Research Governance: can values change?

“It's a question of science,” said Weber “you cannot alter a scientific fact.” Corelli frowned, “I don't care about science. It's an irrelevance. It's a moral principle you cannot alter, not a scientific fact.” “We disagree.” said Weber amiably “It's obvious to me that ethics change with the times as science does.” from Captain Corelli's Mandolin by Louis de Bernières.

Following the consultation initiated by the UK Health Departments in 2009, the harmonized UK-wide version of the Governance Arrangements for Research Ethics Committees (GAfREC) has now been finalised and published on the Department of Health. Researchers undertaking their investigations on NHS staff no longer have to submit their proposals to NHS Research Ethics Committees (REC's) for ethical approval. It is for employers to ensure their duties as employers when their employees take part in research. Where proposals do not require such NHS review it becomes the responsibility of Universities who are also required to comply with the Economic and Social Research Council's Framework for Research Ethics principles, requirements and standards. In effect research undertaken on NHS staff outside of the university context, such as that from drug companies for example, will not receive any formal ethical review at all. It seems that moral principles can be changed as it evidently was once the view that all research on NHS human subjects needed the protection of an NHS ethical review process. Could it be the case that NHS staff have become so self-reliant now that they no longer need the safeguard once afforded them by REC's? Or in the drive to change research governance procedures could there be an abiding concern that real opportunities to improve the protection of the human subject in research are being overlooked?

It is unclear about the motive behind this change and it may well be that the intention is to locate the responsibility for developing adequate ethics protocols firmly and squarely in the hands of those most likely to understand best practice and the expectations of health professionals. However, the more cynical among us may be forgiven for thinking at the same time this is a well-crafted way of dealing with the administrative burden and heavy workload of REC's, particularly given their latest decrease in numbers. It is also not evident if this move will actually promote a quality research culture or streamline the research journey for investigators. One of the issues is that since the changes came into effect from September, NRES, R&D offices and other organizations now have to develop supporting guidance and modify their procedures where necessary and this has resulted in a haphazard approach between the different departments. In some areas researchers are still being asked to fill in the notably tedious IRAS forms while others asked only for the research protocol.

Furthermore following evaluation of a successful pilot scheme which began in September 2009, NRES has introduced procedures for a Proportionate Review of ethical proposals. The PR service is now being phased in across all REC centres in England, and its implementation is also being considered by Research Ethics Service managers in Scotland, Wales and Northern Ireland. The PR process aims to provide ‘for expedited, proportionate review of research studies raising no significant ethical issues, including projects involving straightforward issues which can be identified and managed routinely in accordance with standard research practice and existing guidelines’. Under the system of PR any new applications will be reviewed by a sub-
committee rather than at a full REC meeting, with the aim of notifying the final decision to the applicant within 14 calendar days of receiving a valid research application. The timing and criteria behind the implementation of this process will depend on the individual operational considerations at each REC centre. It seems that the old adage that everything comes round in circles is apparently true, as it was not so long ago that research proposals submitted by students below doctorate level, did not require formal REC review. Does this signal yet again a two tier research value system where some research is afforded the prestige of a formal REC review and others not?

Obviously values can and do change, however, this requires vigilance in ensuring that when making the change we do not lose sight of what once may have seemed important, or evaluate the message it sends to those affected by it.