COLLEGE OF MEDICINE AND VETERINARY MEDICINE
ETHICAL REVIEW OF RESEARCH

1.1 Overview
Research involving human subjects, their tissues or data should be ethically reviewed and is normally put through the National Research Ethics Service (NRES) system. I detail below the different situations we regularly deal with in the College of Medicine and Veterinary Medicine (CMVM).

Although NRES is mainly set up to handle research involving NHS patients, Lothian Research Ethics Committees (RECs) also review projects involving healthy volunteers if NHS resources e.g. premises are used for the research.

When a project is sent through NRES, the procedures detailed on their website are followed. http://www.nres.npsa.nhs.uk. Within the College, the ACCORD Clinical Research Governance and QA unit provides support and advice to any researchers needing it. We are also working on developing a website which will provide written information and guidance.

For undergraduate student research - the Student Selected Component (SSC) modules within medical degree courses are modules providing the opportunity for students to initiate, plan and carry out a research project. A system is in place to pre-assess if a project requires full ethical approval via the NRES system.

The University also has a process to handle research involving students - applicants who wish to recruit University of Edinburgh students to a project should submit the relevant form to the 'CMVM Advisory Committee for the use of student volunteers on experimental work' together with a copy of their NRES ethics submission (if applicable). The essential points covered are i) whether students might feel that they are pressured to take part or that saying no might influence grades or assessments and 2) whether they are being asked to commit time that is not compatible with their course.

To ensure research that is not appropriate for the NRES system is adequately reviewed, we propose to establish a single CMVM ethics committee. This is likely to replace the current processes detailed above for the SSC modules and research involving students.

1.2 ACCORD Office
The Academic and Clinical Central Office for Research and Development (ACCORD) was established with the aim of improving and streamlining joint working to support research in general in Edinburgh. It builds on the Joint Working Protocol between the University of Edinburgh and NHS Lothian, and works to implement the Research Governance Framework and the regulatory requirements of the EU Clinical Trials Directive and other legislation.

Most clinical research studies are now co-sponsored between the University of Edinburgh and NHS Lothian reflecting the fact that most academic research is embedded within the NHS with the aim of improving patient outcomes. Members of the University Governance Office attend the weekly NHS Lothian Research and Development Scientific and Risk Assessment meetings where Management Approval for research is given. Since all academic investigator led Clinical Trials of Investigational Medicinal Products which fall under the EU Clinical Trials Directive and the corresponding UK regulations are co-sponsored by ACCORD.

Researchers are instructed to contact the ACCORD Office before submitting their funding and ethics applications. They then receive advice on their applications and appropriate sponsorship paperwork.

Within the ACCORD Office, a Scientific Adviser has been appointed to the Research Ethics Committees (RECs) in Lothian. Part of the post holder’s role is to consider if undergraduate student projects are required to be considered by to a local REC.
1.3 Edinburgh Clinical Trials Unit
Edinburgh Clinical Trials Unit (ECTU) was established to provide specific services to support researchers, including help with grant applications, protocol development, ethical and regulatory approvals, trial management, monitoring, software development, data management, statistical analysis and reporting.

1.4 Research support for the College of Humanities and Social Science
The Research Governance Manager is regularly contacted by researchers from this College, particularly Clinical Psychology students requiring sponsorship for their research studies. This helps to ensure a consistent approach to the handling of ethical issues surrounding research and human subjects.

1.5 Wellcome Trust Clinical Research Facility (WTCRF) Education Programme
(http://www.wtcrf.ed.ac.uk/education/defaulteducation.htm)
The College continues to support this very useful resource, based at the Western General Hospital. Regular courses include:
- Good Clinical Practice (GCP) & the EU Clinical Trials Directive
- The Research Governance Framework
- How to complete an ethics form
- How to practice evidence-based research
- Preparing for an MHRA Inspection (body regulating the Clinical Trials Directive etc.

1.6 Medicines and Healthcare products Regulatory Agency (MHRA)
In 2008/09 the University of Edinburgh was inspected by, and received a favourable report from, the MHRA. The inspection covered research that is classified as a Clinical Trial of an Investigational Medicinal Product (CTIMP), and focused on specific CTIMPs and University processes to manage trial activities.