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Date: 30 September 2014 – Scottish Chief Scientist Office

Consultation: 'Scottish Government Health Research Strategy'

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.
The principles to which the Scottish Council on Human Bioethics subscribe are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB's response can be shared internally with other Scottish Government policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.

The SCHB is very grateful to the Scottish Chief Scientist Office for this opportunity to respond to the consultation on the ***Scottish Government Health Research Strategy***. It welcomes its intention to promote public consultation, understanding and discussion on this topic.

Response from the Scottish Council on Human Bioethics

Note: Not all questions will be addressed.

General Comment: The SCHB is very concerned that the six guiding principles which are suggested to help maintain Scotland's position at the forefront of international health research do not include any provisions specifically protecting the rights, privacy, dignity, safety and welfare of potential human research participants. This is a serious omission and should be addressed as a matter of importance to rebalance the priorities mentioned. Responsible research can never be undertaken without putting research participants first and treating them with respect. It is not just a matter of encouraging research and making Scotland globally competitive by relaxing the safeguards towards these persons who give of their time and good will to the biomedical research community.

The "*de-cluttering of the pathway for the regulation and governance of health research by taking a proportionate and streamlined approach to research governance*" should never be undertaken at the expense of the research participants or of their rights.

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?

Scottish Council on Human Bioethics Response

No comment.

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?

Scottish Council on Human Bioethics Response

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?

Scottish Council on Human Bioethics Response

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?

Scottish Council on Human Bioethics Response

The CSO should make sure that all Boards take adequate steps to promote the availability of resources to support research.

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?

Scottish Council on Human Bioethics Response

The SCHB agrees that the proposed steps to both free up and promote the availability of NRS resources should address current concerns over lack of time and support in clinical departments.

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?

Scottish Council on Human Bioethics Response

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?

Scottish Council on Human Bioethics Response

The SCHB would be very concerned about the proposal to introduce a single assessment that will integrate elements of ethics and R&D approvals. It believes that such a system may give rise to a conflict of duties and interests since ethics and R&D consider a research application from different perspectives. Such a proposal may even undermine the ethical requirements relating to the protection of research participants since the R&D advantages of a research application may begin to be considered at the expense of any ethical concerns. It is, therefore, preferable that both perspectives are examined separately to emphasise the independence of the ethical considerations.

The SCHB agrees 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.

The SCHB is of the opinion that any new document that gives greater emphasis to supporting research rather than policing it should be welcomed. This, however, should not be at the expense of the rights, privacy, dignity, safety and welfare of potential human research participants.

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?

Scottish Council on Human Bioethics Response

The SCHB welcomes the Chief Scientist Office's requirement that the newly restructured NHS Research Scotland Networks show evidence of involvement with the public in their work and embed patient and public involvement in their management processes.

The SCHB notes that it is often very difficult for research participants to obtain the final results of the research in which they participated. It is also noticed that the engagement of these participants in the research is not often encouraged which is unfortunate since it may deter them from participating in future studies.

The SCHB agrees that a trial register would be of benefit to patients seeking trials and that it may be an effective way to partner patients with researchers.

The SCHB would also support the possibility for patients to give consent, on a website, for them to be assessed for entry into trials by comparing their medical records against the eligibility criteria for the relevant study.
This would avoid the unethical practice called Research to Consent (also called Consent for Consent) which can be described as research to access medical records in order to identify eligible research participants to be approached to see if they would like to participate in a research study. Generally, such access is undertaken by research professionals who are not members of the clinical care team.

The problem is that consent is needed to access the medical records of patients to invite them onto a research project. This is a complex and untested legal situation with regard to accessing, without consent, personal identifying information by research professionals who are not part of the clinical care team. The **Medical Research Council (MRC)**, UK **Department of Health** and the **British Medical Association** have all sought to examine this issue to some extent. However, the legality of such a procedure remains uncertain in many circumstances.

Research to Consent by research professionals who are not members of the clinical care team could be legally challenged under the ***Data Protection Act 1998***, especially in Scotland where such research cannot be brought before a **National Information Governance Board for Health and Social Care (NIGB),** or similar body, such as in England.

In order to address this problem of consent, it would be advisable for all organisations that maintain patient records to ensure that patients:

> (1) are aware that research professionals with the same duty of confidentiality as NHS employees may see patient notes;
> (2) have consented to these professionals accessing their data, and
> (3) may be invited to participate in research projects if they so wish.[1]

Whether this is happening in practice, however, remains an open question.

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

[1] Medical Research Council, Consent for Consent, 2007, http://www.dt-toolkit.ac.uk/_db/_documents/Consent_for_Consent_DRAFT.pdf (Accessed on 3 May 2012).

only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

Scottish Council on Human Bioethics Response

The SCHB strongly disagrees that electronic NHS patient records should be used to alert GPs to research studies for which their patients may be eligible. Only NHS staff responsible for the care of the patient should be able to access electronic NHS files without further consent. This is the general thrust of the ***Data Protection Act 1998*** and it is clearly stated on most application forms for persons to register with a general medical practice that: "*Health condition and treatment information which could identify you will not be used for research purposes by the NHS unless you have consented to this*." Any exceptions could end up being challenged in the courts and may undermine the confidence of the general public in the NHS.
Guidance should be obtained about this proposal, as a matter of urgency, from the Deputy Information Commissioner for Scotland who was established through the ***Data Protection Act 1998***.

Patients need to be informed of the identity of the Data Controller and the purposes to which their data will be put. Data subjects should always be aware that their personal information can be used for research purposes (they must know their data are being processed, by whom and for what purpose) and data processing for research should be 'compatible' with the purpose for which the data were originally obtained.

The Data Controller will need to comply with the informed consent requirements of the Act in respect of this processing.[2] It follows that a patient cannot be deemed to have consented to something of which he or she was ignorant.

The Act applies to all forms of records including paper, electronic and other images. It requires organisations to process fairly and lawfully any information which might enable a patient to be identified.

A process whereby NHS records of patients are accessed by NHS staff working in secure facilities, *but who are not responsible for the care of these patients and without these patient's consent*, should never be possible. As a result it should not be possible for these NHS professionals to forward potential patients names to their GPs or hospital consultants for consideration in research. Such behaviour would be unacceptable and liable to legal challenge in Scottish and European courts.

More specifically, the **Information Commissioner's Office** in Scotland has confirmed that:
"The Data Protection Act 1998 (the Act) is quite clear that, in the absence of reliance on any overriding exemption, explicit consent is required prior to processing sensitive personal data such as a GP medical file."

The Commissioner's Office also reiterated that strict consent requirements were necessary, indicating:
"As the data controller, it is for the GP to obtain consent for processing and this might be carried out via written invitation to participate in the research by consenting to access to their medical file. The invitation should provide an explanation of the nature of the research and assurances that no individual will be identified in the results."
Adding:
"In no way could reliance on advertising in the GP surgery be considered to be explicit consent which is deemed to be fully informed and freely given: failure to object should not be assumed as active consent."[3]

[2] UK Information Commissioner, Use and Disclosure of Health Data, May 2002, http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/health_data_-_use_and_disclosure001.pdf (Accessed on 19th of August 2010), page 13.

[3] Information sent to the SCHB by the Information Commissioner's Office on the 5th of August 2010. See also, Calum MacKellar, The use, in research, of patients' medical information when their consent cannot be obtained is not sufficiently regulated in Scotland, BMJ, 26 October 2010 http://www.bmj.com/rapid-response/2011/11/03/use-research-patients-medical-information-when-their-consent-cannot-be-obt

This was again re-emphasised by the Information Commissioner's Office in 2012 when it stated that "*fair processing requires that individuals are normally informed in advance about the nature and purposes of any processing, including research. As such, I would be very concerned if patient files are being accessed without the appropriate data protection obligations adhered to as required by the Act."*[4]

The SCHB is aware (and very concerned) that researchers from the **Scottish Primary Care Research Network (SPCRN)** are already going through thousands of non-anonymised patient records of GP surgeries without seeking appropriate consent from the patients (only the GPs are being asked to consent) for Research to Consent. This is a procedure whereby researchers out with the surgery access patient identifiable files in a surgery to invite them, on behalf of the GP, onto a research project. All network staff hold NHS contracts or honorary contracts which, according to the **SPCRN**, enables them to access GP patient electronic records.
SPCRN staff go into practices and search patient electronic records using READ codes[5] (such as social circumstances, ethnicity and religion, clinical signs, symptoms and observations) to identify potentially eligible study participants (sometime network staff even open patient records if they need to verify medication details/diagnosis). The Network member of staff then generates a list of potential participants which is screened by the GP to exclude patients who are not suitable to be contacted due to e.g. recent bereavement, terminal illness etc.

Once the GP has screened the list, the Network member of staff mail-merges the patient names and addresses with the approved invitation letter from the GP practice to the patient. This is sent out to patients on practice headed paper signed by the GP together with a patient information sheet and any other relevant information. The letter invites patients to contact the research team if they are interested in taking part in the study using a reply and SAE enclosed with the letter.
Thus, **SPCRN** staff provide GP practices with a research service to undertake searches of their electronic databases to identify potentially eligible patients and work on behalf of the healthcare team under practice staff supervision.[6]

However, the SCHB notes that Research to Consent by research professionals who are not members of the clinical care team could still be challenged under the ***Data Protection Act 1998***.
Indeed, it is likely that **SPCRN** staff would be considered as part of the research team and not as healthcare professionals from the GP practice. For example, **SPCRN** could even, theoretically, be replaced by a private company (with its staff retaining their honorary NHS contracts) undertaking such Research to Consent projects for profit.

Thus, the obstacles in seeking to undertake research on, for example, thousands of medical files from GP practices in Scotland remain formidable. This is because there is no suitable legal setting or organisation, such as in England, which could examine the needs of the researchers and approve, where appropriate, the use of medical files without the consent of the patients.

Moreover, it is difficult to see how NHS Research Ethics Committees in Scotland would accept, in an appropriate way, an application to use GP medical files without the specific consent of the individual or without any additional legislation.

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?

Scottish Council on Human Bioethics Response

[4] Information sent to the SCHB by the Information Commissioner's Office on the 9th of March 2012.

[5] Read codes are the standard clinical terminology system used in General Practice in the United Kingdom. It supports detailed clinical encoding of multiple patient phenomena including: occupation; social circumstances; ethnicity and religion; clinical signs, symptoms and observations; laboratory tests and results; diagnoses; diagnostic, therapeutic or surgical procedures performed; and a variety of administrative items.

[6] Information received by the SCHB from Dr Alison Hinds, Manager, Scottish Primary Care Research Network University of Dundee on the 30th of April 2012.

No comment.

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?

Scottish Council on Human Bioethics Response

No comment.

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?

No comment.

Scottish Council on Human Bioethics Response

Chapter 4 – Working in Collaboration

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

Scottish Council on Human Bioethics Response

Another key area of partnership the CSO should be seeking to build is with Medical Ethics Charities.

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

Scottish Council on Human Bioethics Response

No comment.

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

Scottish Council on Human Bioethics Response

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?

Scottish Council on Human Bioethics Response

No comment.

Question 17: Do the current CSO personal awqrd schemes targeted to meet our future needs? If not, should CSO conduct a wider review of its capacity building schemes?

Scottish Council on Human Bioethics Response

No comment.