CSO RESEARCH STRATEGY

JUNE 2014

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PREFACE

1. The vision of CSO is to support and increase the level of high quality health research conducted in Scotland for the health and financial benefits of our population, so that Scotland is recognised globally as a "come to place" for health science.

2. This strategy aims to provide clarity and coherence on what we need to do to achieve this vision, and builds upon *Investing in Research, Improving Health,* published in 2009, to identify those key areas where we can and should make a difference. In doing so however it is important to recognise the wider context of the research landscape. CSO research funding comes from the Scottish Government Health Directorates, with the overarching aim of improving the health of the people of Scotland. However CSO is part of a much wider ambition. The Quality Strategy set out our collective aim of providing the highest quality healthcare to our population around three ambitions – Safe, Person Centred and Effective. More recently the 2020 Vision Route Map set out 12 priority areas for action in pursuit of sustainable high quality health and social care services in Scotland. Research has a key role to play in defining, delivering and evaluating key aspects of these documents.

3. Looking forward in this context, we have identified six guiding principles that we believe will help maintain Scotland's position at the forefront of health research internationally. The same principles also support a bold vision of creating partnerships across the health and academic sector to deliver world class excellence, by harnessing research and innovation and translating it into outstanding clinical outcomes, education, improvements in population health and wealth gain for Scotland:

- 1. Build whenever we can on the strong science infrastructure that exists across our Universities in Scotland with vibrant PhD and post doctorate communities
- 2. Seek out and deliver collaborative partnerships with a tripartite mission of research, education and delivery of quality health care, underpinned by a significant NHS Scotland research infrastructure investment
- 3. Exploit our ability to link information from health, social care and non-health sources using data to support better treatment, safety and research
- 4. De-clutter the pathway for the regulation and governance of health research by taking a proportionate and streamlined approach to research governance
- 5. Deliver collaborative arrangements with the biotechnology, pharmaceutical, informatics and medical devices industries.
- 6. Collaborate across the NHS family and with other funders to develop research programmes that add value, and position Scotland as a single research site when it makes good sense to do so.

4. Since taking up post as Chief Scientist I have been impressed by the range of research activities funded or co-ordinated through the Chief Scientist Office. To seek to progress them all with equal vigour would be beyond our means and indeed impractical for a country of our size.

5. This Strategy Update has therefore focused on five key areas for action that we feel will make a real difference to delivery, and will lend direct support to the guiding principles. These are (i) Efficient R&D Support for Research (ii) Partnership with Scottish Patients and Public (iii) Targeted Deployment of Resources (iv) Working in Collaboration and (v) Investing in Research.

6. Of these, I would like to emphasise the use of data, and the contribution of health research to Scotland's National Outcomes. Firstly, this strategy update sets out our ambition for the use of informatics not only to gear up the research landscape, but also to work in partnership with the NHS to use data to transform the way the NHS operates. Informatics is arguably a key to making the provision of high quality health care sustainable, perhaps the biggest challenge facing all healthcare providers and Governments in the next 20 years.

6. Secondly, we must also be mindful of the contribution research makes to the Scottish Government's purpose of increasing sustainable economic growth. This year has seen significant new and external investment in our informatics capability and our universities continue to attract UK funding on a scale disproportionate to our size. We have also seen a year on year increase in the value of the commercial research contracted through NHS Research Scotland, the revenues from which flow back into the NHS and the wider economy.

7. While identifying the five specific areas for priority action within this Strategy Update, the wider contribution made by other parts of the research community is not forgotten, nor is the wider ambition that research serves. Nevertheless, we believe the time is right to focus to ensure we deliver not only on the ambitions of *Investing in Research, Improving Health* but also on the original vision of the contribution CSO makes to the health of Scotland. It is forty years since the Chief Scientist Office was established, and Sir Andrew Watt Kay described CSO in *Health Bulletin* as "a partnership within which science will have more influence on the Government's central policy-making activities than before, and which will contribute more directly and more effectively to the task of making the best use of science and technology for the needs of the community as a whole." We believe this strategy is an important milestone as we seek to transform lives and communities and support the improvement of NHS Scotland over the next forty years.

Professor Andrew Morris FRSE F MedSci, Chief Scientist Health

INTRODUCTION – OUR NATIONAL AMBITION

1. Scotland has a proud heritage in the field of health research. Our previous Strategy *Investing in Research, Improving Health* set out our ambition of placing Scotland at the international forefront of clinical translational research and the development of systems medicine. That ambition is a reminder of how quickly the research landscape can change, with Stratified Medicine and Informatics widely seen as the new areas where we must compete to be globally competitive.

2. The ambition of this Strategy is therefore to increase the level of high quality research conducted in Scotland, for the health and financial benefits of our population. The Strategy focuses on five key areas that underpin success in the conduct of current and future research, aimed at supporting clinical research across a vast number of disease areas. Our patients and public rightly expect a focus on their needs as well as the ambitions of our research community. While CSO will continue to support new and promising research modalities, it is essential to the long term sustainability of our ambitions that opportunities exist for all high quality research to be supported.

This draft Strategy identifies 5 areas critical to our future success:

- Efficient R&D Support for Research
- Partnership with Scottish Patients and the Public
- Targeted Deployment of Resources
- Working in Collaboration
- Investing in the Future

3. Each of these areas are the subject of a chapter, setting out our proposals, and where appropriate – questions, with a view to realising our national ambition.

CHAPTER 1 - EFFICIENT R&D SUPPORT FOR RESEARCH

1.1 It is critical to the success of our national ambitions that research in Scotland is supported by efficient structures in the NHS – both for R&D governance purposes and for ethical approval. Since the publication of the last Strategy NHS Research Scotland (NRS), a partnership between Scottish Health Boards and CSO, has continued to deliver efficient and prompt approval for study start-up. In 2013 the median time across Scotland to approve non-commercial studies was 13 working days and 22 for commercial studies. Further, the last few years have seen even greater efficiencies with the introduction of a single costing for all studies – commercial and non-commercial – now in place. As a consequence of this business-like approach significant interest and support has been expressed from industry, as evidenced by the strategic collaborations with some of the world's largest clinical trials contract research organisations and pharmaceutical companies. In the area of research ethics, our REC approval times remain among the fastest in the UK. It is our ambition to build on this success and deliver even greater efficiencies.

Management of NHS Research Scotland Activity

1.2 Central to the NRS ethos is working on a pan-Scotland basis. NRS operates in four regional nodes, with oversight and strategic direction achieved through the NRS Strategy Board that meets monthly to progress issues of relevance to the overall operation of NHS research in Scotland.

1.3 The success of NRS relies substantially on the close working relationship between the NHS Board R&D staff and CSO. This is a defining characteristic of NRS and it works well.

1.4 However the burden of managing NRS activity within the NHS falls disproportionately on the 4 nodal R&D Directors, and the successful delivery of NRS and CSO policy through them is key to success. At present CSO allocates an additional allowance to their Boards in recognition of the additional time commitment to national business, but has not defined formally their NRS nodal responsibilities.

1.5 Further, having key national R&D Directors of the appropriate standing and commitment is vital to its future success. It is therefore important to clarify both the key responsibilities of these national posts and CSO's expectations on their replacement.

1.6 CSO will therefore define the job description of a nodal R&D Director and become formally involved in the recruitment of new appointments to these key posts.

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 term, and if so what term would be appropriate?

1.7 CSO currently spends in excess of £2m annually on R&D Office staff across Scotland. This is a significant investment of public funds although compared to other countries in the UK is not excessive. CSO allocates funds for this function based on the level of research the Health Board is undertaking, but currently allows complete flexibility in deploying those funds.

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?

1.8 NRS has operated well through the current system of generic issues being considered and determined once on behalf of Scotland. However if we are to support efficiently the increased commercial activity being attracted to Scotland, and use management information more effectively to drive improvements, further evolution is required. At present co-ordination and assessment of management information is fragmented and sometimes hinders strategic consideration of issues at the NRS Strategic Board.

1.9 We therefore propose the creation of an NRS General Manager (NRS-GM) with a small support team collectively working as the NRS General Manager Services (NRS-GMS). They will undertake the high level co-ordination of NRS activities and specific NRS operational functions previously undertaken directly by the NHS or CSO, including budgetary aspects.

1.10 Being able to act independent of all Health Boards – and being seen to do so – is critical to the success of the NRS-GMS. Equally, becoming an integral part of the wider NRS initiative is key; it is not our intention to create a new management layer between CSO and the Health Boards. CSO has considered a number of options and concluded that contracting with Scottish Health Innovations Ltd (SHIL) to undertake this function is the appropriate way forward. SHIL - jointly owned by Scottish Ministers, NHS Tayside and the National Waiting Times Centre Board and funded by CSO - is already part of the research and innovation landscape and engages well with the Health Boards in a quasi-independent manner.

1.11 The new NRS-GMS will assume responsibility for conducting the NRS annual activity based funding and annual reporting exercises currently managed through CSO. The NRS-GMS will also assume responsibility for the oversight and financial management of the CSO Service Support Costs and Infrastructure budgets. This will not replace the current responsibilities of the NRS nodes to manage these funds efficiently, but will provide a better oversight of their deployment than has been possible to date. The NRS-GMS will also work with the distributed NRS national functions, particularly the NRS Permissions Co-ordinating Centre and the NRS Industry Manager, to co-ordinate activity and provide regular reports and advice to the NRS Strategy Board. The NRS-GMS will also become the NRS Strategy Board secretariat with the NRS-GM a new member of that Board.

1.12 The contract for the NRS-GMS will be awarded for an initial period of 3 years.

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?

Management of NRS Investments

1.13 At the core of an efficient NHS R&D management system is close collaboration with both NHS and academic researchers. While the strategic investments referred to in Chapter 3 are designed to meet national need and bridge some of the gaps between NHS and academic investment in key areas, most of the investments made through NRS are designed to ensure either that NHS researchers have the time to undertake research for the benefit of our patients, or the necessary NHS staff (e.g. nurses) are available to support the research.

1.14 Even though these investments have been ongoing for a number of years, not all researchers are aware of the significant investments in staff and researcher time made to support their work. As a consequence some studies are still being declined in the belief that the required support will not be available, losing the opportunity for more patients to participate in research. Feedback from our Networks and Specialty Groups also indicate a belief that resources are not always available to support studies. It is therefore critical that the Health Boards regularly assess with their NHS and academic researchers how well the deployment of the funds meet their needs in terms of providing the necessary support for all eligible studies.

1.15 Promoting these CSO investments within the research community, and publicising CSO's condition of grant that the first call on the use of our deployed funds is supporting eligible research, is an activity that may not have been afforded sufficient priority in the past. **CSO will therefore require that all Boards take adequate steps promote the availability of resources to support research.** Further, to ensure resources are deployed where the need exists, we will require joint planning of NRS Infrastructure investments with NRS Network and Specialty Group leads as a condition of funding. These steps, alongside the intention to make infrastructure funding fully activity based from 2016, should make the link between the research activity and the infrastructure played to support it more transparent.

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?

1.16 Infrastructure support aside, one of the main barriers to undertaking more research is the lack of clinician time. Although CSO allocates £12.7m per annum to Boards through its NRS Researcher Support budget to meet the time of staff conducting research, how this funding is used to "buy out" researcher time is not usually understood by researchers. Although in recent years a number of Boards have taken steps to allocate this funding to clinical departments in line with research activity in others it remains embedded in the wider NHS allocations and is not identifiable as a research resource, or managed as such. CSO intends freeing up this resource so that it is fully deployed in transparently supporting research activity. **NRS Researcher Support will be fully allocated for researcher time and**

associated activities by April 2016. CSO will approve the Board methodology to ensure it meets our expectations.

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?

Management of NRS Networks and Specialty Groups

1.17 During 2013 CSO consulted on changes to the NRS Topic Networks and Specialty Groups to improve their impact on clinical research in Scotland. The consultation identified a need for closer engagement between these groups and the research community, and in the case of Specialty Groups greater support for their activities within the NRS Infrastructure.

1.18 Those findings are now being implemented through the following changes:

- The paramount focus of NRS Networks and Specialty Groups will be to recruit to studies on time and to target
- NRS Networks and Specialty Groups will proactively support all eligibly funded research within their clinical areas and no longer "adopt" studies they wish to support
- Three Specialty Group areas with high levels of activity Cardiovascular, Musculoskeletal and Reproductive Health and Childbirth – will have new delivery managers appointed
- All other Specialty Groups will have NRS nodal delivery managers to oversee recruitment and support the Specialty Group lead
- The Network lead role will be extended to support oversight of study delivery and lead strategic development as NRS Champions
- NRS Champions will also be appointed for the three Speciality Group areas with high levels of activity
- All Network and Specialty Group lead appointments will be by open competition and regularly reviewed

1.19 Taken together these changes, alongside the new joint planning proposal mentioned should ensure that all eligible studies in Scotland have managerial oversight of recruitment and an escalation procedure to resolve problems.

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 Specialty Groups?

The Research Ethics Service, NHS R&D and University Systems

1.20 A distinct feature of the Scottish research landscape is the close working relationship between the NHS Research Scotland Ethics Service and the wider Health Board R&D functions. When England decided to separate out the ethics service into a distinct organisation, CSO chose to integrate the ethics and R&D

functions more closely within the Health Boards. This closer working, along with the appointment of ethics Scientific Officers, has removed many of the artificial barriers between these two functions and streamlined the process of obtaining the necessary approvals for study commencement. We therefore welcome the Health Research Authority's review of these services in England with a view to closer integration.

1.21 In pursuit of greater efficiency in study start-up, the Health Research Authority proposes introducing a single assessment that will integrate elements of ethics and R&D approvals. Scotland already has commendable approval times for both ethics and NHS R&D and as such, while it is critical to maintain a common system across the UK, we will await the details of how the HRA single assessment delivery model will operate before deciding whether it would be sensible to adopt it in Scotland. Experience of the UK ethics systems suggest that a unified system can be delivered through different structures and operational models working to the same principles. It will therefore be important to await further details of the HRA's proposals before committing Scotland to significant organisational change.

1.22 Meanwhile, it is imperative that Scotland continues to lead the agenda on streamlining the approvals process and reducing bureaucracy. It is widely recognised that the role of both ethics and NHS R&D is to facilitate good research, yet much activity is focused on gatekeeping rather than assisting researchers to undertake their research. CSO believes that with a more proactive approach to early support for researchers many of the issues that arise at the formal approvals process might be avoided. There are already examples of good practice in both ethics and NHS R&D but there is a need to formalise this approach across both services.

1.23 CSO recognises that much of the current way of working has been driven by the Research Governance Framework, which focuses on responsibilities rather than outcomes. At a strategic level, CSO, the Health Research Authority and the other devolved administrations are therefore undertaking a review of the current Research Governance Framework to create a new document that gives greater emphasis to supporting research rather than policing it. Further, we will initiate discussions within and outwith Scotland on how the paperwork and significant volume of guidance and Standard Operating Procedures associated with ethics and NHS R&D functions can

be reduced – both have increased significantly over the years. We will also seek to combine the Scottish Research Ethics Service and NRS R&D Offices into a single integrated service for researchers while retaining the independence of the REC decision making function.

1.24 To signal our intention that both ethics and NHS R&D should place a greater emphasis on supporting research rather than focusing on approving it, **we propose these functions should be renamed as NRS Integrated Support Services.** Such changes will make Scotland well placed to participate in the emerging Health Research Authority plans for a single assessment.

1.25 CSO has responsibility for NHS systems, but considering them in isolation from those in their related universities will not be sensible. Scotland has a commendably close relationship between its NHS and academic institutions, at a strategic as well as operational level, and as a consequence many of the issues that arise in other

parts of the UK from universities operating independently do not arise. Joint offices are common and are to be commended, and routine co-sponsorship of research is a good example of the two organisations working closely together for the researcher's benefit.

1.26 We believe there is a responsibility on universities to support NRS policies for streamlined and efficient systems and implement them without modification. Health Science Scotland - comprising the lead universities, their NHS Boards and CSO - provides a suitable forum for strategic discussion and resolution of issues should they arise.

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?

CHAPTER 2 - PARTNERSHIP WITH SCOTTISH PATIENTS AND THE PUBLIC

2.1 The Scottish public are at the heart of clinical research, both as healthy volunteers participating in early stage studies and as patients benefiting from improved diagnosis or treatments. Without patients enrolling to take part in clinical research, very little of the research in the NHS would be possible. The insights and views of patients, carers and relatives are also immensely useful in ensuring the successful delivery of well-designed, scientifically valid research that has relevance to the people of Scotland.

CSO Public Involvement Group

2.2 Since 2001 CSO has involved the Public in both Grant Funding and Policy areas through the CSO Public Involvement Group. We acknowledge that the Public Involvement Group plays a key role in representing the public's interest in CSO's work, providing a vital lay view of policy and research proposals.

2.3 Over the last 6 months we have carried out a fundamental review of public involvement activities both within CSO and the NRS research Network structures. While there was much excellent work being undertaken by the CSO Group under the leadership of its Chair Joan Munro, we recognize jointly that there are opportunities to enhance the work of that group in providing advice and support to CSO. Key areas to be taken forward include:

- The group will be renamed the CSO Public Engagement Group (PEG).
- There will be broader representation in the work of CSO, including lay participation at CSO policy and strategic committees
- There will also be greater lay involvement in the planning and review process of CSO investments such as funded units, Bio-repositories and the focus of CSO grants
- The role of lay representation in raising public awareness in the understanding of clinical research will be developed further

2.4 Our NRS Networks also heavily involve the public at steering group level as well as directly with research. However there is more that can be done in developing best practice in these areas and we propose bringing these groups together to build a greater sense of common enterprise. CSO will continue to encourage the component parts of NRS to directly engage with patients and patient groups, and further develop ways in which members of the public can be empowered to become actively involved in clinical research.

2.5 CSO will require the newly restructured NRS Research Networks to show evidence of involvement with the public in their work, and to embed patient and public involvement in their management processes.

Scottish Health Research Register

2.6 CSO is also funding an initiative for members of the public who wish to express an interest in being contacted about participating in research. Following registration on the Scottish Health Research Register (SHARE), details of participants will be maintained on a database of those who are willing to be approached about taking part in research studies. Through electronic linkage of health information, SHARE will be able to identify potential recruits for studies far more efficiently than at present. Initially funded through a CSO small grant, SHARE has now been brought within the NRS Infrastructure budget to ensure sustainability and facilitate larger scale recruitment. There are already over 25,000 people on the SHARE register, but the long term goal is to create a far larger register for use in relevant studies.

2.7 Although SHARE provides an opportunity for many to indicate a general willingness to be approached to take part in research, routes for facilitating involvement for patients who want to take part in specific studies are relatively underdeveloped. Patients may wish to contact investigators directly if they become aware that a study is enrolling patients with a specific diagnosis. However given the very specific scientific design of most trials, entry to studies cannot be guaranteed, and there is currently no process to manage such requests appropriately. For this reason CSO is also committed to explore the creation of a Scottish Clinical Trial Register.

2.8 Although medical researchers often find it difficult to identify suitable patients for clinical trials, it is often equally hard for patients interested in taking part in trials to find clear, accessible information about studies. Current lists of active studies do not generally provide lay summaries of what projects involve, and current mechanisms to signal an interest are not always direct or well-maintained.

2.9 CSO will develop a secure website allowing NHS patients across Scotland to identify clinical trials which are actively seeking participants. Patients will be able to review a list of available studies, and express their interest online. Patients will be able to express an interest in studies open anywhere in Scotland which may require them to travel. Any studies that are only recruiting locally will be identified as such on the Register. When applying through the website, a patient will give consent that they can be assessed for entry into trials by comparing their medical records against the eligibility criteria for the relevant study. A response will be provided to the patient within a short period of time. If the patient meets the study general eligibility criteria, their details will be passed to the study investigator for a more detailed assessment and consideration. The Register will work closely with SHARE, and patients who have not been found eligible for their preferred study will be given the opportunity to register for SHARE, which will provide an additional mechanism for them to identify studies of interest to t hem. A pilot Trial Register will be developed initially.

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?

NRS Recruitment Service

2.10 NHS clinical data is routinely used to inform planning decisions. Care of some chronic conditions, such as diabetes, has been transformed by the availability of electronic systems to track the progress of the disease. Clinical registries have also been invaluable in gathering data to inform the development of clinical practice, services and research.

2.11 Aggregate data derived from NHS health records allows planning and feasibility assessments of the potential success of research projects to be made. However, individual patient data is not currently used to inform patients about research projects that would be of personal relevance to them.

2.12 We recognise there is a sensitivity over who has access to patient clinical data. Projects such as SHARE therefore require potential participants to register their general agreement for their electronic records to be checked. This, however, limits the identification of patients who may have access to new treatments available through clinical trials to those who have previously registered an interest. As a consequence, patients undergoing treatment in the NHS are not routinely informed of research taking place that could be relevant to them.

2.13 We believe offering patients participation in clinical studies should be a key aim of the NHS as an integrated part of patient care. Assisting GPs and hospital consultants in identifying patients who might be invited to participate in a research study relevant to their condition is therefore a service we believe worthy of consideration. We believe NHS staff using NHS patient records solely to advise GPs and hospital consultants of trials that may be of interest to their patients strikes an acceptable balance of security and service to patients.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible be 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?

CHAPTER 3 - TARGETED DEPLOYMENT OF RESOURCES (AND INFRASTRUCTURE)

3.1 CSO invests a total of £68m per annum in Scottish research, representing a significant investment from the taxpayer and the Health Directorates in medical research. It is therefore important that these funds are deployed in an efficient and transparent way. However it is also important that all such investments are reviewed regularly against competing demands for funding and are not considered ring-fenced for any particular discipline or geographical area.

3.2 The need for regular review has been emphasised by the need to invest in new or emerging technologies to allow Scotland to remain at the forefront of medical research. In recent years the importance of Stratified Medicine as a means of transforming the way the NHS diagnoses disease and provides care has been recognised as an important area in which research is essential, while the capacity to transform the way the NHS operates through informatics is only now beginning to be realised. For this reason CSO needs to ensure that it has an acceptable balance of longer-term commitments and flexible funds to deploy as new priorities and initiatives emerge. At present there is an imbalance towards the longer-term. **CSO will therefore free up a proportion of its budget to be deployed in support of new initiatives**.

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?

3.3 To ensure existing investments remain a priority and have a suitable focus we propose a number of reviews of long standing areas of investment. Proposals for the review of existing areas of investment are set out below.

Response Mode Grants

3.4 CSO funds research projects throught its two response mode funding commitments. At any one time around 100 CSO funded studies are active with a value of around £15m. Early findings from ResearchFish evaluation database suggest that CSO grants generate a considerable volume of additional activity. It is certainly true that CSO grants are highly valued by the research community and demand has never been higher.

3.5 Over the last 2-3 years we have taken steps to streamline the structure and administration of our response mode funding, and the changes have delivered efficiencies for applicants as well as for the Office. We are currently exploring the adoption of a new grants system that will deliver further efficiencies. However such is the demand for CSO grants, only one out of every five is able to be funded.

3.6 In terms of the type of research CSO funds, we currently focus our funding on early-phase development, pilot and feasibility studies that will equip researchers based in Scotland with the evidence needed to develop convincing high quality applications to the larger UK-wide funding streams. In the CSO Experimental and Translational Medicine Research Committee, for example, 50% of applications were

for between £150k and £224k with 33% of applications at or around £225k upper limit. 17% of applications were for under £150k. However given the significant investment of over £8m per annum that CSO contributes to the NIHR NETSCC funding streams (such as HTA and EME) to allow access for Scottish researchers, the question arises as to whether any of the applications CSO has funded could equally or more appropriately have been considered by the NETSCC schemes. **CSO will explore with NETSCC the interface between our two funding streams to ensure the focus of CSO grants is both clear and complementary.**

3.7 CSO will also explore the possibility of raising the upper limit for applications from its current value of £225,000, although a significant increase in the grant funding limit within the same or reduced annual budget would raise issues of future viability of the Committees.

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?

NRS Strategic Investments

3.8 Chapter One referred to the important role CSO funding plays in supporting NHS studies. Since April 2008 CSO has been investing an additional £10m per annum in NRS Infrastructure. Phased in over three years, this budget was allocated to the Health Boards in Grampian, Greater Glasgow and Clyde, Lothian and Tayside to ensure that new staff were in place both to support current NHS research needs and deliver our ambitions for the future. Critically, CSO allowed the Boards to determine the specific areas in which to deploy the new staff to best meet CSO's strategic aims. Now that these investments have been in place for some time, it is appropriate to review the effectiveness of these investments and the extent to which they are contributing to our national ambition.

3.9 Given the range of functions covered by the NRS Infrastructure investment, it is clear that the underpinning infrastructure will be determined by the needs of current research activity, while for more speculative investments (eg biorepositories, safe havens) detailed metrics are required to assess how well the Health Board investments are delivering tangible research benefits relative to the funds deployed. With clinicians indicating that there are still unmet needs to support ongoing studies (e.g. research nurses) there may also be a need to assess the prioritisation of the resources. The paramount priority for deployment of resources in CSO Funding Agreements with the Health Boards is supporting current studies; we will ensure this principle is clearly applied across all our investments, with funding being redeployed where necessary.

3.10 The aforementioned £10m infrastructure allocation was delivered as a redeployment of resources already allocated to Health Boards for NHS Programmes of research. Those Programme funds often had little relationship to the scale of the wider research activity in those Boards and as a consequence the deployment of

these resources has been seen as inequitable by those Health Boards who were relatively underfunded. From 2016 CSO will revise the allocation of underpinning infrastructure funds to ensure a more equitable deployment of resource based on activity.

3.11 With the current NRS Infrastructure contracts terminating in March 2015 it is also important to review the impact of specific infrastructure investments rather than make broad judgements covering the totality of the resource deployed.

3.12 CSO therefore intends dividing the NRS Infrastructure allocation into specific areas of investment, with each area being managed as a distinct budget. Under this arrangement, underpinning infrastructure deployed to support current needs (such as research nurses) will be managed and assessed separately from strategic investment for the future (such as national networks of biorepositories and health informatics 'safe-havens').

3.13 Such an arrangement will facilitate a phased approach to the review and contracting for NRS Infrastructure investments, rather than the full \pounds 50m investment over the 5 year period being evaluated *en bloc*. This will ensure any movement of funds is incremental. It will also ensure that the anticipated outputs from each area of investment can be properly projected and measured. Early priorities for such review are the \pounds 1.1m per annum investment in NRS Biorepository network, and the \pounds 0.9m per annum investment in safe havens.

3.14 For NRS Biorepositories, CSO is keen to ensure than an appropriate emphasis is placed on the creation of a network for the supply of tissue for non-commercial and industry research, with resource deployed on a scale proportionate to that output. Collection and retention of human tissue that is unlikely to be required for research purposes is both costly and unethical. To date there has been little focus on matching resource to anticipated need, while the ongoing collection, storage and management of tissue creates increasing pressures on limited CSO resource and expectations for continuing funding.

3.15 With stratified medicine assuming greater prominence we anticipate an upturn in demand, but whether that will focus on the provision of fresh tissue or utilise the investment in stored tissue, and on what scale, is yet to be determined. It is important that this demand is properly assessed and matched with investment. A review of the NRS Biorepository opportunities and investments will be conducted in the course of 2014-15.

3.16 Likewise, the rapid development of health and bio-informatics research infrastructure in Scotland, following the launch of e-DRIS and the development of the Farr Institute, requires us to ensure that the NRS safe havens investment is suitably targeted towards a national network and adding value. We anticipate that a fully functioning network of NRS safe havens will be a valuable resource, both in its own right as a vehicle through which research quality data can be accessed and as a resource that will support Farr research activity. Income will flow from activity associated with both these routes and will therefore be a proxy for demand. Given the stage of development of Farr, and the need to have clear governance and independent inspection arrangements in place for the safe havens, CSO recognises

that an early review similar to that for Biorepositories would be premature. A review of the NRS Safe Haven opportunities and investments will therefore be conducted in the course of 2016-17.

CSO Core Funded Research Units

3.17 CSO invests in six Units:

- The Health Economics Research Unit
- The Health Services Research Unit
- Institute of Hearing Research
- Social and Public Health Sciences
- The Nursing, Midwifery and Allied Health Professions Research Unit
- Scottish Collaboration for Public Health Research and Policy

3.18 The Units' chief role is as centres of excellence for research disciplines that are central to Scotland's health needs. Total investment in Units represents £3.9m or 5.8% of CSO's annual expenditure. Each Unit enjoys an effective working partnership between the CSO and the Units' host institutions, and in three cases the Units are co-funded with the Medical Research Council. All Units are subject to a quinquennial review ensuring a strategic "fit" with CSO's priorities; a parallel scientific review is intended to ensure that their work contributes to the Scottish Government's strategy and purpose.

3.19 Given the scale of this investment, CSO needs to ensure that the relevance of each Unit to CSO's Strategic direction is regularly reviewed and assessed against the funds deployed. Similarly there is a need to ensure that the areas of work undertaken within the Units are a priority for CSO or Scottish Government colleagues. Finally, Units provide different functions such as undertaking research in areas of strategic need, providing policy advice and capacity building. These are quite different functions, possibly requiring different scales of investment over varying periods.

3.20 The CSO Units are an important investment and our intention to review their strategic fit and purpose is not through any discontent with their performance; however to review all other major areas of investment and omit the Units would not be sensible. CSO will therefore conduct a strategic review of Unit purpose and funding in the course of 2015-16.

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?

CHAPTER 4 - WORKING IN COLLABORATION

4.1 The benefits of collaborative working across disciplines is fully recognised and well established in research. However the practice of organisations from different sectors operating in close collaboration for mutual benefit has taken longer to develop.

4.2 Working in collaboration is one of the six guiding principles articulated in the Preface to this document. This chapter sets out what has been achieved to date and how this should be progressed in the future.

Strategic Collaborations with Industry

4.3 Since the creation of NRS, working closely with industry has been a key priority. The NRS Industry Partnership Forum was formed in 2010 to ensure close liaison between the NHS and the pharmaceutical industry. Co-chaired by CSO and the ABPI, it provides a forum for positive discussion on how NHS Boards and companies can streamline their delivery of clinical studies.

- 4.4 NRS currently has strategic collaborations with four industry partners:
 - Announced in 9 February 2012, the Strategic Alliance with PPD is intended to cover a broad range of Phase I III trials across multiple therapeutic areas
 - NRS becoming a Quintiles Prime Site was announced at the inaugural NRS conference in October 2012, designed to increase the number of contract clinical trials conducted in Scotland.
 - On 31 October 2013 the Minister for Public Health announced that NHS Research Scotland has been awarded Pfizer global INSPIRE status, making Scotland a location of choice for Pfizer studies.
 - Most recently in May 2014, NRS entered into a Strategic Alliance with Roche, through which an increased number of contract and investigator initiated studies would be placed in Scotland.

4.5 Both Quintiles and PPD have bases in Scotland. These collaborations therefore contribute not just to Scotland's economic growth but also to the sustainability of our company base.

Strategic Partnerships

4.6 As indicated in the guiding principles, collaboration between the NHS and its academic partners is critical to the success of our strategic aims of increasing the volume of research undertaken in Scotland and maximising the value of our electronic health records. Health Science Scotland, a Scotland wide collaboration between the most research active Health Boards and their linked universities, is an excellent example of partnership in practice. It is recognized that there are

opportunities to add greater value through better alignment of NRS and Health Science Scotland activities. CSO proposes to support both functions under the aegis of the NRS General Manager.

- 4.7 Other key partnerships include:
 - <u>Pharmaceutical, Medical Device and Biotech companies</u>. Through collaboration with industrial partners a greater number of patients can benefit by participating in clinical trials, income can be generated for the NHS and the Scottish economy be supported. Although partnership with the pharmaceutical industry is already well developed, links with the Medical Device and Biotech sectors are less well established. Additionally, most of the trials placed through NRS come from overseas with few studies coming from the Scottish Medical Device and Biotech companies. CSO intends building on existing partnership arrangements and will enter into discussions with sector representatives and Scottish Enterprise with a view to increasing the number of medical device and biotech studies placed through NRS.
 - <u>Other Government Departments</u> It is critical to the successful delivery of our ambitions that Scotland plays positively into the UK research structures; for this reason the clinical themes of our NRS Networks and Specialty Groups mirror those in England. While Scotland will pursue policies that best suit our distinct NHS structures and way of working, in key areas such as funding, governance and research ethics we will continue to work closely with other organisations to harmonise procedures. This will include, for example, working with the Health Research Authority in England to improve the landscape for clinical researchers.
 - <u>NIHR</u> CSO currently contributes £8m per year to ensure that researchers based in Scotland can access key NIHR programmes such as Health Technology Assessment and Efficiency and Mechanism Evaluation. With CSO project grants focused on early phase work with clear translational potential, access to UK-wide funding streams is essential to translate CSO-funded development, feasibility and pilot studies into full scale evaluations. We shall continue to work with the research community to ensure that the wider research funding landscape is well understood, and that Scottish success in securing funds from UK funding streams is maintained.
 - <u>Medical Research Charities</u> Working in partnership with the charity sector is a priority for CSO, and for that reason we have recently announced joint funding initiatives with Prostate Cancer UK, Alzheimer's Research UK, the Stroke Association, Parkinson's UK, Action Duchenne and the Muscular Dystrophy Campaign. We will continue to work with leading medical research charities to explore possible co-funding opportunities, for both research projects and capacity building initiatives.

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

Partnership in Innovation

4.8 In addition to the above partnerships, the Scottish Government published its 'Health and Wealth in Scotland: a Statement of Intent for Innovation in Health' in June 2012. This highlighted the ambition of Scotland to be a world leading centre for innovation in health through partnership working between Government, NHSScotland, industry and academia. An Innovation Partnership Board has been established to lead work on improving uptake of innovative health technologies and treatments, with Health Innovation Partnerships established in Medical Technologies, Digital Health and a Strategic Engagement Group created for Medicines. Collaborative research involving the NHS and other partners, including industry, will have an integral role in the realisation of this ambition.

4.9 Scottish Health Innovations Ltd (SHIL) is a significant contributor to the innovation agenda. Funded by CSO, SHIL works in partnership with the NHS to identify and progress innovative ideas coming from NHS staff. Examples include:

- The U-NET, a type of groin wound dressing the first product to be licensed out by SHIL.
- The ACR (Ambulance Child Restraint) is an innovative, flexible, fully adjustable system for the safe, effective handling of young patients being transported in ambulances. It is now widely used in ambulances across the UK.
- The Nasal Clip. The nose clip is a single use product for treating noncomplicated nose bleeds by applying appropriate pressure to the nose thus stemming the blood flow.
- The Prism Glasses are a Class 1 medical device designed to be used in stroke treatment as well as phantom limb pain.

International Partnership

4.10 Working collaboratively in Scotland is relatively easy because of our culture and scale. However if we are to realise our ambition of being world class in our research we must look outwith our geographical boundaries for independent advice on strategic issues. It is some years now since CSO convened its Chief Scientist Committee, with its membership drawn largely from within Scotland and its remit focused on specific Scottish issues. If Scotland is to deliver on its Global ambitions then it must have access to advice on a similar scale.

4.11 CSO therefore wishes to explore the creation of a new CSO International Advisory Board to provide expert advice on strategic research issues. Meeting once a year, with membership comprising key global leaders in their field, it would provide high level advice on the steps Scotland should be taking to deliver on its aspirations.

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?

Partnership within the Health Directorates

4.12 While it is essential for CSO to continue to be outward looking in delivering success, we must also ensure that we use our research expertise to support key initiatives of importance to the Health Directorates. Underpinned by the Healthcare Quality Strategy for Scotland, the NHS in Scotland has made significant strides in improving patient safety and the quality of care in recent years. Quality Improvement is now a unifying theme of NHSScotland and increasingly across public service. To date NHSScotland has been heavily reliant on international expertise to drive changes forward and there has been limited research to develop new knowledge, or publication of our work in respected peer reviewed journals. As a consequence there is considerable scope to expand the volume of research related to quality improvement science in the context of the Scotlish health care system.

4.13 For this reason CSO is a partner in the recent creation of a Scottish Improvement Science Collaborating Centre (SISCC), co-funded in collaboration with NHS Education Scotland, the Scottish Funding Council and the Health Foundation.

4.14 The vision for the SISCC is of a national resource and centre of expertise in improvement science research, development and knowledge translation. It will serve practitioners, policymakers and researchers, putting evidence at the heart of quality improvement in Scotland's health and care. It will foster innovation in creating, disseminating and applying improvement knowledge, and will design and execute research to lead to improvement in quality of health and care. The Centre will be based at the University of Dundee but it will be a large-scale collaboration involving universities, health boards, local authorities, patients, carers, communities and advocacy groups.

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

CHAPTER 5 - INVESTING IN THE FUTURE

NHS Research Capacity

5.1 The capacity of NHS clinicians to undertake research is a key area if we are to see the planned increase in research activity. The combination of many research active clinicians approaching retirement age and new consultants finding it difficult to have time allocated for research is a specific concern. To address the latter, CSO introduced a programme of NRS Career Resarch Fellowships in 2011, designed to support early stage clinicians participate in research. Three rounds of Fellowships have now been awarded, investing £6m over a four year period in support of 74 Fellows.

5.2 The 74 active Fellows are engaged in activities across the clinical spectrum from stroke to motor neuron disease to cancer to paediatric surgery, and all have been chosen both for their personal career intentions regarding NRS and the potential for their research to have a real impact on patient care.

5.3 CSO aims to maintain active NRS Fellows at this level for the forseeable future.

5.4 One clinical area in which CSO has historically invested significant funds to develop capacity is Primary Care. From the Research Practice Scheme (1996 to 2004) to the Scottish School of Primary Care (2000 to 2010) and the Primary Care Research Career Awards (2003 to present). The Primary Care Research Career Award enabled some of the most successful researchers whose talents were originally nurtured through the Research Practice Scheme to acquire further research experience and training, and indeed some have gone on to obtain professional appointments. Demand for this scheme has dropped over recent years and the scheme has not run in the last "two" due to lack of interest. Ensuring that research is both developed and carried out in the primary care setting of NHSScotland is still a relevant aim and CSO will therefore consider whether to maintain this scheme in its present form.

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?

Clinical Academic Capacity Building

5.5 Clinical academics are a valuable resource for Scotland, and complement the capacity building activity within the NHS. As University employees who spend at least half of their working week delivering and developing clinical services for the NHS, clinical academics undertake research that not only improves Scotland's health and healthcare, but also drives economic growth through the burgeoning Scottish Life Sciences industry. There is currently a risk that carefully nurtured early-career clinical academics may be attracted to long-term career posts outside Scotland.

5.6 In a strategic intervention aimed at retaining clinical academics at the crucial career initiation stage, in 2008 the Scottish Funding Council invested £7.7m in a

pathfinder scheme to appoint 19 senior clinical fellows over a five-year period. The objective was to identify, recruit and retain the very best early-career clinical academics in Scotland; to this end universities guaranteed permanent posts for those appointed through a rigorous process. In 2011, following a very positive evaluation of the first three years of appointment to the Scottish Senior Clinical Fellowship (SSCF) scheme, SFC support was confirmed to October 2013 and so allow two further rounds of appointment to this field-leading scheme in 2012 and 2013. A key marker of success has been that of 15 Senior Fellows have already been awarded professorial status by their host university.

5.7 The CSO is supportive of renewal of the SSCF Scheme to ensure that Scotland is able to recruit and retain the very best early-career clinical academics who will play a crucial role in improving the health, healthcare and wealth of our nation. We will work with key partners to deliver on this aim.

5.8 Ensuring the development of a strong cadre of researchers who can, in future, contribute to the evidence in the areas of health services and public health remains a key focus for CSO. Our Personal Fellowships in HSPHR have evolved over time to address key needs in the research community, and we are currently supporting 15 individuals through these Fellowships. We intend to continue to support excellent early stage investigators through our PhD and Postdoctoral Fellowships in this area, considering key strategic issues as they arise. We will continue to ensure that the translatability of the research that these Fellows conduct is a key part of the selection process.

5.9 More generally, CSO funds a number of other personal and capacity building schemes but funds do not permit matching all schemes in place in neighbouring countries. Since many of these schemes have been in place for a number of years, they may not be optimalls focused on our future priority needs.

Question 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?

A Biomedical Informatics Research Strategy for Scotland

5.10 Scotland has long been a pioneer in the use of linked health service data for research. Data linkage is a highly efficient way to evaluate the capacity of interventions to deliver patient and population health benefit. It allows us to measure long term outcomes in clinical trials, assess the safety of new and existing medicines and healthcare interventions, and to evaluate the impact of interventions across the whole population.

5.11 Using our existing linkage capability, researchers in Scotland have shown, for example, that cholesterol lowering drugs can reduce the risk of heart attacks for up to 15 years after beginning treatment, that early term deliveries account for a larger share of cases of special educational needs than do preterm deliveries, and that banning smoking in public places can reduce hospital admissions for acute coronary syndrome and asthma, and the incidence of a range of pregnancy complications.

5.12 Record linkage capability is developing rapidly, and Scotland must work hard to remain at the international forefront.

The Ambition

5.13 Much has been done already by way of key investments to improve the quality of the NHS datasets and develop the infrastructure for their utilisation. Key developments to date include:

- The Scottish Health Informatics Programme (SHIP)
- e-Health Informatics Research Centre (e-HIRC)
- The Farr Institute
- Health Informatics Research Advisory Group (HIRAG)

5.14 However there is an overarching need to ensure that these investments are appropriately coordinated and focused on providing a coherent and structured informatics policy to direct activity and future investment across Scotland. Scotland cannot rely only on past success, and must consider how to maximise the economic return on this internationally competitive research strength, by consolidating and expanding the role of the biomedical informatics industry as a dynamic contributor to Scotland's economic growth and social wellbeing.

Recent developments

5.15 We therefore plan to publish the health and bio-informatics research strategy in 2014, and then move quickly to implement its key recommendations, so that the benefits of a more efficient system of governance and a strong, flexible federal network of safe havens begin to flow as soon as possible, and the returns on the investment in the e-HIRCS, Farr, ADRC and national data linkage service are maximised.

NRS Stratified Medicine Applied Research Programme

5.16 Many of the investments through the NRS Infrastructure funding are designed to support new areas of research. One such area is stratified medicine, where using NHS data, tissue and imaging analysis has the capacity to radically transform the way treatments are provided to patients. If the ambition of providing a patient with the right treatment the first time is to be realised, then there is a need to evidence the economic benefit to the NHS of such an approach in addition to the obvious benefit to the patient.

5.17 CSO will therefore fund a £1.2m NHS Stratified Medicine Applied Research Programme designed to evidence the value of adopting a stratified approach. Focused on evidencing the value of existing yet unadopted stratified approaches, rather than seeking to develop new ones, we anticipate that it will provide the health economic evidence base for the subsequent adoption of the technology or process

ANNEX

SUMMARY OF PROPOSALS

Chapter 1 – Efficient R&D Support for Research

1.6 CSO will therefore define the job description of a nodal R&D Director and become formally involved in the recruitment of new appointments to these key posts.

1.9 We therefore propose the creation of an NRS General Manager (NRS-GM) with a small support team collectively working as the NRS General Manager Services (NRS-GMS). They will undertake the high level co-ordination of NRS activities and specific NRS operational functions previously undertaken directly by the NHS or CSO, including budgetary aspects.

1.15 CSO will therefore require that all Boards take adequate steps to promote the availability of resources to support research.

1.16 NRS Researcher Support will be fully allocated for researcher time and associated activities by April 2016. CSO will approve the Board methodology to ensure it meets our expectations.

1.23 We will also seek to combine the Scottish Research Ethics Service and NRS R&D Offices into a single integrated service for researchers while retaining the independence of the REC decision making function.

1.24 We propose these functions should be renamed as NRS Integrated Support Services.

Chapter 2 – Partnership with Scottish Patients and the Public

2.5 CSO will require the newly restructured NRS Research Networks to show evidence of involvement with the public in their work, and to embed patient and public involvement in their management processes.

Chapter 3 – Targeted Deployment of Resources and Infrastructure

3.2 CSO will therefore free up a proportion of its budget to be deployed in support of new initiatives.

3.6 CSO will explore with NETSCC the interface between our two funding streams to ensure the focus of CSO grants is both clear and complementary.

3.10 From 2016 CSO will revise the allocation of underpinning infrastructure funds to ensure a more equitable deployment of resource based on activity.

3.12 CSO therefore intends dividing the NRS Infrastructure allocation into specific areas of investment, with each area being managed as a distinct budget.

3.15 A review of the NRS Biorepository opportunities and investments will be conducted in the course of 2014-15

3.16 A review of the NRS Safe Haven opportunities and investments will therefore be conducted in the course of 2016-17.

3.20 CSO will therefore conduct a strategic review of Unit purpose and funding in the course of 2015-16.

Chapter 4 – Working in Collaboration

4.6 CSO intends building on existing partnership arrangements and will enter into discussions with sector representatives and Scottish Enterprise with a view to increasing the number of studies placed through NRS.

4.11 CSO therefore wishes to explore the creation of a new CSO International Advisory Board to provide expert advice on strategic research issues. Meeting once a year, with membership comprising key global leaders in their field, it would provide high level advice on the steps Scotland should be taking to deliver on its aspirations.

4.13 For this reason CSO is a partner in the recent creation of a Scottish Improvement Science Collaborating Centre (SISCC), co-funded in collaboration with NHS Education Scotland, the Scottish Funding Council and the Health Foundation.

Chapter 5 – Investing in the Future

5.3 CSO aims to maintain active NRS Fellows at this level for the foreseeable future.

5.7 The CSO is supportive of renewal of the SSCF Scheme to ensure that Scotland is able to recruit and retain the very best early-career clinical academics who will play a crucial role in improving the health, healthcare and wealth of our nation. We will work with key partners to deliver on this aim.

5.15 We therefore plan to publish the health and bio-informatics research strategy in 2014, and then move quickly to implement its key recommendations, so that the benefits of a more efficient system of governance and a strong, flexible federal network of safe havens begin to flow as soon as possible, and the returns on the investment in the e-HIRCS, Farr, ADRC and national data linkage service are maximised.

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ANNEX

SUMMARY OF 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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

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?

Chapter 4 – Working in Collaboration

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

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

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