STATUTORY INSTRUMENTS

2024 No. 262

HUMAN TISSUE, ENGLAND AND WALES
HUMAN TISSUE, NORTHERN IRELAND

The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024

Made - - - -	*29th February 2024*
Laid before Parliament	*1st March 2024*
Coming into force - -	*1st April 2024*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 34(1) and 52(1) of the Human Tissue Act 2004(**1**).

The Secretary of State has consulted the Welsh Ministers and the relevant Northern Ireland Department(**2**) in accordance with section 52(8) of that Act.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 and shall come into force on 1st April 2024.

(2) These Regulations extend to and apply in England and Wales, and Northern Ireland.

Interpretation

2. In these Regulations—

"donor" means a person who donates one or more organs, whether donation occurs during lifetime or after death;

"recipient" means a person who receives a transplant of one or more organs;

"relevant clinician" means any of the following whether practising as such a clinician in a transplant centre or a non-transplant centre—

(a) a specialist nurse involved in living donor care;

(b) a specialist nurse involved in recipient care;

(**1**) 2004 c. 30.

(**2**) See section 54(1) of the Human Tissue Act 2004 which defines "relevant Northern Ireland department" as the Department of Health, Social Services and Public Safety.

(c) a transplant surgeon;

(d) a physician involved in living donor care;

(e) a physician involved in recipient care.

Supply of information regarding specified offences

3.—(1) Where a relevant clinician has reasonable suspicion that one or more of the offences listed in paragraph (2) may have been committed, the clinician must, as soon as reasonably practicable, supply to the Human Tissue Authority(**3**) such information specified in Schedule 1 as is known by the relevant clinician.

(2) The offences are—

(a) sections 32 (prohibition of commercial dealings in human material for transplantation), 32A (offences under section 32 committed outside UK) and 33 (restriction on transplants involving a live donor) of the Human Tissue Act 2004(**4**);

(b) section 2 (human trafficking) of the Modern Slavery Act 2015(**5**), where section 3(4) (meaning of exploitation) of that Act applies in relation to the person; and

(c) section 2 (human trafficking) of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015(**6**), where section 3(4) (meaning of exploitation for purposes of section 2) of that Act applies in relation to the person.

(3) Paragraph (1) does not apply where—

(a) the reasonable suspicion arose other than in the course of the relevant clinician's profession; or

(b) the relevant clinician has reason to believe that another relevant clinician has previously supplied information to the Human Tissue Authority in connection with the same suspected offence.

Supply of information regarding organ transplants performed outside the United Kingdom

4.—(1) Where the conditions in paragraph (2) are met, the relevant clinician must, as soon as reasonably practicable, supply to the Human Tissue Authority such information specified in Schedule 2 as is known by the relevant clinician.

(2) The conditions are—

(a) in the course of their profession, the relevant clinician becomes aware of an organ transplant having taken place outside the United Kingdom; and

(b) the recipient is—

(i) habitually resident in England, Wales or Northern Ireland, whether they are a United Kingdom national or not; or

(ii) a United Kingdom national who is not habitually resident in England, Wales or Northern Ireland.

(3) In this regulation "United Kingdom national" means an individual who is—

(a) a British citizen, a British overseas territories citizen, a British National (Overseas) or a British Overseas citizen;

(**3**) The Human Tissue Authority is a non-departmental public body of the Department of Health and Social Care, established by the Human Tissue Act 2004.
(**4**) Section 32A was inserted by section 170(1) of the Health and Care Act 2022 (c. 31).
(**5**) 2015 c. 30.
(**6**) 2015 c. 2 (N.I.)

(b) a person who under the British Nationality Act 1981(**7**) is a British subject; or

(c) a British protected person within the meaning of that Act.

(4) Paragraph (1) does not apply if the relevant clinician has reason to believe that another relevant clinician has previously supplied information to the Human Tissue Authority in connection with the same organ transplant as referred to in paragraph (2)(a).

Supply of information

5. A supply of information under these Regulations does not breach any obligation of confidence owed by the person supplying the information.

Signed by authority of the Secretary of State for Health and Social Care

Andrea Leadsom
Parliamentary Under Secretary of State
Department of Health and Social Care

29th February 2024

(**7**) 1981 c. 61

SCHEDULES

SCHEDULE 1

Regulation 3(1)

Information in relation to suspected offences

1. The full name of the relevant clinician supplying the information to the Human Tissue Authority, their contact details, the position they hold and the place at which they hold it.

2. The offence or offences listed in regulation 3(2) which the relevant clinician reasonably suspects may have been committed.

3. The following information about the donor or potential donor, recipient or intended recipient, and any other persons believed to be involved in the commission of an offence specified in regulation 3(2)—

(a) full name,

(b) whether the person is a donor or potential donor, recipient or intended recipient, or is believed to have other involvement in the commission of the offence,

(c) date of birth, and

(d) gender.

4. The relationship between the donor and recipient, or the relationship between the potential donor and intended recipient, if one exists.

5. A description of the organ believed to be transplanted or which is intended to be transplanted.

6. A description of the indicators that an offence specified in regulation 3(2) may have been committed.

SCHEDULE 2

Regulation 4(1)

Information in relation to organ transplants performed outside the United Kingdom

1. The full name of the relevant clinician supplying the information to the Human Tissue Authority, their contact details, the position they hold and the place at which they hold it.

2. The following information about the recipient—

(a) full name,

(b) date of birth,

(c) age at the time of organ transplantation,

(d) gender,

(e) whether the recipient was treated at the relevant clinician's centre before travelling outside the United Kingdom for organ transplantation,

(f) status of the recipient on the United Kingdom organ transplant list, when they travelled outside the United Kingdom for organ transplantation,

(g) whether the recipient was referred for organ transplantation outside the United Kingdom and if such a referral took place, the reason or reasons for this, and

(h) country or countries of legal citizenship or residency.

3. The following information about the donor—

(a) full name,

(b) whether the donor was living or deceased at the time of the organ donation,

(c) date of birth,

(d) age at time of the organ donation,

(e) gender, and

(f) country or countries of legal citizenship or residency.

4. The relationship between the donor and recipient, if one exists.

5. A description of the organ believed to have been transplanted.

6. The date of the organ transplantation.

7. The country, city and centre where the organ transplantation took place.

8. Whether the relevant clinician's centre has contact details for the clinician who performed the organ transplant or the centre where the organ transplant took place.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations specify information that relevant clinicians must provide to the Human Tissue Authority in connection with organ transplants.

Regulation 3 imposes a duty on relevant clinicians to provide the information prescribed in Schedule 1 (where it is known) to the Human Tissue Authority, where that relevant clinician has a reasonable suspicion that one or more of the offences listed in the regulation may have been committed. Regulation 3 also provides exceptions to the requirement to provide information, where the relevant clinician becomes aware of the information outside the course of their profession, or if they believe that another relevant clinician has already made a report in respect of that offence.

Regulation 4 imposes a duty on relevant clinicians to provide the information that is prescribed in Schedule 2 (where it is known) to the Human Tissue Authority about organ transplants that have taken place outside of the United Kingdom where the recipient is a United Kingdom national (whether living in the United Kingdom or not) or is otherwise habitually resident in the United Kingdom. The duty applies where a clinician becomes aware of such a transplant in the course of their profession. Regulation 4 also creates an exception so that a relevant clinician is not required to supply the specified information if they believe another relevant clinician has already supplied information to the Human Tissue Authority in respect of the same organ transplant.

Regulation 5 provides that a supply of information under these Regulations does not breach an obligation of confidence owed by the relevant clinician who provides the information to the Human Tissue Authority.

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