



Government Response to the Consultation on the draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020

Organs, tissues and cells to be excluded from the new system of organ and tissue donation in England (known as ‘opt-out’ or ‘deemed consent’)

Presented to Parliament by the Secretary of State for Health and Social Care by Command of Her Majesty

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Definitions

- Opt-out or deemed consent: the new consent arrangements that the Government aims to introduce from spring 2020 mean that all adults over 18 are considered potential organ and tissue donors after death, unless they make a decision that they do not want to be a donor, they have nominated a representative to make a decision on their behalf after death, or are in an excluded group. The excluded groups are: people who lacked mental capacity to understand deemed consent for a significant period before their death, children under 18, and people ordinarily resident in England for less than 12 months immediately before their death. Based on previous feedback, for the purposes of this document, the new policy will be referred to as 'organs, tissues and cells to exclude from deemed consent'.
- Express consent: for the purposes of this document, express consent is where someone, or their nominated representative, or family or close friends, can give or have explicitly given consent to donate.
- Family: those that are in a 'qualifying relationship' to the deceased. Within the Human Tissue Act 2004, this is: a spouse, civil partner or partner; a parent or child; a brother or sister; a grandparent or grandchild; a niece or nephew; a stepfather or stepmother; a half-brother or half-sister; a friend of longstanding. In cases where there is no family, 'family' means close friends of the deceased person.
- Tissues: a group or layer of cells that perform specific functions. For example, skin tissue is a group of skin cells.
- Organs: a relatively independent part of the body that carries out one or more special functions. Examples of organs include the kidneys, heart, lungs, and liver. In some cases, where the whole organ cannot be used, part of the organ may be transplanted instead.
- Novel and rare transplants: transplants that are new and are usually at a research or practical evaluation stage, or have gone through research and service evaluation stages, but are still rare and unusual. An example of a novel transplant would be face transplantation. An example of a rare transplant would be limb transplantation.
- Routine transplants: common and well-established transplants that are offered on the NHS. It is intended that these will be included in deemed consent and are listed at Annex C.

- Relevant material: parts of the human body, other than gametes (eggs and sperm), which consist of or include human cells. In the Human Tissue Act 2004, references to relevant material from a human body exclude embryos outside the human body, or hair and nail from the body of a living person.
- Permitted material: relevant material that may be removed, stored or used for the purposes of transplantation under deemed consent if the conditions are met. All relevant material is permitted material unless it is specified in the draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020. The regulations, updated following consultation, are in Annex A.
- Advanced Therapy Medicinal Products (ATMP): therapies made from tissues, cells or genes after manipulation in a laboratory. They are used for treatment of a disease or injury and often use human cells and tissues as starting materials. The majority of ATMPs use tissues or cells from live donors and use and re-insert the patient's own cells. For example, an ATMP can treat knee damage by taking cartilage cells from a living patient, growing and modifying them in the lab, and re-injecting them into the patient's knee. ATMPs using cells from deceased donors are considered a type of novel transplant.
- Cornea donation: the cornea is the clear tissue at the front of your eye. For the purposes of this document, cornea donation refers to any donation that would give someone back the gift of sight. It is also possible to retrieve other areas of the eye, such as sclera and limbal cells. Cornea donation requires the whole eye to be removed, but not transplanted.
- Code of Practice: practical guidance for healthcare professionals involved in organ and tissue donation, retrieval, and transplantation. Following public consultation, the Human Tissue Authority (HTA) has revised Code of Practice A and Code of Practice F: Part Two. Code F: Part One has not been changed but has been included with Part Two for completeness. Code A includes minor edits to signpost healthcare professionals to the revised Code F.

Executive Summary

In October 2017, the Government made a bold commitment to change the current system of organ and tissue donation in England to help more people receive a much-needed organ and tissue transplant. At the time of writing, over 5,200 people in England are waiting for a transplant. By the time a suitable organ is found, some people have become too ill to receive one. Last year alone, 777 patients were removed from the transplant list and a further 400 died while on the active list waiting for a transplant.

As the Government set out in the [consultation document](#) on introducing opt-out in England and the subsequent [Government Response](#), under the new system, if someone has died and they have not made a decision about organ and tissue donation before their death, the default position will be that consent to donate will be considered to be in place (unless they have nominated someone else to make a decision for them after death or are in one of the excluded groups). The excluded groups are: those under the age of 18; ordinarily resident in England for less than 12 months before their death; or lacked mental capacity to understand the system for a significant period before their death. This new system of consent is known as 'opt-out' or 'deemed consent'. It is intended that the new system will come into force on 20 May 2020 subject to Parliament's approval of the secondary legislation and Human Tissue Authority's Codes of Practice.

In the new system, the family of the deceased will continue to be consulted and they will still be able to provide information on their loved one's wishes. If they have information that their loved one would not have wanted to donate their organs, tissues and/or cells, organ donation will not go ahead.

The Government's view is that deemed consent should only apply to organs, tissues and cells considered to be 'routine' transplants. Novel or rare transplants, including situations in which cells from a retrieved organ would be used to create an Advanced Therapy Medicinal Product (ATMP), should continue to require express consent. This is because ATMPs is a novel technology and the public may not expect such transplants to be included in deemed consent.

It is intended that the following routine transplants of organs, tissues and cells are included in deemed consent:

- heart, transplanted either as a whole organ or for heart valves;
- lung(s);

- liver, transplanted either as an organ or for liver cells (called ‘hepatocytes’), unless they are used for an ATMP;
- kidneys;
- pancreas, transplanted either as a whole organ or for pancreatic cells which produce insulin (called ‘islets’), unless used for an ATMP;
- intestinal organs (small bowel, stomach, abdominal wall, colon, spleen);
- eye;
- nervous tissue;
- arteries/veins/blood vessels;
- bone;
- muscle;
- tendon;
- skin; and
- rectus fascia (tissue that encases abdominal muscles).

These transplants are common. However, as only 1 in 100 people die in circumstances that would allow donation, there are a lot of people on the UK waiting list for such a transplant. For example, in 2018, 4,500 people had their sight restored through receiving donated corneas (part of the eye) but there is a need for an additional 700 eye donations per year to meet the needs of potential patients.

On 29 April 2019, the Government launched a public consultation¹ to seek views on a proposed list of organs, tissues and cells to exclude from deemed consent as these would be used for novel transplants. The Government has considered the results of the consultation very carefully and is grateful for the considered views on the proposed list of organs, tissues and cells to exclude from deemed consent.

Following the responses to the consultation, the Government has revised the draft regulations. The indicative list is set out in the draft ‘Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020’ and is subject to Parliamentary approval.

¹ Organ and tissues to be excluded from the new system of organ and tissue donation in England (known as “opt-out” or “deemed consent”). Available at: <https://www.gov.uk/government/consultations/opt-out-organ-donation-organs-and-tissues-excluded-from-the-new-system>

Following consultation, the revised draft regulations in **Annex A** have been amended as follows:

- i) the regulations have been revised to clarify further that tissue from sexual and reproductive organs, including skin, will not be transplanted without express consent regardless of the type of transplant, routine or novel. This is to give assurance and put beyond doubt that no part of reproductive organs and tissues will be covered by deemed consent;
- ii) linked to the above change, in line with comments, the list of the component parts of the female reproductive system has been expanded and now includes vagina, labia, clitoris, vulva, cervix, perineum and fallopian tube(s). Prostate for the male reproductive system has also been added;
- iii) the drafting of the regulations has been reviewed to clarify further that specific tissues, for example bone, skin and muscle when needed for novel transplants, will require express consent. Unlike tissues for reproductive organs, these tissues will not require express consent when needed for a routine transplant;
- iv) lung and renal epithelial cells have been added to cells excluded if used for an Advanced Medicinal Product (ATMP);
- v) 'eyes' have been removed from the draft regulations following further clinical advice that eyes would not be transplanted even if a novel transplant, such as a face transplant, would be possible; and
- vi) following further clinical advice, the regulations have been revised to allow the trachea to be transplanted as part of a heart-lung transplantation which is a routine transplant. Transplantation of the trachea will still require express consent in all other circumstances.

The transplantation of most of the organs, tissues and cells listed in the draft regulations is not currently possible and will require significant medical advances. The purpose of these regulations is to give clarity and certainty that, if and when, these novel transplants are undertaken in this country, they will be outside the scope of deemed consent. Use of organs, tissues and cells for non-transplantation purposes, such as research, is outside the scope of deemed consent.

If a novel transplant became standard practice and there was high demand for transplants of that organ or tissue, the Government would need to consider whether it should be removed from the list of organs, tissues and cells excluded from deemed consent. Before doing so, the Government would need to carefully consider the changes, consulting as appropriate with, for example, NHS Blood and Transplant, NHS England and clinicians, and any other relevant stakeholders. If the Government decided to go ahead, it would need to lay regulations in Parliament for debate and approval to make the change. If approval was granted, it would issue a Written

Ministerial Statement explaining why the change has been made and the impact it will have, to give Parliament and the public a single clear statement of the new position for deemed consent. The Government does not expect to change the regulations in the near future.

The following sections set out the detailed results of the public consultation and the Government Response.

The public consultation on what transplants should continue to require express consent

The Government's original consultation about changing the consent arrangements from an opt in to an opt out system ('deemed consent') in England generated 17,047 responses.

As part of the ongoing engagement with stakeholders, all those who had responded to that consultation were contacted again to give their views on what organs, tissues and cells should be excluded from deemed consent. The consultation was also promoted on social media, while stakeholders used their respective platforms to share more widely. There was also some coverage in the media.

The consultation on organs, tissues and cells to exclude from deemed consent ran for 12 weeks, from 29 April 2019 to 22 July 2019. 3,279 responses were received, 25 of which were from organisations.

The proposed list of organs, tissues and cells on which the Government consulted, the draft 'Human Tissue (Permitted Material: Exceptions) (England) Regulations', were annexed to the consultation document.

Analysing the responses

The consultation asked:

- i) whether the draft regulations were clear and easy to understand;
- ii) whether the Government's list of the organs, tissues and cells which should require express consent, was appropriate;
- iii) what tissues of the human body from the proposed list should require express consent if they were going to be used for a novel transplant; and
- iv) whether the removal of specific cells, if used in Advanced Therapy Medicinal Products (ATMPs), should require express consent.

The final question invited respondents to cover any additional points.

The responses provided invaluable insight into the views of the public and organisations about which organs, tissues and cells should still require express consent under the new system. The responses were analysed by the Organ Donation policy team at the Department of Health and Social Care with support from the analytical team and clinical input.

Summary of consultation responses and Government Response

This section provides a summary of the analysis of the questions asked in the consultation and sets out the Government Response.

Question 1: Do you believe that the regulations as drafted are clear and comprehensive?

Summary of responses

Response	Count	%
Yes	3,055	93.2%
No	211	6.4%
Not answered	13	0.4%
Total	3,279	100.0%

Table 1: *Breakdown of the responses to Question 1.*

Analysis

3,266 people responded to this question. 283 respondents used the free text box to provide additional comments. 13 respondents did not answer the question at all.

As set out in Table 1, 3,055 respondents said that they understood how the regulations were drafted and the list of organs, tissues and cells which should be excluded. Some found the use of double negatives – ‘excluding from opt-out’ - in the Government’s explanation of the regulations, confusing.

Of those who provided additional comments, some argued that no organs should be excluded from deemed consent, citing various reasons: that the new system would be simpler and easier to understand; more people would be helped; and that availability of organs, tissues and cells for novel transplants would help develop pioneering medical procedures.

Other respondents took the opposite view and proposed more organs should be excluded from deemed consent, such as eyes and female genitalia (see further analysis of Question 2 below).

A proportion of respondents asked how the Government was going to keep updated the list of what is excluded from deemed consent. Others wanted more detail about the rationale for proposing certain organs to be excluded but not others, while there were also questions about what would happen if someone opted out of organ and

tissue donation completely. The need for public communication on the options available was frequently highlighted.

Government Response to Question 1

Addressing the many points raised in the comments, the Government would like to clarify further the rationale for excluding novel transplants from deemed consent and other operational issues.

Medical science can advance rapidly, making new procedures and types of transplants possible. However, it can take many years for a new transplantation procedure to become standard practice. This is because of the need for careful evaluation at each stage of its development to ensure that it is safe, effective, ethical for patients, and meets the needs of the population. Novel transplants (e.g. face transplantation) are still in the service evaluation phase and are not offered on the NHS, other forms of transplants such as limb transplants, are offered on the NHS but are rare as demand for them is very small, so donation is limited to a small number of hospitals. Since 2012, only six limb transplants have taken place in the UK.

The Government considers that because novel transplants are new, and in most cases are still at an experimental stage, their inclusion in deemed consent would be outside what the public would consider as common transplants. Including them in deemed consent would not be consistent with the policy objective of changing the system in order to help those who are on a waiting list for a routine transplant. It would also contradict assurances given in Parliament that deemed consent would only apply to routine transplants.

While the proposed regulations mean that express consent will still be required for novel transplants, requiring express consent does not mean that the regulations prevent novel transplants from taking place in the UK, which was a concern for some. As mentioned, there is a limb transplant programme in the UK and other novel procedures may become possible. The aim of the legislation is to exclude novel transplants from deemed consent regardless of the scientific developments.

There were questions about how the list of excluded organs, tissues and cells will be updated in the future.

It is not expected that the list will be amended in the near future. Whether the organ, tissue or cells which currently requires express consent for transplantation is included in deemed consent in the future, will be determined by a number of factors. Even if a procedure is no longer novel from a technological point of view, it does not mean that the organs, tissues and cells will be automatically covered by deemed consent. Issues such as evidence, public acceptability, the sensitive nature of certain transplants and clinical need would require further consideration. If the Government decided that the list of what is excluded from deemed consent had to be updated,

the Secretary of State would consult such other persons as (s)he considers appropriate and would need to make regulations in Parliament. The Government would also issue a Written Ministerial Statement explaining why the change has been made and the impact it will have, to give Parliament and the public a single clear statement of the new position for deemed consent.

The Government also wishes to clarify that if someone has registered on the NHS Organ Donor Register (ODR), they can specify which routine organs, tissues and/or cells they want to donate. Under the new system, it will still be possible to use the ODR in the same way and select organs, tissues and cells to donate, or tell your family and friends. When someone has made a decision against organ donation, for example, by using the ODR or telling their friends and family, that means that no organ and tissue donation will go ahead whether it is for routine or novel transplants.

Finally, the Government understands the potential for confusion in using the phrase 'excluding from opt-out' and for clarity will refer to the policy as 'organs, tissues and cells to be excluded from deemed consent'.

Question 2: Do you agree with the Government's proposed list of excluded transplants?

Summary of responses

The Government proposed that the list of transplants below should continue to require express consent, if and when, such transplants become possible in the future in the UK:

Brain	Mouth	Nose
Hand	Face	Arm
Upper arm	Forearm	Lower arm
Finger	Leg	Lower Leg
Thigh	Foot	Toe
Spinal cord	Trachea (windpipe)	Testicle
Uterus	Embryo (inside the body)	Ovary
Foetus	Umbilical cord	Placenta
Penis		

Agree with the proposed list	Count	%
Yes	1,767	53.9%
No	1,337	40.8%
Don't know / Not answered	175	5.3%
Total	3,279	100.0%

Table 2: Breakdown of the responses to Question 2: Do you agree with the Government's proposed list of excluded transplants?

Analysis

More than half of the respondents agreed with the Government's proposals about what should be excluded from deemed consent. 1,512 respondents (1,337 and 175 above) did not explicitly agree:

Response	Count	%
Exclude some but not all	642	42.4%

Response	Count	%
Exclude none	522	34.6%
Exclude all ²	348	23.0%
Total	1,512	100.0%

Table 3: Breakdown of the responses to the follow-up question in Question 2.

The 642 of the 1512 individuals who believed that some of the proposed organs should be excluded from deemed consent, selected the following organs:

Organ to be excluded	Count	% (of 642)
Trachea	102	15.9%
Spinal cord	154	24.0%
Limbs ³	180	28.0%
Uterus	186	29.0%
Penis	221	34.4%
Mouth/Nose	228	35.6%
Placenta/Umbilical Cord	256	39.9%
Testicles/Ovary	311	48.4%
Brain	336	52.3%
Face	370	57.7%
Embryo/Foetus	446	69.4%

Table 4: Breakdown of the follow-up question for the 642 individuals who believed that some but not all organs should be excluded from deemed consent.

Further comments in Question 2

1,629 respondents used the free text box to add additional comments in Question 2. While the majority agreed with the Government's proposed list of organs, tissues and cells to exclude, there were various comments on specific organs and tissues. The main ones were:

- exclusions from deemed consent should be either limited to reproductive organs and tissues; and/or organs, tissues and cells which would disfigure the

² Either by selecting exclude all or selecting all organs individually.

³ Defined as: Hand/Forearm/Upper arm/Arm/Foot/Leg/Lower leg/Finger/Thigh/Toe

body after death (face/limbs); and/or organs, tissues and cells relating to identity, usually stated to be brain and face.

- several stated that the list of excluded organs was too long and should be simplified, while others proposed specific organs, tissues and cells to be removed from the proposed list. Of the 600 respondents who used the free text box to comment on specific organs, several stated that the trachea (33%), limbs (26%), and spinal cord (14%) should be included in deemed consent.
- 72% (51 of 71 responses) of individuals who suggested a specific organ to be excluded from deemed consent mentioned the eyes. Reasons cited included that eyes were linked to identity; and/or that most people were sensitive about them; and that in some religions, eyes are required to see God in the afterlife. In the same group of responses, 21% (15 of the 71 responses) felt that more parts of the female reproductive system should be added to the list to make it commensurate with those for males.
- many expressed concern about the potential transplantation of reproductive organs and tissues and asked for clarity on the situation with embryos and foetuses. The question of whether the regulations should apply to sperm and eggs was also raised by many, unsure if these would be transplanted with testicles and ovaries. Others were concerned about the prospect of transplanting genetic material that could be used to produce offspring.
- compared to the trachea, spinal cord, and limbs, a smaller number of respondents stated that the uterus, placenta, umbilical cord, and other individual organs should be included (rather than excluded) in deemed consent.
- finally, some commented that there should be no exclusions from deemed consent, while others asked how to opt out of novel transplants.

Government Response to Question 2

The Government has considered all suggestions and has noted that the majority of respondents agreed with the proposed list of what should be excluded (almost 54% of all respondents).

In respect of the trachea, the brain and spinal cord, the Government wishes to clarify that these are novel transplants and maintains the view that their transplantation should require express consent, unless a trachea is removed during a heart-lung transplantation which is a routine transplant. In all other circumstances, the transplantation of the trachea will still require express consent.

In compiling the list of organs, tissues and cells to exclude from deemed consent, the Government took wider policy considerations into account. Given that there is a UK-wide organ donation allocation system, maintaining broad consistency on organs, tissues and cells to exclude from deemed consent enables healthcare professionals

working across borders to have a common understanding of what is a routine transplant, which is also reassuring to patients and their families.

The proposed list of what is excluded from deemed consent in England is broadly consistent with the policy in Wales, with a few additions: the trachea, prostate, component parts of the female reproductive system and cells to be used for ATMPs. Wales are planning to consult on bringing their regulations in line with the proposed regulations in England. Scotland have recently consulted on their proposed list.

Cornea donation

The Government has considered the suggestion that eyes should require express consent but remains of the view that cornea donation (which requires the whole eye to be removed, but not transplanted) should be included in deemed consent. This is because cornea donation is the most common form of donation and transplantation is therefore neither novel nor rare. In 2018, around 4500 corneas were transplanted in 100 different transplanting centres. The Government therefore intends to take the same position as in Wales and include cornea donation in deemed consent.

The Government recognises that some may find the idea of cornea donation difficult. It has therefore asked NHS Blood and Transplant to clarify in communications that the NHS Organ Donor Register will continue to allow individuals to select which organs, tissues and cells they would like to donate, but they can also make their preferences clear to their friends and family, as now.

The Government would like to confirm that following further clinical advice as a result of the consultation, the eye is not be retrieved as part of a face transplant. For this reason, 'eye' has now been removed from the list of excluded tissues as it would not be part of a novel transplant. The Government will review this position if there is a change in the future.

Reproductive system

The Government agrees that donation of eggs as part of the female reproductive system and sperm as part of the male reproductive system should require express consent. This requirement is already specified in the Human Fertilisation and Embryology Act 1990 which covers gametes (eggs and sperm). The Human Tissue Act 2004 which governs organ and tissue transplantation does not cover gametes. Therefore, it is not possible to add gametes to the list of what should be excluded.

In contrast, ovaries, testicles, embryos inside the body and fetuses have been included in the list of what should be excluded, for completeness, as they are captured by the Human Tissue Act 2004 which applies widely to human cells (but not to gametes or embryos outside the body). In practice, and depending on the intended use of these tissues, the Human Fertilisation and Embryology Act 1990 might also apply to some of them. In relation to ovarian and testicular tissue, if transplant technology develops to make transplantation of donor tissue possible, mechanisms will need to be put in place to ensure appropriate regulation.

Regarding the many comments received on the implications of transplanting embryos, the Government wishes to clarify that it is not technically possible to transplant an embryo as any such attempt would lead to the termination of pregnancy.

In fertility treatment where embryos are transferred as part of in-vitro fertilisation, implantation usually occurs around 3-4 days after embryo transfer. It would not be possible to remove the embryo after it has been transferred because this would almost certainly destroy the embryo itself, or its chances of normal development and an established pregnancy in the new recipient. 'Embryo (inside the body)' has been added to the list of what should be excluded to put beyond doubt that together with other reproductive tissue and sexual organs, it will not be covered by deemed consent.

The Government also agrees with comments that further parts of the female reproductive system should be added to make the list commensurate with the list of parts of the male reproductive system. As suggested in responses, the list has now been updated to also list vagina, labia, clitoris, vulva, cervix, fallopian tube(s), and prostate. Finally, the Government would like to confirm that the regulations do not allow tissue from sexual and reproductive organs to be transplanted without express consent. This is to give assurance and put beyond doubt that reproductive organs and their tissues, even if required for a routine transplant, will be excluded from deemed consent.

Question 3: Which of the following should be excluded from deemed consent if they are part of a rare or novel transplant?

This question asked what tissues should be excluded if used for novel or rare transplant (such as limb transplants for example):

Eye	Nervous tissue	Artery/vein
Bone	Muscle	Tendon
Skin		

An example was given to draw a distinction between tissues used for routine transplants as currently and tissues which would be used for novel or rare transplants: in the new system, arteries used for a liver transplant which is a routine transplant would not require express consent but arteries required for a leg transplant, which is a rare transplant, would.

Summary of responses

Response	Count	%
Exclude none	1,659	50.6%
Exclude all ⁴	1,119	34.1%
Excludes some but not all	501	15.3%
Total	3,279	100.0%

Table 5: Breakdown of the responses to Question 3.

Analysis

As shown in Table 5, 1,659 respondents out of the 3,279 believed that no tissues should be excluded from deemed consent.

The 501 respondents who believed that some tissues should be excluded, responded as follows:

Tissue to be excluded	Count	% (of 501)
Tendons	90	18.0%
Muscles	98	19.6%
Arteries and veins	109	21.8%
Bones	130	25.9%

⁴ Either by selecting exclude all or selecting all organs and tissues individually.

Tissue to be excluded	Count	% (of 501)
Nervous tissue	172	34.3%
Skin	189	37.7%
Eyes	331	66.1%

Table 6: *Breakdown of the follow-up question to Question 3 for the 501 individuals who believed that some tissues should be excluded.*

Government Response to Question 3

The Government has noted that the majority believed that no tissues should be excluded when used for a novel transplant. However, the Government's view is that consent to a novel transplant should also include the tissues required for such a transplant, as the tissues are an integral part of the organ which would require express consent.

There were queries about whether the exclusion of the limbs would also mean that tissue which is currently removed from them as part of a routine transplant, would require express consent in future. The Government would like to clarify that the regulations allow tissues for routine transplants to continue to be taken under deemed consent (for example bone or skin from the leg but used for a routine transplant) but that when taken together to form a whole structure, such as a hand or leg to be used in a novel transplant, then express consent will always be needed.

Question 4: Which of the following should be excluded from deemed consent if they are retrieved for use in an Advanced Therapy Medicinal Product (ATMP)?

- liver cells;
- limbal stem cells (found in the cornea); or
- pancreatic cells.

These three types of cells were proposed as requiring express consent if used for an ATMP. ATMPs are classified as ‘medicines’ and are created from tissues, cells and genes after manipulation in a laboratory. Most commonly, they are used for treatment of a disease or injury and often use human cells and tissues from living donors. It is however possible to also use cells from deceased donors, in which case an ATMP would be considered a type of novel transplant.

Summary of responses

Response	Count	%
Exclude none	1,989	60.7%
Exclude all ⁵	1,173	35.8%
Excludes some but not all	117	3.6%
Total	3,279	100.0%

Table 7: Breakdown of the responses to Question 4: which of the following should be excluded from deemed consent if they are retrieved for use in an Advanced Therapy Medicinal Product.

Analysis

1,989 respondents out of the 3,279 total respondents to the consultation believed no cells should be excluded for the use of ATMP under deemed consent. Almost 36% took the opposite view, while a fairly small number of respondents wanted some exclusions.

The 3.6% (117 of 3,279) of individuals who believed that some cells should be excluded answered as follows:

Cells to be excluded	Count	% (of 117)
Pancreatic cells	20	17.1%
Liver cells	24	20.5%

⁵ Either by selecting ‘exclude all’ or selecting all organs, tissues and cells individually.

Cells to be excluded	Count	% (of 117)
Limbal stem cells (found in the cornea)	93	79.5%

Table 8: Breakdown of the follow-up to Question 4 for the 117 individuals who believed that some cells should be excluded, but not all.

As shown in Table 8, 17.1% of 117 respondents who proposed to exclude some cells but not all, wanted pancreatic cells excluded. 20.5% of these respondents wanted liver cells excluded. For limbal stem cells, there was strong support for their exclusion, with 79.5% of the 117 respondents wanting to exclude them.

Following further clinical input, it was also proposed that lung and renal epithelial cells should be excluded from deemed consent. The rationale given was that as transplant technology advances, it may be possible to transplant them in the future and this would require careful oversight and introduction.

Government Response to Question 4

The Government has considered carefully all responses and has noted that the majority believed no cells from deceased donors should be excluded for the use of ATMP.

Although cells from living donors have led to major medical advances, using cells from deceased donors is considered a novel form of transplant and it is appropriate that express consent is in place for donating such cells. ATMPs are manufactured by pharmaceutical companies, allowing scope for donated tissues and cells to potentially be used for commercial purposes and profit. This raises questions around the level of understanding of the donor about the use of the cells and wider ethical questions. The Government would like to see further medical advances and encourage scientific innovation like ATMPs, but considered this must be balanced with the rights of individuals and their families. Excluding ATMPs from deemed consent will maintain the current position on consent and will not introduce any new obstacle to their development.

Question 5: Any other comments on the regulations not covered in these questions (please limit your comments on the proposed regulations rather than on deemed consent on which the Government has consulted on previously).

The final question gave respondents the opportunity to add any further points.

Summary of responses

Many comments were repeated, such as the need to publicise the new system and the opportunity to be able to opt in or opt out of novel transplants.

There were suggestions that the Government should review the list of excluded organs, tissues and cells regularly to ensure it was up to date. Many observed that scientific advances meant that some transplants could become more common and therefore there was a possibility to cover them in deemed consent in the future.

Government Response to Question 5

All of these points have been addressed in the previous sections of the Government Response.

Revisions to draft regulations

The Government has considered the results of the consultation very carefully and is grateful for the considered views on the proposed list of organs, tissues and cells to exclude from deemed consent. Following the responses to the consultation, it has revised the draft regulations. The updated indicative list is set out in the draft 'Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020' and is subject to Parliamentary approval.

The revised draft regulations are in **Annex A** and have been amended as follows:

- i) given the focus of many of the comments on the component parts of the reproductive organs and tissues, the regulations have been revised to clarify further that tissue from sexual and reproductive organs will not be transplanted without express consent regardless of the type of transplant, routine or novel. This includes skin from these organs. This is to give assurance and put beyond doubt that no part of reproductive organs will be covered by deemed consent;
- ii) linked to the above change, in line with comments, the list of the component parts of the female reproductive system has been expanded and now includes vagina, labia, clitoris, vulva, cervix, perineum and fallopian tube(s). Prostate for the male reproductive system has also been added;
- iii) the drafting of the regulations has been reviewed to clarify further that specific tissues, for example bone, skin and muscle when needed for novel transplants, will require express consent. Unlike tissues for reproductive organs, these tissues will not require express consent when needed for a routine transplant, as now;
- iv) lung and renal epithelial cells have been added to cells excluded, if used for an Advanced Therapy Medicinal Product (ATMP);
- v) 'eyes' have been removed from the draft regulations following further clinical advice that eyes would not be transplanted if a novel transplant such as a face transplant would be possible. We will reconsider this position if there is a change in the future; and
- vi) following further clinical advice, the regulations have been revised to allow the trachea to be transplanted under deemed consent as part of a heart-lung transplantation which is a routine transplant. Transplantation of the trachea will still require express consent in all other circumstances.

In the Explanatory Memorandum to the regulations, further clarity has been provided to explain that 'exclusion' means that organs, tissues and cells listed in the regulations will continue to require express consent as now and will not be covered by deemed consent.

Next steps

The next stage for these draft regulations is for them to be debated for approval by both Houses of Parliament.

Alongside this, following public consultation, the Human Tissue Authority (HTA) has updated its Codes of Practice for healthcare professionals involved in organ and tissue donation, retrieval, and transplantation. The revised Code of Practice F has been laid in Parliament in draft with Code of Practice A.

The main changes to reflect guidance on deemed consent have been made to Code F: Part Two. Code F: Part One has not been changed but has been included with Part Two for completeness. Code A includes minor edits to signpost healthcare professionals to the revised Code F. Pending Parliamentary approval of the draft regulations and the Codes of Practice, the revised Codes will be brought into force by directions made by the HTA.

The Government will use commencement regulations to bring the remaining deemed consent provisions into effect, which will stipulate in law the 20 May 2020 date when deemed consent goes live.

Annex A – The draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 following consultation

Draft Regulations laid before Parliament under section 52(4) of the Human Tissue Act 2004, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

HUMAN TISSUE, ENGLAND

The Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020

Made - - - - - ***

Coming into force - - - - - ***

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 3(9) and 52(1) of the Human Tissue Act 2004⁽⁶⁾.

In accordance with section 52(10)⁽⁷⁾ of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

In accordance with section 52(4) of that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement, extent and application

—(1) These Regulations may be cited as the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and come into force on 20th May 2020.

These Regulations extend to England and Wales only.

These Regulations apply in relation to activities done in England for the purpose of transplantation⁽⁸⁾.

⁽⁶⁾ 2004 c. 30 (“the 2004 Act”); subsection (9) was inserted into section 3 by section 1(1) and (5) of the Organ Donation (Deemed Consent) Act 2019 (c. 7) (“the 2019 Act”).

⁽⁷⁾ Section 52(10) was amended, so far as relevant, by section 2(1) and (7) of the 2019 Act.

⁽⁸⁾ See section 54(3) of the 2004 Act as to references to transplantation in that Act.

Relevant material that is not permitted material

—(2) Paragraphs (2) to (5) specify types of relevant material⁽⁹⁾ for the purposes of the definition of “permitted material” in section 3(9) (“appropriate consent”: adults) of the Human Tissue Act 2004.

Subject to paragraphs (3) and (4), the whole or any part of the following is specified—

arm;
brain;
face;
finger;
foot;
forearm;
hand;
leg;
lower leg;
mouth;
nose;
spinal cord;
thigh;
toe;
trachea;
upper arm;
cervix;
clitoris;
embryo (inside the body)⁽¹⁰⁾;
fallopian tube;
foetus;
labia;
ovary;
penis;
perineum;
placenta;
prostate;
testicle;
umbilical cord;
uterus;
vagina;
vulva.

The following is not specified in so far as it is disaggregated from any of the relevant material specified in sub-paragraphs (a) to (p) of paragraph (2)—

artery;
bone;
muscle;

⁽⁹⁾ See section 53 of the 2004 Act for the meaning of “relevant material”.

⁽¹⁰⁾ See section 54(6) of the 2004 Act for the meaning of “embryo”. That subsection was substituted by paragraph 24 of Schedule 7 to the Human Fertilisation and Embryology Act 2008 (c. 22).

nervous tissue;
skin;
tendon.

The whole or part of the trachea is not specified in so far as it is attached to a lung.

The following types of cells are specified only in so far as all or part of the cells is for use in, or as, an advanced therapy medicinal product—

limbal stem cells;
liver cells;
lung epithelial cells;
pancreatic cells;
renal epithelial cells.

In this regulation, “advanced therapy medicinal product” has the same meaning as in the Human Medicines Regulations 2012⁽¹¹⁾.

Signatory text

Address
Date

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Human Tissue Act 2004 (c.30) (“the 2004 Act”). Section 3 of the 2004 Act makes provision for the interpretation of “appropriate consent”. This term is used in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult.

Section 3(6) provides that, in relation to certain activities done in England, in certain circumstances, appropriate consent means deemed consent. Certain of those activities involve the removal, storage or use, for the purpose of transplantation, of “permitted material”. Section 3(9) defines “permitted material” as “relevant material” (as defined by section 53 of the 2004 Act) other than relevant material of a type specified in regulations. These Regulations specify types of relevant material that will not be “permitted material”. Permitted material is not subject to deemed consent.

Regulation 2(2) specifies the whole or any part of certain relevant material, for example the arm, brain and face.

Regulation 2(3) provides that the types of relevant material listed in that paragraph, which are component parts of relevant material specified in regulation 2(2)(a) to (p), are not specified when detached from the latter.

Regulation 2(4) provides that the whole or part of the trachea, which is listed in paragraph (2), is not specified if it is connected to a lung.

Regulation 2(5) specifies certain types of cells as relevant material, for example limbal stem cells, in so far as all or part of the cells is for use for the purpose of transplantation in the form of an advanced therapy medicinal product. Regulation 2(6) provides that in regulation 2(5), “advanced therapy medicinal product” has the same meaning as it does in the Human Medicines Regulations 2012 (S.I. 2012/1916).

A full impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

⁽¹¹⁾ S.I. 2012/1916, as prospectively amended by S.I. 2019/775 from IP completion day. “IP completion day” is defined in Schedule 1 to the Interpretation Act 1978 (c. 30).

Annex B – Consent for novel transplants

The list of organs, tissues and cells below will continue to require express consent:

- brain
- spinal cord
- face
- nose
- mouth
- trachea (windpipe) – unless removed with the heart and lungs as part of a heart-lung transplantation, which is a routine transplant
- arm
- upper arm
- forearm
- hand
- finger
- leg
- thigh
- lower leg
- foot
- toe
- ovary
- uterus
- penis
- testicle
- foetus
- placenta
- umbilical cord
- vagina
- labia
- vulva
- clitoris

- cervix
- fallopian tube(s)
- prostate
- perineum
- embryo (inside the body)
- limbal stem cells, renal epithelial cells, liver cells, and pancreatic cells – if they are used for an ATMP
- nervous tissue, artery, bone, muscle, tendon and skin – consent will be sought only if used as part of a novel or rare transplant, but not routine, unless they are part of a reproductive organ.

Unless you have opted out of organ donation, if you die in a hospital that runs a novel transplant programme, you are a suitable donor and there is someone on a waiting list for such a transplant, your family will be asked whether you expressed a decision to donate your organs, tissues and cells for novel transplants. Their consent will be sought to go ahead with a novel transplant, if this is a possibility.

This means that the new law allowing deemed consent for organ and tissue donation will not apply to any of the organs, tissues and cells listed in Annex B.

Annex C – Routine transplants that will be included in deemed consent

These are common and well-established transplants that are offered on the NHS. If someone has made a decision to not donate some or all of their organs, tissues and/or cells before spring 2020, this decision will still apply after deemed consent comes into force.

- heart, transplanted either as a whole organ or for heart valves
- lung(s)
- liver, transplanted either as an organ or for liver cells – unless the liver cells are for use for an Advanced Therapy Medicinal Product (ATMP)
- kidneys
- pancreas, transplanted either as a whole organ or pancreatic cells – unless the pancreatic cells are for use for an ATMP
- intestinal organs (small bowel, stomach, abdominal wall, colon, spleen)
- cornea
- nervous tissue
- arteries/veins/blood vessels
- bone
- muscle
- tendon
- skin
- rectus fascia (tissue that encases abdominal muscles)

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