DÁIL ÉIREANN

AN BILLE UM FHÍOCHÁN DAONNA (TRASPHLANDÚ, SCRÚDÚ IARBHÁIS, SCRÚDÚ ANATAMAÍOCH AGUS TAISPEÁINT PHOIBLÍ), 2022
HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL EXAMINATION AND PUBLIC DISPLAY) BILL 2022

LEASUITHE TUARASCÁLA
REPORT AMENDMENTS

[No. 121a of 2022] [07 November, 2023]

DÁIL ÉIREANN

An Bille um Fhíochán Daonna (Trasphlandú, Scrúdú Iarbháis, Scrúdú Anatamaíoch agus Taispeáint Phoiblí), 2022
—AN TUARASCÁIL

HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL EXAMINATION AND PUBLIC DISPLAY) BILL 2022
—REPORT

Leasuithe
Amendments

1. In page 7, to delete line 13 and substitute the following:

"the carrying out of post-mortem examinations in hospitals and other non-hospital settings and the regulation of such activity;".

—An tAire Sláinte.

2. In page 12, to delete lines 31 to 33 and substitute the following:

"(iii) the seeking and obtaining of post-mortem consent in relation to any proposed post-mortem activity in respect of a relevant person in accordance with *Part 3*.".

—An tAire Sláinte.

3. In page 13, to delete lines 3 to 5 and substitute the following:

"(iii) seeking and obtaining of post-mortem consent in relation to any proposed post-mortem activity in respect of a relevant person in accordance with *Part 3*,".

—An tAire Sláinte.

4. In page 15, line 35, to delete "2005)," and substitute "2005), or".

—An tAire Sláinte.

5. In page 21, between lines 22 and 23, to insert the following:

"12. (1) All hospitals must have a policy in place requiring all families of suitable donors to be asked to give consent to their loved ones' organs and tissues to be used for transplant and records must be kept with statistics to be published in the Annual Audit of Potential Organ Donors. A designated requester must tell the families of suitable donors that their loved ones' organs and tissues can be used for transplant.".

—David Cullinane.

6. In page 24, between lines 23 and 24, to insert the following:

"Review of operation of Relevant Organ Donation Opt-Out Register

17. (1) The Minister shall, not later than 3 years after the commencement of this section, carry out a review of the operation of the Relevant Organ Donation Opt-Out Register.

(2) In carrying out a review under *subsection (1)*, the Minister may consult with such and so many persons and he or she considers appropriate.".

—An tAire Sláinte.

7. In page 24, between lines 23 and 24, to insert the following:

"Transplantation and Donation Audit

17. The Minister shall by way of regulation direct the Executive to publish an annual audit of the activities of procurement organisations and transplantation centres which includes:

(a) The number of deaths in hospitals;

(b) The number of potential donors;

(c) The number of donors requested to donate;

(d) The number of donors assessed as being medically suitable for donation and where donation was not feasible, identifies the reasons;

(e) The responses of families or next of kin to organ donor requests, classified by reason;

(f) The number of organ retrievals, classified by the reason retrieval was not feasible; and

(g) The number of transplants, classified by the reason transplantation was not feasible.".

—Róisín Shortall.

8. In page 27, to delete lines 32 to 34 and substitute the following:

"(b) the removal of the organ for the purpose of transplantation is for therapeutic benefit and no reward has been or is to be given, and there is no other alternative therapeutic method of comparable effectiveness;".

—David Cullinane.

9. In page 27, to delete lines 32 to 34 and substitute the following:

"(b) no reward has been or is to be given for the removal of the organ for the purpose of transplantation and there is no other alternative therapeutic method of comparable effectiveness;".

—Gino Kenny.

10. In page 27, line 33, after "recipient" to insert "or recipients in the case of an approved State sharing scheme,".

—Róisín Shortall.

11. In page 28, to delete lines 20 to 22 and substitute the following:

"(b) the removal of the organ for the purpose of transplantation is for therapeutic benefit and no reward has been or is to be given, and there is no other alternative therapeutic method of comparable effectiveness;".

—David Cullinane.

12. In page 28, to delete lines 20 to 22 and substitute the following:

"(b) no reward has been or is to be given for the donation of such tissues and there is no other alternative therapeutic method of comparable effectiveness;".

—Gino Kenny.

13. In page 29, to delete lines 8 to 10 and substitute the following:

"(b) the removal of the organ for the purpose of transplantation is for therapeutic benefit and no reward has been or is to be given, and there is no other alternative therapeutic method of comparable effectiveness;".

—David Cullinane.

14. In page 29, to delete lines 8 to 10 and substitute the following:

"(b) no reward has been or is to be given for the removal of the organ for the purpose of transplantation and there is no other alternative therapeutic method of comparable effectiveness;".

—Gino Kenny.

15. In page 29, line 9, after "recipient" to insert "or recipients in the case of an approved State sharing scheme,".

—Róisín Shortall.

16. In page 30, line 35, to delete "*section 10* and any regulations made under that section" and substitute "*section 10*".

—An tAire Sláinte.

17. In page 31, lines 16 and 17, to delete "Minister for Public Expenditure and Reform" and substitute "Minister for Public Expenditure, National Development Plan Delivery and Reform".

—An tAire Sláinte.

18. In page 32, to delete line 4 and substitute the following:

"(e) at least 2 shall be patient advocates and, of those 2, at least one may be a donor patient advocate.".

—An tAire Sláinte.

19. In page 32, between lines 4 and 5, to insert the following:

"(f) at least one shall be an adult member of donor families.".

—David Cullinane.

20. In page 35, to delete lines 34 to 38, to delete pages 36 and 37, and in page 38, to delete lines 1 to 4, and substitute the following:

"CHAPTER 50
RELEVANT ORGAN DONATION REGISTER

Relevant Organ Donation Register

31. (1) The Executive shall, as soon as practicable after the commencement of this section, establish and maintain in such form as it considers appropriate, a register to be known as the Relevant Organ Donation Register (in this Part referred to as "the Register").

(2) The Executive shall make an entry in the Register of the details specified in *subsection (3)* of *section 32** in respect of an adult who has registered their wishes in relation to their relevant organs in accordance with that section.

(3) Where the Executive has made an entry in the Register, it shall contact the person in respect of whom the entry has been made, in the manner specified by the Executive, to confirm the details of the entry.

(4) Only the Executive may access the information contained in the Register and the contents of the Register shall not be available to the public.

(5) The Executive shall take such steps as it considers necessary to ensure that the particulars entered in the Register are accurate.

(6) The Executive may, for the purposes of maintaining the accuracy of the Register and, where it considers it appropriate to do so, amend or delete any particulars entered in the Register.

Application to register choice in relation to being relevant organ donor

32. (1) An adult (in this section referred to as the "applicant") may apply to the Executive to register their choice in relation to being an organ donor of their relevant organs and where they do so, the Executive shall register that choice on the Register.

(2) An application under *subsection (1)* shall—

(a) be in writing or online, and

(b) subject to *subsection (3)*, be in such form and manner as is specified by the Executive.

(3) When making an application under *subsection (1)*, an applicant shall provide the following information to the Executive:

(a) their forename, surname and any former surnames;

(b) their mother's birth surname;

(c) their address;

(d) their sex;

(e) their nationality and date and place of birth;

(f) their personal public service number (if any) (within the meaning of section 262 of the Social Welfare Consolidation Act 2005);

(g) where known, their individual health identifier (within the meaning of the Health Identifiers Act 2014);

(h) such other information as the Executive may, from time to time, reasonably specify for the purposes of maintaining the Register.

(4) A person may apply to the Executive to—

(a) amend their information on the Register provided in accordance with *subsection (3)*, or

(b) change their choice provided in accordance with *subsection (1)* and have their details amended in the Register.

(5) An application under *subsection (4)* shall—

(a) be in writing, and

(b) be in such form and manner as specified by the Executive.

(6) A registered decision on the Register by a person under *subsection (1)* shall remain on the Register for the lifetime of that person unless they change their choice in accordance with *subsection (4)(b).*

(7) A person shall not make—

(a) an application under subsection (1) to register any person other than themselves on the Register, or

(b) an application under *subsection (4)(a)* or *(b)* in respect of the information or choice contained on the Register relating to any person other than himself or herself, without that person's knowledge and consent.

(8) A person who contravenes *subsection (7)* shall be guilty of an offence.

Application to ascertain if choice is registered on Register

33. (1) A relevant professional shall, for the purpose of determining whether or not deemed consent applies in respect of a deceased person, apply to the Executive to ascertain whether or not the deceased person has registered their choice on being an organ donor in accordance with *section 32**.

(2) On receipt of an application under *subsection (1)*, the Executive shall, as soon as practicable, consult the Register and confirm whether or not the person the subject of the application has registered their choice on being an organ donor.

(3) An application under *subsection (1)* shall be made in such form and manner as may be specified by the Executive.

(4) Where a relevant professional has received information provided by the Executive in relation to a person in accordance with *subsection (2)*, they may disclose such information to the designated family member—

(a) where the person the subject of the application has registered their choice in relation to organ donation on the Register in accordance with *section 32** and the designated family member has enquired about potential organ donation relating to the person concerned, or

(b) where the person the subject of the application has not registered their objection to organ donation on the Register in accordance with *section 32** and deemed consent applies to the proposed donation.

(5) A relevant professional shall not remove any relevant organ for the purposes of transplantation activities from a person where the person has registered their objection to organ donation on the Register in accordance with *section 32** and that objection has not been withdrawn at the time of the person's death.".

—David Cullinane.

[* *This is a reference to the section proposed to be inserted by this amendment.*]

21. In page 38, betwen lines 4 and 5, to insert the following:

"Review of the Opt-Out Register

34. The Minister shall, within two years of the passing of this Act, lay a report before both Houses of the Oireachtas reviewing the organ donation opt-out register and examining the merits of introducing a corresponding organ donation opt-in register.".

—Róisín Shortall.

22. In page 43, between lines 24 and 25, to insert the following:

"(2) By the substitution of the following regulation for Regulation 25:

"25 (1) The HSE shall—

(a) keep a record of and publish the annual activities of procurement organisations and transplantation centres, at hospital level, including aggregated numbers of living and deceased donors and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with European Union and national provisions on the protection of personal data and statistical confidentiality, to include:

(i) Deaths in hospitals;

(ii) Number of potential donors;

(iii) Number of donors actually requested to donate;

(iv) Number of donors assessed as being medically suitable for donation with classification of reasons why donation is not feasible;

(v) Families or next of kin response to organ donor requests with classification of reasons;

(vi) Number of organ retrievals with classification of reasons why retrieval is not feasible;

(vii) Number of transplants with classification of reasons why transplantation is not feasible,

(b) draw up and make publicly accessible an annual report on activities referred to in paragraph (a), and

(c) establish and maintain an updated record of procurement organisations and transplantation centres.”.”.

—David Cullinane.

23. In page 44, to delete line 1 and substitute the following:

“ “coronial post-mortem examination” means a post-mortem examination directed by or on behalf of a coroner under the Coroners Acts 1962 to 2023 in relation to a deceased person;”.

—An tAire Sláinte.

24. In page 45, to delete lines 35 to 38 and substitute the following:

“38. (1) Subject to *subsection (2)*, this Part shall apply to post-mortem activities and coronial post-mortem examinations that take place on or after the commencement of this section in a hospital (whether public or private) and a reference in this Part to a “hospital” includes a reference—

(a) to a private hospital, and

(b) to a facility (howsoever described) other than a hospital or relevant facility, within the meaning of section 2 of the Act of 1962, where post-mortem activities are carried out in accordance with this Part by service providers (within the meaning of section 2 of the Health Act 2004), pursuant to section 38 of that Act.”.

—An tAire Sláinte.

25. In page 46, to delete lines 4 to 7 and substitute the following:

“(b) subject to the operation as necessary of sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O of the Act of 1962, coronial post-mortem examinations.”.

—An tAire Sláinte.

26. In page 46, to delete lines 10 to 13 and substitute the following:

"39. (1) Subject to *subsections (3)* and *(4)**, the Minister may make such regulations as he or she considers necessary or expedient for the management in the most respectful and appropriate manner possible of post-mortem activities and coronial post-mortem examinations that take place in a hospital.".

—An tAire Sláinte.

[**This is the correct reference if amendment no. 28 is accepted.*]

27. In page 46, to delete lines 16 to 27 and substitute the following:

"(a) procedures for the retention, storage, disposal or return of material removed from the body as part of the coronial or non-coronial post-mortem examination, where such action is consistent with guidelines but shall not include tissue samples held on blocks or slides, trimmings or bodily fluids removed during the examination;

(b) the arrangements to be put in place by hospitals for—

(i) the management of authorisations (within the meaning of section 2 of the Act of 1962) under section 33F of that Act,

(ii) the designation of persons or classes or persons responsible for the management of such authorisations, and

(iii) the carrying out of the authorisations received from the coroner in that regard;

(c) incidents and particulars of incidents to be notified to the Authority;

(d) prescribing the retention periods for records and samples arising from non-coronial post-mortem activities, each of which periods (other than in the case of records and samples which are toxicology samples, trimmings or bodily fluids) shall not be less than 5 years;".

—An tAire Sláinte.

28. In page 46, to delete lines 30 to 33.

—An tAire Sláinte.

29. In page 46, between lines 38 and 39, to insert the following:

"(d) the Chief State Pathologist;".

—An tAire Sláinte.

30. In page 47, to delete lines 7 to 10.

—An tAire Sláinte.

31. In page 52, line 4, to delete "shall be retained" and substitute "shall".

—An tAire Sláinte.

32. In page 52, line 5, to delete "with" and substitute "be retained".

—An tAire Sláinte.

33. In page 52, line 6, to delete "the medical records" and substitute "with the medical records".

—An tAire Sláinte.

34. In page 52, lines 8 and 9, to delete "be retained in accordance" and substitute "in accordance".

—An tAire Sláinte.

35. In page 52, line 12, to delete "for such period" and substitute "be retained for such period".

—An tAire Sláinte.

36. In page 54, line 28, to delete "there is a risk" and substitute "where there is a risk".

—An tAire Sláinte.

37. In page 55, to delete line 28 and substitute the following:

"51. (1) A hospital at which post-mortem activities or coronial post-mortem examinations, as the case may be, take place or will take place shall, subject to *subsection (2)*, as soon".

—An tAire Sláinte.

38. In page 55, between lines 32 and 33, to insert the following:

"(2) A nominated person shall be an employee of the hospital concerned and shall be a suitably qualified person by reason of his or her training and experience to discharge the responsibilities of a nominated person.".

—An tAire Sláinte.

39. In page 55, line 34, to delete "activities" and substitute "activities or coronial post-mortem examinations".

—An tAire Sláinte.

40. In page 55, line 36, to delete "activities" and substitute "activities or coronial post-mortem examinations".

—An tAire Sláinte.

41. In page 56, to delete lines 6 to 9 and substitute the following:

"(3) A hospital in which post-mortem activities or coronial post-mortem examinations take place or will take place shall inform the Authority of the name and particulars of the person nominated under *subsection (1)*.".

—An tAire Sláinte.

42. In page 56, to delete lines 14 to 16 and substitute the following:

"(5) A hospital at which post-mortem activities or coronial post-mortem examinations take place shall, notwithstanding the nomination by the hospital of a nominated person, at

all times remain responsible for, and accountable to the Authority in respect of, compliance with this Part.".

—An tAire Sláinte.

43. In page 56, line 22, to delete "definition" and substitute "definitions".

—An tAire Sláinte.

44. In page 56, to delete lines 23 and 24 and substitute the following:

" "Act of 1962" means the Coroners Act 1962;

"coronial post-mortem examination" has the same meaning as it has in *section 38* of the *Act of 2023*;

"non-coronial post-mortem examination" has the same meaning as it has in *section 38* of the *Act of 2023*;

"relevant facility" has the same meaning as it has in section 2 of the Act of 1962;

"relevant sections of the Act of 1962" means sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O;".

—An tAire Sláinte.

45. In page 56, to delete lines 25 to 27 and substitute the following:

"(b) in section 8(1)—

(i) in paragraph (n), to substitute "(S.I. No. 256 of 2018);" for "(S.I. No. 256 of 2018).", and

(ii) by the insertion of the following paragraphs after paragraph (n):

"(o) to monitor compliance with *Part 3* of the *Act of 2023* and any regulations made under that Part;

(p) to monitor compliance with the relevant sections of the Act of 1962 and with any regulations made by the Minister for Justice under section 331 of that Act.".".

—An tAire Sláinte.

46. In page 56, to delete lines 29 to 40, and in page 57, to delete lines 1 to 19 and substitute the following:

" "Provision of information to Authority for purposes of monitoring compliance with *Part 3* of *Act of 2023* and relevant sections of Act of 1962 in accordance with subsection (1)(o) and (1)(p) of section 8

12A. (1) A hospital, within the meaning of *section 38* of the *Act of 2023*, at which post-mortem activities or coronial post-mortem examinations take or will take place shall, as soon as practicable after the commencement of this section and in any event, not later than 3 months after such commencement, notify the Authority in writing of

the following, namely:

(a) the name and particulars of the nominated person nominated in that behalf pursuant to *section 52* of the *Act of 202*3;

(b) in the case of a hospital where post-mortem activities or coronial post-mortem examinations take place or will take place, the name and address of the hospital;

(c) in the case of a hospital where post-mortem activities or coronial post-mortem examinations take place or will take place, the details of post-mortem activities or coronial post-mortem examinations that take place or will take place on the premises.

(2) Where the hospital changes in a material way any of the matters notified under subsection (1), the hospital shall as soon as possible and, in any event, not later than 28 days after the material changes, inform the Authority in writing and provide it with details of the changes.

(3) Without prejudice to the generality of subsection (1), the Authority may require the Executive or the hospital at which the post-mortem activities or coronial post-mortem examinations take place or will take place to provide it within such reasonable period as the Authority may require with any information or statistics the Authority requires in order to determine the level of compliance by the Executive or hospital with *Part 3* of the *Act of 2023*.

(4) Where a person receives a request under subsection (3) from the Authority, he or she shall comply with such request.",".

—An tAire Sláinte.

47. In page 57, to delete lines 21 to 39, and in page 58, to delete lines 1 to 15 and substitute the following:

"(i) in subsection (1)(a), by the substitution of "section 8(1)(c)," for "section 8(1)(c), or",

(ii) by the insertion, in subsection (1), of the following paragraphs after paragraph (b):

"(c) monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or

(d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,",

(iii) in subsection (2)(a), by the substitution of "section 8(1)(c)," for "section 8(1)(c), or", and

(iv) by the insertion, in subsection (2), of the following paragraphs after paragraph (b):

"(c) monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or

(d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act.",

(e) in section 73—

(i) by the substitution of the following subsection for subsection (1):

"(1) If an authorised person considers it necessary or expedient for the purposes of—

(a) monitoring compliance with standards in accordance with section 8(1)(c),

(b) an investigation referred in in section 8(1)(d),

(c) monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or

(d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,

the authorised person may enter and inspect at any time—

(i) any premises owned or controlled by the Executive, the Agency or a service provider,

(ii) any premises used or proposed to be used, for any purpose connected with the provision of services described in section 8(1)(b), or

(iii) any relevant facility.",

(ii) by the insertion of the following after subsection (3):

"(3A) If an authorised person considers it necessary or expedient for the purposes of monitoring compliance—

(a) with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or

(b) with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act in accordance with section 8(1)(p),

the authorised person, at any time, may carry out the functions conferred on the authorised person under this section and sections 75 and 76 to the extent that the functions relate to any premises referred to in subsection (1).",

(iii) in subsection (4)—

(I) by the substitution of the following paragraph for paragraph (a):

"(a) inspect, take copies of or extracts from and remove from the premises any documents or records (including personal records) relating to the discharge of its functions by the Executive or the Agency or the discharge of the functions of the coroner in so far only as it relates to monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act, or to the services provided by a service provider or at a designated centre,",

and

(II) in paragraph (c)(i), by the substitution of "section 8(1)(d), or monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act" for "section 8(1)(d)",

(iv) in subsection (5)(b)—

(I) in subparagraph (i), by the substitution of "section 8(1)(d), or monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o) or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act," for "section 8(1)(d)", and

(II) in subparagraph (ii), by the substitution of "investigation or to the monitoring of compliance with regulations or," for "investigation or,",

and

(v) in subsection (7)—

(I) in paragraph (a), by the substitution of "section 8(1)(c)," for "section 8(1)(c), or", and

(II) the insertion of the following paragraphs after paragraph (b):

"(c) monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o), or

(d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,",

(f) in section 75—

(i) in subsection (1)(a), by the substitution of "section 8(1)(d) or monitoring compliance with *Part 3* of the *Act of 2023* in accordance with section 8(1)(o)

or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act" for "section 8(1)(d)", and

(ii) in subsection (2)(a)(i), by the substitution of "section 8(1)(d) or monitoring compliance with *Part 3* of the Act of 2023 in accordance with section 8(1)(o) or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act" for "section 8(1)(d)",

and

(g) in section 77A(2), to substitute the following paragraph for paragraph (a):

"(a) the monitoring of compliance with standards under section 8(1)(c), compliance with *Part 3* of the *Act of 2023* under section 8(1)(o) and compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,".".

—An tAire Sláinte.

48. In page 58, line 37, to delete "within a period of 14 days from" and substitute "on and after".

—An tAire Sláinte.

49. In page 59, lines 16 and 17, to delete "district or circuit, as the case may be," and substitute "district".

—An tAire Sláinte.

50. In page 59, line 25, to delete "activities" and substitute "activities or coronial post-mortem examinations".

—An tAire Sláinte.

51. In page 60, line 4, to delete "activities" and substitute "activities or coronial post-mortem examinations".

—An tAire Sláinte.

52. In page 61, to delete lines 14 and 15.

—An tAire Sláinte.

53. In page 61, line 27, to delete "Court considers" and substitute "Court considers appropriate".

—An tAire Sláinte.

54. In page 61, between lines 29 and 30, to insert the following:

"Amendment of section 2 of Act of 1962

56. Section 2 of the Act of 1962 is amended by—

(a) the insertion of the following definitions:

" '*Act of 2023*' means the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2023*;

'Authority' means the Health Information and Quality Authority;

'designated person' means—

(a) in relation to a hospital, the person designated in that behalf by the hospital concerned to receive and act in accordance with authorisations from family members of deceased persons under section 33F, and

(b) in relation to a relevant facility, the person designated in that behalf to receive and act in accordance with authorisations from family members of deceased persons under section 33F;

'Executive' means the Health Service Executive;

'healthcare professional' means—

(a) a registered medical practitioner,

(b) a registered nurse or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011, or

(c) a member of one or more of the following designated professions within the meaning of section 3 of the Health and Social Care Professionals Act 2005, namely:

(i) medical scientist;

(ii) psychologist;

(iii) social care worker;

(iv) social worker;

(v) such other designated profession within the meaning of the said section as the Minister considers appropriate and may prescribe by regulations;

'hospital' has the same meaning as it has in *section 38* of the *Act of 2023*;

'operator' means, in relation to a relevant facility, the person who has ultimate responsibility for the running of the relevant facility;

'register of relevant facilities' shall be construed in accordance with section 33J;

'relevant facility' means—

(a) the Dublin District Mortuary, or

(b) any other facility (howsoever described), other than a hospital, where post-mortem examinations take place in accordance with this Act and which is specified in the register of relevant facilities as being such place;

‘relevant sections’ means sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O;”,

and

(b) by the substitution of the following definition for the definition of “stillborn child”:

“ ‘stillborn child’ has the same meaning as it has in the Act of 2004;”.”.

—An tAire Sláinte.

55. In page 61, between lines 32 and 33, to insert the following:

“ “(2A) A registered medical practitioner may, when carrying out a post-mortem examination in accordance with subsection (1), be assisted (whether by way of technical or clinical assistance) in carrying out such examination by an appropriately qualified healthcare professional or other person who, in the opinion of the registered medical practitioner carrying out or supervising the examination, is sufficiently qualified or has the relevant training or experience to provide such assistance.”.

—An tAire Sláinte.

56. In page 61, line 33, to delete “(2A) A registered” and substitute “(2B) A registered”.

—An tAire Sláinte.

57. In page 61, to delete lines 38 to 40, and in page 62, to delete lines 1 and 2 and substitute the following:

“(2C) Where the post-mortem examination has been conducted in a hospital, any material removed from the body under a direction in subsection (1) shall be preserved, stored and recorded in accordance with regulations made in that regard by the Minister for Health under *section 40* of the *Act of 2023*.”.

—An tAire Sláinte.

58. In page 62, to delete lines 3 to 8 and substitute the following:

“(2D) Where the post-mortem examination has been conducted in a relevant facility, any material removed from the body under a direction in subsection (1) shall be preserved, stored and recorded, in accordance with regulations made in that regard by the Minister under section 33I.”.”.

—An tAire Sláinte.

59. In page 62, to delete lines 9 to 15.

—An tAire Sláinte.

60. In page 62, line 16, to delete "following subsection" and substitute "following subsections".

—An tAire Sláinte.

61. In page 62, to delete lines 17 to 34 and substitute the following:

" "(3A) In providing the information under subsection (3), a coroner shall notify or cause to be notified a family member of the deceased person, the subject of the information, that approval by the family member (in this Act referred to as an 'authorisation') will be sought in respect of the final management of certain material of the deceased person.

(3B) Subsequent to the information being provided to a family member under subsection (3), the coroner shall further notify or cause to be notified the family member concerned that certain material has been retained for the purposes of the post-mortem examination.

(3C) Where at any time following a post-mortem examination, a coroner on foot of receipt of confirmation from a registered medical practitioner directed to make that examination is satisfied that retention of material from the body of the deceased is no longer necessary, or where the provisions of section 33(4) apply, he or she shall notify or cause to be notified a family member of the deceased person of that fact.

(3D) A notification under subsection (3C) shall inform the family member, the recipient of the notification of the following, namely:

(a) that the coroner has requested the designated person in the hospital or relevant facility where the post-mortem examination took place to contact the family member;

(b) the contact details of the designated person;

(c) that the designated person will request an authorisation from the family member for the final management of certain material retained following that examination;

(d) the authorisation for final management of material shall provide for—

(i) the return of material removed from the body where such return is consistent with guidelines, but shall not include tissue samples held on slides or blocks or trimmings or bodily fluids removed during the post-mortem examination,

(ii) the disposal of the material, by the designated person in a hospital or relevant facility, or

(iii) the use, by the hospital or relevant facility, of the material to further clinical teaching, medical education or research prior to ultimate disposal.",".

—An tAire Sláinte.

62. In page 62, to delete lines 37 to 41 and substitute the following:

"(7) In this section, 'technical or clinical assistance', in relation to the carrying out of a post-mortem examination, includes the removal by a person providing the assistance, of a part of a body from the deceased adult, child or foetus, the subject of the examination concerned.".".

—An tAire Sláinte.

63. In page 62, after line 41, to insert the following:

"Amendment of section 33B of Act of 1962

57. Section 33B of the Act of 1962 is amended by the deletion of subsection (1).".

—An tAire Sláinte.

64. In page 63, to delete lines 3 to 43, to delete page 64, and in page 65, to delete lines 1 to 7 and substitute the following:

" "Authorisation for final management of material removed from body of deceased person

33F. (1) Where—

(a) a post-mortem examination of a deceased person has taken place in a hospital or relevant facility, and

(b) the designated person in the hospital or relevant facility has been requested by or on behalf of the coroner to request an authorisation from a family member of the deceased person, the subject of the post-mortem examination,

the designated person in the hospital or relevant facility where the post-mortem examination took place shall request an authorisation from the family of the deceased person, the subject of the post-mortem examination, for the final management of certain material from the body of the deceased person which was retained following that examination.

(2) The designated person shall ensure, in so far as practicable, that the authorisation shall be provided in the terms referred to in section 33(3D)(d)(i), (ii) or (iii) in respect of the final management of the material concerned.

(3) When an authorisation is received by a designated person in respect of the final management of material, he or she shall, as soon as practicable—

(a) give effect to the authorisation,

(b) notify the coroner concerned that the authorisation has been so given effect, and

(c) make this information available to the family member of the

deceased should it be so requested by the family member.

(4) Where no authorisation is received by the designated person under subsection (3) or where efforts to contact family members of the deceased have not proved successful, the designated person shall inform the coroner concerned of that fact and the coroner shall be authorised to direct the final management of the material concerned by the designated person.

(5) The final management of any material, other than material referred to in section 33(3D)(d)(i), removed from the body of a deceased person shall not be made where the coroner concerned is satisfied that such material may be required for evidential purposes in a relevant legal process and has notified the designated person in that regard.

(6) The management of any material stored—

(a) in a hospital shall be carried out in accordance with regulations made in that regard by the Minister for Health under *section 40* of the *Act of 2023*, or

(b) in any relevant facility shall be carried out in accordance with regulations made in that regard by the Minister.

Provisions to apply when no authorisation received for final management of material removed from body of deceased person

33G. In a case to which section 33F(4) applies, the coroner shall direct that the final management of the material concerned be carried out by the designated person, or such other person as appears to the coroner to be appropriate in the hospital or relevant facility, as the case may be, where the material is stored, in accordance with section 33(3D)(d)(ii) or (iii) as is appropriate in the circumstances.

Provisions to apply when designated person not available or in position to receive or to act on authorisation for final management of material removed from body of deceased person

33H. (1) Where a coroner is notified or otherwise becomes aware that a designated person is not available or not otherwise in a position to receive or act in accordance with an authorisation for the final management of material removed from the body of a deceased person, the coroner shall—

(a) seek or confirm the authorisation of the family member in respect of the final management of certain material removed from the body of the deceased person, the subject of the authorisation, and

(b) direct the final management of the material in accordance with the authorisation received.

(2) When the coroner has completed the matters referred to in subsection (1), he or she shall endeavour in so far as is practicable to make this information available to the family member of the deceased should it

be so requested.

Regulations in respect of management of material retained following coronial post-mortem examinations made in relevant facilities

33I. (1) Without prejudice to the generality of section 3, the Minister may make such regulations as he or she considers necessary or expedient for the purpose of proper management in the most respectful and appropriate manner possible of material retained in the course of coronial post-mortem examinations that are made in relevant facilities.

(2) In particular, but without prejudice to the generality of subsection (1), regulations under subsection (1) may provide for any or all of the following matters:

(a) procedures for the retention, storage and management of material removed from the body as part of the coronial post-mortem examination, where such action is consistent with any guidelines made in that regard;

(b) the arrangements to be put in place to facilitate receipt of notification of authorisations under section 33F(1), including the designation of persons or classes of persons to whom such notifications shall be given and the procedures for the carrying out of authorisations received in that regard;

(c) the return of any material referred to in paragraph (a) to a family member of the deceased person other than tissue samples held on slides or blocks or trimmings or bodily fluids removed during the examination;

(d) the form of notifications under sections 33(3B), 33(3C) and 33 (3D);

(e) the form of authorisations under 33F;

(f) the form of notification of details of relevant facilities under section 33J;

(g) any additional information as the Minister considers may reasonably be required for the purposes of the register of relevant facilities;

(h) the particulars of notification of incidents to be declared to the Authority;

(i) any other matters which are necessary or expedient for the purposes of giving effect to subsection (1).

(3) Before making regulations under subsection (1), the Minister shall consult such persons as he or she considers appropriate, including all or any of the following:

(a) a representative of the Coroners Society of Ireland;

(b) a pathologist from the Royal College of Physicians of Ireland, Faculty of Pathology;

(c) the Chief State Pathologist;

(d) the Executive;

(e) the Authority;

(f) the Minister for Health.

Register of relevant facilities

33J. (1) As soon as may be after the commencement of this section, the Minister shall—

(a) request in writing each coroner who is for the time being holding office to provide the Minister in such form and manner as may be prescribed and within such period as may be prescribed details of any relevant facility where the coroner directs post-mortem examinations to be made in accordance with this Act, and

(b) establish and maintain in such form as he or she considers appropriate, a register of relevant facilities (in this Act referred to as the 'register of relevant facilities') to which the regulations under section 33I shall apply.

(2) Where a coroner receives a request in writing under subsection (1)(a), the coroner shall comply with that request.

(3) Notwithstanding the generality of subsection (1)(a), where, at any time, a coroner is of reasonable opinion that a facility (howsoever described) where he or she directs post-mortem examinations to be made in accordance with this Act is a relevant facility, he or she shall notify the Minister in writing of that opinion for the purpose of having that facility registered in the register of relevant facilities.

(4) The register of relevant facilities shall contain the following information, namely:

(a) the name of the relevant facility;

(b) the location of the relevant facility;

(c) the operator of the relevant facility;

(d) the chief executive officer (howsoever described) of the relevant facility;

(e) the nominated person in relation to the relevant facility;

(f) any additional information as the Minister considers may reasonably be required and as may be prescribed under section 33I.

(5) If a particular entered in the register of relevant facilities is incorrect, the coroner in respect of the relevant facility to which the particular

relates shall, as soon as may be after becoming aware of its being incorrect, inform the Minister thereof accordingly.

(6) The Minister shall, at regular intervals as may be agreed between the Minister and the Authority and, in any event, when a material change is made to the register, provide a copy of the register to the Authority.

Nominated person

33K. (1) Subject to subsection (2), a relevant facility at which post-mortem examinations take place shall, as soon as practicable after the commencement of this section and, in any event, not later than 12 weeks after such commencement, nominate in writing at least one suitably qualified person for the purposes of the relevant sections (in this section referred to as a 'nominated person').

(2) A nominated person shall be an employee of the relevant facility concerned and shall be suitably qualified person by reason of his or her training and experience to discharge the responsibilities of a nominated person.

(3) A nominated person shall have the following responsibilities, namely:

(a) to notify, in accordance with any guidelines, the Authority of the post-mortem examinations that take place in the relevant facility in relation to which he or she is the nominated person.

(b) to ensure that an annual report of post-mortem examinations that take place in the relevant facility is compiled and submitted to the Authority;

(c) to maintain or cause to be maintained records in accordance with regulations under section 33I;

(d) without prejudice to the powers of the Authority under *Part 3* of the *Act of 2023* and section 8 of the Health Act 2007, to monitor compliance with the relevant sections and any regulations under section 33I and notify the Authority in writing when he or she becomes aware of any breach of a provision of those sections or regulations;

(e) to liaise with the Authority from time to time and when requested to do so by the Authority.

(4) The operator of a relevant facility at which post-mortem examinations take place shall, notwithstanding the nomination by the relevant facility of a nominated person, at all times remain responsible for, and accountable to the Authority in respect of, compliance with regulations under section 33I.

Authority to monitor compliance with relevant sections – authorised persons etc.

33L. (1) The Authority shall, pursuant to section 8(1)(p) of the Health Act

2007, monitor compliance with the relevant sections and any regulations made by the Minister under section 33I.

(2) An authorised person appointed under section 70 of the Health Act 2007 shall be deemed to be an authorised person for the purposes of this section.

(3) A relevant facility shall, as soon as practicable after the commencement of section 33K and, in any event, not later than 12 weeks after such commencement, notify the Authority in writing of the following, namely:

(a) the name and particulars of the nominated person nominated in that behalf pursuant to section 33K;

(b) the name and address of the premises at which the post-mortem examinations take place or are intended to take place;

(c) the post-mortem examinations which take place or are intended to take place on the premises.

(4) Where a relevant facility changes in a material way any of the matters notified under subsection (3), the relevant facility shall as soon as possible and, in any event, not later than 28 days after the material changes, inform the Authority in writing and provide it with details of the changes.

(5) Without prejudice to the generality of subsection (3), the Authority may require the coroner or relevant facility at which post-mortem examinations take place or will take place to provide it within such reasonable period as the Authority may require with any information or statistics the Authority requires in order to determine the level of compliance by the relevant facility with regulations under section 33I.

(6) Where a person receives a request under subsection (5) from the Authority, he or she shall comply with such request.

Compliance notices

33M. (1) Where an authorised person is of the opinion that there is non-compliance by a a relevant facility with the relevant sections or any regulations made under section 33I, the authorised person may, following consultation with the Chief Executive Officer of the Authority or such other officer of the Authority so designated for that purpose, serve, or cause to be served, on the operator of the relevant facility concerned a notice (in this Act referred to as a 'compliance notice') in accordance with this section.

(2) A compliance notice shall be signed by the authorised person who is issuing the notice or the person referred to in subsection (1) whom he or she consulted with in relation to the notice concerned and shall—

(a) specify the requirement of the relevant sections or regulations

under section 33I with which there has not been compliance,

(b) for the purposes of ensuring compliance by the relevant facility concerned, require the operator of the relevant facility by such date as is specified in the notice to do or refrain from doing such act or acts as is or are so specified in the notice, and

(c) contain information regarding the bringing of an appeal under section 33N against the notice, including information on the manner in which any such appeal shall be brought.

(3) A compliance notice shall, unless an appeal is brought under section 33N, come into operation on the expiry of 14 days from the date of service of the notice.

(4) Where a person on whom a compliance notice has been served fails to comply with the notice at any time on or after the date on which the notice comes into operation, he or she shall be guilty of an offence and shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.

(5) Summary proceedings for an offence under subsection (4) may be brought and prosecuted by the Authority.

Appeal of compliance notice

33N. (1) The operator of a relevant facility on whom a compliance notice has been served may within 14 days of service of the compliance notice appeal to the District Court in respect of the notice or any requirement therein.

(2) Where an appeal is brought under this section, the District Court may—

(a) confirm the compliance notice, or

(b) direct the authorised person to withdraw the compliance notice concerned.

(3) Where the District Court makes an order under subsection (2)(b), the compliance notice shall cease to have effect.

(4) Where the District Court confirms a compliance notice, the notice as so confirmed, shall come into operation on the expiry of 14 days of the date of confirmation or such later date as the court may determine.

(5) The jurisdiction conferred on the District Court under this section shall be exercised by a judge of that court for the time being assigned to the district court district in which the person on whom the compliance notice is served ordinarily resides or carries on any profession, business or occupation.

Prohibition orders

33O. (1) Where an authorised person is of the opinion that—

(a) there is a serious and material non-compliance with a requirement of the relevant sections or any regulations under section 33I, and

(b) there is—

(i) a need in the public interest to immediately cease any or all of the post-mortem examinations, the subject of the opinion concerned, or

(ii) a failure to comply with a compliance notice,

the authorised person may, with the approval of the Chief Executive Officer of the Authority, or another officer of the Authority designated for that purpose, serve, or arrange to have served, on the operator of the relevant facility, an order (in this Act referred to as a 'prohibition order') in accordance with subsection (2).

(2) A prohibition order shall be signed by the authorised person issuing it, or the person referred to in subsection (1) who approves the issuing of the prohibition order and shall—

(a) state that the authorised person is of the opinion that one or more of the grounds specified in subsection (1) for the serving of a prohibition order exists,

(b) specify the particular serious and material non-compliance, public interest need or failure, as the case may be, at issue,

(c) where relevant, identify the part or parts of the compliance notice with which there has not been compliance, and

(d) as appropriate, direct the operator of the relevant facility served with the order to cease, or arrange for the cessation of, any or all of the post-mortem activities specified in the order concerned.

(3) The approval referred to in subsection (1) or subsection (6), as the case may be, may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.

(4) A prohibition order shall take effect—

(a) where the prohibition order so declares, immediately upon receipt of the order by the person on whom it is served, or

(b) in any other case—

(i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or

(ii) where an appeal is taken, on the day immediately following the

day on which the prohibition order is confirmed on appeal or withdrawn or the day specified in the prohibition order as the date on which it is to come into effect, whichever is the later.

(5) The bringing of an appeal against a prohibition order which is to take effect in accordance with subsection (4)(a) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is concluded.

(6) In the event of non-compliance or delay by the operator of a relevant facility on whom the prohibition order has been served, an authorised person shall, with the approval of the Chief Executive Officer or another officer designated for that purpose by the Authority, take whatever steps are considered necessary to ensure compliance with the direction given under this section.

(7) The operator of a relevant facility on whom a prohibition order is served who is aggrieved by a prohibition order may, within the period of 7 days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the district court district in which the prohibition order was served on him or her and, in determining the appeal, the judge may—

(a) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or

(b) where he or she is not so satisfied of the matters referred to in paragraph (a), allow the appeal and cancel the prohibition order.

(8) Where on the hearing of an appeal under this subsection a prohibition order is confirmed, notwithstanding subsection (5), the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.

(9) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under subsection (5) shall at the same time notify the Authority of the appeal or the application and the grounds for the appeal or the application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.

(10) The Board of the Authority shall be notified at the next available meeting of the Board of the service of a prohibition order.

(11) The Chief Executive Officer of the Authority may, for stated reasons, revoke or vary a prohibition order made in accordance with this section and the Board shall be notified at the next available meeting of the Board of any such revocation or variation and the reasons therefore.

(12) The Chief Executive Officer of the Authority shall, in the public interest make such arrangements as he or she considers necessary or appropriate to bring the matter giving rise to a prohibition order to the attention of the public.

(13) (a) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application to it in that behalf by the Authority, by order prohibit the continuance of the activities.

(b) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.”.”.

—An tAire Sláinte.

65. In page 70, to delete lines 35 to 40, and in page 71, to delete lines 1 to 7 and substitute the following:

“(4) Upon receipt of an application for a licence under this section, the Medical Council shall—

(a) in the case of an applicant institution in respect of which more than 2 years has elapsed since an inspection was last carried out on the institution,

(b) where the applicant institution is making an application to become a licensed institution for the first time, or

(c) where the Medical Council with good reason considers it appropriate to do so,

cause an inspection to be undertaken of one or more premises which is or are identified in the application as being the premises at which anatomical examinations will be undertaken by the licensed institution if the licence is granted and prepare a written report following such inspection.”.

—An tAire Sláinte.

66. In page 103, between lines 4 and 5, to insert the following:

"Amendment of Health Act 2004

100. The Health Act 2004 is amended, in section 55G, by the substitution of the following paragraph for paragraph (a):

"(a) an authorised person appointed by the Health Information and Quality Authority in accordance with section 70 of the Health Act 2007 to—

(i) monitor compliance with standards in accordance with section 8 (1)(c) of the Health Act 2007,

(ii) undertake an investigation under section 9 of the Health Act 2007,

(iii) monitor compliance, under section 8(1)(o) of the Health Act 2007, with *Part 3* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2023*, or

(iv) monitor compliance, under section 8(1)(p) of the Health Act 2007, with the relevant sections (within the meaning of the Health Act 2007) of the Coroners Act 1962 and regulations made by the Minister for Justice under section 33I of that Act,".".

—An tAire Sláinte.