EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE (PERMITTED MATERIAL: EXCEPTIONS) (ENGLAND) REGULATIONS 2020

2020 No. 521

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

1.2 This Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Organ Donation (Deemed Consent) Act 2019 ("the 2019 Act") amended the Human Tissue Act 2004 ("the 2004 Act") to allow consent for organ donation from deceased donors to be deemed in specified circumstances. These new arrangements have been referred to as "deemed consent" but "opt-out" has generally been used in public communication including in the press. Under the amended provisions, consent for organ and tissue donation in England is considered to be in place for adults, unless they made a decision during their lifetime that they did not want to donate their organs or tissue, or asked a representative to make a decision on their behalf after death, or are in one of the excluded groups.

2.2 The 2019 Act also introduced into the 2004 Act a new regulation-making power for the Secretary of State to specify in regulations the types of organs, tissue and cells to which deemed consent does not apply. These regulations, therefore, set out a list of organs, tissue and cells that, following a full 12-week public consultation, the Government has proposed should not be permitted to be removed, stored or used for transplantation with deemed consent. Their inclusion in the regulations means that for their transplantation, the express consent of the potential donor before their death, or their nominated representative or their family after death, will need to be in place. The Organ Donation (Deemed Consent) Act 2019 only applies in respect of deceased donors. Deemed consent does not apply to donation of solid organs and tissue whilst a person is alive ('living donation').

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Regulation 2(2) specifies the types of relevant material (whole or part) that are not permitted material. However, it also separately lists relevant material which may, on an ordinary reading of the regulations, already be listed as a part of relevant material already specified (e.g. leg is specified in regulation 2(2)(h) and lower leg is specified in regulation 2(2)(i)). The list is intended to strike a balance, by setting out the individual types of organs, tissue and cells that are not permitted material, to provide clarity and public confidence, and including wide enough structures so that it is not necessary to detail their more detailed anatomical components. For example, leg and lower leg are specified separately. It was not felt appropriate to list leg without lower leg, because a leg transplant and a lower leg transplant are separate procedures, and to provide

certainty and put beyond doubt, that their more detailed components (e.g. a knee) was included without needing to be listed separately. Further, this drafting approach is consistent with the equivalent regulations currently in operation in Wales (The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015).

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 This instrument applies to England only.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only. Wales already have similar regulations in place. Following the passage of a new law to implement deemed consent in Scotland, Scotland are expected to put legislation for novel transplants in place.

5. European Convention on Human Rights

5.1 The Minister of State for Care, Helen Whately, made the following statement regarding Human Rights:

"In my view the provisions of the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The Human Tissue Act 2004 ("the 2004 Act"), which governs organ donation and transplantation in England, Wales and Northern Ireland, includes provisions with respect to activities involving human tissue, such as organ and tissue transplantation. There is a separate Act in Scotland. The 2004 Act authorises the removal, storage and use of organs, tissue and cells for the purpose of transplantation from deceased donors if there is "appropriate consent". The meaning of appropriate consent differs depending on whether the deceased is an adult or child. The Organ Donation (Deemed Consent) Act 2019 Act does not change the consent requirements under the Human Tissue Act 2004 Act in respect of children under 18.

6.2 The Organ Donation (Deemed Consent) Act 2019 ("the 2019 Act") amends the 2004 Act in respect of what constitutes "appropriate consent" for adults. It introduces a new provision that allows in England, for consent to remove, store or use organs, tissue or cells from deceased adults for the purposes of transplantation, to be deemed, unless certain circumstances apply. Those circumstances are: if the individual made a decision during their lifetime that they did not want to donate their organs, tissue or cells; asked a representative to make a decision on their behalf after death; or are in one of the excluded groups from deemed consent (see paragraph 6.4).

6.3 Further, under the new arrangements, the family of the deceased will continue to be consulted and they will still be able to provide information about their loved one's wishes. If they have information that their loved one would not have wanted to donate their organs and/or tissue, organ and/or tissue donation will not go ahead. The amendments to the 2004 Act made by the 2019 Act set out those that are in a "qualifying relationship" to the deceased can provide information that would lead a reasonable person to conclude that the deceased would not have consented to the donation. A

person in a qualifying relationship to the deceased is broadly a close family member or friend and is defined in section 54(9) of the 2004 Act.

6.4 The amended 2004 Act provides further exceptions. It excludes from deemed consent people who are ordinarily resident in England for less than 12 months immediately before dying. A person is ordinarily resident if they are living lawfully and voluntarily in England as part of the regular order of their lives whether for a short or more permanent duration. The overall principle is that ordinary residents need to have a settled status and be living in England voluntarily, but in some cases even if they meet these criteria, they may not consider England as their home and so would not be ordinarily resident. Whether a person has or has not been ordinarily resident in England for 12 months before their death is a question of fact that will need to be determined in the particular circumstances of their case. Consent also cannot be deemed in respect of people who have lacked the capacity to understand deemed consent for a significant period before dying.

6.5 Deemed consent does not apply in respect of all organs, tissue and cells. It is only the storage, removal and use of organs, tissue and cells that fall within the definition of "permitted material" in section 3(9) of the Human Tissue Act 2004, as amended by section 1(5) of the 2019 Act, that may be subject to deemed consent. The definition of "permitted material" in the 2004 Act is any relevant material (defined in section 53 of the 2004 Act) other than that which is specified in regulations. The regulations, therefore, specify what is not "permitted material" under the Act. As the primary intention of introducing deemed consent is to increase the number of routine transplant opportunities, the regulations ensure that rare or novel transplants will not be permitted without express consent. The regulations list organs, tissue and cells, the transplant of which is novel or rare. Removing, storing or using these types of organs, tissue and cells for the purpose of transplantation will require express consent, therefore consent cannot be deemed.

6.6 The inclusion of organs and tissue in the regulations is to future-proof the legislation in respect of transplants that are currently carried out elsewhere in the world or are currently anticipated as likely to be carried out in the UK in future. Taking a robust approach to novel and rare transplants will re-assure the public that deemed consent will only apply to routine transplants such as heart, lung, kidney and liver.

7. Policy background

What is being done and why?

7.1 The 2004 Act, as amended by the 2019 Act, does not specify what types of organs, tissue and cells may be removed, stored or used for transplantation with deemed consent. Rather, the 2004 Act only permits consent to be deemed in respect of the removal, storage or use of "permitted material". "Permitted material" is defined as relevant material that is not specified in regulations. "Relevant material" is a defined term in the 2004 Act (section 53) and is any material made up of or including human cells, other than gametes, embryos that are outside the human body or hair and nail from a living person.

7.2 The regulations set out therefore a list of organs, tissue and cells that, following consultation, the Government proposed should not be permitted to be removed, stored or used for transplantation with deemed consent. It also sets out that certain types of human tissue and cells that form part of other organs or tissue transplanted more

routinely may only be removed, stored or used for transplantation with express consent where they form part of a novel or rare transplant. For example, arteries used for a liver transplant (a routine transplant) are permitted material and could be removed, stored or used under deemed consent but arteries required for a leg transplant (a rare transplant) would not be permitted material and express consent would be required.

7.3 The Secretary of State has a duty to make arrangements for facilitating organ and tissue transplantation. In considering policy options, Ministers must comply with the Public Sector Equality Duty, their general duties under the National Health Service Act 2006 and the requirements of the Family Test.

7.4 The Government sought to engage the public and to seek their views on those organs and tissue to be excluded from deemed consent. As the regulations maintain the current position on consent for novel forms of transplant, the Government has considered it unlikely that there would be an impact on groups with protected characteristics or families. Continuing the current requirements also fall within the Secretary of State's NHS Act 2006 duties. In particular, regarding impact on families, decisions about organ donation may occur at a highly emotional time and key transition point following the death of a relative. This can place pressure on family members though it will be felt differently depending on the nature of family relationships and individual people involved. There is no evidence that organ donation decisions under deemed consent impacts families most at risk of deterioration of relationship quality and breakdown. The legal framework sets out arrangements for gaining consent but in every potential donor situation, there will still be a number of discussions with family members, for example on confirming medical history. The family will also be able to provide information if they know that their relative would not have wanted to donate their organs, as outlined in paragraph 6.3.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This is the first exercise of the power. Consolidation is not taking place.

10. Consultation outcome

10.1 The Department of Health and Social Care ran a 12-week public consultation on the draft regulations from 29 April 2019 to 22 July 2019 and received 3279 responses. 25 of these responses were from organisations. 93% of all respondents said that they understood the draft regulations. The majority of respondents agreed with the proposed list of organs, tissue and cells that should still require express consent: 53.9% agreed, 40.8% disagreed, 5% said they did not know and 0.3% did not respond.

10.2 One of the main suggestions raised by respondents was that more parts of the reproductive system should require consent to be given expressly in order to be transplanted. To address this, the regulations have been updated with an expanded list of reproductive organs and have clarified further that tissue from reproductive organs and tissue will not be transplanted without express consent. This is to give assurance and put beyond doubt that reproductive organs and tissue will not be covered by deemed consent under any circumstances.

10.3 Many also mentioned that gametes (sperm and eggs) should be added to the list of what is excluded from deemed consent. Gametes are not permitted material for the purposes of deemed consent because they fall outside the definition in the 2004 Act as amended by the 2019 Act. Therefore, there is no need to be specified in the Regulations. To re-assure the public, the Government Response clarified that the regulation of gametes is already governed by the Human Fertilisation and Embryology Act 1990 and that gametes are outside of the scope of the Human Tissue Act 2004, including deemed consent.

10.4 The draft regulations included "embryo inside the body" as being excluded from deemed consent. The Government Response explained that although removal of the embryo from the womb would terminate the pregnancy and therefore the transplantation would not be possible, "embryo inside the body" was included for completeness because it falls within the definition of "relevant material" set out in the Human Tissue Act 2004. Therefore, unless explicitly covered in the draft regulations, although technically not possible to transplant a living embryo, not including "embryo inside the body" may mean removal would be lawful under deemed consent.

10.5 Some respondents suggested eyes should be excluded from deemed consent. The Department considered these views and has responded to these objections by explaining in the Government Response that cornea transplants (which requires the whole eye to be removed, but not transplanted) are a routine transplant. In 2018, around 4500 corneas were transplanted. More than 8 out of 10 people who register on the NHS Organ Donor Register agree to donate their corneas alongside other organs. Given that cornea transplants are routine and there is a shortage of cornea donations, the Government intends to take the same position as in Wales and include corneas in deemed consent. The Government Response also highlights that, as before, people can use the NHS Organ Donation Register (ODR) to record that they do not wish to donate their corneas or they can tell their family and friends.

10.6 The transplantation of the trachea is a novel transplant, however, following further clinical advice as part of the consultation, the Government can confirm that the trachea is also removed during a heart-lung transplantation, which is a routine transplant. When it is removed as part of a heart-lung transplant, the trachea is attached to the lungs. Therefore, the regulations have been revised so that the trachea is specified in the regulations as not being permitted material (and so requiring express consent for removal, storage, or use) except when it is attached to a lung. This means that the removal, storage and use of the trachea as part of a heart-lung transplant may fall under deemed consent but a novel trachea transplant would not.

10.7 The regulations list specific cells from deceased donors called Advanced Therapy Medicinal Products (ATMPs). Although more than half of respondents proposed that the use of cells from deceased donors for ATMPs should be allowed under deemed consent, the Government will proceed as proposed and will exclude them from deemed consent. ATMPs have led to some important medical breakthroughs, however, ATMPs from deceased donors is novel. The Government still considers that their transplantation needs to be monitored to ensure that they remain ethical, especially as their development could be used for profit from pharmaceutical companies. Taking into account the views of the organisations that responded, following further clinical input the Government has also expanded the list of cells to include lung and renal epithelial cells.

10.8 The Department published the Government Response with the full results following the consultation as a Command Paper on 25 February 2020, available at

https://www.gov.uk/government/consultations/opt-out-organ-donation-organs-and-tissues-excluded-from-the-new-system, and issued a Written Ministerial Statement to Parliament alongside it, available at https://www.parliament.uk/writtenstatements.

11. Guidance

11.1 The Human Tissue Authority, which regulates organ, tissue and cell donation and transplantation has been consulting on revised Codes of Practice to reflect the policy on deemed consent. The Codes are intended to provide healthcare staff with practical guidance about how the new system is expected to work in practice. Following Parliamentary approval, the Human Tissue Authority will provide supplementary guidance on novel transplants.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because, as no impact to the current position has been identified as a result of these regulations as they maintain the status quo, there have been no revisions to the original Impact Assessment.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 NHS Blood and Transplant's Research, Innovation, and Novel Technologies Advisory Group (RINTAG) will be monitoring this legislation and will be recommending whether any revisions are necessary. It is worth highlighting that even if a transplant may cease to be novel, this does not automatically mean that it will be covered under deemed consent. If any revisions are proposed, the Government will consider how best to take forward, taking a number of considerations into account, such as evidence, public acceptability and clinical need.

14.2 The regulations do not include a statutory review clause, as this does not have an impact on small businesses.

15. Contact

15.1 Marina Pappa, Head of Organ Donation at the Department of Health and Social Care, (telephone: 0207 972 4465, email: Marina.Pappa@dhsc.gov.uk), can be contacted with any queries regarding the instrument.

15.2 Jeremy Mean, Deputy Director, Health Ethics, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Helen Whately, Minister of State for Care at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.