

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments										
1 Duty to promote transplantation	<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 primarily require an extensive education and awareness programme prior to implementation, we agree that 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. We feel that due consideration should be given to the fact that, although the emphasis of the legislation document is transplantation, the public focus will be on consent for <u>organ donation</u>.</p> <p>The legislation does not explicitly consider that lack of 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>										
2 Authorisation of transplantation duties	<p>(1) Transplantation activities are lawful if done—</p> <p>(a) with express consent where that is required (see sections 3, 5, 6 & 7 below) or</p> <p>(b) otherwise with deemed consent (see sections 4 & 8).</p> <p>(2) The following are transplantation activities for the purpose of this Act—</p> <p>(a) storing the body of a deceased person for use for the purpose of transplantation,</p> <p>(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,</p> <p>(c) storing for use for the purpose of transplantation any relevant material which has come from a human body,</p> <p>(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—</p> <p>(a) the relevant material has been imported into N. Ireland from outside N. Ireland and</p> <p>(b) its removal from a person's body took place outside N. Ireland.</p>	<p>The purpose of “(without the need for consent)” in para 3 is unclear. Clarification would be helpful as to what type of situation / circumstances this would pertain.</p>										
3 Express consent: 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 (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="271 1050 1379 1449"> <thead> <tr> <th data-bbox="271 1050 898 1086">Case</th> <th data-bbox="898 1050 1379 1086">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="271 1086 898 1118">1. The person is alive.</td> <td data-bbox="898 1086 1379 1118">The person's consent.</td> </tr> <tr> <td data-bbox="271 1118 898 1206">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="898 1118 1379 1206">The person's consent.</td> </tr> <tr> <td data-bbox="271 1206 898 1326">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="898 1206 1379 1326">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="271 1326 898 1449">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 under the appointment.</td> <td data-bbox="898 1326 1379 1449">Consent of a person who stood in a qualifying relationship to the person immediately before death.</td> </tr> </tbody> </table> <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.</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 under the appointment.	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 this being a <u>hierarchical</u> 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> <p>The Explanatory Memorandum section relating to Clause 3 (page 4) makes use of the phrase “harvesting of organs”. Engagement with donor families over many years has identified that this terminology is often distressing to relatives. It would be preferred if alternatives (e.g. “donating”, “retrieval”, “gifting”) could be used instead (e.g. for any intended material / guidance being issued as part of the public awareness campaign).</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 under the appointment.	Consent of a person who stood in a qualifying relationship to the person immediately before death.											

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments										
<p>4 Deemed consent: deceased adults</p>	<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 –</p> <p>(a) such efforts as are reasonable in the circumstances have been made to contact persons who stood in a qualifying relationship with the person immediately before death,</p> <p>(b) a person (Q) who stood in a qualifying relationship with the person immediately before death affirms that the person would not have objected to that transplantation activity, and</p> <p>(c) Q has reasonable grounds for believing that the person would not have objected to that transplantation activity.</p> <p>(3) This section applies if—</p> <p>(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—</p> <p>(a) if the person is an excepted adult (see section 5),</p> <p>(b) to consent for a transplantation activity that involves removal of excluded relevant material.</p> <p>(5) The code of practice referred to in the Schedule makes further provision on deemed consent, affirmations and objections to affirmations.</p>	<p>The relevance of (2) point (c), following from (2) 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-riden in any circumstances? What are the consequences for a Specialist Nurse – Organ Donation if retrieval is not pursued in such a case?</p> <p>ii) The action to be taken in a situation of the absence of someone in a qualifying relationship, but an individual who is a nominated individual being present, but who is unaware of the deceased’s wishes is not clear.</p>										
<p>5 Express consent: excepted 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 the person is an excepted adult.</p> <p>(3) An “excepted adult” means—</p> <p>(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</p> <p>(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" data-bbox="271 1082 1379 1444"> <thead> <tr> <th data-bbox="271 1082 898 1114">Case</th> <th data-bbox="898 1082 1379 1114">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="271 1114 898 1173">1. A decision of the excepted adult to consent, or not to consent, was in force immediately before death.</td> <td data-bbox="898 1114 1379 1173">The excepted adult’s consent.</td> </tr> <tr> <td data-bbox="271 1173 898 1262">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 data-bbox="898 1173 1379 1262">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="271 1262 898 1356">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 data-bbox="898 1262 1379 1356">Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.</td> </tr> <tr> <td data-bbox="271 1356 898 1444">4. None of cases 1, 2 or 3 applies in relation to the excepted adult.</td> <td data-bbox="898 1356 1379 1444">Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.</td> </tr> </tbody> </table> <p>(6) But this section does not apply to consent for a transplantation activity that involves removal of excluded relevant material.</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 adult’s 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 excepted adult.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.	<p>Definition of capacity and legal framework thereof in N.I. is currently in development (further to the Bamford Review) as the Mental Capacity Bill is still at the Committee stage. It would be helpful to have this legislation finalised to ensure clarity and to support decision-making in organ transplantation circumstances.</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 to 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 (3)(b), 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 (3)(b), 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 adult’s 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 excepted adult.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.											

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments														
<p>6 Express consent: children</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 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" data-bbox="271 248 1379 1219"> <thead> <tr> <th data-bbox="271 248 750 284">Case</th> <th data-bbox="750 248 1379 284">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="271 284 750 363">1. The child is alive and case 2 does not apply.</td> <td data-bbox="750 284 1379 363">The child's consent.</td> </tr> <tr> <td data-bbox="271 363 750 576">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 data-bbox="750 363 1379 576">Consent of a person who has parental responsibility for the child.</td> </tr> <tr> <td data-bbox="271 576 750 687">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 data-bbox="750 576 1379 687">The child's consent</td> </tr> <tr> <td data-bbox="271 687 750 884">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 data-bbox="750 687 1379 884">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="271 884 750 1066">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 data-bbox="750 884 1379 1066">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 data-bbox="271 1066 750 1219">6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</td> <td data-bbox="750 1066 1379 1219">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> <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>	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 a child is considered competent to make decision about consent is required.</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 if a child is in care – is there still on-going parental responsibility or is it the responsibility of the relevant authority?</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.															

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments												
<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="271 475 1379 1497"> <thead> <tr> <th data-bbox="271 475 750 512">Case</th> <th data-bbox="750 475 1379 512">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="271 512 750 683">1. The adult is alive</td> <td data-bbox="750 512 1379 683">The adult’s consent.</td> </tr> <tr> <td data-bbox="271 683 750 836">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="750 683 1379 836">The adult’s consent</td> </tr> <tr> <td data-bbox="271 836 750 1066">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="750 836 1379 1066">Consent given by the person or persons appointed.</td> </tr> <tr> <td data-bbox="271 1066 750 1315">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="750 1066 1379 1315">Consent of a person who stood in a qualifying relationship to the adult immediately before death.</td> </tr> <tr> <td data-bbox="271 1315 750 1497">5. The adult has died and none of cases 2, 3 or 4 applies in relation to the adult.</td> <td data-bbox="750 1315 1379 1497">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.	5. The adult has died and none of cases 2, 3 or 4 applies in relation to the adult.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.	<p>Further clarity is required regarding para 2 – “relevant material <u>of a type specified by the Department...</u>” It is noted that further regulations will be developed in this regard and this would be welcomed.</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.													
5. The adult has died and none of cases 2, 3 or 4 applies in relation to the adult.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.													

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments														
<p>7 Express consent: transplantation activities involving excluded material (contd)</p>	<p>(5) For a child, the meaning of express consent is set out in the table below:</p> <table border="1" data-bbox="271 172 1379 1027"> <thead> <tr> <th data-bbox="271 172 826 204">Case</th> <th data-bbox="826 172 1379 204">Meaning of Express Consent</th> </tr> </thead> <tbody> <tr> <td data-bbox="271 204 826 272">1. The child is alive and case 2 does not apply.</td> <td data-bbox="826 204 1379 272">The child's consent</td> </tr> <tr> <td data-bbox="271 272 826 437">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 data-bbox="826 272 1379 437">Consent of a person who has parental responsibility for the child.</td> </tr> <tr> <td data-bbox="271 437 826 555">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 data-bbox="826 437 1379 555">The child's consent</td> </tr> <tr> <td data-bbox="271 555 826 687">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 data-bbox="826 555 1379 687">Consent of the person or persons appointed.</td> </tr> <tr> <td data-bbox="271 687 826 852">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 data-bbox="826 687 1379 852">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 data-bbox="271 852 826 1027">6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</td> <td data-bbox="826 852 1379 1027">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> <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.</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 of 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.	
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 of 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>8 Deemed consent: activities involving material from living adults who lack capacity to consent</p>	<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 clause appears to be confined to lack of capacity in living donors. The potential Donation after Circulatory Death (DCD) donor will also be alive at the time consent is taken, but transplantation activities occur after death.</p> <p>Para 2 needs clarification as it could 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. It is noted (page 7 of the Explanatory Memorandum) that “the Department <u>may</u> make regulations setting out the circumstances in which consent may be deemed”. We would welcome provision of such regulations to ensure adequacy of protection of patients in this category.</p>														

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments
<p>9 Appointed representatives</p>	<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>(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.</p>	<p>There are issues with:</p> <ul style="list-style-type: none"> -identification of appointed representatives (i.e. How will clinical staff be able to identify whether or not a representative has been appointed? Where will the details of appointed persons be recorded? How will these be accessed (e.g. if the appointment is only detailed in the donor’s will)? How will it be ensured that information regarding appointed representatives remains up-to-date over the passage of time (eg contact details)? - 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>Should (5)(a) and (5)(b) be separated by “or”?</p> <p>Further clarity would be helpful with regards to (10)(b).</p>
<p>10 Qualifying relationships</p>	<p>(1) The following are qualifying relationships for the purpose of this Act—</p> <p>(a) spouse, civil partner or partner,</p> <p>(b) parent or child,</p> <p>(c) brother or sister,</p> <p>(d) grandparent or grandchild,</p> <p>(e) child of a brother or sister,</p> <p>(f) stepfather or stepmother,</p> <p>(g) half brother or half sister,</p> <p>(h) friend of long standing.</p>	<p>It is not explicitly clear in the Bill whether the qualifying relationships listed are hierarchical or of equal standing. We would assume that a hierarchy does apply (as per the Human Tissue Act), but feel that this could be made more explicit in the wording of this clause.</p>

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments
10 Qualifying relationships (continued)	<p>(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.</p> <p>(3) The Department may by order amend subsection (1).</p> <p>(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.</p>	No comments.
11 Offences	<p>Prohibition of transplantation activities without consent</p> <p>(1) A person commits an offence if the person does, without consent, a transplantation activity.</p> <p>(2) But a person does not commit an offence under subsection (1) if—</p> <p>(a) the person reasonably believes—</p> <p>(i) that he or she does the activity with consent, or</p> <p>(ii) that what he or she does is not a transplantation activity,</p> <p>(b) section 2(3) applies, or</p> <p>(c) section 15(1) applies.</p> <p>(3) A person ("P") commits an offence if—</p> <p>(a) P falsely represents to a person whom P knows or believes is going to, or may, do a transplantation activity—</p> <p>(i) that there is consent to the doing of the activity, or</p> <p>(ii) that the activity is not a transplantation activity, and</p> <p>(b) P knows that the representation is false or does not believe it to be true.</p> <p>(4) A person guilty of an offence under this section is liable—</p> <p>(a) on summary conviction to a fine not exceeding the statutory maximum,</p> <p>(b) on conviction on indictment to imprisonment for a term not exceeding 3 years, or to a fine, or both.</p>	No comments.
12 Offences by bodies corporate	<p>For the purposes of this Act, section 20(2) of the Interpretation Act (Northern Ireland) 1954—</p> <p>(a) applies with the omission of the words "the liability of whose members is limited", and</p> <p>(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.</p>	No comments.
13 Prosecutions	<p>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.</p>	No comments.
14 Annual report on transplantation	<p>(1) The Department must lay before the Assembly, in each financial year, a report about transplantation activities in that year.</p> <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>	<p>A wealth of data is collated and reported on by NHSBT on an ongoing basis via the UK Transplant Registry. These reports provide extensively detailed data regarding the number and nature of transplants both at individual organisational level, and including UK comparisons. It would be helpful to know whether it is envisaged that this existing data infrastructure can be used to address (2)(b), or whether additional data collection processes will need to be implemented within the Trust.</p>

Section	Human Transplantation Bill content	Queries / 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>	No comments.
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>	No comments.
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>	No comments.

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments
18 Interpretation	<p>(1) In this Act— “adult” means a person who attained the age of 18 years, “child” means a person who has not attained the age of 18 years, “Department” means the Department for Health, Social Services and Public Safety, “qualifying relationships” has the meaning given in section 10, “relevant material” has the meaning given in section 17; and “excluded relevant material” has the meaning given in section 7, “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— (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, (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, (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>	No comments.
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>	No comments.
20 Consequential amendments to the Human Tissue Act 2004	20. The Schedule (consequential amendments to the Human Tissue Act 2004) has effect.	No comments.
21 Commencement	<p>(1) The following provisions come into operation 3 months after the day this Act receives Royal Assent— (a) this section, (b) section 1, (c) sections 18 and 22.</p> <p>(2) The other provisions of this Act come into operation on 31 May 2018.</p>	No comments.
22 Short title	This Act may be cited as the Human Transplantation Act (Northern Ireland) 2015.	No comments.

Section	Human Transplantation Bill content	Queries / Comments / Suggested Amendments
<p>Schedule - Consequential amendments to the Human Tissue Act 2004</p>	<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)— (a) the existing text becomes subsection (1), (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)— (a) in subsection (2)(d) after “this Act” insert “and the Human Transplantation Act (Northern Ireland) 2015”, (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)— (a) in subsection (1) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1ZA)”, (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.”, (c) in subsection (4) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1ZA)”, (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.”.</p>	<p>No comments.</p>

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”.