SUPPLEMENTARY SUBMISSION FROM DEPUTY MINISTER FOR HEALTH AND COMMUNITY CARE

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HUMAN TISSUE (SCOTLAND) BILL: HOSPITAL POST-MORTEM AUTHORIZATION FORMS

At the stage 1 evidence session on 25 October, the Committee raised with me its concerns about the formalities of authorisation prescribed in the Bill. I explained that these requirements would translate into authorisation forms, on which the provisions of the Bill would be set out as a series of statements and tick boxes, ensuring that the formalities would be met in each case. To illustrate this, I undertook to let the Committee have copies of the draft adult and child hospital post-mortem authorisation forms as they stand at present.

A copy of these forms is attached to this letter. I should explain that they are based on the Bill as introduced, and that they represent work in progress.

The forms are based on those developed by the Review Group on Retention of Organs at Post-Mortem and published in its Phase 3 report. The adult and child forms were then piloted through focus groups which included parent or family support groups, pathologists and staff from Intensive Care Units. This was to ensure that they would command the support of both relatives and health professionals and take full account of the practical needs of families and hospital staff. Some further changes are now being made to take account of the terms of the Bill.

The development of standard authorisation forms for use across Scotland responds to the wish for consistency of approach expressed by both families and health professionals as a result of past experience, where local forms of very different type were in use. For the same reason, the clinical standards covering the hospital post-mortem examination process developed by NHS Quality Improvement Scotland were written in anticipation of the introduction of standard post-mortem forms. We consulted widely on whether the need for standardisation meant that the forms should be prescribed in Regulations, to ensure that these are the only forms which can be used in future, and there was general agreement that they should be.

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Section 47 of the Bill provides a mechanism for this. The intention is that completion of the forms, once their content has been finalised, will be the only means by which the specified types of authorisation can be provided.

Because of the different requirements relating to the capacity to give authorisation, two types of draft forms have been developed, one for a hospital post-mortem examination on an adult, the other for an examination on a baby or child. Given the different requirements in respect of children under and over 12, we are considering splitting the baby/child form to produce a separate version for each of these cases.

It is essential that the content of the form should be on a single sheet, partly so as to appear less daunting to the family, but also so that the forms can be produced in triplicate. This means that the family can be given the top copy, as a permanent record of exactly what they have authorised. A copy will be retained with the deceased’s medical records, emphasising the importance of the post-mortem examination as part of the continuum of care provided by the NHS. A copy will also go to the pathologist who is to perform the examination, so that he or she knows exactly what has been authorised.

The intention is that families will not just be presented with the forms and expected to complete them, but will be invited to sit down with a member of hospital staff who has been trained to help them through the forms. The forms can also be read in conjunction with 2 information leaflets, but those discussing with the family the possibility of a post-mortem examination will need to be sensitive to the amount of information they require. Some families will wish little or no information about what is involved; others will wish considerable detail. There is a basic leaflet which is short and which provides important general information and this will always be offered to the family. The second leaflet is more detailed and explains the post-mortem process. This will be offered to the family if they indicate they wish more detail.

The other significant feature of the forms is the different way in which they treat tissue samples and organs. This reflects in particular the emotional significance attached to organs, as revealed by the reaction to the revelations about organ retention. It also reflects the fact that the creation and retention of tissue samples is, for the pathologist, the most important outcome of a well-conducted post-mortem examination.

In drawing up the draft forms it has been a challenge to achieve a clear layout which also covers explicitly every option available to the family. In looking at the detail of the forms, the Committee will wish to be aware that some further work is needed on the baby/child form in particular. Each time there is a reference in section 1 to the situation of the child over 12, the form of words ‘I am the person with parental rights and responsibilities/nominee for’, will need to be changed to ‘I have parental rights and responsibilities for/I am the nominee of...’. In section 3A(ii), the statement ‘Whole organs will only be retained with your authorisation’ needs to be amended to read ‘Whole organs will only be retained on instructions left by the deceased or with your authorisation’, to take account of the fact that, in terms of the Bill, a child between 12 and 16 is able to give authorisation for these matters him or herself. The declaration in 3A(ii) also needs to be adjusted to take account of the fact that the person making the declaration could be the nominee of a child aged 12 or over.
I am content for these forms to be shared publicly by the Committee, on the understanding that the forms are clearly labelled as drafts based on the Bill as introduced. We intend to undertake a further round of consultation of key interests, which means that there are likely to be further developments before the forms are finalised. Their content will of course need to reflect any relevant changes to the Bill in its progress through the Parliament.

I do hope the Committee finds sight of these draft hospital post mortem examination forms helpful at this stage.

Yours sincerely

LEWIS MACDONALD
Authorisation for the Hospital Post-Mortem Examination of an Adult

Section 1a. Authorisation of a full post-mortem examination

☐ I am/we are the nominated representative(s) of ____________________________

OR

☐ I am the nearest relative of ____________________________

☐ We have told hospital staff that we have no reason to believe that the person named above would be unwilling for a post-mortem examination to be carried out and (b) for parts of the body to be removed or retained and used for the purposes of audit, medical education training or research.

☐ I confirm that I am 16 years of age or over

☐ I/we authorise the carrying out of a full post-mortem examination on the person named above, which involves keeping small tissue samples as blocks and slides, samples of blood and bodily fluids, and may involve taking photographs and X-rays. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2]

OR

Section 1b. Authorisation of a limited post-mortem examination

☐ I/we authorise the carrying out of a limited post-mortem examination on the person named above, which involves keeping small tissue samples as blocks and slides and may involve taking photographs and X-rays. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2]

Please say what you authorise to be examined:

☐ head ☐ chest ☐ abdomen

☐ other (please state what is to be examined)

Section 2. Authorisation of Removal and Retention, and Detailed Examination of Whole Organs

There may be benefits in retaining whole organs for further examination. If so, you will be asked if you are willing to complete this section. WHOLE ORGANS WILL ONLY BE RETAINED ON INSTRUCTIONS LEFT BY THE DECEASED OR WITH YOUR AUTHORISATION.

☐ I authorise the retention of the deceased's organs

☐ brain ☐ heart

☐ other – please specify ____________________________

Section 3. After the retention for detailed examination (please choose one option)

☐ Return to the body: I/we authorise the hospital to return the organs to the body. I/we understand that this may delay the funeral.

OR

☐ Hospital disposal: I/we authorise the hospital to arrange for disposal of the organs.

OR

☐ Collection by funeral director: I/we authorise my funeral director to collect and arrange for disposal of the organs.

OR

☐ Gifting of whole organs for education, training, audit and medical research. I/we wish to donate a retained organ for the following purpose (please tick as many as you wish)

☐ I authorise the retention for audit

☐ I authorise the retention for medical education

☐ I authorise the retention for training

☐ I authorise the retention for research
Section 4. Other requests or conditions

Would you like to make any other requests or conditions about the post-mortem examination or any retention or future use of tissue or organs? If no, please tick box.  

If yes, hospital staff should document here any special authorisations or conditions taken or required for this case:

I confirm that

☐ I have asked if the deceased had authorised the matters covered by this form.

☐ I have attached a copy of any instructions left by the deceased or a note of any objections he or she is believed to have had.

☐ I have offered information to the deceased's nominated representative(s)/nearest relative about the procedures involved and the reasons for the investigations requested. I have offered to explain any procedures and options available in the level of detail that the nominated representative(s)/nearest relative wish and have given any explanations asked for.

☐ I have explained that unless the procedures authorised have already taken place the authorisation given by the nominated representative(s)/nearest relative can be withdrawn at any time, and that an amended version of this form would be passed to the person who would otherwise have undertaken the post-mortem examination.

Written information given:

☐ Basic Leaflet

☐ Advanced Leaflet

☐ None

Signature of staff witnessing authorisation

Date

Name (BLOCK CAPITALS)

Job title

Position

Telephone contact no.

Bleep

I am/We are the deceased’s nominated representative(s)/nearest relative and I am/We are not aware of anyone with a closer relationship who should be asked about these matters. The post-mortem examination has been explained to me and I/We feel that I/We have been provided with enough information to give the authorisation set out in this form.

Signature of authorising person:

Date

Name of authorising person (BLOCK CAPITALS)
Authorisation for the Hospital Post-Mortem Examination of a Baby or Child

Section 1A(i). Authorisation of a full post-mortem examination on a baby or child who died under 12 years of age

☐ I have parental rights and responsibilities for
and I authorise the carrying out of a full post-mortem examination on my baby or child, which involves keeping small tissue samples as blocks and slides, samples of blood and bodily fluids and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2.]

OR
Section 1A(ii). Authorisation of a full post-mortem examination on a child who died over 12 years of age

☐ I am the person with parental rights and responsibilities/nominee for
and I authorise the carrying out of a full post-mortem examination on my child, which involves keeping small tissue samples as blocks and slides, samples of blood and bodily fluids and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2.]

OR
Section 1B(i). Authorisation of a limited post-mortem examination on a baby or child who died under 12 years of age

☐ I have parental rights and responsibilities for
and I authorise the carrying-out of a limited post-mortem examination on my baby or child, which involves keeping small tissue samples as blocks and slides, samples of blood and bodily fluids and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2.]

Please say what you authorise to be examined:
☐ head ☐ chest ☐ abdomen
☐ other (please state what is to be examined)

OR
Section 1B(ii). Authorisation of a limited post-mortem examination on a child who died over 12 years of age

☐ I am the person with parental rights and responsibilities/nominee for
and I authorise the carrying-out of a limited post-mortem examination on my child, which involves keeping small tissue samples as blocks and slides, samples of blood and bodily fluids and may involve taking photographs, X-rays and scans. These will be kept as part of the medical record and may be used for medical education, training, audit and research. [See also section 2.]

Section 2. Authorisation of uses of the post-mortem medical record

After the post-mortem examination, the information gained as well as the images, X-rays and small tissue samples will be kept as part of the medical record and may be used for other purposes

☐ I authorise the use for audit
☐ I authorise the use for medical education
☐ I authorise the use for training
☐ I authorise the use for research

Section 3A(i). Authorisation of Removal and Retention, and Detailed Examination of Whole Organs on a Baby or Child who died under 12 years of Age

There may be benefits in retaining whole organs for further examination. If so, you will be asked if you are willing to complete this section. WHOLE ORGANS WILL ONLY BE RETAINED WITH YOUR AUTHORIZATION.
Section 4. Other requests or conditions

Would you like to make any other requests or conditions about the post-mortem examination or any retention or future use of tissue or organs? If no, please tick box.

If yes, hospital staff should document here any special authorisations or conditions taken or required for this case:

I confirm that

☐ I have offered information to the nominated person with parental rights and responsibilities about the procedures involved and the reasons for the investigations requested, I have offered to explain any procedures and options available in the level of detail that the nominated person with parental rights and responsibilities wish and have given any explanations they asked for.

☐ If only one person with parental rights and responsibilities is present, I have asked whether there is likely to be objection to post-mortem examination from the other person with parental rights and responsibilities.

☐ I have explained that unless the procedures authorised have already taken place the authorisation can be withdrawn at any time, and that an amended version of this form would be passed to the person who would otherwise have undertaken the post-mortem examination.

Written Information given:

☐ Basic leaflet

☐ Advanced leaflet

☐ None

Signature of person with parental rights and responsibilities or nominated representative giving authorisation

The post-mortem examination has been explained to me and I feel I have been provided with enough information to give the authorisation set out in this form.

Name of person with parental rights and responsibilities/nominee (BLOCK CAPITALS)

_________________________

Signature

☐ I confirm I am over 18 years of age

Date

Name of person with parental rights and responsibilities/nominee (BLOCK CAPITALS)

_________________________

Signature

☐ I confirm I am over 18 years of age

Date

Signature of member of staff witnessing authorisation:

Date

Name

Job title

Position

Telephone contact no.

Beep
Dear Roseanna,

HUMAN TISSUE (SCOTLAND) BILL: ADULTS WITH INCAPACITY

On 25 October, when I appeared before the Health Committee to give oral evidence on the Human Tissue (Scotland) Bill, I gave a commitment to provide the Committee with a summary of the responses received by the Executive on its consultation on adults with incapacity in respect of the issues covered by the Bill.

This summary is enclosed, along with a list of the names of the organisations and persons who responded to this short, focused consultation.

The Executive intends to publish the full text of all the consultation responses on its website, and this should happen shortly. I shall arrange for the hyperlink to be sent to the Clerk as soon as the responses are on the website.

We shall of course take these responses, and those which have been sent to the Committee, into account in considering the adjustments which might be made to the Bill or the Adults with Incapacity (Scotland) Act 2000 to take account of the position regarding donation by living adults with incapacity, and what should happen after the death of the adult with incapacity in respect of the 3 main elements covered by the Bill. As I explained to the Committee, our overall aim is consistency with the principles embodied in the 2000 Act.

I do hope that you and the Committee find the consultation response summary useful and please do contact me if you wish additional information.

Yours sincerely,

LEWIS MACDONALD
HUMAN TISSUE (SCOTLAND) BILL – ADULTS WITH INCAPACITY
CONSULTATION

LIST OF CONSULTEES

Action on Churches Together
Age Concern Scotland
Alzheimer’s Scotland
British Medical Association Scotland
Capability Scotland
Carers Scotland
Chest, Heart & Stroke Scotland
Enable Scotland
Headway Scotland
Law Society of Scotland
Medical & Dental Defence Union Scotland
Mental Welfare Scotland
Neurological Alliance Scotland
Pamis
Parkinson’s Disease Society of the United Kingdom
Professor Sheila McLean, University of Glasgow
Royal College of Nursing Scotland
Royal College of Pathologists Scottish Regional Council
Royal College of Psychiatrists
Scottish Coalition on Learning Disability
Scottish Council on Human Bioethics
Scottish Partnership for Palliative Care
Scottish Law Commission
Scottish Transplant Group
Scottish Transplant Co-ordinators’ Network
Sheriffs’ Association

CONSULTATION RESPONDENTS

Alzheimer's Scotland
British Medical Association Scotland
Enable Scotland
Mr John Forsythe, Chair, Scottish Transplant Group
HM Inspector of Anatomy
Dr D McKeown – Consultant Anaesthetist, RIE
Mental Welfare Commission for Scotland
Professor Sheila McLean, University of Glasgow
Royal College of Anaesthetists Board in Scotland
Royal College of Nursing Scotland
Royal College of Physicians of Edinburgh
Scottish Council on Human Bioethics
Scottish Council of Jewish Communities
Sense Scotland
HUMAN TISSUE (SCOTLAND) BILL: CONSULTATION ON ISSUES RELATING TO ADULTS WITH INCAPACITY – SUMMARY OF RESPONSES

Question 1

Is there any reason why the authorisation arrangements proposed for adults in general by the Bill should not apply to adults with incapacity, provided they had the capacity to make that decision at the time they started to carry an organ donor card or put their name on the NHS Organ Donor Register?

14 respondents commented and all agreed that the authorisation arrangements proposed for adults in general in the Bill should also apply to adults who give authorisation when competent and subsequently lose capacity.

Question 2

Does the fact that the adult may subsequently lose capacity, and therefore the capacity to withdraw an existing authorisation, raise any separate issues?

There was general agreement by all 14 respondents that the inability of the adult with incapacity to withdraw authorisation did not raise any separate issues.

Question 3

Should the Bill be used to put beyond doubt in future the issue of a welfare attorney or guardian’s powers to give authorisation for the donation of body parts after the adult’s death, where the adult with incapacity was known to have expressed a view as regards donation before losing capacity? If this should be possible, what proof, if any, should the welfare attorney or guardian be expected to provide of the donation wishes of the adult with incapacity?

The wording of this question caused confusion. It was intended to elicit views on whether the proxy, knowing that the adult before losing capacity had been in favour of donation but had done nothing to indicate that formally, should be able, while the adult was still alive, to complete the process and, for example, put the adult’s name on the Organ Donor Register. Many of the respondents interpreted the question as being about whether the proxy, rather than the nearest relative, should be able to give authorisation after the adult’s death. 3 responses specifically included a statement that a proxy should not be able to put an adult’s name on the Organ Donor Register. 2 of those who responded took the view that a proxy’s role should be extended after the death of the adult for the purposes of the Bill. 3 took the view that there should be no such extension of a proxy’s role, which under the 2000 Act ceases on the death of the adult.

There were differences of opinion over the level of proof which should be provided. Some respondents felt that no additional proof was required, since the proxy would have been appointed on the strength of their close link with the adult with incapacity. Others felt the level of proof should be the same as that required for adults with capacity.
Question 4: Does the fact that an adult who has lacked capacity for many years prior to death unduly prejudice the incapable adult, contrary to the spirit of the 2000 Act, when compared to any capable adult, as regards the opportunity to change their mind about donation? Should the length of time an adult has lacked capacity render invalid any wishes in favour of donation which they had expressed while they still had capacity? If so, what would the appropriate length of time be?

13 responses were received to this Question. 11 did not consider that adults who had lacked capacity for many years would be unduly prejudiced by being unable to change their mind about donation. The same respondents also felt that the duration of incapacity was irrelevant. 1 considered that it did unduly prejudice an incapable adult and 1 considered that donation should not go ahead where a close relative objected.

Question 5: Is there any problem with the role of the nearest relative of an adult with incapacity in respect of the fact that the nearest relative could in theory authorise the donation of body parts from a person who was an adult when they died but had never had capacity in life to express any wishes on the subject themselves?

13 responses were received to this Question. All but 1 commented that there was no reason why the nearest relative should not be able to authorise donation in such a situation.

Question 6: Are consultees generally in favour of the prohibition of the removal of organs, parts of organs and non-regenerative tissue from a living adult with incapacity for the purposes of transplantation to another person? If not, should consideration be given to making the position in Scotland consistent with that proposed for the rest of the UK, i.e. a mechanism should be put in place to allow the Human Tissue Authority to consider the donation of organs, parts of organs or non-regenerative tissue by a living adult with incapacity?

13 responses were received to this Question. 4 respondents commented that donation should go ahead if the adult with incapacity had made an advanced directive or where there were clear benefits to the donor, and 2 favoured prohibition of donation of such material. 7 respondents favoured the route of consistency with the rest of the UK by using the Human Tissue Authority.

Question 7: Do you agree that it should be possible for adults with incapacity to donate regenerative tissue, subject to independent scrutiny of each case?

13 responses were received to this Question. All were in favour of allowing adults with incapacity to donate regenerative tissue, provided adequate safeguards were in place.

Question 8: Should adults with incapacity be able to donate regenerative tissue only to close family members, or should non-directed donation also be open to them?

13 responses were received to this Question. 8 agreed that non-directed donation of regenerative tissue should be open to adults with incapacity, 4 agreed that donation of regenerative tissue from adults with incapacity should be confined to close family members and 1 did not agree that such donation was justified. Adequate safeguards would have to be in place to prevent exploitation or abuse.
Question 9: If the donation of regenerative tissue from an adult with incapacity is to be possible, should the case by case scrutiny be provided:
(a) by conferring a function of the Scottish Ministers so that they can refer cases to the Human Tissue Authority, as will happen in the rest of the UK; or
(b) by adapting the protections in relation to research which are already incorporated in the Adults with Incapacity (Scotland) Act 2000, including an appeal provision?
In the latter case, should there be provision that such tissue could not be removed unless there was no donor with capacity who was a suitable match?

13 responses were received to this Question. 9 were in favour of scrutiny by the Human Tissue Authority, as will happen in the rest of the UK, 2 favoured the mechanism of adapting the Adults with Incapacity (Scotland) Act 2000 and 2 did not respond directly to the first part of the Question. 4 responses agreed that it was preferable to use a donor with, rather than without, capacity. 1 felt that that was discriminatory, and 8 made no comment on this part of the Question.

Question 10: Is there any reason why the authorisation arrangements proposed for adults in general in relation to decisions relating to post-mortem examinations or the Anatomy Act 1984 should not apply to adults with incapacity?

13 responses were received to this Question. 11 agreed that the authorisation arrangements proposed for adults in general should also apply to adults with incapacity, 1 recommended that a post-mortem should not be undertaken without additional authorisation from close relatives and 1 stated that a post-mortem should only be carried out if the cause of death was not known.
HUMAN TISSUE (SCOTLAND) BILL: LIVING DONOR LIVER TRANSPLANTATION

Thank you for your letter of 8 November 2005 asking how the Human Tissue (Scotland) Bill would deal with donations made under the living donor liver transplantation programme which the Minister for Health & Community Care announced would start in Scotland at the beginning of April 2006.

Recognising that the programme raises a range of sensitive issues, Andy Kerr sent each MSP a briefing document on the new service on the morning of 7 November, the day of his announcement. Members may find it helpful to refer to that document in addition to the advice contained in this letter. It made explicit reference to the Human Tissue (Scotland) Bill, pointing out that it contains updated provisions on living donation to ensure that all living donations by adults, including living donor liver donation, will be subject to the additional protection of independent scrutiny by the Human Tissue Authority.

In terms of the specific provisions in the Bill, section 15(1)(b) makes it an offence to remove part of an organ from an adult, but this may be disapp lied where Ministers are satisfied as to certain matters. The reference in section 15 to ‘parts of organs’ was included with developments such as living donor liver transplantation very much in mind. Section 49 of the Bill then enables Ministers to make arrangements for assistance with functions such as that of overseeing transplantations from living donors under section 15, and it is under that power that cases will be referred to the Human Tissue Authority, which is already aware that we will be asking it to take account of the setting up of this programme.

You asked specifically about the position regarding donations under the programme by children below the age of 16. As the briefing pack attached to the Minister’s letter makes
clear, this is an adult to adult transplantation programme. Children under the age of 16 would simply not be eligible for consideration as donors under the programme. This is in line with section 15 of the Bill as introduced. As the Committee is aware, section 15 only permits children to donate regenerative tissue such as bone marrow, and does not provide for any disapplication of the offence under section 15(1)(a) of removing part of an organ from a child. Again, it is our intention that all donations of regenerative tissue from children would be subject to independent scrutiny by the Human Tissue Authority.

I hope this is helpful to the Committee, but if you or the Committee members would like further information, please let me know.

Yours sincerely,

Lewis Macdonald

LEWIS MACDONALD
HUMAN TISSUE (SCOTLAND) BILL: ANATOMY ACT

At the oral evidence session with the Health Committee on 25 October I agreed to consider the inclusion of ‘microscopic’ in the definition of anatomical examination. This was suggested to the Committee by Professor Sue Black of Dundee University, who considered the existing definition too narrow.

We have discussed this with Jeremy Metters, Her Majesty’s Inspector of Anatomy for Scotland, and agree with his view that it would be wrong to include ‘microscopic’ in the definition. Anatomical examination is carried out by the naked eye, and our proposed definition in section 48(2)(a) of the Bill expands on the definition in section 1(1) of the Act to encompass our policy objective of allowing training in reconstructive surgery and examination of the body by other processes and procedures which are not permitted by the restricted wording in the 1984 Act.

If we added ‘microscopic’ to the list of purposes then histological examination of pathology specimens, which is looking through a microscope at the cellular structure of tissues that cannot be seen by the naked eye, will become an anatomical examination. It is not our policy intention to bring the histological examination of pathology specimens within the scope of the Act.

November 2005
I hope the Committee will agree with our reasons for not including microscopic in the definition of anatomical examination. Yours sincerely, Lewis Macdonald.

LEWIS MACDONALD