

Dear Ms Austin,

Thank you for the invitation to comment on the draft bill. Unfortunately the timeframe to read, analyse, confer and formulate a response from the nine intensive care units in Northern Ireland is too short. I would urge the Committee to extend the time available in order to receive a proper consensus opinion from the clinicians at the leading edge of organ donation.

However, in case further time is not made available I wish to advise you that there is concern amongst my colleagues that the bill, as it stands, may not produce the anticipated benefits, may not be cost effective and has potential to slow or reverse recent progress in donation. I enclose comments and queries in template format from my colleague in the Network, Dr Glover, the Regional Clinical Lead for Organ Donation.

In addition I would like to refer to a submission which you will have received separately from another senior colleague, Dr John Trinder, who was the original lead for critical care in NI and who has a particular interest in the area of ethics and organ donation: Though I have not had time to gain region wide support for his submission, I believe it to represent the views of a large group of critical care clinicians and would appeal to the Committee to give the information it contains due consideration.

Yours sincerely,

Dr George Gardiner

Consultant in Intensive Care Medicine

Clinical Lead, Critical Care Network Northern Ireland

Section	Human Transplantation Bill content	Comments / Suggested Amendments										
<p>1 Duty to promote transplantation</p>	<p>(1) The DHSSPS must: (a) promote transplantation, (b) provide information & increase awareness about transplantation, and (c) inform the public about the circumstances where consent to transplantation is deemed to be given, and the role of relatives and friends in affirming that deemed consent.</p> <p>(2) The duty under subsection (1)(c) includes in particular a duty to promote a campaign informing the public at least once a year.</p>	<p>While any change in legislation will require an extensive education and awareness programme prior to implementation, there will be a requirement for on-going awareness to ensure the public are familiar with the legal position in the event of their death. The emphasis of the legislation document is transplantation. However, the public focus will be on consent for organ donation.</p> <p>The legislation does not consider that lack or registered objection may arise as a result of a person being unaware of the existence of the legislation, or having a practical reason for not registering their objection.</p>										
<p>2 Authorisation of transplantation duties</p>	<p>(1) Transplantation activities are lawful if done— (a) with express consent where that is required (see sections 3, 5, 6 & 7 below) or (b) otherwise with deemed consent (see sections 4 & 8).</p> <p>(2) The following are transplantation activities for the purpose of this Act— (a) storing the body of a deceased person for use for the purpose of transplantation, (b) removing from a human body, for use for the purpose of transplantation, any relevant material of which the body consists or which it contains, (c) storing for use for the purpose of transplantation any relevant material which has come from a human body, (d) using for the purpose of transplantation any relevant material which has come from a human body.</p> <p>(3) A transplantation activity of the kind mentioned in subsection (2)(c) or (d) is lawful (without the need for consent) if— (a) the relevant material has been imported into N. Ireland from outside N. Ireland and (b) its removal from a person’s body took place outside N. Ireland.</p>	<p>It is unclear of the purpose of ‘without the need for consent’ in para 3. It is unclear as to which situation this would pertain..</p>										
<p>3 Express consent: adults</p>	<p>(1) Where this section applies, express consent is required for a Transplantation activity involving the body or relevant material from the body of a person.</p> <p>(2) This section applies if (a) the person is an adult, & (b) the case is mentioned in the table below.</p> <p>(3) The meaning of express consent for each case is set out in the table below:</p> <table border="1" data-bbox="322 1129 1413 1506"> <thead> <tr> <th data-bbox="322 1129 913 1161">Case</th> <th data-bbox="913 1129 1413 1161">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="322 1161 913 1193">1. The person is alive.</td> <td data-bbox="913 1161 1413 1193">The person’s consent.</td> </tr> <tr> <td data-bbox="322 1193 913 1289">2. The person has died and a decision of the person to consent, or not to consent, was in force immediately before the person’s death.</td> <td data-bbox="913 1193 1413 1289">The person’s consent.</td> </tr> <tr> <td data-bbox="322 1289 913 1417">3. The person has died, case 2 does not apply, the person had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.</td> <td data-bbox="913 1289 1413 1417">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="322 1417 913 1506">4. The person has died, case 2 does not apply and the person had appointed a person or persons to deal with the issue of consent, but no one is able to give consent</td> <td data-bbox="913 1417 1413 1506">Consent of a person who stood in a qualifying relationship to the person immediately before death.</td> </tr> </tbody> </table>	Case	Meaning of Express Consent	1. The person is alive.	The person’s consent.	2. The person has died and a decision of the person to consent, or not to consent, was in force immediately before the person’s death.	The person’s consent.	3. The person has died, case 2 does not apply, the person had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.	4. The person has died, case 2 does not apply and the person had appointed a person or persons to deal with the issue of consent, but no one is able to give consent	Consent of a person who stood in a qualifying relationship to the person immediately before death.	<p>Table row 4. Those in qualifying relationships are listed in the document. However, no reference is made to a hierarchical order. It would not be expected that all individuals in qualifying relationships are of equal status.</p> <p>Is ODR registration accepted as consent for transplantation activity under the legislation?</p> <p>If someone has previously registered a wish not to consent,, will the family be approached to confirm that this remained the person’s wish?</p>
Case	Meaning of Express Consent											
1. The person is alive.	The person’s consent.											
2. The person has died and a decision of the person to consent, or not to consent, was in force immediately before the person’s death.	The person’s consent.											
3. The person has died, case 2 does not apply, the person had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.											
4. The person has died, case 2 does not apply and the person had appointed a person or persons to deal with the issue of consent, but no one is able to give consent	Consent of a person who stood in a qualifying relationship to the person immediately before death.											

		under the appointment.											
		(4) But this section does not apply— (a) if the person is an excepted adult (see section 5), (b) to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).											
	Section	Human Transplantation Bill content	Comments / Suggested Amendments										
4	Deemed consent: deceased adults	<p>(1) Where this section applies, consent is deemed for a transplantation activity involving the body or relevant material from the body of a person.</p> <p>(2) But deemed consent is only effective if a relative or friend of long standing of the person affirms that the person would not have objected to that transplantation activity.</p> <p>(3) This section applies if— (a) the person is a deceased adult, and (b) section 3 (express consent) does not apply.</p> <p>(4) But this section does not apply— (a) if the person is an excepted adult (see section 5), (b) to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).</p>	<p>This is where point 'c' was missing. The relevance of point c, following from point b is unclear.</p> <p>There are several issues to be clarified:</p> <p>i) What is the expected action if an individual in a qualifying relationship disagrees with the deceased's wishes to donate, for personal reasons? Can the deceased's wishes to donate be over-ridden in any circumstances. What are the consequences for a SNOD if retrieval is not pursued in such a case?</p> <p>ii) The situation of the absence of someone in a qualifying relationship, but an individual who is a nominated individual, but who is unaware of the deceased's is not clear.</p>										
5	Express consent: excepted adults	<p>(1) Where this section applies, express consent is required for a transplantation activity involving the body or relevant material from the body of a person.</p> <p>(2) This section applies if the person is an excepted adult.</p> <p>(3) An "excepted adult" means— (a) an adult who has died and who had not been ordinarily resident in N. Ireland for a period of at least 12 months immediately before dying, or (b) an adult who has died and who for a significant period before dying lacked capacity to understand the notion that consent to transplantation activities can be deemed to be given.</p> <p>(4) For the purposes of subsection (3)(b), a significant period means such a significantly long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.</p> <p>(5) For each case the meaning of express consent is set out in the table below:</p> <table border="1"> <thead> <tr> <th>Case</th> <th>Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td>1. A decision of the excepted adult to consent, or not to consent, was in force immediately before death.</td> <td>The excepted adults' consent.</td> </tr> <tr> <td>2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.</td> <td>Consent given by the person or persons appointed.</td> </tr> <tr> <td>3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.</td> <td>Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.</td> </tr> <tr> <td>4. None of cases 1, 2 or 3 applies in relation to the</td> <td>Consent of a person who stood in a</td> </tr> </tbody> </table>	Case	Meaning of Express Consent	1. A decision of the excepted adult to consent, or not to consent, was in force immediately before death.	The excepted adults' consent.	2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.	3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.	4. None of cases 1, 2 or 3 applies in relation to the	Consent of a person who stood in a	<p>Definition of capacity and legal framework thereof in N.I. Mental Capacity Bill is still at the Committee stage.</p> <p>There is a gap in the definition of 'excepted adult'. The potential donor after circulatory death, who will always still be alive at the time consent is obtained, will, in the vast majority of cases not be competent give express consent at that time, but may have made a decision previously.. It is unclear from the legislation, where this situation is dealt with. It does not appear to be covered in the tables in clauses 3 or 5.</p> <p>Under what conditions can an excepted adult, as per 3b, still give express consent to donation? This creates a situation where someone would have to decide as to whether an excepted adult, by virtue of 3b, had the capacity to consent, or not consent, to transplantation activity.</p>
Case	Meaning of Express Consent												
1. A decision of the excepted adult to consent, or not to consent, was in force immediately before death.	The excepted adults' consent.												
2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.												
3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.												
4. None of cases 1, 2 or 3 applies in relation to the	Consent of a person who stood in a												

	excepted adult.	qualifying relationship to the excepted adult immediately before death.															
	(6) But this section does not apply to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).																
	Section	Human Transplantation Bill content	Comments / Suggested Amendments														
6	Express consent: children	<p>(1) Where this section applies, express consent is required for a transplantation activity involving the body or relevant material from the body of a person.</p> <p>(2) This section applies where the person is a child or has died a child.</p> <p>(3) For each case the meaning of express consent is set out in the table below:</p> <table border="1"> <thead> <tr> <th>Case</th> <th>Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td>1. The child is alive and case 2 does not apply.</td> <td>The child's consent.</td> </tr> <tr> <td>2. The child is alive, no decision of the child to consent, or not to consent is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.</td> <td>Consent of a person who has parental responsibility for the child.</td> </tr> <tr> <td>3. The child has died and a decision of the child to consent, or not to consent, was in force immediately before death.</td> <td>The child's consent</td> </tr> <tr> <td>4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.</td> <td>Consent given by the person or persons appointed.</td> </tr> <tr> <td>5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.</td> <td>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.</td> </tr> <tr> <td>6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</td> <td>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.</td> </tr> </tbody> </table>	Case	Meaning of Express Consent	1. The child is alive and case 2 does not apply.	The child's consent.	2. The child is alive, no decision of the child to consent, or not to consent is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.	Consent of a person who has parental responsibility for the child.	3. The child has died and a decision of the child to consent, or not to consent, was in force immediately before death.	The child's consent	4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.	5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.	6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.	<p>Clarification of when child is competent make decision about consent.</p> <p>If a child is competent to make a decision but fails to do so, does parental responsibility override the child's competence?</p> <p>(?What is the situation of responsibility for child if a child is in care – is there still on-going parental responsibility or is it the responsibility of the relevant authority? – I am not familiar with this area).</p>
Case	Meaning of Express Consent																
1. The child is alive and case 2 does not apply.	The child's consent.																
2. The child is alive, no decision of the child to consent, or not to consent is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.	Consent of a person who has parental responsibility for the child.																
3. The child has died and a decision of the child to consent, or not to consent, was in force immediately before death.	The child's consent																
4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.																
5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.																
6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.																

	<p>(4) In this section a decision or appointment made by a child is only valid if the child was competent to deal with the issue of consent when it was made.</p> <p>(5) But this section does not apply to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).</p>											
<p>Section</p>	<p>Human Transplantation Bill content</p>	<p>Comments / Suggested Amendments</p>										
<p>7 Express consent: transplantation activities involving excluded material</p>	<p>(1) In the case of a transplantation activity that involves the removal of excluded relevant material express consent is required, and such consent must be specific to the removal of excluded relevant material.</p> <p>(2) In this Act “excluded relevant material” means relevant material of a type specified by the Department in regulations.</p> <p>(3) Examples of the types of relevant material that may be specified are composite tissues and other types of material the removal and use of which is considered to be novel.</p> <p>(4) For an adult, the meaning of express consent is set out in the table below:</p> <table border="1" data-bbox="324 646 1411 1481"> <thead> <tr> <th data-bbox="324 646 745 683">Case</th> <th data-bbox="745 646 1411 683">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="324 683 745 798">1. The adult is alive</td> <td data-bbox="745 683 1411 798">The adult’s consent.</td> </tr> <tr> <td data-bbox="324 798 745 970">2. The adult has died and a decision of the adult to consent, or not to consent, was in force immediately before death.</td> <td data-bbox="745 798 1411 970">The adult’s consent</td> </tr> <tr> <td data-bbox="324 970 745 1236">3. The adult has died, case 2 does not apply, the adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.</td> <td data-bbox="745 970 1411 1236">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="324 1236 745 1481">4. The adult has died, case 2 does not apply and the adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.</td> <td data-bbox="745 1236 1411 1481">Consent of a person who stood in a qualifying relationship to the adult immediately before death.</td> </tr> </tbody> </table>	Case	Meaning of Express Consent	1. The adult is alive	The adult’s consent.	2. The adult has died and a decision of the adult to consent, or not to consent, was in force immediately before death.	The adult’s consent	3. The adult has died, case 2 does not apply, the adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.	4. The adult has died, case 2 does not apply and the adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.	<p>Para 2 is not defined. Needs clarity</p>
Case	Meaning of Express Consent											
1. The adult is alive	The adult’s consent.											
2. The adult has died and a decision of the adult to consent, or not to consent, was in force immediately before death.	The adult’s consent											
3. The adult has died, case 2 does not apply, the adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.											
4. The adult has died, case 2 does not apply and the adult had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.											

<p>5. The adult has died and none of cases 2, 3 or 4 applies in relation to the adult.</p>	<p>Consent of a person who stood in a qualifying relationship to the adult immediately before death.</p>
--	--

(5) For a child, the meaning of express consent is set out in the table below:

Case	Meaning of Express Consent
<p>1. The child is alive and case 2 does not apply.</p>	<p>The child's consent</p>
<p>2. The child is alive, no decision of the child to consent, or not to consent, is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.</p>	<p>Consent of a person who has parental responsibility for the child.</p>
<p>3. The child has died and a decision of the child to consent, or not to consent, was in force immediately before death.</p>	<p>The child's consent</p>
<p>4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.</p>	<p>Consent of the person or persons appointed.</p>
<p>5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent, but no one is able to give consent under the appointment.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.</p>
<p>6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person who stood in a qualifying relationship to the child at that time.</p>

(6) In this section a decision or appointment made by a child is only valid if the child was competent to deal with the issue of consent when it was made.

8	Deemed consent: activities involving material from living adults who lack capacity to consent	<p>(1) This section applies where—</p> <p>(a) a transplantation activity involves relevant material from the body of a person (“P”) who—</p> <p>(i) is a living adult, and</p> <p>(ii) lacks capacity to consent to the activity, and</p> <p>(b) no decision of P’s to consent, or not to consent, to the activity is in force.</p> <p>(2) P’s consent to the activity is to be deemed if the activity is done in circumstances of a kind specified by regulations made by the Department.</p>	<p>This appears to be confined to lack of capacity in living donors. The potential DCD donor will also be alive at the time consent is taken, but transplantation activities occur after death.</p> <p>Para 2 certainly needs clarification as it would permit organs to be taken from an individual without their consent. Removal of any organ from a living individual puts that individual at material risk of harm.</p>
Section		Human Transplantation Bill content	Comments / Suggested Amendments
9	Appointed representatives	<p>(1) A person may appoint one or more persons to represent the person after death in relation to express consent for the purposes of section 2.</p> <p>(2) An appointment may be general or limited to consent in relation to such one or more transplantation activities as may be specified in the appointment.</p> <p>(3) An appointment may be made orally or in writing.</p> <p>(4) An oral appointment is only valid if made in the presence of at least two witnesses present at the same time.</p> <p>(5) A written appointment is only valid if—</p> <p>(a) it is signed by the person making it in the presence of at least one witness who attests the signature,</p> <p>(b) it is signed at the direction of the person making it, in that person’s presence and in the presence of at least one witness who attests the signature, or</p> <p>(c) it is contained in the will of the person making it, being a will which is made in accordance with the requirements of Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994.</p> <p>(6) Where a person appoints two or more persons in relation to the same transplantation activity, they are to be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly.</p> <p>(7) An appointment may be revoked at any time.</p> <p>(8) Subsections (3) to (5) apply to the revocation of an appointment as they apply to the making of an appointment.</p> <p>(9) A person appointed may at any time renounce the appointment.</p> <p>(10) A person may not act under an appointment if the person—</p> <p>(a) is a child, or</p> <p>(b) is of a description prescribed by regulations made by the Department.</p> <p>(11) Where a person has appointed a person or persons under—</p> <p>(a) section 4 of the Human Tissue Act 2004, or</p> <p>(b) section 8 of the Human Transplantation (Wales) Act 2013, to deal after death with the issue of consent in relation to an activity done for the purpose of transplantation, the person is also to be treated as having made an appointment under this section in relation to the activity.</p>	<p>There are issues with:</p> <ul style="list-style-type: none"> -identification of appointed representative - scope of appointed representative e.g may have wider responsibilities other than consent for donation. Appointed representative may potentially not have been informed about donation wishes <p>What is the mechanism for ensuring appointed representative has not been revoked?</p> <p>I presume 5a and 5b are separated by ‘or’.</p>

		(12) For the purposes of sections 3, 5, 6 & 7, if it is not reasonably practicable to communicate with a person appointed under this section within the time available if consent is to be acted upon, the person is to be treated as being not able to give consent to an activity under the appointment.	
10	Qualifying relationships	(1) The following are qualifying relationships for the purpose of this Act— (a) spouse, civil partner or partner, (e) child of a brother or sister, (b) parent or child, (f) stepfather or stepmother, (c) brother or sister, (g) half brother or half sister, (d) grandparent or grandchild, (h) friend of long standing.	Hierarchy not referred to.
Section		Human Transplantation Bill content	Comments / Suggested Amendments
10	Qualifying relationships (continued)	(2) For the purposes of this Act, a person is another person’s partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship. (3) The Department may by order amend subsection (1). (4) The code of practice referred to in the Schedule may make further provision on qualifying relationships, in particular on the ranking of qualifying relationships.	
11	Offences	Prohibition of transplantation activities without consent (1) A person commits an offence if the person does, without consent, a transplantation activity. (2) But a person does not commit an offence under subsection (1) if— (a) the person reasonably believes— (i) that he or she does the activity with consent, or (ii) that what he or she does is not a transplantation activity, (b) section 2(3) applies, or (c) section 15(1) applies. (3) A person (“P”) commits an offence if— (a) P falsely represents to a person whom P knows or believes is going to, or may, do a transplantation activity— (i) that there is consent to the doing of the activity, or (ii) that the activity is not a transplantation activity, and (b) P knows that the representation is false or does not believe it to be true. (4) A person guilty of an offence under this section is liable— (a) on summary conviction to a fine not exceeding the statutory maximum, (b) on conviction on indictment to imprisonment for a term not exceeding 3 years, or to a fine, or both.	
12	Offences by bodies corporate	For the purposes of this Act, section 20(2) of the Interpretation Act (Northern Ireland) 1954— (a) applies with the omission of the words “the liability of whose members is limited”, and (b) (where the affairs of a body corporate are managed by its members), applies in relation to the acts or defaults of a member in connection with that member’s functions of management as if that member were a director of the body corporate.	
13	Prosecutions	Proceedings for an offence under section 11 may be brought only by, or with the consent of, the Director of Public Prosecutions for Northern Ireland.	
14	Annual report on transplantation	(1) The Department must lay before the Assembly, in each financial year, a report about transplantation activities in that year.	

		<p>(2) The report must include</p> <p>(a) the steps taken by the Department to fulfil the duties set out in section 1,</p> <p>(b) the number & nature of transplantation activities carried out in accordance with this Act.</p> <p>(3) At least once every five financial years, the report must include—</p> <p>(a) the opinion of the Department as to whether this Act has been effective in promoting transplantation activities, and</p> <p>(b) any recommendations the Department considers appropriate for amending the law so as to promote transplantation activities.</p>	
Section		Human Transplantation Bill content	Comments / Suggested Amendments
15	Preservation for transplantation	<p>(1) Where part of a body of a deceased person lying in a hospital, nursing home or other institution is or may be suitable for use for transplantation, it is lawful for the person having the control or management of the institution—</p> <p>(a) to take steps for the purpose of preserving the part for use for transplantation, and</p> <p>(b) to retain the body for that purpose.</p> <p>(2) Authority under subsection (1)(a) extends only to—</p> <p>(a) the taking of the minimum steps necessary for the purpose mentioned in that provision, &</p> <p>(b) to the use of the least invasive procedure.</p> <p>(3) Authority under subsection (1) ceases to apply once it has been established that express consent making removal of the part for transplantation lawful has not been, and will not be, given and that consent is not deemed to be given.</p> <p>(4) Authority under subsection (1) extends to any person authorised to act under the authority by—</p> <p>(a) the person on whom the authority is conferred by that subsection, or</p> <p>(b) a person authorised under that subsection to act under that authority.</p> <p>(5) An act done with authority under subsection (1) is to be treated as not being an activity to which section 2 applies.</p>	
16	Coroners	<p>(1) Nothing in this Act applies to anything done for the purposes of the functions of a coroner or under the authority of a coroner.</p> <p>(2) Subsection (3) below applies where a person (“P”) knows, or has reason to believe, that—</p> <p>(a) the body of a deceased person, or</p> <p>(b) relevant material which has come from the body of a deceased person, is, or may be, required for the purposes of functions of a coroner.</p> <p>(3) The consent of the coroner is required before P may act on authority under—</p> <p>(a) section 2, or</p> <p>(b) section 15, in relation to the body or material.</p>	

17	Relevant material	<p>(1) In this Act “relevant material” means material, other than gametes, which consists of or includes human cells.</p> <p>(2) In this Act references to relevant material from a human body do not include—</p> <p>(a) embryos from outside the human body, or</p> <p>(b) hair and nail from the body of a living person.</p> <p>(3) In this section “embryo” and “gametes” have the same meaning as they have by virtue of section 1(1), (4) and (6) of the Human Fertilisation and Embryology Act 1990 in the other provisions of that Act (apart from section 4A).</p>	
Section		Human Transplantation Bill content	Comments / Suggested Amendments
18	Interpretation	<p>(1) In this Act—</p> <p>“adult” means a person who attained the age of 18 years,</p> <p>“child” means a person who has not attained the age of 18 years,</p> <p>“Department” means the Department for Health, Social Services and Public Safety,</p> <p>“qualifying relationships” has the meaning given in section 10,</p> <p>“relevant material” has the meaning given in section 17; and “excluded relevant material” has the meaning given in section 7,</p> <p>“transplantation activities” has the meaning given in section 2.</p> <p>(2) In this Act a reference to the appointment of a person or persons to deal with the issue of consent is a reference to an appointment under section 9.</p> <p>(3) For the purposes of sections 6, 7 and 9 a child is competent to deal with the issue of consent if it would appear to a reasonable person that the child has sufficient understanding to make an informed decision.</p> <p>(4) In this Act—</p> <p>(a) references to material from the body of a living person are to material from the body of a person alive at the point of separation,</p> <p>(b) references to material from the body of a deceased person are to material from the body of a person not alive at the point of separation,</p> <p>(c) references to express consent include consent given before the coming into operation of sections 3 to 10.</p> <p>(5) In this Act, references to transplantation are to transplantation to a human body and include transfusion.</p> <p>(6) For the purposes of this Act, material is not to be regarded as from a human body if it is created outside the human body.</p>	
19	Orders and regulations	<p>(1) No order or regulation under this Act may be made unless a draft of the order or regulation has been laid before, and approved by resolution of, the Assembly.</p> <p>(2) Orders and regulations made under this Act may contain such incidental, consequential, supplementary, transitional and savings provisions as appear to the Department necessary or expedient.</p>	
20	Consequential	20. The Schedule (consequential amendments to the Human Tissue Act 2004) has effect (see	

	amendments to the Human Tissue Act 2004	below).	
21	Commencement	<p>(1) The following provisions come into operation 3 months after the day this Act receives Royal Assent—</p> <p>(a) this section,</p> <p>(b) section 1,</p> <p>(c) sections 18 and 22.</p> <p>(2) The other provisions of this Act come into operation on 31 May 2018.</p>	
22	Short title	This Act may be cited as the Human Transplantation Act (Northern Ireland) 2015.	

Section	Human Transplantation Bill content	Comments / Suggested Amendments
Schedule - Consequential amendments to the Human Tissue Act 2004	<p>1. The Human Tissue Act 2004 is amended as follows.</p> <p>2. In section 1 (authorisation of activities for scheduled purposes) after subsection (1) insert—“(1ZA) Subsection (1) does not apply in relation to consent for transplantation activities (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) done in Northern Ireland.”.</p> <p>3. In section 6 (activities involving material from adults who lack capacity to consent)—</p> <p>(a) the existing text becomes subsection (1),</p> <p>(b) after subsection (1) insert—“(1ZA) This section does not apply in relation to transplantation activities (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) done in Northern Ireland. (For provision in these circumstances see section 8 of the Human Transplantation Act (Northern Ireland) 2015).”.</p> <p>4. In section 8 (restriction of activities in relation to donated material), in subsection (6) after “section 1(1) to (3)” insert “or section 2 of the Human Transplantation Act (Northern Ireland) 2015”.</p> <p>5. In section 15 (general functions of the Human Tissue Authority) in paragraph (c)(i) after “this Part” insert “or under the Human Transplantation Act (Northern Ireland) 2015”.</p> <p>6. In section 26 (preparation of codes)—</p> <p>(a) in subsection (2)(d) after “this Act” insert “and the Human Transplantation Act (Northern Ireland) 2015”,</p> <p>(b) in subsection (3) after “deal with consent” insert “(including consent for the purposes of the Human Transplantation Act (Northern Ireland) 2015)”.</p> <p>7. In section 27 (provisions with respect to consent)—</p> <p>(a) in subsection (1) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1ZA)”,</p> <p>(b) after subsection (1) insert—“(1ZA) Those provisions are— (a) section 2(7)(b)(ii) or 3(6)(c) of this Act; (b) section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015.”,</p> <p>(c) in subsection (4) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1ZA)”,</p>	

(d) after subsection (8) insert— “(8C) The duty under section 26(3) shall also have effect, in particular, to require the Authority to give practical guidance on the circumstances in which consent is deemed and whether it has been affirmed under section 4 of the Human Transplantation Act (Northern Ireland) 2015 (deemed consent: deceased adults).”,

(e) in subsection (9) after “subsection (4)” insert “except in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015”,

(f) after subsection (9) insert— “(9A) The relevant Northern Ireland department may by order amend subsection (4) in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015. (9B) Before making an order under subsection (9A) the relevant Northern Ireland department must carry out such public consultation as the department considers appropriate.”.

8. In section 29 (approval of codes)—

(a) after subsection (1) insert— “(1ZA) Where a code of practice to which subsection (1) applies deals with a matter relating to the carrying on in Northern Ireland of a transplantation activity (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) the Authority may not issue the code unless—

(a) a draft of it has been sent to and approved by the relevant Northern Ireland department and laid by that department before the Northern Ireland Assembly, and

(b) the Northern Ireland Assembly has approved the draft by resolution.”,

(b) after subsection (4) insert— “(4ZA) If the relevant Northern Ireland department does not approve a draft sent under subsection (1ZA), the department shall give reasons to the Authority.”.

9. In section 43 (preservation for transplantation) after subsection (6) insert— “(6A) This section does not apply in relation to a part of a body lying in an institution in Northern Ireland. (For provision in these circumstances see section 15 of the Human Transplantation Act (Northern Ireland) 2015).”.

10. In section 52 (orders and regulations) after section (4) insert— “(4ZA) No order under section 27(9A) may be made by the relevant Northern Ireland department unless a draft of the instrument has been laid before and approved by a resolution of the Northern Ireland Assembly.”.

11. In Schedule 4 (section 45: supplementary) after paragraph 11 insert— “*Purpose authorised under section 2 of the Human Transplantation Act (Northern Ireland) 2015*”

11A. Use of the results of an analysis of DNA for a purpose specified in paragraph 7 is use for an excepted purpose if the use in Northern Ireland for that purpose of the bodily material concerned is authorised by section 2 of the Human Transplantation Act (Northern Ireland) 2015.”.

12. In Schedule 5 (powers of inspection, entry, search and seizure)—

(a) in paragraph 3(1)(a) after “2” insert “or under the Human Transplantation Act (Northern Ireland) 2015”,

(b) in paragraph 5(2) after “2” insert “or under the Human Transplantation Act (Northern Ireland) 2015”.