Earl Howe
Health Quality Minister
Department of Health, Richmond House
79 Whitehall, London, SW1A 2NS

24 January 2012

Dear Earl Howe,

During the Committee stage of the Health & Social Care Bill, we raised several issues focused on facilitating and strengthening research across the NHS and public health system.

We welcomed your engagement with these on the floor of the house and were grateful for the further clarification provided in correspondence following the debates. We are very pleased with the progress that has been made on issues relating to research in the NHS and public health system but continue to have some concerns.

We would like to take this opportunity to bring together the remaining points on which the research community would welcome further clarification of the Government's intentions. The concerns raised in this letter are shared by the Academy of Medical Sciences, the Association of Medical Research Charities, Breast Cancer Campaign, Cancer Research UK and the Wellcome Trust.

Below we outline our outstanding concerns, and the action the Government could take to reassure us ahead of report stage. Issues on which we would appreciate further information include:

- Ensuring the independence of the Health Research Authority (HRA)
- Clarifying the extent of the duties towards research and the use of evidence
- Ensuring the necessary accountability and reporting structures are in place to embed and monitor research throughout the health system
- Reviewing the policy on attribution of costs associated with charity funded research
- Unlocking the potential of patient data for research: ensuring a secure and proportionate framework
- Providing clarity on the proposals for education and training

We would be grateful if a response addressing these points could be placed in the House of Lords library ahead of Report stage. Any more detail that you could provide would be invaluable as we consider which issues to pursue at Report stage.

In addition, the All Party Parliamentary Group on Medical Research will be hosting a dinner on the evening of Monday 30th January and we would be delighted if you could join us to discuss these issues with the research community.

Yours sincerely

Lord Willis of Knaresborough Lord Turnberg of Cheadle Baroness Morgan of Drefelin

Cc Dame Sally Davies, Dr Russell Hamilton, Candy Morris – Department of Health

Ensuring the independence of the Health Research Authority (HRA)

There has been significant progress on the establishment of the HRA, and we are entirely supportive of the Department of Health's engagement with the community as the HRA develops. We are pleased to see the HRA established as a Special Health Authority and that plans are already in place to begin streamlining the regulation and governance of health research. We are satisfied that the authority will be able to successfully implement the first phase of its work as a special health authority.

Now that the HRA is established and has begun operation, it is critical that it continues with the appropriate level of independence. To ensure this, **we believe the crucial next step is the appointment of an independent Chair and two independent board members**. We have seen the importance of this approach with other organisations that must quickly secure public trust and represent patient interest, such as the National Institute for Health and Clinical Excellence. **We would value a commitment to replicate this approach for the HRA**.

Clarifying the extent of the duties towards research and the use of evidence

Placing a duty to promote research on the Secretary of State, NHS Commissioning Board and clinical commissioning groups (CCGs) is a significant and extremely welcome development which we hope will result in research being at the centre of the NHS. However, we remain concerned that the duties do not sufficiently specify the activity required to satisfy them and therefore may be limited in their effectiveness. We also seek reassurance of the extent of these duties, ensuring they represent the power and a requirement to act to embed research across the NHS and public health systems at a national level.

For this reason we tabled a number of amendments intended to strengthen and clarify the duties during committee stage and to ensure that mechanisms for upholding them were laid down within the Bill. In the debate on 9 November 2011, you undertook to consider our concerns with a view to, if necessary, introducing amendments at report stage. **We are grateful for your efforts on this topic and hope it will lead to the government strengthening the wording of these duties. We would also welcome clarity over how performance of these duties throughout the system will be assessed and to whom it will be reported.**

Ensuring the necessary accountability and reporting structures are in place to embed and monitor research throughout the health system

During the committee stage of the bill, we tabled a number of amendments probing the planning and reporting requirements of the NHS Commissioning Board and CCGs with regard to their research duties.

Planning and reporting are central to ensuring that innovation and research are successfully embedded throughout the NHS and public health system. If research is a priority for government and is to be recognised as a core role of the system, **it is vital that the NHS Commissioning Board is mandated to explain activity relating to the duties to promote research and innovation in its business plan and annual report**. Without research being embedded in the planning and reporting mechanisms, there is real danger that the focus on research will be lost.

Likewise, in relation to CCGs, we believe that innovation and research duties should be among those specified in the authorisation, planning and reporting requirements. A mechanism is needed to ensure that they provide explicit evidence to the Board that they have exercised their duties towards innovation and research. This will reflect the importance of research as a core role of the NHS. Many of the established CCGs have already published their plans, and research is currently rarely mentioned. This emphasises the need for research and innovation to be embedded at this stage in the transition of structures. Further guidance and support for CCGs on how they should meet their duties, providing clarity over their responsibilities and how they will be expected to report back is crucial at this stage – this could be supported by including planning for research & innovation in the authorisation process of CCGs by the NHS

Commissioning Board. Further, it is important that a consistent approach to planning and reporting in relation to research is taken across CCGs, or national comparisons will not be possible.

It is also important to ensure that there are sufficient incentives to encourage the engagement of CCGs in the research agenda. This is critical in a number of ways, not least in ensuring funding of treatment costs for patients involved in government or charity-funded research projects. We were pleased with the Government's commitment that CCGs and the NHS Commissioning Board will ensure these treatment costs are funded through normal arrangements for commissioning patient care but there remains a gap between intention and practice. **We now need further detail on how this commitment will be taken forward and when guidance will be updated to provide clarity over accountability for these costs and to ensure the full treatment costs of patients taking part in research are met in the new structures.**

Reviewing the policy on attribution of costs associated with charity funded research

Medical research charities represent a core element of the research environment in the NHS – as you know in 2009-10 over 3000 clinical studies were conducted in the NHS; 37 per cent were funded by AMRC members.

Charities choose to fund research within the NHS because of the world-class research environment it offers. Medical research charities pay the direct research costs associated with studies, but generally do not pay for the costs of hosting and supporting research, as this falls outside their charitable objects. An effective model for meeting all the costs associated with research in the NHS is vital to enabling the medical research charities to continue to play such a strong role.

The Department of Health guidance (ARCO) – which aims to attribute the various costs associated with research projects in the NHS – is being revised to provide clarity for all partners in the process. The latest revision of the guidance (AcoRD) was presented to medical research charities at the end of last year. Unfortunately this does not address some of the community's key concerns and questions remain over how charities can comply with the cost allocation principles it sets out. There is a sense of urgency to resolve the existing uncertainty as structures start to transition and budgets are moved around.

We would value the reconvening of the original working group to complete development of a new set of guidance, providing an effective model for meeting all the costs associated with research in the NHS, in as timely a manner as possible. This working group should consist of the Department of Health and devolved nations, representatives from the National Institute for Health Research (NIHR) Clinical Research Network and funders. This group should aim to clarify how the guidance will be implemented within an agreed timeline, including agreeing definitions for allowable costs.

Unlocking the potential of patient data for research: ensuring a secure and proportionate framework

There have been a number of announcements recently articulating the government's desire to unlock the potential of patient data for use in research. The new secure Clinical Practice Research Datalink combined with the proposal to consult the public on introducing an 'opt out' clause in the NHS constitution are both positive steps forward in this highly complex area. We understand that pilot studies in the North West reveal the willingness of patients to allow the use of their medical data for research and this should provide an encouraging model on which the government should build to ensure significant health benefits for patients and the public. Medical research charities will play a valuable role in developing public confidence in these initiatives, as demonstrated by the development of the UKCRC leaflet *Your Health Records Save Live.* **The government should involve medical research charities as they take these initiatives forward,**

We welcome the intention for the HRA to take on the Secretary of State's role in assessing applications for the use of confidential information for medical research. We would hope that the HRA takes on additional remit in the area of

regulation of patient data in research, enabling comprehensive oversight of this area and the ability to provide clear guidance for researchers.

We eagerly anticipate the publication of the Government's information strategy by April this year. **This strategy must place sufficient emphasis on the importance of data in research**, including observational studies and recruitment to clinical trials, and we hope that it will provide an overview of the exciting developments in this area. Anonymous data is not always a suitable resource for research and sometimes researchers will need access to identifiable information – for example without this, studies providing important data on the correlation between proximity to power lines and the risk of childhood leukaemia could not be conducted. **The use of identifiable information in research must be included in the information strategy, including consideration of how the regulatory and governance framework can protect patient confidentiality and engender public trust, while facilitating research that is in the wider public interest.**

Providing clarity on the proposals for education and training

Developing a healthcare workforce that understands and can utilise research and innovation to improve patient care is crucial to successfully embed a culture of research and innovation across the health system.

We are pleased to see further detail in *Liberating the NHS: Developing the Healthcare workforce – from design to delivery*. We welcome the national oversight that Health Education England (HEE) will provide. **This must – in collaboration with the local education and training boards (LETBs) – include oversight of trainee numbers.**

We are pleased to see that LETBs will be hosted by HEE and that they will work closely with the new Academic Health Sciences Networks (AHSNs). We are, however, concerned that the composition of the LETBs remains unclear. In particular, we understand from the proposals that LETBs will work closely with higher education institutions and that 'the Board will include representation from local education providers'. **We would value confirmation that universities will be full members of these Boards**.

We support the aim to engage service providers in education and training, but it is important to recognise that as employers they should not be placed in a position to dictate the educational content of training programmes locally. To minimise conflicts of interest, academic-health alliances should be at the heart of LETBs. A single model for LETBs incorporating these points would ensure consistency across the country. It is important too that hospital Trusts be accountable for the provision of adequate conditions and the facilities needed for training in their organisations.

We welcome the decision to retain post graduate deans and their Deaneries but stress that they must have sufficient independence to be able to perform their quality management function effectively. In this light, we wish to have clarity about whether they will be employed by HEE, as we would like to see, or by LETBs.

We welcome the confirmation that you plan to introduce amendments at Report stage to ensure commissioners of services in the new system will foster high-quality education and training in the health sector. It is important that all providers of care support high quality education and training and we look forward to seeing these amendments.