

1	Should CSO and the Health Boards set any eligibility criteria for nodal R&D Directors? Should appointment of a nodal R&D Director be for a specific time, and if so what term would be appropriate?	<p>Yes, the CSO should have clearly-defined criteria for recruiting the nodal R&D Directors. Of particular importance, from the perspective of Boards associated with nodal lead Boards, is that the R&D Director should view inclusive working as a priority for the nodes, to help expand best-practice, introduce standardisation in practice, and take advantage of efficiencies and benefits from opening up access to research opportunities to all patient populations associated with the node.</p> <p>Rather than a strictly time-limited appointment, which may discourage long-term planning and development, suggest comprehensive performance reviews be built in to the process (perhaps every three years), with the CSO retaining the option to seek a new appointment if it deemed performance / delivery to be unsatisfactory.</p>
2	CSO proposes to approve the functions of staff in R&D Offices; should CSO seek to standardise local R&D functions across Scotland, or is it preferable to allow local flexibility?	<p>It is desirable to have a range of core, standardised, deliverable management functions defined, and perhaps enshrined within the funding agreements, perhaps with incentives for excellent delivery performance.</p> <p>Standard, proscriptive job descriptions are not desirable, as this would reduce the flexibility of Boards to develop research in line with local needs and priorities, functional structures and models of working.</p>
3	Are there other NRS functions that might usefully be transferred from the Health Boards or CSO to the new NRS-GMS? Are there functions not currently being undertaken that the NRS-GMS might carry out?	<p>It would be helpful if the new NRS-GMS could act as the hub for provision of definitive, specialised advice related to issues such as IRMER Radiology Regulations, PIC sites, cross-border legal considerations (e.g. tissue/DNA, Adults with incapacity, research involving children), etc. It is important to handle these latter</p>

		<p>issues consistently, particularly when we (NRS) are involved in studies approved by REC in England, but where legal position could be compromised in Scotland.</p> <p>Consideration could possibly be given to NRS-GMS acting as a hub for advice to Universities with regards student research issues – such as who should be Sponsor, what Peer review is necessary, who should be Chief Investigator, etc. This may, however, be outwith their remit.</p>
4	To what extent should the joint planning of the deployment of infrastructure resources be formalised? Should there be a formal record of such discussions?	<p>Joint planning of infrastructure resources is desirable, and we expect there may be greater clarity on how this could be formalised following the CSO infrastructure reviews that will be taking place over the coming period. A circulated and accessible record of discussions – with opportunities for suggestions / feedback / input – from all Boards would potentially be of great benefit in both ensuring plans are optimal, but also in helping maximise the benefits for all Boards, researchers and patient populations to be derived from those investments.</p>
5	Taken together, will these steps to both free up and promote the availability of NRS resources address current concerns over lack of time and support? If not, are there other steps CSO should take?	<p>The above proposals could help in this regard, with better efficiency through standardisation and better understanding of, and access to shared infrastructure resources.</p>
6	Are there any further changes that should be made to improve the efficient delivery of patients to studies through the NRS Networks and Speciality Groups?	<p>We see best delivery when local, experienced Clinical Trials Nurses are available to work in partnership with committed local Principal Investigators.</p> <p>It will be interesting to see how the NRS Nodal Delivery Managers will actually help local teams on the ground. We would suggest this should be in the form of practical, supportive assistance rather than purely oversight / performance management - one suggestion would be for them to act as trainers / mentors, sharing best practices in terms of strategies for maximising recruitment, patient searches, etc.</p>

7	<p>To what extent do delays continue to occur as a consequence of differing NHS and university requirements? To what extent is closer integration of NRS and university functions possible and desirable?</p>	<p>The question specifically relates to University / NRS common working / functions. For the non-Nodal-Lead Boards, one of the main issues related to student projects – these take up a disproportionate amount of R&D support time. Closer integration with regards processes for gaining NHS approval (including REC approval), would certainly be beneficial in terms of efficiency. See also previous comment re: NRS-GMS</p> <p>The relevant section of the Draft CSO Strategy also addresses the setting up of NRS Integrated Support Services. Efficiencies are certainly possible through avoiding multiple checking of the same documents by Universities RECs / NHS RECs / NRS PCC / Generic Reviewer. There is a need to clarify who carries out document validation, and what such validation actually entails. While supportive of NRS Integrated Support Services in principle, this needs to be carefully considered - R&D and NHS RECs may, for instance, review a document from differing perspectives, and so each may not pick up issues deemed relevant by the other.</p> <p>From the perspective of those completing the IRAS forms, and easy win would be, if technically possible, to amalgamate the IRAS NHS R&D and NHS REC forms.</p>
<p>Chapter 2 – Partnership with Scottish Patients and Public</p>		
8	<p>Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?</p>	<p>Supportive of this aspiration in principle, but the logistics, and the management of public expectations, would have to be very carefully thought through. Systems of pre-screening of patients (perhaps carried out centrally) would have to be in place to avoid placing unsupportable burdens on local study teams – this, of course, may be difficult given the need to be able to access detailed medical history, etc. A system whereby researchers can communicate with clinical teams more effectively in other Boards to identify potentially eligible patients may be more</p>

		practical, and effective.
9	Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?	Yes, this could be highly beneficial in terms of enhancing access for patients to relevant studies, and in delivering appropriate levels of recruitment.
	Chapter 3 – Targeted Deployment of Resources and Infrastructure	
10	What proportion of CSO funding should be available for deployment in new research initiatives relevant to the NHS? In what areas should CSO seek to disinvest to free up resources?	No comment.
11	Is the focus of the CSO response mode grant schemes adequately defined and understood by the research community? Should there be a narrower focus to complement and avoid overlap with other funding streams Scottish researchers have access to? What is a realistic upper level for CSO grants to allow worthwhile projects to progress?	Limited comment: A level of overlap is helpful, in that it helps encourage and support a wider selection of researchers, and avoids limiting the funding opportunities available to new researchers.
12	What should determine the creation and continued funding of a CSO unit? Should any new unit have a plan for CSO funding to be time limited?	Limited comment: New units should, where necessary, have a plan for CSO funding to be time limited. This is dependent on the intended function of the Unit (e.g. units intended to develop new researchers in a particular field or profession could have a requirement to generate grant / commercial income above a specified level within a period of time).
	Chapter 4 – Working in Collaboration	
13	Are there other key areas of partnership CSO should be seeking to build?	No comment.

14	Would the creation of a CSO International Advisory Board be a positive step in raising Scotland's research profile and supporting our ambition? What should be the make-up of such a Board	No comment.
15	Are there other areas where CSO funded research could better support the Health Directorates Quality agenda?	No comment.
	Chapter 5 – Investing in the Future	
16	Is the Primary Care Research Career Award scheme suitably focused to attract suitable high quality applicants? If not, what would a revised focus be?	No experience of this scheme, therefore no comment.
17	Are the current CSO personal award schemes targeted to meet our future needs? If not, should CSO conduct a wider review of its capacity building schemes?	The NRS Research Fellowship awards have been a success in developing a highly-active commercial research portfolio in a previously untapped specialty, and this is certainly a model we would like to see continue.