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'NRES proposals ahead of planning for further service improvement and evaluation'

Consultation response by the Faculty of Pharmaceutical Medicine

30/01/12

The Faculty of Pharmaceutical Medicine ('the Faculty') appreciates the opportunity to comment on the proposals made in this consultation document for further improvements to the NRES in light of the Academy of Medical Sciences report and the changing status of NRES as part of the HRA. The Faculty recognises the quality improvements that the NRES has achieved in recent years, but agrees with the Academy of Medical Sciences report that, "UK health research activities are being seriously undermined by an overly complex regulatory and governance environment" and that further improvements are required.

We have structured our response around the following headings:

i. Timelines for REC approval
ii. Template designs
iii. Prior assessment and approval on some aspects of the ethical review
iv. Programme approvals
v. Provisional opinions
vi. Extending validation to preliminary assessment
vii. Consistency and robust review
viii. Reduction in the number of RECs
ix. Chief Investigator attendance of REC meetings
x. Training of REC members
xi. NRES transparency/NRES performance indicators

We hope that you find our comments useful. Please do not hesitate to contact us if you require any clarification on any matters.

i. Timelines for REC approval

The Faculty believes that the timelines for REC approval have extended such that they have an important impact on our international competitiveness. We welcome any proposals to increase the efficiency of RECs, to shorten timelines, and to reduce costs. Indeed, we recommend that attempts are made to develop review timelines so that they match the MHRA timelines. For example, the MHRA response for Phase 1 studies is available always within 14 days (i.e. two weeks) of a valid submission. A final response in case of an initial non-acceptance is on average available within 21 days (i.e. three weeks) of the valid first submission. REC review times are considerably longer at present, REC approvals are usually achieved after a minimum of 35 days (i.e. five weeks) of the valid submission, often later.

ii. Template designs

The Faculty is concerned that the proposed template study designs could stifle innovation and are unlikely to be beneficial to the research process. If these plans are implemented, there also needs to be some protection to ensure that a non-template study is not a justification for less timely reviews. Template studies might be restricted to certain areas of research e.g. products that are already licensed. We believe that an alternative to a template section for study design could be the simplification of the application document.

iii. Prior assessment and approval on some aspects of the ethical review

The Faculty believes that there is potential for the development of prior approval of the researcher for studies conducted in accredited phase 1 units or for other accredited sites. Both RECs and investigators would benefit from prior approval of sites and PIs for categories of research, such that site-specific assessment becomes less of a burden. We note that for Phase 1 units there is a process already in place via the MHRA Phase 1 accreditation scheme, which is accepted by NRES as a main part of the site specific assessment.

iv. Programme approvals

We believe that programme-based approvals are a logical extension to the current umbrella protocols often used in Phase 1; however we seek clarification as to how a new system would differ to that currently in place, which incorporates several parts, each with separate objectives, into the same study. The individual project notification would need a faster turnaround time than a new submission and we have concerns that a new system could further slow down approvals.

v. Provisional opinions

The Faculty believes that RECs currently underuse the option of issuing a conditional favourable opinion rather than a provisional opinion, often resulting from relatively minor issues, such as the REC simply requiring that the researcher make the REC's listed changes to the information sheet. This could be addressed by additional training of REC members and chairs to enable them to trust that the investigator will not commence a study until the conditions are met. We believe that conditional favourable opinions could save at least one week compared to provisional opinions.

vi. Extending validation to preliminary assessment

This proposal could be beneficial as long as the new function is filled by a professional with suitable experience and the process does not increase the total validation and review timelines. This central NRES function could also advise ethics committees on previous studies with similar design/compounds etc. which would be helpful to ensure consistency, and the coordinator may be well placed to judge whether the IRAS filter has been correctly used, whether the application is of an appropriate type for review by the relevant committee, and whether overall quality is sufficient (e.g. extent of typos). A process to ensure data protection and confidentiality would need to be in place as many sponsors may not wish details of their studies to be shared beyond their REC.

vii. Consistency and robust review

We welcome any efforts to improve the consistency of decision making. We recommend that working groups be tasked to develop guidelines and standards to ensure that consistency is improved. Proposed areas could be advertising, volunteer payments, insurance, etc.

viii. Reduction in the number of RECs

We recognise the recent improvements in the quality and consistency of ethical review associated with the reduction in the number of RECs. However, we are concerned that further reduction in the REC numbers could have a negative impact on the UK's ability to provide a first-class service. The Faculty understands that the number of committees currently approved to review Phase 1 studies exceeds the demand when purely looking at the numbers of studies in relation to the available committees. However, when looking at the capacity of Phase 1 committees spread over a given month it becomes apparent that there is a lack of availability of experienced committees to meet timelines comparable to those the MHRA meets.

This is a challenge that NRES needs to address in the near future by improving retention of experienced committee members and chairs and by providing training to less experienced committees so that the current shortfall can be rectified. Geographical balance of suitable, experienced committees is also important.

ix. Chief Investigator attendance of REC meetings

We believe that it is not practical for chief investigators (CI) to attend every meeting. CIs can attend local meetings (which are usually in the evening), and are available on the telephone for REC meetings at a distance. It seems that this arrangement has proved satisfactory to both CIs and RECs so far.

x. Training of REC members

The Faculty is happy to see a focus on training of ethics committee members on the latest developments in clinical research and new, often complex study designs, the development of guidance documents and the emphasis on learning reviews. Whilst the REC review should not duplicate the review undertaken by the MHRA, it is necessary for REC members to understand study designs and potential risks to ensure an adequate assessment of ethical aspects. We believe that whilst these changes are important, to be truly effective they need to be introduced in parallel with a simpler, speedier review process.

xi. NRES transparency/NRES performance indicators

The Faculty believes that it is not sufficient to show that the NRES can maintain its current performance with less staff and reduced costs. The ultimate measure of success would be recognition of the UK as a centre of excellence for clinical research as shown by an increase in the number of high quality clinical studies performed here. Further, it is essential that the proposed efficiency gains are not undermined by local health authority requirements e.g., separate, non-parallel, R&D approval. This was raised by the AMS and given as a target role for the HRA, but hasn't been addressed.

We recommend that NRES should apply a similar approach to the MHRA by publishing their performance data on a monthly basis:
http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/UKclinicaltrialauthorisationassessmentperformance/index.htm