EXPLANATORY MEMORANDUM TO

THE HUMAN TRANSPLANTATION (WALES) ACT 2013 (CONSEQUENTIAL PROVISION) ORDER 2015

2015 No.

1. This Explanatory Memorandum has been prepared by the Wales Office and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The instrument ("the Order") makes necessary provision in consequence of the coming into force of the Human Transplantation (Wales) Act 2013 ("the 2013 Act").

2.2 The main purposes of the Order are to make provision to: amend the Human Tissue Act 2004 ("the 2004 Act") to provide that a transplantation activity that takes place in England or Northern Ireland, with relevant material that comes from Wales, is lawful without the need for consent under section 1(1) of the 2004 Act; and to amend the 2004 Act so that where a person has appointed a representative to deal after death with the issues of consent in relation to a transplantation activity under section 8 of the 2013 Act, the nomination made under the 2013 Act or the 2004 Act will apply no matter whether the transplantation activity takes place in Wales or in England or Northern Ireland.

2.3 The secondary purpose of the Order is to make amendments to the Quality and Safety of Organs Intended for Transplantation Regulations 2012 ("the 2012 Regulations") to make reference to the deemed and express forms of consent for transplantation activities taking place in Wales for the purposes of licensing the retrieval of material under those Regulations.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This is the third Order to be made under section 150 of the Government of Wales Act 2006. The others, unrelated to this Order are: the Local Government (Wales) Measure 2009 (Consequential Modifications) Order 2010 (SI 2010/212) and the Natural Resources Body for Wales (Consequential Provision) Order 2013 (SI 2013/1821).

3.2 The relevant provisions of the Order are necessary in light of changes to the law around consent to organ and tissue donation in Wales, to ensure the continued smooth operation of the organ transplantation programme which operates on a UK-wide basis.

4. Legislative Context

4.1 The National Assembly for Wales passed the 2013 Act on 2 July 2013 and it was given Royal Assent on 10 September 2013. Only sections 1, 2, 21 and 22 of the Act were commenced on Royal Assent. The remaining provisions will be fully commenced by 1 December 2015, to allow for a two-year period of communications with the Welsh public on the new law.

4.2 Prior to the coming into force of the 2013 Act, all statutory provisions on consent for the use of bodies and relevant materials were set out in the 2004 Act which applies to England, Wales and Northern Ireland. The 2004 Act authorises certain activities, including the removal and use of organs and tissues, for a number of purposes that are set out in Schedule 1 to that Act. One of these is use for the purpose of transplantation. Under the 2004 Act, "appropriate consent" is required for the use of organs and tissues for the purposes listed in the Schedule. The meaning of appropriate consent differs depending on whether the relevant material is obtained from an adult or child, but the overarching principle is that the consent must be given expressly.

4.3 The purpose of the 2013 Act is to change the way in which consent, for the purposes of transplantation, is to be given to organ and tissue donation in Wales. The 2013 Act provides that in the absence of express provision in relation to consent, consent will be deemed to have been given in most cases. This means that, after death, a person's consent will be deemed to have been given unless they had expressed a wish for or against donation. The notion of "appropriate consent" from the 2004 Act is therefore replaced by two concepts, "express consent" (which replicates "appropriate consent") and "deemed consent".

4.4 There are several exceptions to deemed consent, including children, those who are not ordinarily resident in Wales and those who lack capacity to understand the notion of deemed consent. In such cases, express consent (which has the same meaning as appropriate consent set out in the 2004 Act) will apply. It is also the case that if a family member or friend of long standing can provide information to show the deceased person objected to donation, then deemed consent will not apply. This involvement of family and friends in the discussion around organ donation is why the system is termed a "soft opt-out" system.

4.5 With the exception of deemed consent applying in Wales, the system of express consent in England, Northern Ireland (and in certain cases in Wales) therefore remains the same.

4.6 The 2013 Act sets out in one place the main provisions relating to consent for transplantation activities in Wales. As a result, the Act restates certain sections

of the 2004 Act directly related to consent for the purposes of transplantation. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the 2004 Act. Certain other provisions of the 2004 Act not directly related to consent but applicable to transplantation, have not been restated in the 2013 Act, but continue to apply in Wales. These include provisions relating to the Human Tissue Authority, restriction of activities in relation to donated materials, restriction on transplants involving a live donor and information about transplant operations.

4.7 The Order will maintain the effective cross-border flow of organs and tissues through an amendment to section 1 of the 2004 Act, which has the effect of disapplying the need for "appropriate consent" in respect of organs and tissues donated in Wales and their use in England and Northern Ireland. The amendment recognises that either "express" or "deemed" consent will have been given in Wales, thus making the storage and use of the materials lawful in England and Northern Ireland. In addition, the Order makes an amendment to section 4 of the 2004 Act to recognise that where a person has appointed a representative to deal after death with the issues of consent in relation to a transplantation activity under section 8 of the 2013 Act, the nomination made under the 2013 Act or the 2004 Act will apply no matter whether the transplantation activity takes place in Wales or in England or Northern Ireland.

4.8 The Order will have effect from 1 December 2015 when all the remaining sections of the 2013 Act have come into force. Some of those sections (7, 8 and 9) will come into force before 1 December 2015 for the purpose of making regulations and the remainder will come into force on 1 December 2015, at which time this Order will take effect.

5. Territorial extent and application

Although the Order has UK wide extent, the amendments it makes have the same extent as the provisions being amended. Therefore the amendments to the 2004 Act extend to England and Wales and Northern Ireland, but the amendments to the 2012 Regulations extend to the UK. However, the Order only has practical application to activities in relation to transplantation undertaken in England and Northern Ireland.

6. European Convention on Human Rights

The Rt. Honourable Stephen Crabb MP, Secretary of State for Wales, has made the following statement:

"In my view the provisions of the Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 are compatible with Convention rights."

7. Policy background

7.1 The UK has historically suffered a chronic shortage of organs for transplantation and has had one of the lowest donation rates in Europe. As a result, people are dying whist waiting for a suitable organ to become available. In 2012/13 in Wales, 36 people died before they could receive a transplant and over 200 others were on the waiting list. The numbers are even greater at a UK-wide level.

7.2 There have been a number of notable achievements across the UK since 2008. In January of that year, following a comprehensive review of organ donation in the UK the Organ Donation Taskforce (ODTF) produced its report, *Organs for Transplants.* The report made 14 recommendations aimed at improving the infrastructure and funding of organ donation, with a view to increasing organ donation rates by 50 per cent within five years. The Wales Organ Donation Implementation Group was set up to ensure the recommendations were implemented in Wales. As a result of the work done following the ODTF report, the aim of achieving the 50 per cent increase across the UK was achieved by 2013.

7.3 These developments have seen improvements in the identification and referral of potential donors, new roles of clinical lead and specialist nurse in organ donation, and an increase in the number of families approached. However, the area of consent to donation has remained largely unchanged. It is at this stage in the organ donation pathway where most donations are lost and the UK continues to have one of the highest family refusal rates in Europe.

7.4 The Welsh Government seeks to improve the rates of donation in Wales and is of the view that the area of consent requires a different approach. Its view is that better consent rates will be achieved through the introduction of a soft opt-out system of consent to organ donation. The Welsh Government's review of international evidence in 2012 suggested an association between those countries with opt-out type systems for consent, and an increased donation rate.

7.5 In seeking to legislate in this area, the Welsh Government considered the evidence relating to alternative methods for increasing consent to donation, many of which have been considered by numerous committees and which have been debated in public. However, these other options were discounted at an early stage as being either impractical to implement and enforce (i.e. mandated

choice) or culturally unacceptable to the public (i.e. hard opt-out system). The Welsh Government also considered there to be insufficient international evidence to show they will have the desired effect.

7.6 As part of *Taking Organ Donation to 2020*, the new strategy for making further improvements to the process, the Welsh Government will support efforts across the rest of the UK to increase consent rates as part of the current opt-in system. However it remains of the view that a soft opt-out system of the kind to be introduced in Wales from 1 December 2015 will provide the breakthrough in public attitudes and awareness which will ultimately lead to a significant increase in the consent rate.

7.7 The Welsh Government's view is that the introduction of a soft opt-out system, together with an extensive communication and education programme encouraging people to make a decision and to ensure their families know their wishes will increase the number of organs available for transplantation by some 25 per cent, and create a change in society in Wales where agreeing to organ and tissue donation becomes the norm rather than the exception. Introducing a soft opt-out system should narrow the gap between the numbers of people who say that they would be willing to donate an organ (around 9 out of 10 people in a recent Welsh survey) and those who actually do.

7.8 A wide-ranging communications and engagement campaign is now underway in Wales to ensure the public understands the new soft opt-out law and the choices with which they are presented. These choices are to express your consent one way or the other (opt in, or opt out) or to do nothing and have your consent deemed. In a deemed consent situation family or friends of long standing will be able to say whether they were aware of an unregistered objection to organ donation and in such instances consent would not be deemed and donation would not go ahead.

7.9 As described above, it is not intended to alter the way in which organs and tissues are collected or allocated, and the existing UK-wide arrangements will continue, hence the requirement for this Order to be put in place so that organs donated in Wales under the 2013 Act may be used in other parts of the UK. This means Wales will still share a transplant waiting list with the rest of the UK and organs will be allocated on the basis of clinical need and suitable match. Welsh residents have benefited from being part of the UK-wide arrangements for many years and there are no plans to alter this as the new arrangements for consent to donation in Wales are introduced. Nor is it intended to alter the arrangements for licensing the retrieval of material, which will still be carried out on a UK-wide basis, hence the change made by this Order to the 2012 Regulations. This change recognises that "consent" for the purposes of licensing the retrieval of material under those Regulations is defined

by reference to deemed and express consent under the 2013 Act where the retrieval takes place in Wales.

7.10 The organs and tissues donated under the current opt in arrangements are: in respect of organs - the kidney, heart, liver, lungs, pancreas and the small bowel and for tissues - bone, skin, tendons, meniscus, heart valves and vessels, eyes and, infrequently, trachea. Current opt in arrangements do not cover novel forms of donation and transplantation such as face or limb transplants. For those and any other types of donation, the express consent of qualifying relations is always sought and the consent given by the deceased individual (for example on the Organ Donor Register) is not relied upon. The 2013 Act provides the Welsh Ministers with a power to make regulations setting out which organs will be excluded from the new deemed consent arrangements.

7.11 In terms of the appointed representative, both the 2004 and 2013 Acts provide for a person to be able to nominate another individual to deal after death with the issue of consent to donation. Whilst this is a rarely-used provision under the current arrangements, discussions during the passage of the 2013 Act suggested that it may be an attractive option for some people e.g. in some faith groups where reference to a religious leader on the matter of organ donation may be appropriate. As part of the preparation for the implementation of the 2013 Act, NHS Blood and Transplant is redeveloping the existing Organ Donor Register in order that it will be capable of capturing decisions to be a donor (opt in), decisions not to be a donor (opt out decisions) as well as information regarding appointed representatives. This Order provides for appointments made by adults under either the 2004 Act or the 2013 Act to be recognised and to have effect no matter whether the transplantation activity takes place in Wales, England or Northern Ireland.

7.12 It should be noted that the 2013 Act includes a provision for children to appoint a representative, which is not a provision within the 2004 Act. This was included in the 2013 Act following an assessment of the legislation against the requirements of the Rights of Children and Young Persons (Wales) Measure 2011, and the increasing emphasis in the courts on the autonomy of the child. Since adults are able to make the choice to appoint a representative, the same opportunity is now also available to children if they have the understanding to make an informed decision whether to donate or otherwise. However, since this provision does not exist within the 2004 Act, the Order does not provide for such an appointment made in Wales to be recognised where the transplantation activity takes place in England and Northern Ireland. In that situation, consent would be sought from a person with parental responsibility or, where no such person exists, a qualifying relation. However, the fact that a child had appointed a representative will be able to be viewed by NHS staff on the register, irrespective of where the child died, and this information could be used in the

conversation with the family, although it would have no legal standing outside Wales.

8. Consultation outcome

8.1 In the drafting of this Order the Wales Office has consulted key UK Government Departments. Their comments were taken into account in the drafting of this Order. There has been no public consultation on this Order because it is in consequence of the National Assembly for Wales's decision to legislate on the matter of consent to donation for the purposes of transplantation. A number of public consultations have already taken place on the primary legislation, as described below.

8.2 There has been a significant amount of engagement and consultation with the public and stakeholders on this issue since 2008. The Welsh Government's then Minister for Health and Social Services launched public debates on organ donation in Wales between October 2008 and January 2009. This included a series of public meetings across Wales, including an inter-faith meeting and took account of written views and a telephone survey.

8.3 This public engagement confirmed support for increasing organ donation rates. A wide range of suggestions were put forward on how this may be achieved, including possible changes to the law to in relation to consent for organ donation.

8.4 In May 2009, the Welsh Government published a consultation paper '*Options for changes to the organ donation system in Wales'*. The result of the consultation showed strong public support for a change in the law to introduce a soft opt-out system of organ donation in Wales.

8.5 The Welsh Labour Manifesto for the May 2011 elections contained a commitment to introduce a soft opt-out system for organ and tissue donation in Wales. A similar commitment was also contained in other party manifestos. Following the return of a Labour-led Welsh Government, in his legislative statement of 12 July 2011 the First Minister committed the Welsh Government to *"provide for an opt-out system of organ donation, backed by a comprehensive communication programme"*.

8.6 A White Paper followed, setting out the Welsh Government's intention to legislate on this matter. Entitled 'Proposals for Legislation on Organ and Tissue Donation', the White Paper was published for a twelve week public consultation period between 7 November 2011 and 31 January 2012. It outlined the broad principles the Welsh Government would follow in bringing forward the policy and sought views on how the arrangements should work in practice. A total of

1,234 responses were received. During the consultation period Welsh Government officials held a series of 13 public meetings across Wales to explain the current process, answer questions on how the proposals would work and to listen to the views of attendees. A total of 166 people attended the meetings. Furthermore, eight meetings with key stakeholders were held during the consultation period: three meetings with the NHS in Wales and meetings with Specialist Nurses and Clinical Leads on Organ Donation, Professional Bodies, the Voluntary Sector and representatives from faith groups. These meetings considered the details of the policy proposals contained in the White Paper and focused in particular on the practical arrangements around the implementation of the policy.

8.7 The Welsh Government's report on the Consultation Summary was published on 8 March 2012 and all the responses were put on the website on 18 April. The summary report included details of the organisations notified of the White Paper consultation and a list of respondents.

8.8 A further consultation on a draft Bill and Explanatory Memorandum took place between 18 June and 10 September 2012 and a total of almost 3,000 responses were received, the vast majority of which took the form of a standard letter which raised a number of specific issues about organ donation. During the consultation period seven stakeholder meetings were held across Wales, which were also open to members of the public. The consultation responses highlighted a number of key issues which required further clarification or explanation, including the role of family members, explanations about brain death and other concerns about diagnosis of death, as well as more detailed points on the drafting of the Bill. A Consultation Summary report was published on 19 October 2012 and all the responses were published on the Welsh Government website.

9. Guidance

No guidance will be issued on the terms of the Order. This memorandum explains the purpose and context of the Order. A Code of Practice issued by the Human Tissue Authority will provide practical advice on the operation of the new legislation in Wales.

10. Impact

A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies. The impact of the instrument on the public sector is minimal. A full impact assessment was carried out on the primary

legislation at the time of its introduction to the National Assembly for Wales and was revised following Stage 2 scrutiny of the Bill.

11. Regulating small business

This Order does not result in any material changes to the regulatory regimes and as such has no material impact on small businesses.

12. Monitoring and review

This Order makes consequential changes in connection with the implementation of the Human Transplantation (Wales) Act 2013, the impact of which will be reviewed by the Welsh Government. There are no plans for a separate review of the effects of this Order.

13. Contact

13.1 Queries about the content of the instrument or this memorandum should be addressed to Leanne James, Wales Office, (Tel: 029 2092 4200, email: leanne.james@walesoffice.gsi.gov.uk).

13.2 Owen Robinson, Wales Office, can answer legal queries about the instrument (Tel: 0207 270 0400, email: owen.robinson@walesoffice.gsi.gov.uk).