

## **Submission from the Academy of Medical Royal Colleges to the Ad Hoc Advisory Group on NHS Research Ethics Committees**

1. The Academy of Medical Royal Colleges welcomes this opportunity to make a brief submission to the Ad Hoc Advisory Group on NHS Research Ethics Committees. The Academy would be pleased to respond to consultations on any subsequent proposals to improve the ethical and regulatory approval of research projects.
2. The Academy's attention has been drawn to the fact that some projects that would formerly have been classified as 'research' are now claimed by the investigators to be 'audit' so as to circumvent the necessity for REC approval. This concern was highlighted by the lay representative on the Academy; it could have implications for patient safety. The Academy advises that investigators would be more likely to seek REC approval (rather than regard the project as 'audit') if the process of REC approval was simplified and made less burdensome, but without loss of safeguards for the subjects (patients, healthy volunteers, etc.)
3. The Academy is particularly concerned that the current regime of regulatory ethics is stifling small-scale but potentially informative research projects that carry no risk of physical or psychological harm. The long and detailed COREC form may be appropriate and proportionate for large-scale projects, particularly those with the potential risk of harm or lack of benefit.
4. The Human Tissue Act 2004 will make it unlawful to use human bodily material for research unless it has REC approval and, unless the material is anonymised, appropriate consent. Such research projects are often done initially on a small scale, simply to demonstrate proof of principle or technical feasibility. It is now less likely that such tissue-based research will be initiated because the REC approval process is often grossly disproportionate to the scale of the project and the degree of risk, if any, to the subjects from whom the tissue originates. Consequently, the full project never gets underway and the potential benefit for patients and the public is never realised.

5. Colleagues in the UK have reported that they have been unable to collaborate in multi-centre international research projects because the current regime of regulatory ethics in the UK operates at a more stringent level. The Academy believes that this could be detrimental to the public benefit and to the prosperity of clinical research in the UK.
6. We recommend that steps are taken to ensure greater uniformity and consistency of decisions taken by local RECs on similar or identical research projects. In some centres the project may be approved by the LREC, whereas the same project is not approved by another LREC. For this reason, it is reported that some investigators recruit additional collaborating centres, not for scientific reasons, but simply to enable the project to qualify for submission to a multi-centre REC.

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9 February 2005