**Do I Need to Apply to the MVLS Research Ethics Committee?**

**An Update on MVLS Ethics Committee Policy**

The MVLS College Research Ethics Committee reviews research proposals for non-clinical research involving human subjects, human material and data. Full detail on the University of Glasgow procedures for college ethics committees can be found here (<http://www.gla.ac.uk/media/media_227478_en.pdf>). If the non-clinical research involves risk to participants (either physical, mental or psychological), invasive procedures, a significant time or other burden, vulnerable groups, deception, human tissue, foetal material or risk of disclosure of sensitive data, then MVLS Ethics Committee approval must be obtained.

There are particular challenges and ‘grey areas’ for the MVLS committee because many University employees perform both clinical research, engage in clinical audit and service evaluation as part of their NHS practice, and utilise freely available and anonymised data.

**Clinical Research**

Clinical research must be reviewed by an appropriate NHS Research Ethics Committee (NHS REC). Clinical research includes research proposals involving:

1. patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
2. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.
3. access to data, organs or other bodily material of past and present NHS patients.
4. foetal material and IVF involving NHS patients.
5. the recently dead in NHS premises.
6. the use of, or potential access to, NHS premises or facilities.

The MVLS Ethics Committee cannot give approval for such research projects. Full details for applying to the NHS Research Ethics committees (NHS REC) can be found here (<http://www.hra.nhs.uk>). If you are involved in clinical projects being conducted abroad, you must ensure that appropriate ethical scrutiny and review has been performed. In exceptional circumstances the MVLS Ethics Committee may review such projects.

**Is it Clinical or Non-Clinical Research?**

It is not always easy to distinguish between non-clinical and clinical research. Clinical research is described above and such projects must be reviewed by an NHS REC. Non-clinical human research includes other projects, which apply systematic procedures of investigation to human beings, whatever the nature of the research; whether, for example, it be physical, social or psychological.

**Clinical Research, Audit or Service Evaluation?**

Audit and service evaluation are a key component of NHS practice and such projects do not require ethical review by an NHS REC. It can be difficult, and it is a matter of judgement, whether a project is audit, service evaluation or research. It is the responsibility of the investigator to establish if a project is research or not. If you are uncertain, you can obtain guidance from the NHS R&D department (via Judith.godden@ggc.scot.nhs.uk). Advice can also be obtained from the MVLS Ethics Committee but must be sought from the NHS R&D department if the project is clinical research.

There are important key discriminators between audit, service evaluation and research. Detailed guidance on this can be found here (<http://www.hra-decisiontools.org.uk/research/>). Briefly, the intent of audit and service evaluation is to measure standards of care. They assess established care processes and measure whether they are working. They may further be used to assess the impact of change in practice on such processes. Generally, audit will assess an intervention that has firm support of the clinical community. Research aims to develop new generalizable knowledge that will inform the community concerned with that topic, theme or practice. Research typically compares interventions or assesses ways of doing things. Thus, audit and service evaluation cannot involve allocation to different treatments or randomisation and should not involve additional burden on the participant.

The MVLS Research Ethics Committee does not require to review audit or service evaluation projects that serve to evaluate established care processes for the purposes of informing NHS practice. In the past, data have been collected under the auspices of a clinical audit with the intent that they will form a research project for a higher degree. The decision as to whether the Ethics Committee will review focuses at least in part on the intent of the project. Even though an NHS REC may not wish to review such projects, it is advisable to seek advice from both the NHS and MVLS Ethics Committee.

It is important to recognise the governance requirements for engaging in clinical audit or service evaluation. The individual must have a role within the relevant NHS department, or in the case of a student, be supervised by an appropriate NHS staff member.

**What if I Want to Publish My Work?**

It is not true that ethical approval is needed before a project can be considered for publication; either in manuscript or abstract form. Audit can be deemed suitable for publication by a journal if the findings are unexpected, important or informative. Many scientific societies encourage presentation of audit. If publication is your primary intent, you should consider carefully the primary aim of the project and the questions being asked. If you are seeking to generate novel data, the project could be considered research. Regardless, it is important you have considered these issues and can demonstrate that your project followed University of Glasgow and NHS REC policies, and was conducted in keeping with the Declaration of Helsinki. Further details on the requirements before publication can be found here (<http://www.icmje.org/icmje-recommendations.pdf>).

**Research Involving Already Secondary and Already Available Data**

A considerable amount of research is conducted on secondary data (data collected by others that is already gathered and available) or data held by researchers from previous projects. If you are planning further research using data you hold, the research is in keeping with the original consent, and raises no new ethical issues, then further ethical approval is not needed.

An example of secondary data is data held by the Information Services Division of NHS National Services Scotland or administrative data held by other government agencies. Use of NHS originated data will require application to the Public Benefit and Privacy Panel for Health and Social Care. Research using such data does not typically require review by the MVLS ethics committee. In certain circumstances it might, including studies into vulnerable groups, where there is a risk of disclosure (such as very rare conditions or studies limited to small geographical areas), or where there is reputational risk to the University. Remember that clinical projects would require review by an NHS REC, not the MVLS Ethics Committee. Advice can be sought from the MVLS Research Ethics Committee in cases of uncertainty. It is expected any member of the University engaging in such research has appropriate training in data governance. A further important example includes data contained in trial registries and repositories, typically with the consent of the participant. Approval is typically needed from the data source but separate approval by the MVLS Ethics Committee is not needed.

Some clinical research projects are performed using resources such as the NHS GGC Safe Haven or the UK Clinical Practice Research Database (CPRD). These have established governance processes often including NHS REC approval for use of anonymised data. Such projects do not require review by the MVLS Ethics Committee. Note that some of these projects may require NHS REC approval.

In summary, if your project has approval via an established governance mechanism, or uses only secondary or existing data and raises no new ethical concerns, then MVLS Ethics Committee approval is not required.

**Course Evaluation or Evaluation of Teaching Methods**

This is considered good practice and a normal part of academic life. Such projects do not require MVLS Ethics Committee review but should be authorised by the appropriate authority within Schools / Institutes. Such projects could include interviews with staff members provided it is within their area of professional competence and the intent is to inform teaching methods. However, as with Audit (above), if publication is the primary intent of the project, it is likely you are seeking to generate novel data and the project would be considered research. In the case of uncertainty or where projects carry ethical risks then advice can be obtained from the MVLS Ethics Committee.