

# Report on the Public Consultation Process on Proposals for a Human Tissue Bill

December 2017

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# Section 1: Introduction

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A public consultation was held by the Department of Health from 28<sup>th</sup> August 2017 – October 9<sup>th</sup> 2017 to seek the views of the public and key stakeholders on a proposed Human Tissue Bill. This report outlines the views, opinions, and recommendations of those who completed questionnaires or made submissions to the Department of Health on the proposed new legislation.

## **Executive Summary**

On 11<sup>th</sup> July 2017, the Government approved the preparation of the General Scheme and Heads of a Human Tissue Bill. It is proposed that the General Scheme will regulate the removal, retention, storage, use and disposal of human tissue from deceased persons; provide general conditions for the removal, donation and use of organs and tissues from deceased and living persons for the purposes of transplantation; and provide for an opt-out system of consent for organ donation and for an associated register. The Human Tissue Bill will implement the key recommendation of the Madden Report on Post-Mortem Practices and Procedures that no hospital post-mortem examination should be carried out and no tissue retained for any purpose whatsoever without authorisation.

The Department of Health launched a six week public consultation process in August 2017 with a view to obtaining the views of the public and key stakeholders on the legislative proposals. Respondents were invited to express their views, interests, and concerns on a range of key issues relating to the development of a Human Tissue Bill.

Twenty four questions were presented to respondents listed under the five headings: Post Mortem Practice; Anatomical Examination/Education and Training of Medical Professionals; Public Display; Consent; and Organ Donation and Transplantation. Participants were presented with information regarding the proposals in each of these areas and asked to provide comments, opinions, or recommendations.

A total of 257 complete responses were submitted via online questionnaire, with a further 4 responses sent via e-mail. Two hundred and nine questionnaire respondents (80.1%) identified as members of the public, 36 (13.7%) identified as medical practitioners/educators,

and 27 (10.3%) identified as members of stakeholder organisations. Some participants selected more than one option, leading to a total of greater than 100%.

The following is a summary of respondents' views on the questions asked under each of the five key areas.

### *Post Mortem Practice*

One hundred and seventy respondents commented on the proposals for Post Mortem Practice.

- Sixty-five respondents (38.2%) approved of the proposals.
- Eighty-five (50%) stated that they had no objection to the proposals.
- Six respondents (3.5%) disagreed with the proposals.
- The remaining fourteen (8.2%) responded with comments that did not pertain to the proposals for Post Mortem Practice or used the comments box to request clarification on specific issues.

### *Anatomical Examination/Education and Training of Medical Professionals*

One hundred and sixty-seven participants commented on the proposals for anatomical examination/education and training of medical professionals.

- No respondents who commented on the proposals as presented had any disagreement with the proposals.
- Many commenters emphasized the importance of respect for the deceased alongside the importance of ongoing medical training.

### *Public Display*

One-hundred and seventy respondents commented on the proposals for Public Display.

- Respondents were in broad agreement with the proposals.
- Two (1.2%) respondents expressed direct disagreement with the proposals.
- Thirty-five respondents (20.6%) expressed some reservation with the idea of public display itself and some aspects thereof, but did not disagree with licensing the practice.

## *Consent*

Respondents were presented with the proposals regarding consent for the use of tissue in hospital post mortems, anatomical examination, education & training, public display and research conducted as a secondary activity after one of these activities. Participants then responded to a series of questions asking “How likely would you be to consent...” to each of these activities. These questions had five response options from 1 (Very Unlikely) to 5 (Very likely).

- Hospital Post Mortem
  - The majority of participants indicated that they would be likely or very likely to consent to a hospital post mortem being conducted on themselves (70.8%) or on a loved one (69.5%).
  - Participants were also asked about the information they would like to receive to help them make decisions on consent for hospital post mortems. The majority of participants would like to be told which organs will be removed, how long they will be kept, and how they will be returned to the family/disposed of. In addition, a majority of respondents wished to know the purpose for which the material is being removed, and the benefits of the information to be received.
- Anatomical Examination/ Education and Training.
  - Participants responded with a relatively even spread of results from “Very Unlikely” to “Very Likely”.
- Public Display
  - A majority of participants (54.8%) said they would be very unlikely to consent to their body being used as part of a public display.
- Research
  - The most common response (28%) was that they would be likely to consent.

## *Organ Donation and Transplantation*

One hundred and eighty participants commented on the proposals for organ donation and transplantation.

- One hundred and seventeen of these responses indicated agreement with the proposed system (65%).

- Twenty-three (12.7%) commented with no objection to the proposals.
- Twenty-two (12.2%) respondents opposed the proposals.
- The remaining eighteen (10%) asked questions in their comments or made comments not directly related to the proposals.

Respondents were also asked about the likelihood that they would opt out of organ donation.

- A majority (70.8%) of respondents said that they would be very unlikely to opt out of organ donation.
- A majority (71.2%) also stated they would be very likely to consent to organ donation on behalf of a deceased loved one.

Respondents were asked the questions “What methods should be available for signing up to the opt-out register?” and “Do you have any further suggestions for the operation of the opt-out register?”

- Many comments emphasized that the public would need to be clearly informed about the introduction of such a register and that signing up to opt out should be easy to do for those who wish to do so.
- A number of people expressed the wish for an opt-in register to operate alongside the opt-out register and that signing up to opt-in would prevent next-of-kin overruling their wishes to donate.
- Most commenters also expressed their support or opposition to the register, echoing their responses to the previous question.

Participants were asked the questions “Would the proposed opt-out system encourage you to discuss your intentions regarding organ donation with your family?” and “What measures could be taken to encourage discussion of wishes surrounding organ donation amongst families?”

- Most participants (83.4%) indicated that these proposals would encourage them to discuss organ donation with their families.
- In comments, participants emphasized a desire to see public information campaigns encouraging people to discuss organ donation and featuring people who have benefitted from organ donation. These views were shared by people both for and against the proposals.



## **Overview of the Public Consultation Process**

The Department of Health launched a six week consultation process beginning on 28<sup>th</sup> August 2017 and ending on the 9<sup>th</sup> of October 2017. The objective of the consultation was to obtain the views of the public on a proposed Human Tissue Bill to legislate for the recommendations of the Madden Report and introduce an opt-out system for organ donation. The outcome will inform the drafting of the Heads of Bill.

The public consultation was announced via press release on the 28<sup>th</sup> August and advertised on the Department of Health's website. The consultation was further advertised in the national newspapers on Friday September 1<sup>st</sup> and via the Department of Health Twitter account in the final week of the consultation. Some stakeholders, including the Irish Donor Network, the Irish Kidney Association, the Irish Lung Fibrosis Association, and transplant centres were also alerted to the consultation opportunity.

## **Methodology**

The consultation questionnaire was hosted on Survey Monkey. The questionnaire was presented in three sections.

The first section (Questions 1-5) presented respondents with a brief outline of the proposals and scope of the proposed Bill, and asked for demographic information.

The second section (Questions 6-15) presented information on the proposals relating to consent and regulation for post-mortem procedure, anatomical examination, education & training, and public display of body parts. Comments on each set of proposals were invited.

Participants were then presented with information regarding consent for the regulation for post-mortem procedure, anatomical examination, education & training, and public display of body parts. They were then asked a series of questions of the form "how likely would you be to consent to" each of these designated activities. This section also included questions about the types of information respondents would like to receive to inform their decision. These questions were designed as a gauge of participants' concerns and attitudes regarding the use of human tissue after death.

The third section (Questions 16-24) presented participants with information on the proposals for organ donation and transplantation. Participants were invited to comment on the proposals. Participants were also asked how likely they would be to opt out of organ donation or to consent to organ donation on behalf of a deceased family member.

This section also asked questions about raising public awareness of organ donation and prompting conversations amongst families about wishes regarding organ donation.

## Section 2: Detailed Analysis of Submissions

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### **Demographic Information (Q1-5)**

Two hundred and fifty-seven responses to the consultation were collected via Survey Monkey, with a further 4 submissions received via e-mail.

Of the questionnaire respondents who entered a gender, one hundred and fifty were female and 77 were male. The remaining participants did not enter a gender.

Of the questionnaire respondents who entered their age, 76 participants were aged from 18-35 years (32.5%), 99 were aged 36-55 years (42.3%), 57 were aged 56-75 years (24.4%), and 2 participants were aged 75 years or over (0.9%).

Participants were resident throughout the country, with 48% of questionnaire respondents resident in Dublin.

Of the 261 participants, 209 identified as members of the public (80.1%), while the remainder was made up of medical professionals (10.3%), educators (3.4%), and members of interested organisations (10.3%). Some participants marked themselves as more than one of the above categories, leading to a total of more than 100%.

## Designated Activities (Q6-15)

### Post Mortem Practice and Procedure

Before responding to questions on the proposals on Post Mortem practice, participants were presented with the following information:

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#### Post Mortem practice (Recommendations of the Madden Report)

The proposed legislation will implement the recommendations of the Madden Report on Post Mortem Practices and Procedures (2006) relating to consent provisions for hospital post mortems and provisions on the retention, storage, use and disposal of organs and tissue from deceased persons following post mortem examination.

The major recommendation of the Madden Report was that there is a need for legislation to create a framework for consent, both for hospital post mortems and for the use or retention of any part of the body for any reason following a post mortem.

The provisions of the Bill will not affect the practice of a Coroner's post mortem, for which consent is not required. It is proposed that this legislation will complement the provisions in the Coroner's Act 1962.

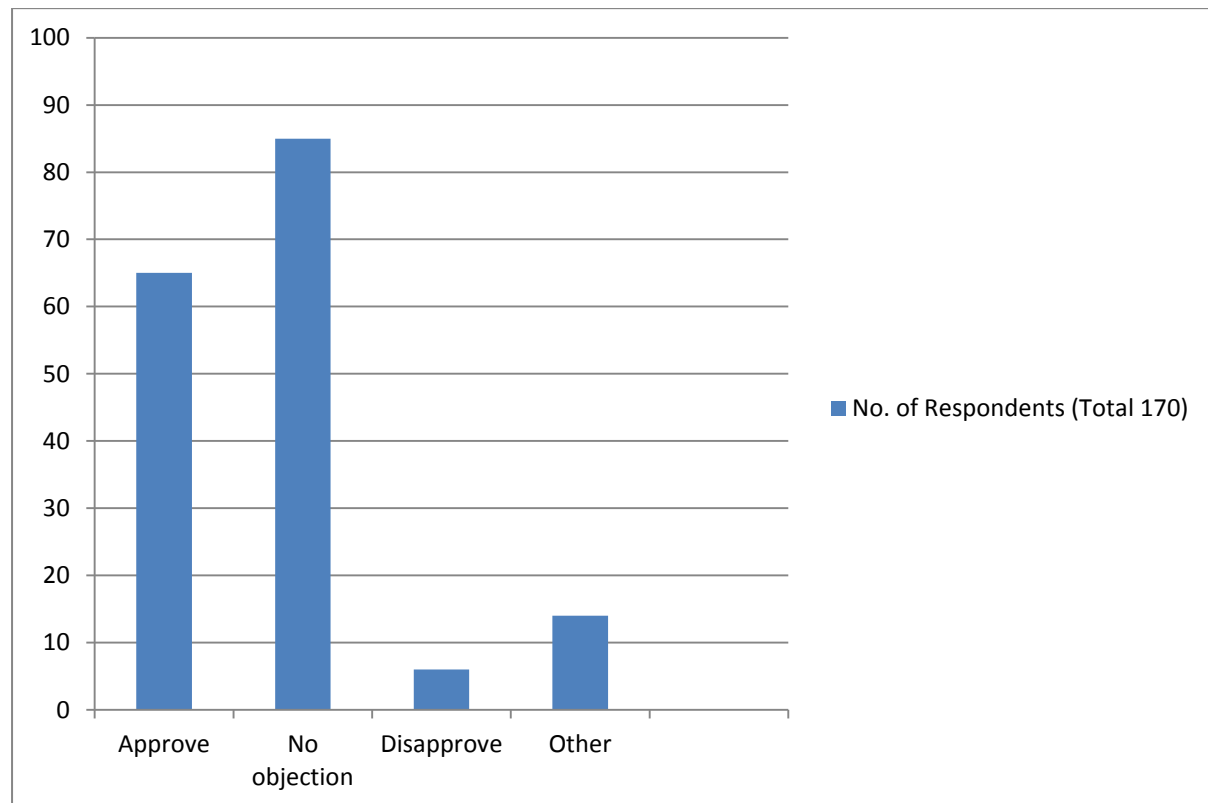
It is proposed that the Bill will provide for a coherent overall policy framework and will ensure consistency in relation to the process of seeking consent and record management relating to hospital post mortem examinations.

It is proposed that a hospital post mortem may be conducted for one (or more) of the following reasons:

- Determining or providing more information on the cause of death;
- Providing information on the effectiveness of a medical or surgical intervention administered to the person;
- Obtaining scientific and medical information which may be of benefit to another person now or in the future;
- Education & training of medical professionals;
- Clinical audit.

***Question 6: Do you have any views/comments on the above proposals regarding post mortem practice and procedures?***

**Chart 1: Breakdown of comments on post mortem practice and procedure**



One hundred and seventy participants responded to the question. Sixty-five (38.2%) respondents expressed support for the above proposals. Eighty-five (50%) respondents had no objection. Six (3.5%) opposed the proposals. The remaining fourteen respondents (8.2%) made comments that did not pertain to the question asked, or used the comment box to ask a question.

A few individuals who expressed approval had small caveats or concerns. Most common (5 commenters) was a concern with the inclusion of clinical audit as a reason for performing a hospital post mortem.

The Office of the State Pathologist made a submission to the consultation that included comments on the proposals surrounding post-mortem practice. They expressed a concern that hospital autopsies account for less than 1% of autopsies performed annually in Ireland, and as such, the scope of the regulations regarding organ retention may be too narrow.

The Irish Hospice Foundation also made comments on the above proposals. They expressed agreement with the legislation, but added the recommendation that the policy framework “pay specific attention to communicating in sensitive situations” and that “comprehensive guidance” will be required as part of staff training and a public information campaign.

The Coroners Society of Ireland commented that “an appropriate distinction needs to be made between organ retention procedure and samples for histology and toxicology”.

The Irish Thoracic Society’s submission expressed agreement with the proposals.

## **Anatomical Examination/ Education and Training**

Before participants responded to questions on Anatomical Examination/ Education and Training, they were provided with the following information:

### **Anatomical Examination/Education & Training of Medical Practitioners**

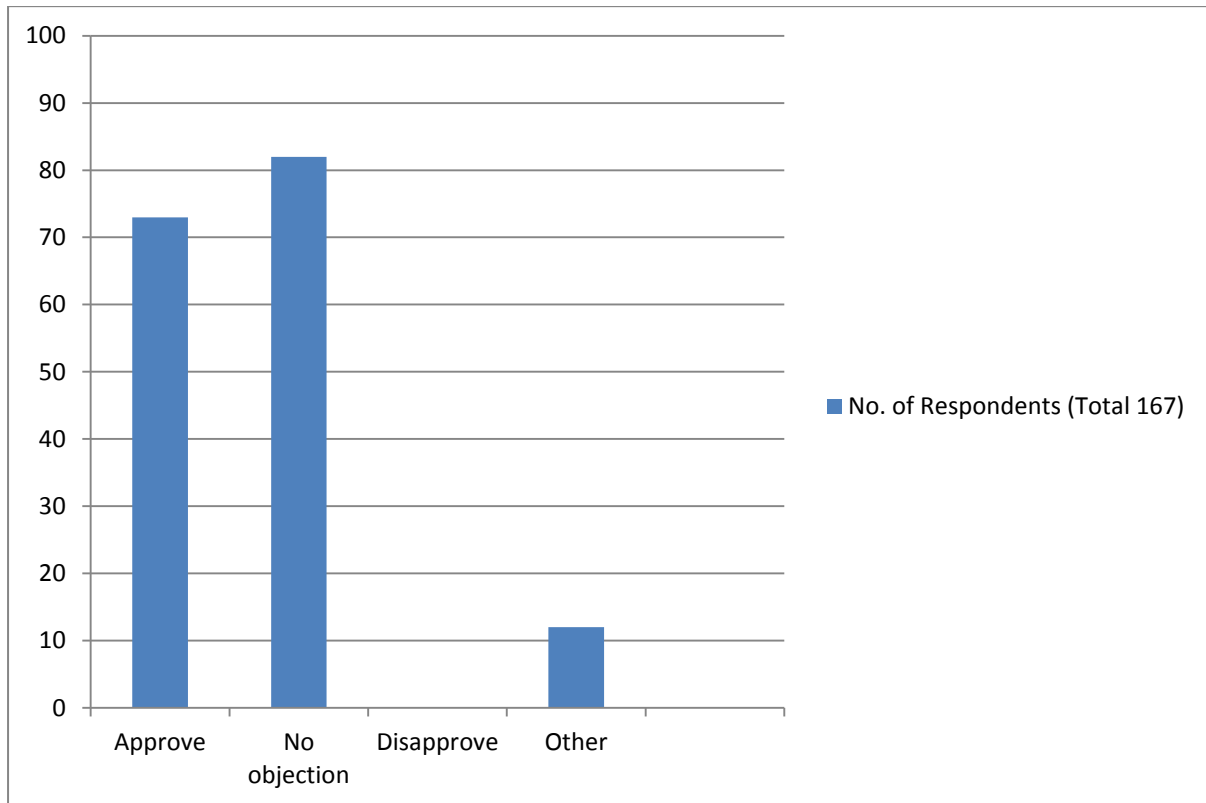
Anatomy is the study of the structure of the body and anatomical examination is the examination of a deceased body or its constituent parts for the purposes of education, training or research.

The practice of anatomy is currently regulated under the Anatomy Act 1832. It is proposed that the Human Tissue Bill will repeal this Act and replace it with an updated framework in relation to licensing, consent, the donation of bodies to anatomy schools and provisions for the setting of guidelines and standards to be met in the practice of anatomy.

It is proposed that the legislation will also include provisions to regulate the use of human organs and tissue in the education & training of medical practitioners. The intention is to provide for the regulation of education & training practices not covered by anatomy.

***Question 7: Do you have any views/comments on the above proposals regarding Anatomical Examination/Education and Training of Medical Professionals?***

**Chart 2: Breakdown of comments on Anatomical Examination/Education and Training of Medical Professionals**



One hundred and sixty seven participants responded to the proposals on Anatomical Examination/Education and Training. Seventy-three people (43.7%) expressed agreement with the proposals, and 82 respondents had no objection (49.1%). The remaining 12 (7.1%) made comments unrelated to the proposals as presented or used the comment space to ask questions.

Seven medical practitioners emphasised the importance of access to cadavers and other human tissue for the ongoing training of medical staff.

The Irish Hospice Foundation commented: “Medical Students require early value based education in order to respect and preserve dignity of donor organs. It is important to recognize that family members are also affected and should be considered in training, education, and practice”.



## Public Display

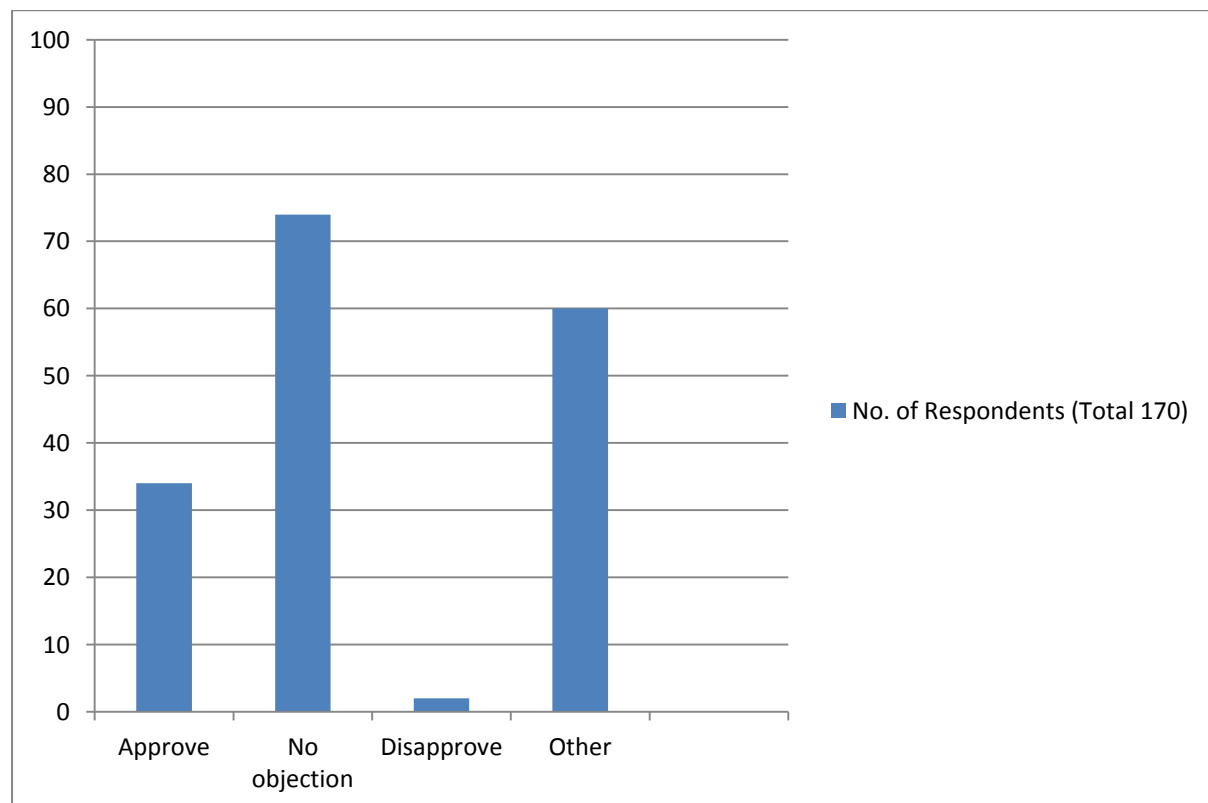
Before participants responded to questions on Public Display, they were provided with the following information:

### Public Display

It is proposed that the public display of bodies or body parts after death, whether temporary or permanent, will require a licence by an appropriate regulatory authority. Before a licence is issued the appropriate regulatory authority will require documentary evidence of provenance and consent. It is envisaged that the proposed legislation will include exemptions for activities associated with funerals, the display of religious relics and for the display of bodies and body parts after death where the death occurred over one hundred years ago.

***Question 8: Do you have any views/comments on the above proposals regarding Public Display?***

Chart 3: Breakdown of comments on Public Display



One hundred and seventy people responded to the proposals on Public Display.

Thirty four respondents (20%) expressed approval for the proposals, and 74 (43.5%) participants had no objection to the proposals. Two (1.2%) people expressed direct disagreement with the proposals. Thirty-five other commenters (20.6%) expressed disagreement with the idea of public display in general, particularly under circumstances

other than funerals. Some stated that public display should be banned entirely, especially in circumstances where human tissue is publicly displayed for profit.

Medical professionals emphasized the role public display could have in public and medical education, but also expressed a need for tight controls on this process.

The Irish Hospice Foundation commented “Licences must uphold principles of dignity, respect, privacy, and compassion.”

The Professional Embalmers’ Association of Ireland “welcome the exemption related to public display associated with activities with funerals”.

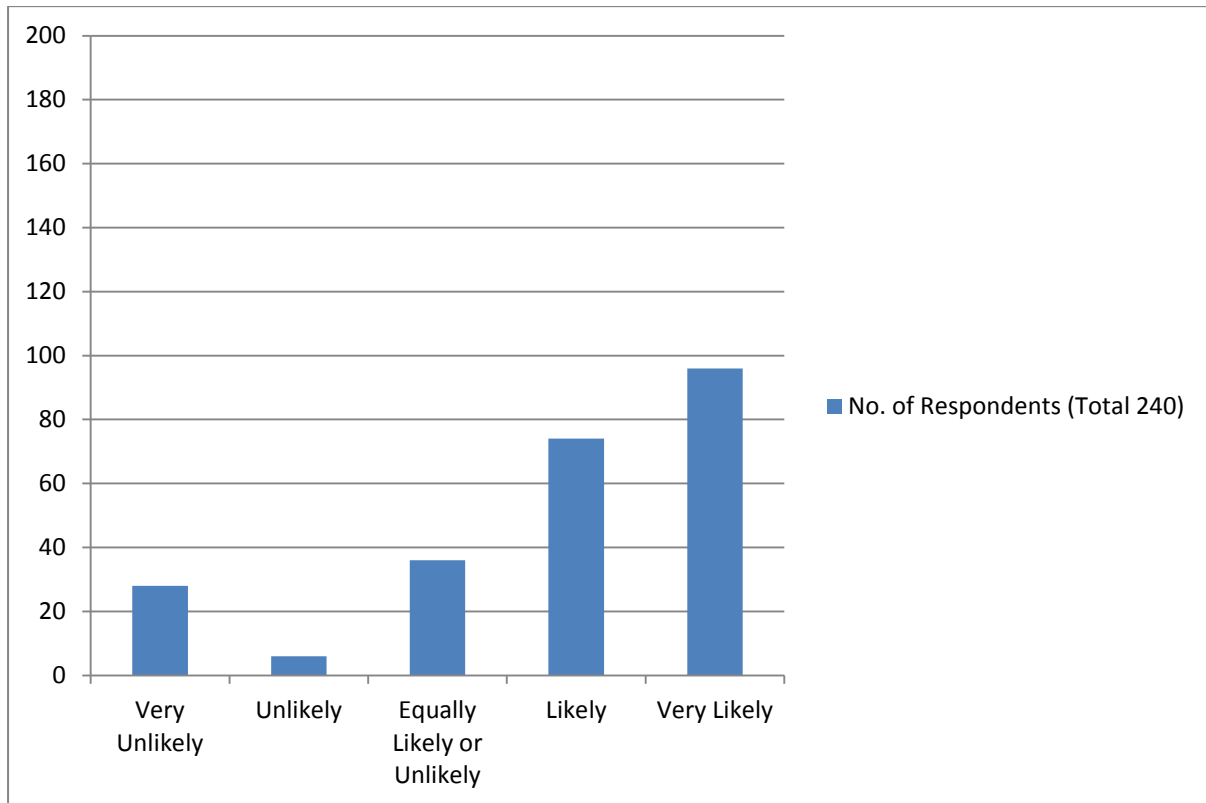
## **Consent**

Respondents were presented with the proposals regarding consent for the use of tissue in hospital post mortems, education & training, public display, and research conducted as a secondary activity after one of these activities. Following from this information, participants then responded to a series of questions asking “How likely would you be to consent...” to each of these activities.

Answers were on a five point scale ranging from “Very Unlikely” to “Very likely”.

**Question 9: “How likely would you be to consent to doctors performing a hospital post mortem after your death?”**

Chart 4: “How likely would you be to consent to doctors performing a hospital post mortem after your death?”



The majority of participants indicated that they would be likely or very likely to consent. Ninety six (40%) respondents said they were “Very likely” to consent and 74 (30.8%) responded that they were “Likely” to consent. Thirty six (15%) were “Equally likely or unlikely” to consent. Six respondents (2.4%) were “Unlikely” to consent and 28 (11.6%) were “Very unlikely” to consent.

***Question 10: “What information would you like to receive from medical professionals to help you make that decision?”***

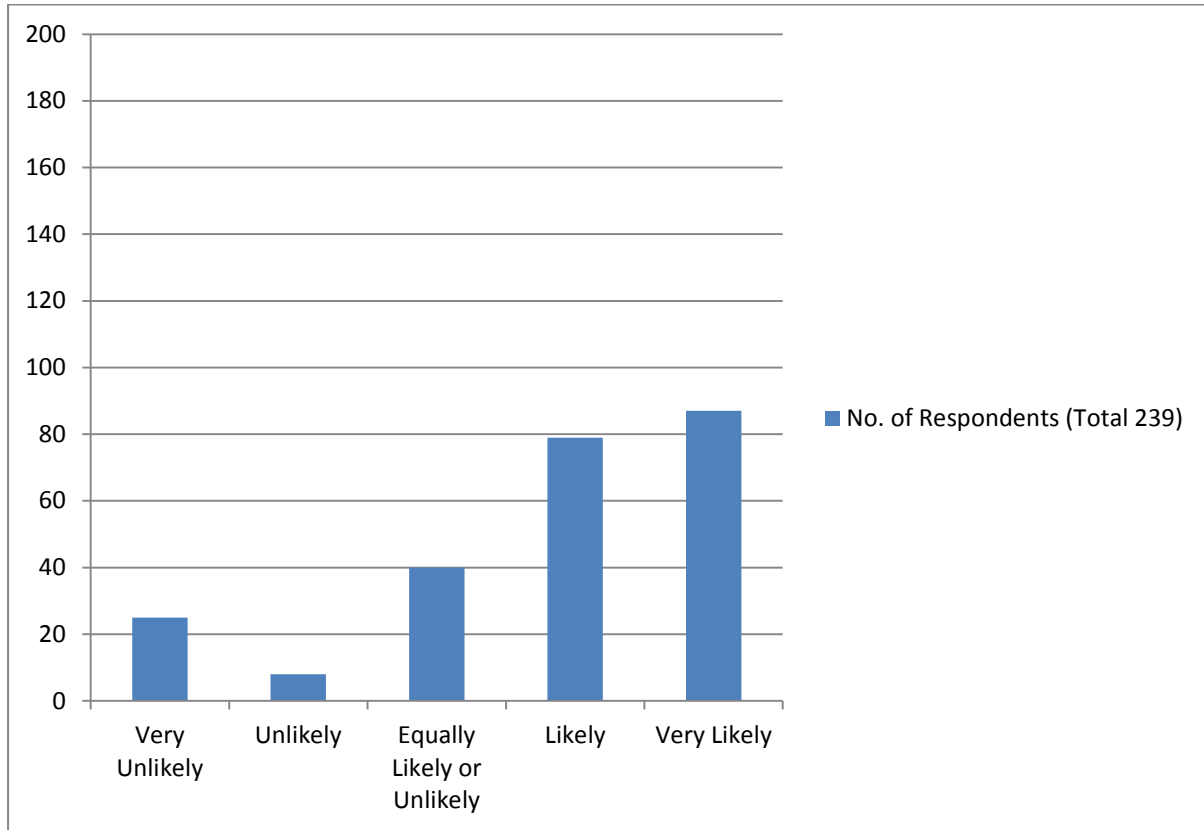
**Table 1: What information would you like to receive from medical professionals to help you make that decision?**

ANSWER CHOICES	RESPONSES	
Which organs will be removed?	64.17%	154
How long will they be kept?	62.08%	149
How will they be returned to the family/disposed of?	65.83%	158
An overview of the medical procedure	38.33%	92
A detailed account of the medical procedure	17.08%	41
A very detailed account of the medical procedure	14.17%	34
The purpose for which the material is being removed	77.50%	186
The benefits of the information to be gained.	80.83%	194
Other (please specify)	13.75%	33
Total Respondents: 240		

Two hundred and forty participants responded to this question. Respondents were presented the above list of response options. Participants could tick any number of boxes, leading to totals of greater than one hundred percent. The majority of participants would like to be told which organs will be removed (64.2%), how long they will be kept (62.1%), and how they will be returned to the family/disposed of (65.8%). In addition, a majority (77.5%) of respondents wished to know the purpose for which the material is being removed and the benefits of the information to be received (80.8%). Responses under “Other” often made reference to a concern for who would have access to the data generated by such a procedure and that people be informed of any third parties with access to the material.

***Question 11: If doctors requested to perform a hospital post mortem on a loved one after their death, how likely would you be to consent?***

**Chart 5: If doctors requested to perform a hospital post mortem on a loved one after their death, how likely would you be to consent?**



Two hundred and thirty-nine participants responded to the question.

The majority of participants indicated that they would be likely or very likely to consent. Eighty seven respondents (36.4%) said they were “Very likely” to consent and 79 (33.1%) responded that they were “Likely” to consent. Forty (16.7%) were “Equally likely or unlikely” to consent. Eight respondents (3.3%) were “Unlikely” to consent and 25 (10.4%) were “Very unlikely” to consent.

***Question 12: What information would you like to receive from medical professionals to help you make this decision?***

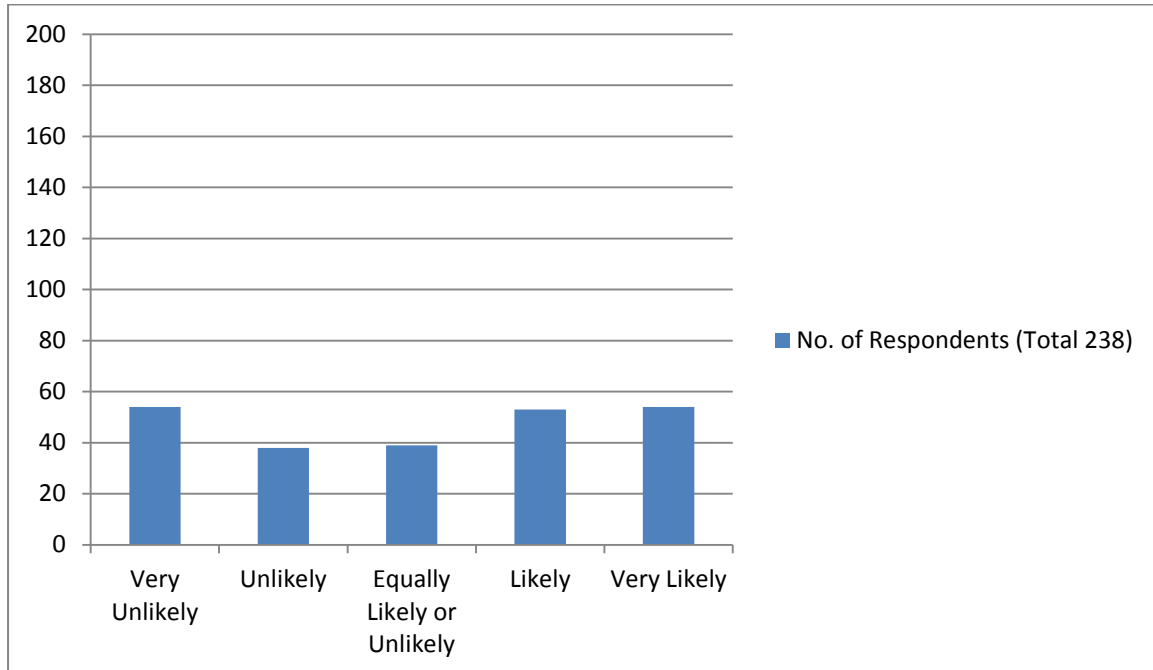
**Table 2: What information would you like to receive from medical professionals to help you make that decision? (Hospital post mortem for loved ones).**

ANSWER CHOICES	RESPONSES	
Which organs will be removed?	60.92%	145
How long will they be kept?	60.08%	143
How will they be returned to the family/disposed of?	64.29%	153
An overview of the medical procedure	41.60%	99
A detailed account of the medical procedure	16.81%	40
A very detailed account of the medical procedure	15.55%	37
The purpose for which the material is being removed	74.37%	177
The benefits of the information to be gained	77.73%	185
Other (please specify)	15.55%	37
Total Respondents: 238		

Two hundred and thirty eight participants responded to this question. Respondents were presented the above list of response options. Participants could tick any number of boxes, leading to totals of greater than one hundred percent. The majority of participants would like to be told which organs will be removed (60.9%), how long they will be kept (60.1%), and how they will be returned to the family/disposed of (64.3%). In addition, a majority of respondents wished to know the purpose for which the material is being removed (74.4%), and the benefits of the information to be gained (77.7%).

***Question 13: How likely would you be to consent to your body being used in the practice of anatomy/education & training after your death?***

**Chart 6: How likely would you be to consent to your body being used in the practice of anatomy/education & training after your death?**

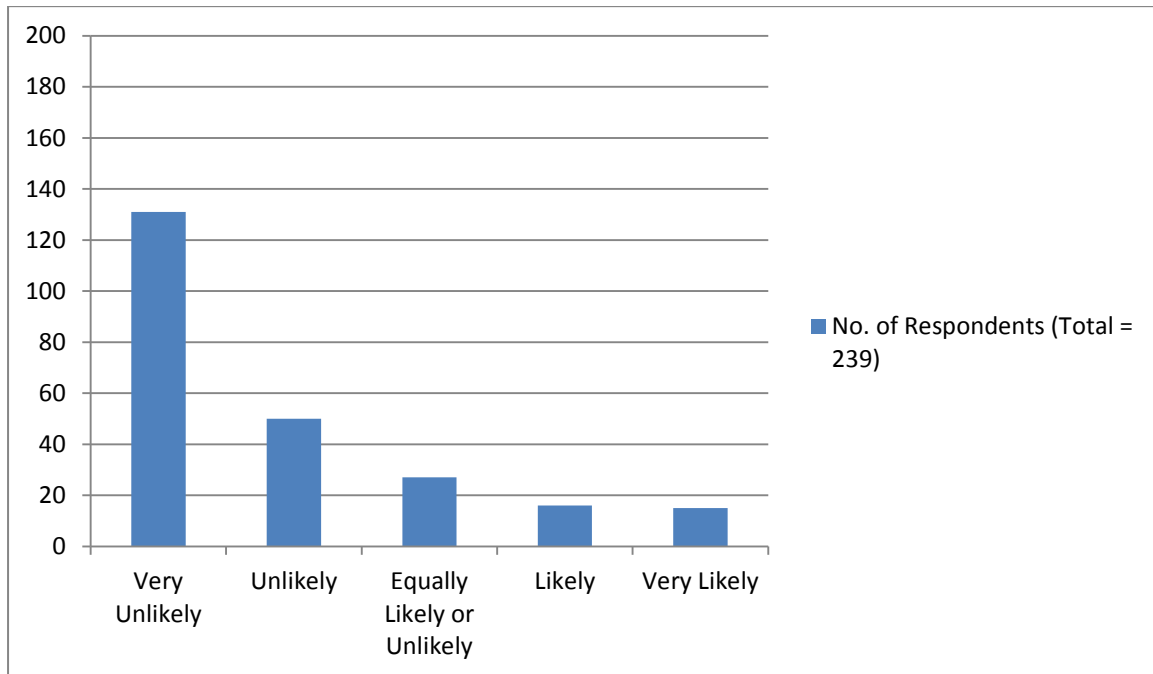


Two hundred and thirty-eight participants responded to the question.

Fifty-four (22.7%) respondents said they were “Very likely” to consent and 53 (22.3%) responded that they were “Likely” to consent. Thirty-nine (16.4%) were “Equally likely or unlikely” to consent. Thirty-eight (16%) were “Unlikely” to consent and 54 (22.7%) were “Very unlikely” to consent.

***Question 14: How likely would you be to consent to your body being used for public display after your death?***

Chart 7: Question 14: How likely would you be to consent to your body being used for public display after your death?



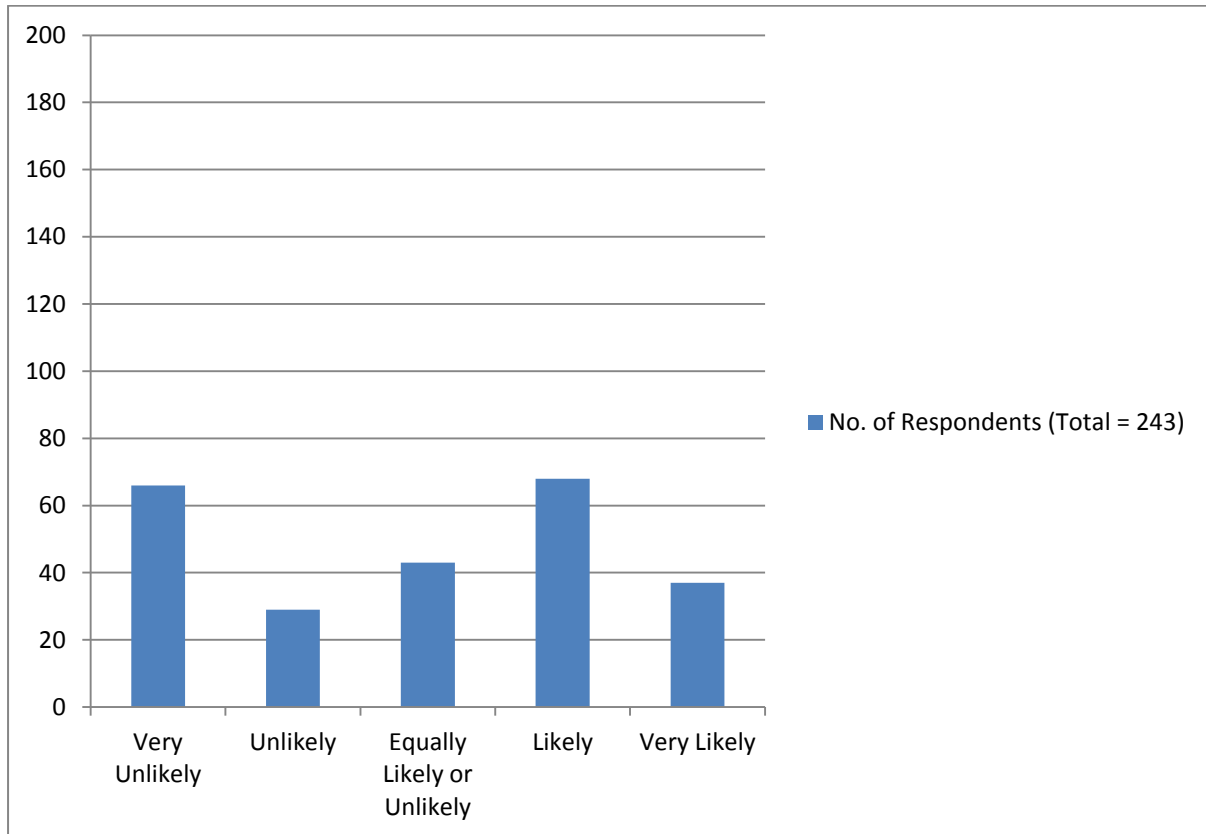
Two hundred and thirty-nine participants responded to this question.

One hundred and thirty-one participants responded that they would be “Very unlikely” to consent (54.8%) and 50 indicated that they were “Unlikely” to consent (20.9%). Twenty seven participants (11.3%) were “Equally likely or unlikely” to consent. Sixteen participants were likely to consent (6.7%) and 15 respondents were “Very likely” to consent (6.3%). These results reflect the earlier comments on public display (see Q8), in that participants were uncomfortable with certain aspects of the practice. It should be noted that participants were generally in favour of licensing the practice.



***Question 15: How likely would you be to consent to research being conducted on your body as a secondary activity following a post mortem, anatomical study, education & training, or public display?***

**Chart 8: How likely would you be to consent to research being conducted on your body as a secondary activity following a post mortem, anatomical study, education & training, or public display?**



Two hundred and forty-three participants responded to this question.

Thirty seven (15.2%) respondents said they were “Very likely” to consent and 68 (28%) responded that they were “Likely” to consent. Forty-three (17.7%) were “Equally likely or unlikely” to consent. Twenty-nine (11.9%) were “Unlikely” to consent and 66 (27.2%) were “Very unlikely” to consent.

## Organ Donation and Transplantation (Q16-24)

### Organ Donation and Transplantation

Before responding to questions on Organ Donation, participants were given the following information:

#### Organ Donation and Transplantation

Organ transplantation takes place in three centres in Ireland:

- the National Renal Transplant Service, Beaumont Hospital;
- the National Liver Transplant Service, St Vincent's University Hospital;
- the National Heart and Lung Transplant Service at the Mater Misericordiae University Hospital.

In 2016 a total of 280 people received a life-saving organ transplant in Ireland. A total of 172 kidney transplants (122 from deceased donations and 50 from living donors); 58 liver transplants; 35 lung transplants and 15 heart transplants were performed.

The proposed legislation will provide for general conditions on the donation, removal and use of organs and tissue from deceased and living donors for the purposes of transplantation.

The proposed legislation will also prohibit the commercialisation of human organs and tissue for transplantation and the trafficking of organs for transplantation.

#### Opt Out System for Organ Donation

Currently in Ireland, the decision on organ donation rests with the next-of-kin of the deceased, including where the deceased person had an organ donor card or had indicated their wish to become an organ donor on their driving licence.

The Programme for Partnership Government includes a commitment to propose legislation for family consent and an opt-out register for organ donation. The proposed legislation will provide for the establishment of an Organ Donor Register to record the decision of individuals to opt out of organ donation.

Under the proposed system, an adult person's consent will be deemed unless a person has, while alive, registered their wish to opt out of organ donation. A person will be able to record their wish to opt out of organ donation by signing up to the Register.

If a person has recorded their wish to opt out of organ donation, their organs will not be available for transplantation.

It is envisaged that a person can remove their name from the Register at any time, should they wish to do so.

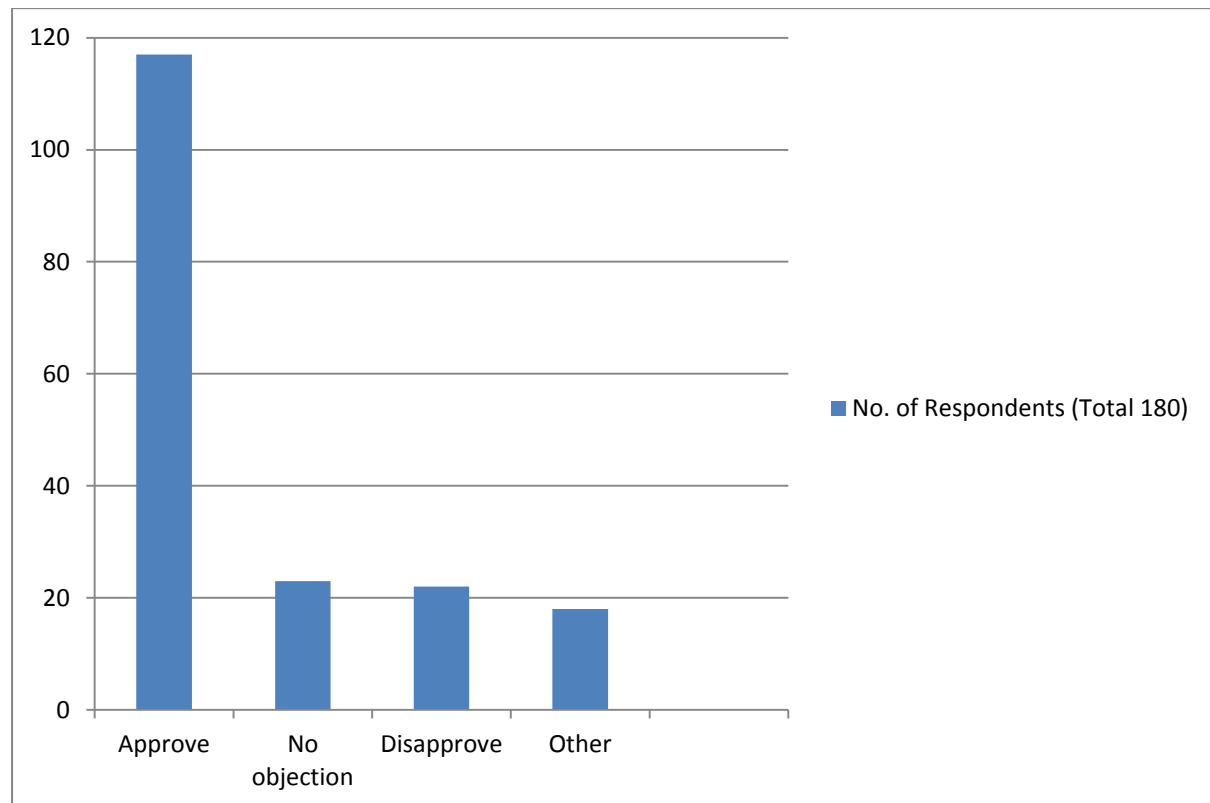
If a person has not recorded a wish to opt out, their consent will be deemed to have been given for organ donation. It will be considered that, by not opting out, the person has no objection to becoming an organ donor.

However, even if a person has not opted out, their next of kin will be consulted about the donation of the deceased person's organs. If the next of kin objects to the person becoming a donor, the person's organs will not be donated.

The opt-out system will apply to the following organs: kidney, liver, pancreas, heart and lung. It is envisaged that the proposed legislation will include provisions to allow the Minister for Health to expand the list of organs encompassed by the legislation.

***Question 16: Do you have any views/comments on the proposals regarding organ donation and transplantation?***

**Chart 9: Breakdown of comments on organ donation and transplantation**



One hundred and eighty participants responded to the question.

One hundred and seventeen respondents expressed support for the proposals (65%). Of these, four supported the proposals but also expressed a desire for a strong opt in option which could not be bypassed by the wishes of the next-of-kin and four supported the proposals while emphasising the need for additional resources to be allocated to gain the maximum benefit from these changes. Twenty-three (12.7%) respondents had no objection to the proposals. Twenty-two participants disagreed with the proposals (12.2%). Of these, 15 respondents specified a preference for the current opt-in system. Two respondents disagreed with organ donation in its entirety. The remainder (10.1%) asked questions in their comments or made comments not directly related to the proposals.

The Church of Ireland Church and Society Commission submission commented on the introduction of an opt-out register. The Commission welcomed measures to increase organ donation rates but favoured “expressed consent” over an opt-out system. They maintained that altruistic giving “lies at the heart of organ donation” and that “This essence may be

undermined by legislation for presumed consent.” In addition, they suggested that “improved education measures and specialised training” such as the presence of dedicated transplant teams would achieve the goal of increasing donation without undermining the “gift” nature of organ donation.

The Irish Donor Network, the Strange Boat Donor Foundation, and the Union of Students Ireland expressed strong support for the proposals. The Irish Lung Fibrosis Association (a member of the Irish Donor Network) commented that “The introduction of a soft opt-out organ donation system has the potential to increase the number of potential organ donors and lifesaving transplant operations that can be carried out. Family discussions on organ donation should become a routine part of end-of-life care after all treatment options have been exercised. A soft opt-out system will ensure the next-of-kin will always be involved in the decision making process and their wishes respected”.

The Irish Kidney Association (IKA) made a detailed submission with regard to organ donation. They expressed the idea that “infrastructure and support services” are key factors in increasing organ donation rates. Rather than introducing soft opt-out, the IKA advocates for a National Organ Donor Registry that presents citizens with the following form:

**If I die in the circumstances that organ and tissue donation can be considered  
(Tick one box only)**

I consent to, and Authorise, the retrieval of all my useful organs and tissue to help others

I consent to the retrieval of all my useful organs and tissue to help others, provided that authorisation is sought from my next-of-kin

I consent to my next-of-kin deciding whether the retrieval of my organs and tissue should occur

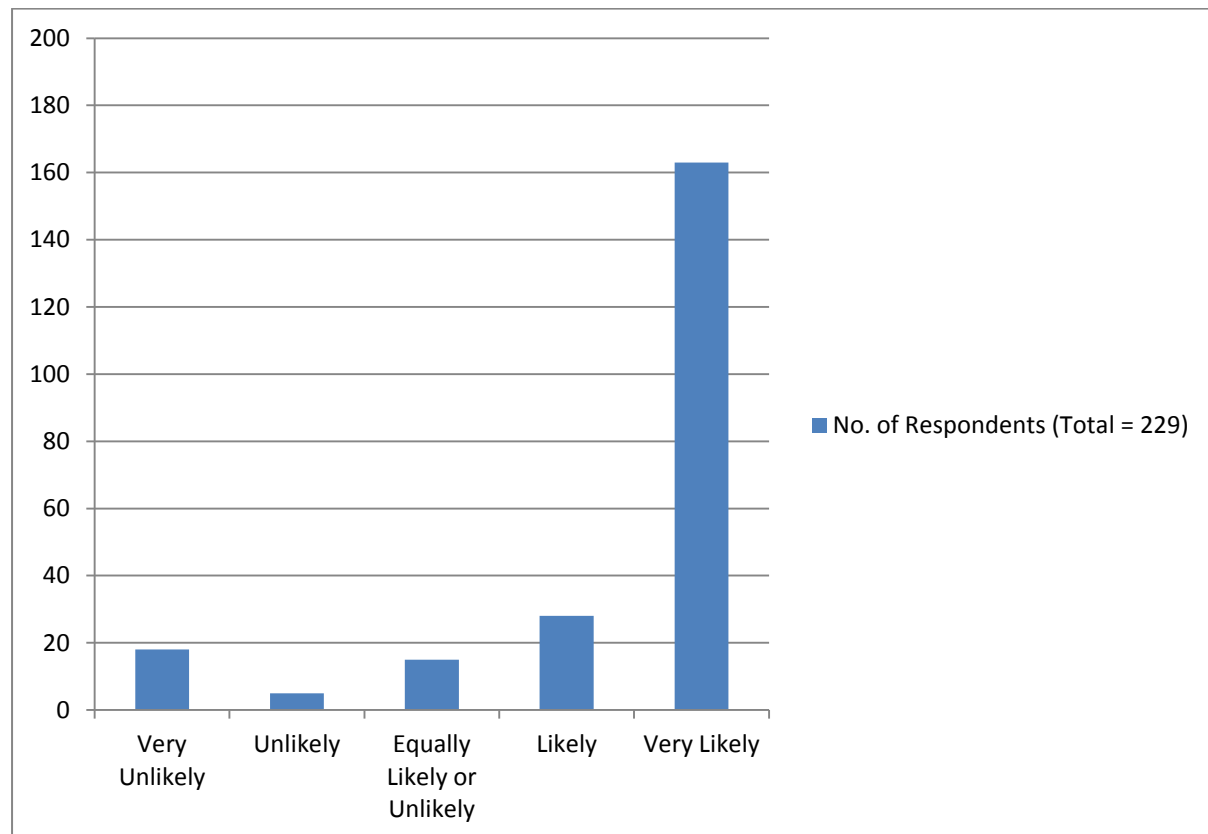
I do not consent to my organs and tissues being retrieved

The Clinical Leads for Organ Donation and Group Organ Donation Nurse Managers submitted comments on the opt-out proposals. Similar to the IKA, they draw attention to the vital importance of infrastructure and support services in increasing donation rates. They support “the appointment of Key Organ Donation Personnel with a commitment to organ donation in every hospital with an ICU in the country, training of ICU staff in all aspects of

Organ Donation, a National Organ Donation Audit, and a funding model whereby hospitals which support organ donation are reimbursed appropriately.”

**Question 17: How likely would you be to consent to organ donation on behalf of a deceased love one, if you were in the position of making that decision?**

Chart 10: How likely would you be to consent to organ donation on behalf of a deceased love one, if you were in the position of making that decision?

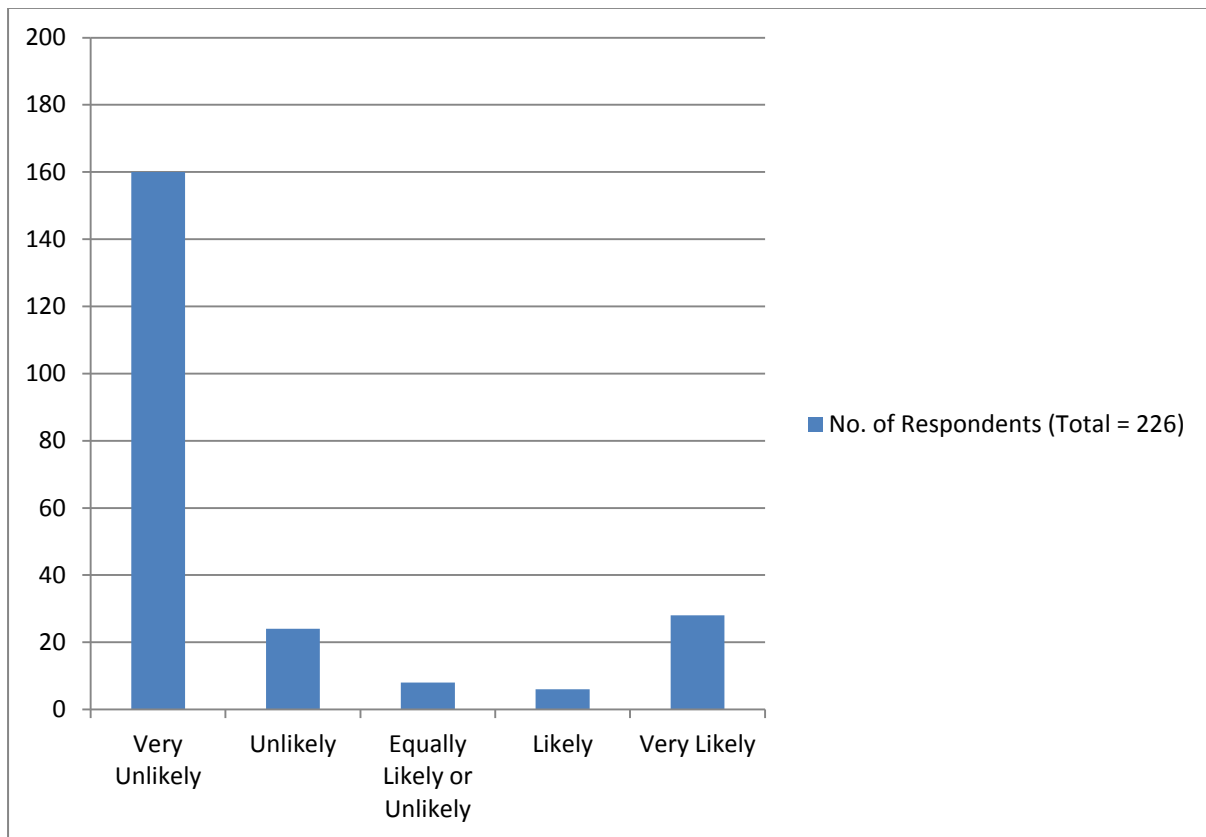


Two hundred and twenty nine participants responded to this question.

One hundred and sixty three participants (71.2%) stated that they would be “Very likely” to consent to organ donation on behalf of a deceased loved one and 28 (12.2%) would be “Likely” to consent. Fifteen participants (6.6%) were “Equally likely or unlikely” to consent. Five (2.2%) were “Unlikely” to consent and 18 (7.9%) were “Very unlikely” to consent.

***Question 18: How likely would you be to opt out of organ donation?***

**Chart 11: How likely would you be to opt out of organ donation?**



Two hundred and twenty-six participants responded to this question.

One hundred and sixty respondents (70.8%) stated that they would be “Very Unlikely” to opt out of organ donation and 24 participants (10.6%) were “Unlikely” to opt-out. Eight (3.5%) respondents were “Equally likely or unlikely” to opt-out. Six (2.7%) were “Likely” to opt out and 28 (12.4%) would be “Very likely” to opt-out.

***Question 19: What methods should be available for signing up to the register?***

Respondents were given the following options as responses.

- Online
- By Post
- Other (please specify)

More than one response option could be selected.

Two hundred and twenty-eight participants responded to this question. Two-hundred respondents checked “Online”, 168 checked “By Post”, and 78 provided suggestions under the “Other” response.

Commenters suggested various locations where a person would have the ability to opt out and to access information about organ donation, including GP practices, schools, and when accessing other public services. Many commenters emphasized the need for multiple options to maximise accessibility.

***Question 20: Do you have any further suggestions for the operation of the opt-out register?***

One hundred and fifty seven participants commented on this question. Many participants simply re-iterated their views from question 19. Thirteen participants questioned the ability of next-of-kin to over-rule a person’s desire to donate their organs and suggested a hard opt-in register alongside an opt-out register.

Several commenters emphasized the need for clear information to be provided – both about the opt-out register itself, but also about the life-saving potential of organ donation.

Comments also drew attention to the need for any public information campaign to span several types of media – print, radio, television, and internet – to ensure that information reaches all segments of the population.

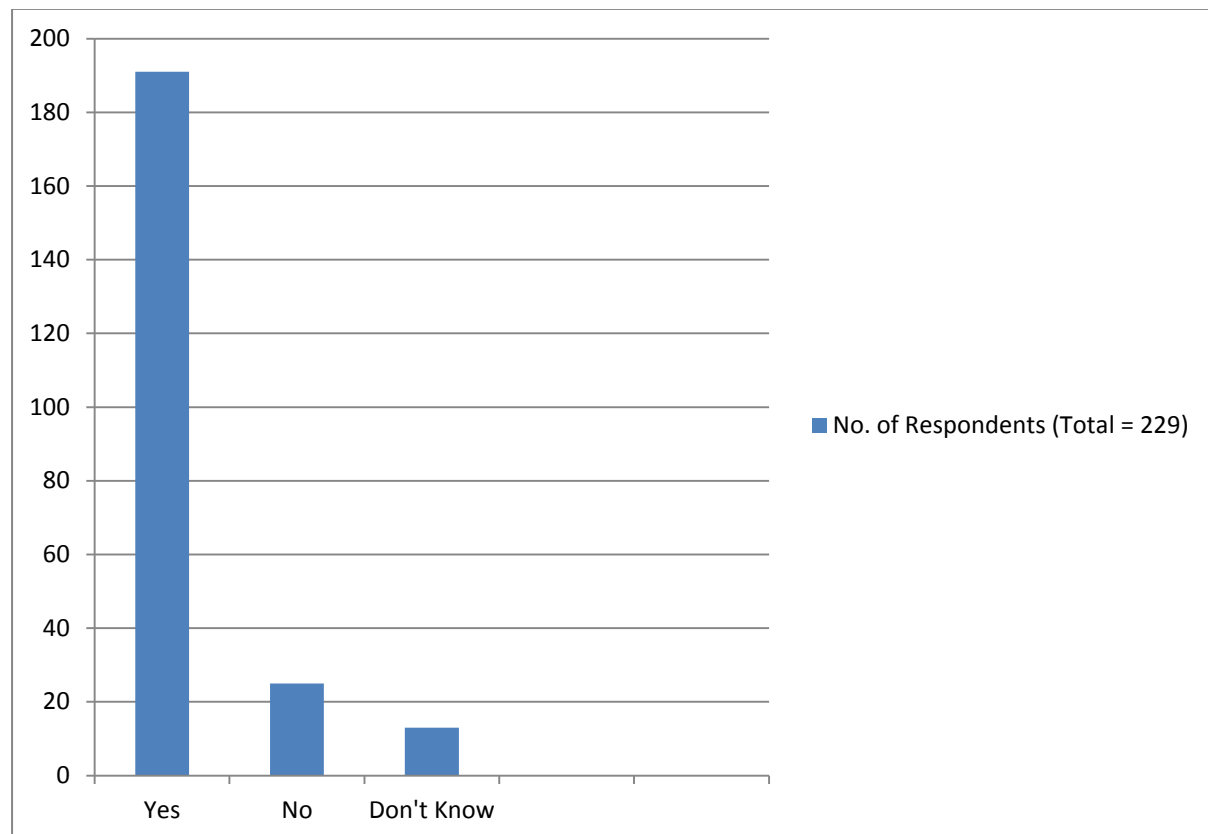
Medical professionals responding to this question emphasised the need for clear, easily understandable information to be presented to families in the position of making a decision on donation, and the need for a robust public information campaign.

The Irish Lung Fibrosis Association commented emphasising that additional funding for the HSE’s Organ Donation and Transplant Ireland should be secured. They also made detailed

suggestions with regard to the operation of the opt-out register.

***Question 21: Would the proposed opt-out system encourage you to discuss your intentions regarding organ donation with your family?***

**Chart 12: Would the proposed opt-out system encourage you to discuss your intentions regarding organ donation with your family?**



Two hundred and twenty nine participants responded to this question.

One hundred and ninety one (83.4%) respondents indicated that the proposals would encourage them to discuss organ donation with their family, while 25 (10.9%) said they would not. Thirteen participants (5.7%) indicated that they didn't know if they would discuss their intentions in future.



***Question 22: What other measures could be taken to encourage discussion of wishes surrounding organ donation amongst families?***

*and*

***Question 23: What other measures could be taken to raise awareness of the public benefits of organ donation?***

One hundred and sixty nine participants responded to question 22 and 168 responded to question 23. Responses to these two questions included the same emphases and suggestions.

Television, radio, and online/social media information campaigns were suggested by many commenters. It was suggested that such campaigns should be launched at regular intervals so that public awareness remains high.

It was also frequently suggested that there should be public information campaigns in schools for students approaching the age of 18, in third level institutions, and in GP practices nationwide.

Many commenters suggested that these campaigns should involve highlighting the stories of those who have benefitted from, or are in need of, organ donations.

Medical professionals emphasized the need for training to ensure that discussions during difficult times are handled with care and respect.

***Question 24: Do you have any further comments regarding the legislation overall?***

One hundred and forty-one respondents made further comments.

Fifty three comments expressed support for the proposals.

The remaining comments touched upon a range of issues, mostly dealing with the proposals for an opt-out system of consent for organ donation, including the following:

- Concern that next-of-kin could override an individuals' decision to donate under a soft opt-out system
- Emphasizing that changing to an opt-out system is not in itself sufficient to increase organ donation
- Expression of a preference for an opt-in system for a variety of reasons

## Introduction

In July 2017, the Government approved the drafting of a Human Tissue Bill to:

- Regulate the removal, retention, storage, use and disposal of human tissue from deceased persons;
- Provide general conditions for the removal, donation and use of organs and tissues from deceased and living persons for the purposes of transplantation; and
- Provide for an opt-out system of consent for organ donation and for an associated register.

The goals of the Human Tissue Bill are underpinned by the principles of protection of the bodily integrity of the individual before and after death, and of respect for the autonomy of the individual and the rights of the bereaved.

The proposed legislation will include, amongst others, provisions, on:

- Post mortem practice and procedures
- Anatomical examination/education & training
- Public display of bodies after death
- Organ donation and transplantation

The purpose of this consultation is to seek your views on the proposals to inform the drafting of the Bill:

- Part 1 of the consultation relates to post mortem practices and procedures, anatomical examination/education & training and the public display of bodies after death;
- Part 2 of the consultation relates to organ donation and transplantation.

All submissions received will be subject to the Freedom of Information Act (2014) By continuing, you acknowledge that you are aware that your responses may be released in response to a Freedom of Information request.

### 1. Name (Optional)

### 2. Gender (Optional)

☐ Male

☐ Female

☐ Other (Specify if desired)

3. Age (Optional)

- ☐ 18-35
- ☐ 36-55
- ☐ 56-75
- ☐ 75+

4. County of Residence (Optional)

5. Are you responding as a... (click all that apply)

- ☐ Member of the public
- ☐ Medical professional
- ☐ Medical/ Scientific Educator
- ☐ Member of an organisation that deals with issues addressed in the bill (Please specify below)
- ☐ Other (please specify)



## **Post Mortem practice (Recommendations of the Madden Report)**

The proposed legislation will implement the recommendations of the Madden Report on Post Mortem Practices and Procedures (2006) relating to consent provisions for hospital post mortems and provisions on the retention, storage, use and disposal of organs and tissue from deceased persons following post mortem examination.

The major recommendation of the Madden Report was that there is a need for legislation to create a framework for consent, both for hospital post mortems and for the use or retention of any part of the body for any reason following a post mortem.

The provisions of the Bill will not affect the practice of a Coroner's post mortem, for which consent is not required. It is proposed that this legislation will complement the provisions in the Coroner's Act 1962.

It is proposed that the Bill will provide for a coherent overall policy framework and will ensure consistency in relation to the process of seeking consent and record management relating to hospital post mortem examinations.

It is proposed that a hospital post mortem may be conducted for one (or more) of the following reasons:

- Determining or providing more information on the cause of death;
- Providing information on the effectiveness of a medical or surgical intervention administered to the person;
- Obtaining scientific and medical information which may be of benefit to another person now or in the future;
- Education & training of medical professionals;
- Clinical audit.

## **Anatomical Examination/Education & Training of Medical Practitioners**

Anatomy is the study of the structure of the body and anatomical examination is the examination of a deceased body or its constituent parts for the purposes of education, training or research.

The practice of anatomy is currently regulated under the Anatomy Act 1832. It is proposed that the Human Tissue Bill will repeal this Act and replace it with an updated framework in relation to licensing, consent, the donation of bodies to anatomy schools and provisions for the setting of guidelines and standards to be met in the practice of anatomy.

It is proposed that the legislation will also include provisions to regulate the use of human organs and tissue in the education & training of medical practitioners. The intention is to provide for the regulation of education & training practices not covered by anatomy.

## **Public Display**

It is proposed that the public display of bodies or body parts after death, whether temporary or permanent, will require a licence by an appropriate regulatory authority. Before a licence is issued the appropriate regulatory authority will require documentary evidence of provenance and consent. It is envisaged that the proposed legislation will include exemptions for activities associated with funerals, the display of religious relics and for the display of bodies and body parts after death where the death occurred over one hundred years ago.

6. Do you have views/ comments on the above proposals regarding post mortem practice and procedures?

7. Do you have views/ comments on the above proposals regarding anatomical examination or education & training?

8. Do you have views/ comments on the above proposals regarding public display?

### Consent

One of the aims of the proposed legislation is to ensure that informed consent has been received before an individual engages in any of the following designated activities:

- Hospital post mortem;
- Anatomy/education & training;
- Public display.

The proposed legislation will also provide that consent is received for any secondary activity, e.g. research that may take place following a post mortem, anatomy/ education & training or public display. Consent for a hospital post mortem can be given by:

- The person in writing (before their death);
- The person orally in the presence of two witnesses; or
- In some circumstances, the person next of kin may be approached to give consent for a hospital post mortem.

It is important that individuals comprehend what they are giving consent for (i.e. informed consent). It is proposed that the legislation will set out guidelines on the information a person requires to make an informed decision with regard to a hospital post mortem.

Consent for the use of tissues and organs for the purposes of anatomy/education & training or public display can be given by:

- The person in writing (before their death); or
- The person orally in the presence of two witnesses.

9. How likely would you be to consent to doctors performing a hospital post mortem after your death?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. What information would you like to receive from medical professionals to help you make this decision?  
(check all that apply)

- |   |  |
|---|--|
| <input type="checkbox"/> Which organs will be removed?                        | <input type="checkbox"/> A detailed account of the medical procedure         |
| <input type="checkbox"/> How long will they be kept?                          | <input type="checkbox"/> A very detailed account of the medical procedure    |
| <input type="checkbox"/> How will they be returned to the family/disposed of? | <input type="checkbox"/> The purpose for which the material is being removed |
| <input type="checkbox"/> An overview of the medical procedure                 | <input type="checkbox"/> The benefits of the information to be gained.       |
| <input type="checkbox"/> Other (please specify)                               |  |

11. If doctors requested to perform a hospital post mortem on a loved one after their death, how likely would you be to consent?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. What information would you like to receive from medical professionals to help you make this decision?  
(check all that apply)

- |   |  |
|---|--|
| <input type="checkbox"/> Which organs will be removed?                        | <input type="checkbox"/> A detailed account of the medical procedure         |
| <input type="checkbox"/> How long will they be kept?                          | <input type="checkbox"/> A very detailed account of the medical procedure    |
| <input type="checkbox"/> How will they be returned to the family/disposed of? | <input type="checkbox"/> The purpose for which the material is being removed |
| <input type="checkbox"/> An overview of the medical procedure                 | <input type="checkbox"/> The benefits of the information to be gained        |
| <input type="checkbox"/> Other (please specify)                               |  |

13. How likely would you be to consent to your body being used in the practice of anatomy/ education & training after your death?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. How likely would you be to consent to your body being used for public display after your death?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

15. How likely would you be to consent to research being conducted on your body as a secondary activity following a post mortem, anatomical study, education & training, or public display?

Very unlikely to consent	Unlikely to consent	Equally likely or unlikely	Likely to consent	Very likely to consent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Part 2

## Organ Donation and Transplantation

Organ transplantation takes place in three centres in Ireland:

- the National Renal Transplant Service, Beaumont Hospital;
- the National Liver Transplant Service, St Vincent's University Hospital;
- the National Heart and Lung Transplant Service at the Mater Misericordiae University Hospital.

In 2016 a total of 280 people received a life-saving organ transplant in Ireland. A total of 172 kidney transplants (122 from deceased donations and 50 from living donors); 58 liver transplants; 35 lung transplants and 15 heart transplants were performed.

The proposed legislation will provide for general conditions on the donation, removal and use of organs and tissue from deceased and living donors for the purposes of transplantation.

The proposed legislation will also prohibit the commercialisation of human organs and tissue for transplantation and the trafficking of organs for transplantation.

16. Do you have any views/comments on the proposals regarding organ donation and transplantation?

### Opt Out System for Organ Donation

Currently in Ireland, the decision on organ donation rests with the next-of-kin of the deceased, including where the deceased person had an organ donor card or had indicated their wish to become an organ donor on their driving licence.

The Programme for Partnership Government includes a commitment to propose legislation for family consent and an opt-out register for organ donation. The proposed legislation will provide for the establishment of an Organ Donor Register to record the decision of individuals to opt out of organ donation.

Under the proposed system, an adult person's consent will be deemed unless a person has, while alive, registered their wish to opt out of organ donation. A person will be able to record their wish to opt out of organ donation by signing up to the Register.

If a person has recorded their wish to opt out of organ donation, their organs will not be available for transplantation.

It is envisaged that a person can remove their name from the Register at any time, should they wish to do so.

If a person has not recorded a wish to opt out, their consent will be deemed to have been given for organ donation. It will be considered that, by not opting out, the person has no objection to becoming an organ donor.

However, even if a person has not opted out, their next of kin will be consulted about the donation of the deceased person's organs. If the next of kin objects to the person becoming a donor, the person's organs will not be donated.

The opt-out system will apply to the following organs: kidney, liver, pancreas, heart and lung. It is envisaged that the proposed legislation will include provisions to allow the Minister for Health to expand the list of organs encompassed by the legislation.

17. How likely would you be to consent to organ donation on behalf of a deceased loved one, if you were in the position of making that decision?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

18. How likely would you be to **opt-out** of organ donation?

Very unlikely	Unlikely	Equally likely or unlikely	Likely	Very likely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

19. What methods should be available for signing up to the register?

- ☐ Online
- ☐ By Post
- ☐ Other (please specify)

20. Do you have any further suggestions for the operation of the Opt Out Register?

One of the aims of the legislation is to make organ donation the norm in Ireland when people pass away in circumstances in which donation is a possibility. The introduction of an opt-out system of consent for organ donation will be accompanied by a publicity campaign aiming to raise awareness of organ donation among individuals and to encourage discussion among families of their intentions in relation to organ donation.

A range of measures have been put in place to foster a strong culture of organ donation, optimise conversion rates and ultimately increase the number of transplantations that are carried out each year.

Steps taken to increase organ donation include:

- the establishment of the HSE's National Organ Donation & Transplantation Office to lead and coordinate organ donation and transplantation;
- the establishment of a National Organ Procurement Service; and
- the appointment of donation personnel across the hospital network.

21. Would the proposed opt out system encourage you to discuss your intentions regarding organ donation with your family?

- ☐ Yes
- ☐ No
- ☐ Don't Know

22. What other measures could be taken to encourage discussion of wishes surrounding organ donation amongst families?



23. What other measures could be taken to raise awareness of the public benefits of organ donation?

24. Thank you for your participation in this public consultation. Do you have any final comments regarding the legislation overall?