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From the Policy Officer
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20 April 2006

Dear Sir/Madam,

NPSA/COREC Consultation on Implementing the recommendations of the *Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*

I am pleased to enclose the response from the Academy of Medical Sciences to the above consultation. This response was prepared by an Academy working group, in consultation with a number of clinical scientists from within the Academy Fellowship. The evidence presented is endorsed by the Academy's Council.

Yours sincerely,

Aileen Aherne

NPSA/COREC Consultation on Implementing the recommendations of the ***Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees***

The Academy of Medical Sciences is grateful for the opportunity to respond to the above consultation. This response was prepared by an Academy working group, in consultation with a number of clinical scientists from within the Academy Fellowship. The evidence presented here is endorsed by the Academy's Council.

The Academy fully supports the key role played by Research Ethics Committees (RECs) in preventing unethical research, but it is essential that in the process RECs do not inadvertently act to prevent scientifically sound and medically important research from taking place. The joint interest of researchers and ethics committees is to ensure that excellent research is carried out for public benefit.

The Fellows of the Academy consider rigorous ethical review to be a crucial step in medical research involving human subjects and we welcome many of the proposals contained in the consultation document. In particular we support the recommendations aimed at speeding up the application process to RECs, decreasing the administrative burden associated with carrying out clinical research and improving consistency in the review of applications. It will be important to monitor any new systems to ensure that these goals are met.

We particularly welcome the proposal to coordinate Research and Development offices with applications to RECs and endorse the adoption of common national systems. We also support the proposal to improve the training available to REC members and the concept of sharing good practice where issues have already been explored. We believe that an improved training strategy will increase consistency between committees.

The introduction of guidelines for studies for which ethical review is not necessary would also be a positive development. This is especially relevant to studies using anonymised patient data, but clarification will be required on exactly which type of studies require review by a full committee. For example, researchers would find it helpful to have guidance on the level of data anonymisation that would require a study to be subject to ethical review. We have concerns about the assumption that all surveys are without ethical risk. A badly designed survey, or one with inappropriate questions, has the potential to cause harm.

There are three areas in particular that we feel are essential to the continued success of RECs:

1. Science and ethics

The Academy does not completely agree with the statement that *'RECs should not reach decisions based on scientific review.'* Rather, we are of the opinion that science and ethics are intrinsically linked together; in many cases it is not possible to reach decisions on ethics without considering the science. Both the scientific and ethical aspects of a study should be considered at the same time by people with the necessary expertise. This is not to say that the committee should undertake a complete scientific review of a given proposal, but some

understanding of the science is normally required. We have received in evidence, examples of RECs where the committee has turned down applications on the grounds that they did not understand the science. We are concerned that a situation such as this could prevent important and beneficial research from taking place. We also believe that scientifically flawed research is unethical.

The Academy believes that any 'Research Ethics Service' must be run by individuals who understand both the scientific and ethical issues. We would not wish to have a situation where a 'scientific officer' could make decisions on the scientific merit of a proposal, without having research experience in the relevant scientific area.

2. Research-active scientists

The Academy considers that it is of over-riding importance that scientists who are active in clinical research should continue to be involved in RECs. In the restructuring of these committees, active researchers must be included in order to contribute the appropriate scientific and clinical expertise that is required for the proper assessment of applications. We believe it would be difficult to predict the possibility of an experiment going wrong, or to understand the relative risks involved, if members of the committee do not understand the science, nor would it be possible for adverse events that are reported to RECs to be adequately assessed in their scientific and clinical context.

We have concerns about the recommendation aimed at decreasing the number of RECs in the UK, which would likely result in an increase in the time commitment required of members. It is unlikely that research active clinicians would be willing to spend as much time serving on an ethics committee as would be required and this must be addressed.

As stated in our recently published report '*Personal data for public good: using health information in medical research'* the Academy is concerned that 'a smaller number of more 'professional' RECs will increase the commitment required of members to the point where scientists with active and substantial research programmes are unable to participate. The exclusion of researchers, particularly those at a more senior level, will leave RECs at a greater risk of becoming distanced from the challenges of conducting research in the current environment.'[1]

3. Local Committees

In the interest of high quality experimental research, we support the maintenance of some local ethics committees, particularly in the fields of experimental medicine, pilot studies and studies involving specialised techniques. A local knowledge of particular specialised areas of research is likely to be of great importance in the evaluation of such studies. We are concerned that a reduction in the number of RECs will mean that the committees may become remote from the sites at which the research is to be undertaken. This makes discussion between applicants and committee members and chairs, whether at committee or prior to application, more difficult. A local committee would also facilitate an effective triage system because the relevant experts would be available for consultation on particular scientific issues. In areas where experimental medicine studies are common, we recommend the reintegration of University and NHS Research Ethics Committees with properly constituted scientific committees.

We hope the evidence presented here is useful to you and we would be pleased to assist the NPSA further if required.

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[1] http://www.acmedsci.ac.uk/images/project/Personal.pdf

Working group members

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