation of this (e.g. if they come direct to the Ethics Committee) they will be forwarded to R&C Services first before being circulated to the Ethics Committee. Consideration of insurance cover is given at this early stage as well. Similarly, there are a number of checks to ensure that any project involving the NHS follows correct procedures. Good links have been developed with staff in the NHS and they are now aware of the personnel within the University who should be contacted if they have any concerns or require further information relating to any individual project submitted for approval.
- **Failure to provide complete information** – it is acknowledged that the risk assessment and sponsorship process considers different aspects from the ethical review process. However, the revised Code of Practice makes it clear that researchers should provide all relevant information at the outset (revisions have also been made to the application form to make it clear what further information is required). In this way all aspects of the study can be considered at each stage. The staff administering the process can identify any gaps in the information provided and seek this out from the researchers.
- **Lack of review structures at departmental level**- the annual monitoring that the University Ethics Committee conducts of the activities of the Departmental Ethics Committee has raised awareness throughout the University of the need for ethical review for all projects involving human subjects. As departments become more familiar with what is required of them the information coming forward from DEC's will become more robust and reliable. This will enhance the University's overall risk management procedures. Dialogue with the departments is continuing on this matter.
- **General awareness of University procedures** – the University Ethics Committee and the administrators working with it are continuing to raise awareness of the new procedures throughout the University. Further steps are required and circulation of more information to departments will be conducted later in the session. It is hoped to time this so that it coincides with the issue of the revised Code of Practice.
- **Training opportunities** – the Committee is keen to provide training opportunities for staff and students within the University to find out more about the need for ethical review and the University procedures now in place. Discussions with the Centre for Academic Practice have been held regarding the addition of relevant information to certain training courses (new supervisors of research students) and the provision of information in the induction packs for new staff.
- **Training for Committee members** – there is a need for new members of the Ethics Committee to receive induction training, as well as continuing training for all members in order to keep abreast of developments and changes in legislation.
- **Succession planning for the Committee** – it is important to ensure that matters of succession planning are addressed. An element of rotation has been built into the period of membership of each of the current members so that a limited number of members demit office in any given year. Consideration will be given to the identification of a Convener to replace Professor Foot in due course, so that there is time for a period of handover before he demits office.
- **Insurance Cover** – consideration of insurance cover is given at the outset of the process. Whenever a submission is received a copy is sent to the University's Insurance Adviser to confirm insurance cover. If there is any doubt, or if additional cover is required, the University's Insurance Broker and Insurers are contacted for advice and guidance as appropriate.

- **External developments** – members of the Committee and the administrators working with the Committee endeavour to keep up to speed with changing external requirements and new legislation. This is achieved by a variety of means, such as through the membership of other Ethics Committees or Glasgow Research Governance Group, attendance at various training seminars, etc. When changes are identified that will impact on the University these are brought to the attention of the Committee and other relevant personnel for action as appropriate.

A summary of this information is provided at Annex 3.

GMcA
26.04.05

Annex 1

Membership of the University Ethics Committee

The membership of the University Ethics Committee is (as at 25 April 2005):

- Professor Hugh Foot, Psychology (Convener)
- Professor John Blackie, Law School
- Dr James Bunney, former Chief Pharmacist, Glasgow Royal Infirmary
- Dr David Carus, Mechanical Engineering
- 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, Student and Occupational Health Service
- Mr Andrew Hosie, Scottish Institute for Residential Childcare
- Dr Deirdre Kelly, Lay member - Senior Consultant, Frontline Consultants
- Dr 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 & Consultancy Services
Ms Zoe Wilson, University Insurance Adviser, Finance Office
Mrs G McArthur, secretary to the Committee.