



## Health Rights Information Scotland

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### **Results of scoping exercise – patient information about consent (authorisation) to use of surplus tissue from the living for medical research and education**

#### **Aim**

HRIS carried out a scoping exercise from January to March 2009 to gauge the need for nationally consistent, quality patient information about consent to use of surplus tissue for medical research and education.

#### **Background**

HRIS is funded by the Scottish Government Health Directorates to produce and maintain patient information on health rights. In November 2008, HRIS was approached by members of staff from the Clinical Governance Support Unit, the Pathology department and Biobank Services of NHS Greater Glasgow and Clyde (NHSGGC) in connection with a working group which was discussing patient information about consent to use of surplus tissue for research and education.

NHSGGC currently use patient information that has gained ethics committee approval. Although the information works well in practice, there are concerns about how to use the information appropriately and effectively to inform patients of their rights and maximise on the potential for use of surplus tissue for research and education.

It was also felt that a nationally recognised resource could go some way to giving patients and professionals the confidence that practice adheres to NHS QIS clinical governance standards<sup>1</sup> and the Human Tissue Authority codes of practice<sup>2</sup>.

#### **Discussion**

Evidence shows that patients tend to support the use of surplus tissue for research and educational purposes. However, patients feel it is important that

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<sup>1</sup> [http://www.nhshealthquality.org/nhsqis/files/CGRM\\_CSF\\_Oct05.pdf](http://www.nhshealthquality.org/nhsqis/files/CGRM_CSF_Oct05.pdf)

<sup>2</sup> [http://www.hta.gov.uk/db/documents/2006-07-04\\_Approved\\_by\\_Parliament\\_-\\_Code\\_of\\_Practice\\_1\\_-\\_Consent.pdf](http://www.hta.gov.uk/db/documents/2006-07-04_Approved_by_Parliament_-_Code_of_Practice_1_-_Consent.pdf)

their approval is sought before their own tissue is used in this way. In addition, the majority of patients are happy to discuss this once, and for consent to be implied for most future use of surplus tissue<sup>3</sup>.

There are many types of tissue and a wide range of reasons why tissue samples can be taken. However, there is a consistent need to gain informed consent for use of surplus tissue. It is therefore hoped that patient information that defines 'tissue' in general terms could be useful in a broad range of settings and would promote consistency of practice. For this reason, we have adopted a definition of 'tissue' that is in line with the Human Tissue Act and the Human Tissue Authority:

*"...material that has come from a human body and consists of, or includes, human cells."*

Discussions with patients about use of surplus tissue need to be well timed and approached sensitively. A patient's level of engagement with this topic will depend on a variety of factors including the severity of their condition and the invasiveness of the prospective procedure. It is likely that patients will be most receptive to this information early in the 'patient journey', for example when clerking-in, prior to non-emergency procedures, elective surgery, or when attending out-patient clinics.

## **Method**

Phase 1 – Desk based research

Phase 2 – Inception meetings with NHSGGC

Phase 3 – Stakeholder consultation

Phase 4 – Follow up meetings

Following phase 1, the results of which are summarised above, HRIS drafted a short questionnaire and discussion paper in partnership with the working group (phase 2). This group was able to recommend individuals, departments and organisations to include in this stage of the exercise:

- NHS Pathology Departments
- NHS Clinical Governance teams
- NHS National Services Division
- Biobank services
- NHS Research and Development Directors

In addition, HRIS distributed the scoping paper to their steering group (membership includes representatives of the GMC, NHS Health Scotland, NHS

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<sup>3</sup> Wendler D. One-time general consent for research on biological samples. *BMJ* 2006;332: 544-7. (4 March.)

QIS and the Scottish Government Health Directorates) and key board contacts (mainly representatives from NHS boards within the patient information and communications departments).

A full distribution list is included as Appendix 1 of this report. Around 60 stakeholders were identified received the paper. Some of this group were able to circulate the paper more widely, for example within the Scottish Government or through the Scottish Pathology Network. Participants were supplied with a discussion paper similar to the introduction of this document and were asked the following questions:

1. Is patient information on this topic currently being used in your health board area? If so, would you be happy to share this with other health professionals in Scotland?
2. Do you feel that there is a need for one national, quality assured resource that can be used across Scotland?
3. Are you aware of any resources of this nature that exist or are planned for development?
4. Do you have any additional comments on the discussion section of this paper that could impact on the development of nationally recognised patient information?

### **Phase 3**

In total, around one third of participants (n=19) responded to the exercise although several respondents were able to include the opinions of other colleagues and departments (7 additional individuals and 5 departmental responses). A full list of the respondents is included as Appendix 2 of this report. On the whole, it was felt that the respondents represented a satisfactory range of stakeholders, covering most Scottish Health board areas and several non-NHS organisations. The following summary considers feedback from the 19 individuals who personally contributed to the exercise.

**Question 1** Is patient information on this topic currently being used in your health board area? If so, would you be happy to share this with other health professionals in Scotland?

Of the 16 respondents who represented a health board area, none stated that generic information on this topic was being used. Only 4 were able to give examples of patient information and all of these were specific to a piece of research or screening programme, e.g. cervical screening. One respondent provided a consent form that is used to gain the consent of patients who are about to receive an operation where 'useful' surplus tissue is likely to be generated. This form contains basic information about the use of surplus tissue but most information is given orally by a trained research nurse.

**Question 2** Do you feel that there is a need for one national, quality assured resource that can be used across Scotland?

Of the 14 respondents who answered this question, 13 stated that nationally consistent patient information was needed. Comments ranged from 'very beneficial for patients and professionals' to 'no demonstrable public demand but would be good practice to have it'. One of these respondents stated that it was the timing, not the need for consistent information, that was a concern as Scottish policy on this topic is yet to be finalised. Lastly, one respondent stated that patient information was not needed and felt that the 'current set up' was adequate as Ethics Committees are equipped to act in the best interests of patients. In addition, they were concerned that giving consent once would effectively be 'signing a blank cheque' for all future research.

**Question 3** Are you aware of any resources of this nature that exist or are planned for development?

Two examples of national patient information were given:

- A Scottish Government leaflet
- Information within the cervical screening leaflet

The Scottish Government leaflet referred to did not deal with this topic. Its focus was the retention of tissue following post-mortem examination. The information contained within the national cervical screening information, produced by NHS Health Scotland, is extremely brief. As a result, it is insufficient information to allow a patient to give informed consent. No respondents knew of similar information that is planned for development. However, information around living donors is currently being considered by the Scottish Government and it was recommended that this is taken into consideration.

**Question 4** Do you have any additional comments on the discussion section of this paper that could impact on the development of nationally recognised patient information?

Sixteen respondents gave extra information in answer this question. Two used this opportunity to restate their support. Participants were not limited to one response each in this section, so of the remaining 14:

- 1 respondent raised several questions that need to be addressed by the working group
  - Definition of the term 'education'
  - Other uses of surplus tissue not covered in the scoping paper: clinical audit, performance assessment, public health monitoring and quality assurance
- 2 mentioned inclusivity issues such as religious beliefs and Equality Impact Assessment.
- 2 mentioned accessibility issues such as translated information and alternative formats.

- 2 stated that there was no need for this information (as opposed to 1 person in question 2). However, one of the respondents qualified their answer by suggesting that information about use of surplus tissue should be included in the HRIS booklet, 'Consent – your rights'.
- 3 recommended appropriate language for the patient information (as the discussion paper was not seen to be user-friendly)
- 3 recommended sources of further information including Craig Gilbert who is taking a lead on policy development at the Scottish Government.
- 3 mentioned the policy context. This included 2 suggestions to wait until national policy has been finalised.
- 5 mentioned concerns about the use of the information which largely reflected the issues raised by the discussion paper, e.g. timing, record keeping and sensitivity. One respondent was concerned that an introduction of the proposed patient information would result in a change of current practice which could have cost and administrative implications.

### **Summary of phase 3**

The scoping exercise identified support and a need for nationally relevant patient information about consent (authorisation) to use of surplus tissue from the living for medical research and education. However, there may be national developments that can inform an appropriate timeframe for information production.

### **Phase 4**

HRIS met with Craig Gilbert, Chief Scientists Office, Scottish Government, on 26 March to establish Scottish policy context and plans to 'improve human tissue collection rates'.

Craig is currently developing Scottish policy, developing standards for Biobanks and commissioning a regulator so that NHS Scotland has a strategy for the collection of human tissue. It is likely that the Human Tissue Authority (HTA), the regulator in England and Wales, will inform policy development and deliver training to Scottish practitioners.

Craig supports 'one time' consent but needs to ensure that Scottish policy is informed by all stakeholders and that the practical challenges of gaining informed consent and record keeping are in place before implementation.

Craig recommends that while the Scottish Government develop a policy and strategy, HRIS and its partners attempt to source good practice in patient information on this topic. Craig felt that no new information should be developed for national use for 12-18 months.

HRIS met with working group at NHGGC on 1 April to discuss the initial findings of the scoping report and to discuss the meeting with Craig Gilbert. NHSGGC had been in discussions with onCore, an English charity funded by the Medical Research Council, the Department of Health and Cancer Research UK. onCore have produced a suit of patient information that gives information about the use of surplus tissue from the living for medical research and education. The information was seen as fit for purpose by the patient information department at the board. This information will inform a revision of the current leaflet used by NHSGGC in June 2009. The team also plan to adapt a poster produced by onCore to promote the patient information. They intend to include revised information in 'patient packs' which are sent to all patients prior to admission.

The Clinical Governance support team have recently audited the consent process in 3 hospitals in NHSGGC. They intend to use these figures as baseline statistics so that the effect of introducing revised patient information and a poster can be measured. The PFPI team have also carried out research into patient satisfaction with the information they have received before, during and after hospital admission. Again, these findings will be used to measure the effectiveness of new information provision.

HRIS agreed to support these developments with the intention of identifying good practice or recommendations that can be fed into national developments in the future. As such, the project will keep a 'watching brief' on consent issues in this area. The possibility of developing nationally relevant patient information will be revisited when scoping HRIS's workplan for 2010/11.

**Matt Johnston**

Project Development Officer  
Health Rights Information Scotland

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## Appendix 1 – distribution list (n=59)

### NHS

- Clinical Governance and communications leads in 14 territorial NHS boards **(28)**
- Pathology departments overseeing Biobank services in 4 NHS boards **(5)**
  - Tayside
  - Grampian
  - Lothian
- Research and development leads in 5 NHS boards **(5)**
  - Tayside
  - Greater Glasgow and Clyde
  - Grampian
  - Highland
  - Lothian
- NHS National Services **(1)**
- NHS Health Scotland **(1)**

### HRIS steering group (18)

Name	Department	Organisation
Sandra Falconer	Directorate of Health and Wellbeing	Scottish Government
Jackie Burman	Health Support Unit	Citizens Advice Scotland
Claudia Pagliari	Division of Clinical and Community Health Sciences	University of Edinburgh
Lynn Thomson	Corporate Communications	NHS Grampian
Rob MacPhail	Scottish Health Council	Delta House
Fiona Montgomery	Health Directorates	Scottish Government
Donna Athanasopoulos	Public Health Resource Unit	NHS Greater Glasgow & Clyde
Sheena Pirrie	Communication	NHS Fife
Susan McKinlay	Clinical Development	NHS 24
Michael Pisanek	Department of Nursing	NHS Lothian
Christopher Homfray	Equalities & Planning Directorate	NHS Health Scotland
Marjorie Gillies	Nursing and Patient Services	NHS Greater Glasgow and Clyde
Martyn Evans		Scottish Consumer Council
Kim Kingan	eHealth Directorate	Scottish Government
Anne Mathie		Scottish Association for

Name	Department	Organisation
		Mental Health
Jean Alcock		Research & Consultancy Services
Lesley Munro		Macmillan Cancer Support
Jackie Bell		General Medical Council Scotland

**Scottish Government (1)**