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SCOTLAND, UK

Date: 16 January 2009 – <u>The Scottish Government – Healthcare Policy and Strategy Directorate</u>

Patients' Rights Bill

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

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious 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 by resolution 217A (III) on 10 December 1948.

The SCHB is very grateful to the Healthcare Policy and Strategy Directorate of the Scottish Government for this opportunity to respond to the consultation on the ***Patients' Rights Bill*****.** It welcomes the Directorate's intent to promote public consultation, understanding and discussion on this topic.

Not all questions will be responded to.

Scottish Council on Human Bioethics Response:

1. Application of International Legal Instruments on Patients' Rights

The SCHB is of the opinion that the Scottish Patients' Rights Bill should respect and apply all the provisions included in:

- The UNESCO **Universal Declaration on Bioethics and Human Rights**[1]
Adopted by acclamation on the 19th of October 2005.

- The Council of Europe **Convention on Human Rights and Biomedicine CETS No.: 164**[2]
Which came into force on the 1st of December 1999.

[1] UNESCO Universal Declaration on Bioethics and Human Rights , http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

[2] Council of Europe Convention on Human Rights and Biomedicine CETS No.: 164, http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=8&DF=12/15/2008&CL=ENG

2. Patients should not have to 'barter' their body parts in exchange for treatment

The SCHB believes that patients should never have to 'barter' their eggs in exchange for fertility treatment in Scotland.

For example this has arisen with the **Glasgow Centre for Reproductive Medicine (GCRM)**[3] which has introduced 'egg bartering' programmes whereby the cost of fertility treatment is considerably reduced in exchange for eggs which the GCRM can then use in the treatment of other women.

Indeed, the specified limit for expenses in the donation of gametes is fixed at £ 250 by the **Human Fertilisation and Embryology Authority**. However, where the price of fertility treatment is reduced by nearly £ 2000, as being proposed by the GCRM, in exchange for egg 'donation', it is not possible to consider this as an altruistic donation. This amount of money is considerable and one which creates serious ethical concerns since £ 2000 worth of treatment is effectively a payment for the eggs.

This practice raises profound ethical concerns relating to the possible exploitation of vulnerable individuals who cannot afford the full costs of fertility treatment and are not, or no longer, eligible to free treatment.

Thus, no individual fulfilling the terms of the ***Human Fertilisation and Embryology Acts of 1990 and 2008*** should ever be placed before a choice of having to barter or sell their gametes, or any other body parts, in exchange for a treatment.

3. Storage, Use and eventual Destruction of Personal Medical Information

The SCHB is of the opinion that the storage, use and eventual destruction of personal medical information in Scotland should be clarified for the benefit of the patients to whom they are relevant.

As indicated by Dr. Rod Muir, Consultant in Public Health with the National Services Scotland Information Services (Information and Statistics Division) in his discussion paper on the topic "*No legislation has been introduced in Scotland covering the processing of health data. This is in contrast to England where the Health and Social Care Act 2002 was passed to legalise certain forms of data processing. Sections 60 and 61 of the Act covered control of patient information and the setting up of the Patient Information Advisory Group (PIAG) … This causes real difficulty and uncertainty for NHS staff. It is therefore a matter of opinion whether NHSScotland has indeed been able to change its procedures or whether change in the law is required*."[4]

Thus, in contrast to England and Wales which has the ***Health and Social Care Act 2001***, no similar statutory legal instrument exists in Scotland which makes sure that the personal medical files of patients are appropriately stored and used.

In this regard, it is worth noting that the passage of the ***Health and Social Care Act 2001*** provided clear evidence of the strength of feeling, particularly within the House of Lords, about the perceived erosion of patient rights with respect to the use of their health files.

In Scotland the **Privacy Advisory Committee (PAC)**[5] was set up by the Scottish Chief Medical Officer in 1990 but its remit only extends to national data sets. PAC acts in a similar manner to the **Patient Information Advisory Group (PIAG)** in England and Wales except that researcher in Scotland are under no statutory obligation to submit their applications to PAC (it is just considered good practice).

The Scottish Government Health Department has been advised that the current situation in Scotland is unclear and that they should at least consider setting up an equivalent body to PIAG in Scotland. However, so far, no change has been forthcoming and there are still difficulties.

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[3] Glasgow Centre for Reproductive Medicine: http://www.gcrm.co.uk/EggShareandDonorProgrammes.html

[4] Dr. Rod Muir, Consultant in Public Health, eHEALTH, Secondary Uses of Information in NHSScotland, 2007-2008, http://www.isdscotland.org/isd/servlet/FileBuffer?namedFile=eHealth_secondary%20uses.pdf&pContentDispositionType=inline (accessed on the 16 December 2008)

[5] ISD Scotland, Privacy Advisory Committee, http://www.isdscotland.org/isd/3048.html

Moreover, in Scotland, patients health files can be retained (indefinitely) for research after the person's death without the patient's express consent.

Of course, there is much which can be gained medically from the information obtained in patients health records even after their death. These records could be for restricted access use by epidemiologists and health researchers only. However, access to this information should only be possible after appropriate consent is obtained.

4. Removal, Storage and Use of Human Tissue for Biomedical Research

4.1. Setting up appropriate statutory regulations to protect patients' rights with respect to tissue banks

In contrast to England and Wales, there is no equivalent to the **Human Tissue Authority** in Scotland to regulate the storage and use of human tissue for research purposes and there is no requirement for a licence to store tissue for research. In other words, continued storage of samples by scientists after the end of the research project may be lawful.

Though ethical approval for specific projects is given for the duration of the project only and continued storage for prospective research should be under appropriate controlled conditions as part of a managed tissue bank a number of difficulties remain:

- First of all, it is very difficult for a patient in Scotland to know if tissue samples originating from his or her body are being stored in one or several tissue banks. Indeed, these samples could have been taken from left over material during surgery after having given broad consent many years ago.
For example, the SCHB was told that the **Glasgow Greater Health Board** is currently obtaining general consent from living donors to use their tissue samples for an indeterminate amount of time, which may mean that the tissue could be used for ever.

- Secondly, in Scotland, and in contrast to England and Wales, there is no way of determining how many tissue banks exist and whether they are respecting good ethical practices.
This also makes it very difficult to then trace human material originating from a patient if he or she changes his or her mind about the use of the material.

4.2. Using cells from patients to clone human or animal human embryos should not take place without their explicit consent

The ***Human Fertilisation and Embryology Act 2008*** for England, Wales, Scotland and Northern Ireland provides an exception to the general requirement for an effective consent for the use of a person's cells to bring about the creation of an embryo or animal-human embryo.

This exception to the requirement for consent applies to all cells stored before the commencement of the consent provisions in the Act (probably sometime in 2009). In addition, the exception applies if:

(1) The licence holder for the research could not reasonably identify the donor;

(2) The donor had died, or was reasonably believed to be dead and consent from a family member or close friend has been obtained working on the basis of a hierarchy established by the ***Human Tissue Act 2004*** (person in a qualifying relationship); or

(3) The donor was not reasonably traceable and if there was reason to believe the donor was dead a person in a qualifying relationship was not reasonably traceable.

In each case, there must not be any information available to the person responsible under the licence for the research to suggest that the donor would have objected to the research. In addition, the **Human Fertilisation and Embryology Authority** has to be satisfied there were reasonable grounds for believing that scientific

research would be adversely affected to a significant extent if the only cells that could be used were those for which consent had been obtained, (or which fall within the exception to consent for adults lacking capacity).

However, because of the ethical sensitivity relating to the cloning procedure to create cloned human embryos and animal-human embryos for destructive research, the SCHB is of the opinion that no cells from persons should be used from a tissue banks, whatever the circumstances, to create embryos for destructive research without the individuals explicit consent.

Moreover, in Scotland, it would be very difficult for a person to know whether or not he or she has any material stored in a tissue bank which could be used to create cloned embryos since the collection of this tissue has taken place over many decades and it is very difficult to know how many such banks exist in Scotland or who has control over them (see paragraph 4.1. above). The number of persons having material in a tissue bank could, indeed, amount to 100,000s of individuals in Scotland.

RESPONDENT INFORMATION FORM

Patients' Rights Bill

Please complete the details below and return it with your response. This will help ensure we handle your response appropriately. Thank you for your help.

Name: ***Scottish Council on Human Bioethics***

Postal Address: ***15 Morningside Road, Edinburgh EH10 4DP***

1. Are you responding: (please tick one box)
~~(a) as an individual~~
go to Q2a/b and then Q4
(b) on behalf of a group/organisation **X**
go to Q3 and then Q4

INDIVIDUALS

2a. Do you agree to your response being made available to the public (in Scottish Executive library and/or on the Scottish Executive website)?
Yes (go to 2b below)
No, not at all

We will treat your response as confidential

2b. Where *confidentiality is not requested*, we will make your response available to the public on the following basis (**please tick one** of the following boxes)

Yes, make my response, name and address all available
Yes, make my response available, but not my name or address
Yes, make my response and name available, but not my address

ON BEHALF OF GROUPS OR ORGANISATIONS:

3 The name and address of your organisation ***will be*** made available to the public (in the Scottish Executive library and/or on the Scottish Executive website). Are you also content for your **response** to be made available?
Yes **X**
~~No~~

We will treat your response as confidential

SHARING RESPONSES/FUTURE ENGAGEMENT

4 We will share your response internally with other Scottish Executive policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for the Scottish Executive to contact you again in the future in relation to this consultation response?
Yes **X**
~~No~~