NHS NATIONAL SERVICES SCOTLAND
CONSULTATION QUESTIONS

Chapter 1 – Efficient R&D Support for Research

Question 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?

Currently nodal R&D Directors are geographic/regionally based posts and it is clear where the territorial Boards sit within this. However there is no reference to the research activities within the national Boards. We suggest that consideration should be given to incorporating them within the existing node structure with more explicit interface with national Boards such as NSS, NHS Health Scotland, NHS Education for Scotland etc.

Question 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?

No comment

Question 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?

No comment.

Question 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?

No comment

Question 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?

No comment.

Question 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?

No comment

Question 7: 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?

We anticipate that combining the research ethics services with NRS should have little impact, as long as it does not make the ethics process any different. Although applying for even simple ethics is a very laborious 85 page online form, once submitted, the response is refreshingly swift and very helpful therefore we hope that would continue.

We note that paragraph 1.24 states an intention that '…both ethics and R&D should place a greater emphasis on supporting research rather than focus on approving it'. Hopefully this is intended to mean supporting sound and ethical research in the public interest. If this is the case, then it would be clearer and more reassuring to the public to include a caveat/ qualifier of this nature.

We do believe that Universities and NHS have different requirements (especially in terms of FEC costs) but are not sure that delays are experienced because of this. In our experience of holding both University and NHS grants we do not encounter different management issues. The principal differences are at the application stage, but that is internal to the institution.

Chapter 2 – **Partnership with Scottish Patients and Public**

Question 8: 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?

We supported the proposed new requirement in paragraph 2.5, which, once implemented should effectively inform governance processes associated with research applications.

One of the questions here relates to the management of expectations that would need to be associated with the setting up of a trial register. Yes, care would need to be taken to avoid the unfair raising of expectations; a particularly vulnerable group here would be patients with life threatening conditions seeking trial drugs as a 'last resort'. However, effective public engagement and appropriate information and support for patients would hopefully help with this.

In relation to Page 2, paragraph 3, 3rd bullet point, we would suggest that an alternative way of expressing this vision principle would be to replace 'exploit' with 'Maximise the benefits of…' or 'Make best use of ….'. This is suggested because 'exploit' can have negative connotations, which would be unfortunate in this particular area of research of which the public is not yet fully aware or informed.

Question 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?

We believe yes, so long as this was done in a strictly controlled and secure manner. Moreover, we believe that alerting an appropriate health professional with an established therapeutic relationship with the patient (e.g. GP, hospital consultant) as suggested here would mean that the welfare considerations associated with how a research invitation might affect an individual can be addressed effectively.

Paragraphs 2.12 and 2.13 highlight correctly the potential sensitivities in this approach. Given the CSO's stated endorsement of the offering of participation in clinical studies to patients as a key aim of the NHS, perhaps consideration could be given to whether the NHS Scotland Charter of Patient Rights and responsibilities http://www.scotland.gov.uk/Resource/0039/00390989.pdf (e.g. the 'Communication and participation' or 'Confidentiality' chapters) could be expanded to include this.

The required changes would likely need to include a patient right to information about clinical trials, with an accompanying description of the process the NHS would use to help ensure this right is met. One practical point to consider on this would be how to ensure that clinicians (GP, consultant) contacted in this way actually respond.

Chapter 3 – Targeted Deployment of Resources and Infrastructure

Question 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?

In relation to funding arrangements, Clinical Academic Fellowships are only available to Doctors and Dentists. Whilst there are numerous examples of other health professionals leading significant research initiatives from within the health service, unfortunately there are also a great many others with potential but little opportunity to pursue it. We would suggest that the CSO explore with the Chief Nurse, and Chief Health Professions Officer, opportunities to extend the fellowship scheme to include other Health Professionals. A single application process and competitive assessment would identify the strongest candidates, from whatever professional group.

Question 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?

Our experience of Experimental and Translational Medicine awards is that they are relatively well funded and genuinely aimed at targeted research to translate science into health benefits. We certainly would like this stream to continue. We believe that these awards would have more impact if they were raised to £300k and/or extended over perhaps 3 years.

Question 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?

With regard to paragraph 3.16, we agree that eDRIS and the Farr Institute developments provide solid infra-structure in Scotland. Relating this to the earlier questions on research funding / and to ensure that these infrastructure resources are fully maximised, we believe that it could be worthwhile considering a set budget / call for research related to data-linkage this may help Scottish based researchers in academia / NHS take opportunities to undertake this work, while also enable eDRIS work to be better planned / predicted.

Chapter 4 – Working in Collaboration

Question 13: Are there other key areas of partnership CSO should be seeking to build?

We would suggest that the national Boards in general, and NSS in particular, be an area of partnership with CSO to provide synergy of national-research activities.

Question 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?

We believe the creation of a CSO international advisory board would be a positive step. International collaborations, including those using linked that can be linked, have great potential, and a strategic advisory group in this area would be helpful. One suggestion for membership from a data perspective would be to have a representative from the data privacy regulatory function from either a European (including Scottish/UK) or non-European (e.g. Australia, Canada) country.

Question 15: Are there other areas were CSO funded research could better support the Health Directorates Quality agenda?

No comment.

Chapter 5 – Investing in the Future

Question 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 comment.

Question 17: Do 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?

We welcome the forthcoming health and bio-informatics strategy to maximise the potential of data linkage to improve health and health services. We feel that it would be important that NSS is part of the partnerships and collaborations to help achieve this aim, utilising our expertise in data knowledge, management, epidemiology, linkage methodologies, and information governance.

We also anticipate its support for not only efficient governance, but also for a system of proportionate governance which recognises and balances potential risks to privacy and the societal benefits to be accrued from sound and ethical research in the public interest.