HUMAN TISSUE AND ORGAN DONATION (LICENSING) REGULATIONS 2025

Index

Statutory Document No. 20XX/XXXX

Human Tissue and Organ Donation Act 2021

HUMAN TISSUE AND ORGAN DONATION (LICENSING) REGULATIONS 2025

Approved by Tynwald:
Coming into Operation:

The Cabinet Office, after consulting with the Department of Health and Social Care in accordance with section 75 of the Human Tissue and Organ Donation Act 2021, makes the following Regulations under sections 7(9), 11, 16(5), 20(8), 32(3), 32(4) and 33(1) of, and paragraphs 10(5) and 13 of Schedule 2 to, the Human Tissue and Organ Donation Act 2021.

PART 1

GENERAL

1 Title

These Regulations are the Human Tissue and Organ Donation (Licensing) Regulations 2025.

2 Commencement

If approved by Tynwald, these Regulations come into operation on [insert date][1].

3 Interpretation

In these Regulations —

"the Act" means the Human Tissue and Organ Donation Act 2021;

"Director of Public Health" has the meaning provided by section 1 of the Local Government Act 1985;

"ethical approval Regulations" means the Human Tissue and Organ Donation (Ethical Approval, Etc.) Regulations 2025[2];

[1] Tynwald procedure – approval required further to section 72 of the Human Tissue and Organ Donation Act 2021.

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with significant levels of autonomy, and a part is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation; and

"Licensing Officer" has the meaning provided by regulation 5 (licensing Officer).

PART 2

EXCEPTIONS FROM LICENSING REQUIREMENTS

4 Exceptions from licensing requirements

(1) The storage of organs, tissue or bodily material that has come from a human body by a person who intends to use it for a scheduled purposes is excepted from paragraph subsection (2)(e)(ii) of section 20 (license requirement) of the Act in the circumstances set out in paragraphs (2) to (4).

(2) Storage of organs, tissue or bodily material that has come from the body of a living person is excepted where the person storing it is intending to use for —

(a) any purposes specified in paragraphs 2 to 5 or 8 to 12 of Schedule 1 (scheduled purposes) to the Act; or

(b) the purpose of qualifying research.

(3) Storage of transplantable material which has come from a human body is excepted where the person storing it is intending to use it for the purpose of transplantation and the storage is for a period less than 48 hours.

(4) Storage of organs, tissue and bodily material (as appropriate) which has come from the body of a deceased person is excepted where —

(a) the person storing it is intending to use for the purpose of qualifying research; or

(b) the organs, tissue or bodily material (as appropriate) —

(i) has come from premises in respect of which a licence for the purposes of —

(A) paragraph subsection (2) of section 20 (licence requirement) of the Act, or

(B) subsection (2) of section 16 (licence requirement) of the Human Tissue Act 2004 (of Parliament),

[2] SD 2025/****.

is in force;

(ii) is stored by a person intending to use for the sole purpose of analysis for a scheduled purpose other than research; and

(iii) will be returned to the premises in respect of which a licence for the purposes of —

(A) subsection (2) of section 20 (licence requirement) of the Act; or

(B) subsection (2) of section 16 (licence requirement) of the Human Tissue Act 2004 (of Parliament),

is in force when the analysis is completed.

(5) For the purposes of this regulation —

(a) "ethical approval is pending" means the period of time —

(i) commencing when an application for ethical approval for research has been submitted to the Director of Public Health further to —

(A) regulation 4 (ethical approval of research for scheduled purposes and paragraph 9(b) of Schedule 3 to the Act); or

(B) regulation 7 (ethical approval for the purposes of relations 5 and 6) of the ethical approval Regulations; and

(ii) concluding when the decision of the Director of Public Health to grant ethical approval for research, or otherwise, has been communicated to the applicant;

(b) "qualifying research" means —

(i) research which is ethically approved for the purposes of subsection (9)(a) of section 7 (authorisation of activities for scheduled purposes) of the Act;

(ii) research which is ethically approved for the purposes of paragraph (a) and (b) of section 13 (activities involving organs or tissue from adults who lack capacity to consent) of the Act; or

(iii) a specific research project for which such ethical approval is pending; and

(c) "transplantable material" has the meaning given in regulation 9 (meaning of transplantable material for the purposes of sections 32 (restrictions on transplants involving a live donor) and section 33 (information about transplant operations) of the Act) of the ethical approval Regulations.

PART 3

APPLICATIONS FOR LICENCES

5 Licensing officer

The Department must provide a member of its staff to act as Licensing Officer to, subject to any directions given by the Department under the Act, grant, vary, suspend or revoke licences for the purposes of section 20 (licence requirement) of, and Schedule 2 (licences for the purposes of section 20) to, the Act.

6 Application forms and submission of applications

(1) Applications for licences should be prepared using the appropriate application form for the activity, as published on the gov.im website.

(2) Once completed the application form must either be —

(a) emailed to [insert email address]; or

(b) posted to —

The Licensing Officer,
Human Tissue and Organ Donation Act 2021
Public Health Directorate, Cabinet Office,
Cronk Coar,
Noble's Hospital, Strang,
Douglas, ISLE OF MAN, IM4 4RJ.

7 Preconditions to grant of licence: requirements for the Licensing Officer to be satisfied a person is a "suitable person" for the purpose of paragraph 6 of Schedule 2 to the Act

For the purposes of paragraph 6 (pre-conditions to grant of licence) of Schedule 2 (licenses for the purposes of section 20) to the Act, the Licensing Officer must be satisfied that a person is a "suitable person" if that person —

(a) has a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent; or

(b) is suitably qualified on the basis of academic qualifications and practical experience,

and has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.

8 Additional procedures in relation to paragraph 10 of Schedule 2 to the Act

(1) This procedure applies when the Licensing Officer receives a notice from a person (P) requesting the opportunity for oral representation under sub-paragraph (3) of paragraph 10 (procedure in relation to licensing decisions) of Schedule 2 to the Act (licenses for the purposes of section 20) to the Act.

(2) Subject to paragraph 10(4) of Schedule 2 to the Act, upon receiving the notice for oral representation from P the Licensing Officer must —

(a) arrange a meeting at a time suitable for P, or a person acting on behalf of P, and the Licensing Officer;

(b) notify P of the date, time and place of the meeting at least 14 days before the date of that meeting;

(c) inform P of the procedures to be followed at that meeting, including that —

(i) the Licensing Officer may receive oral representations from a person acting on behalf of P;

(ii) the Licensing Officer may ask P, or a person acting on behalf of P, questions in relation to the decision to be made by the Licensing Officer; and

(iii) the Licensing Officer may ask P to make an additional written representation to the Licensing Officer no later than 28 days following the meeting.

9 Additional procedures in relation to paragraph 11 of Schedule 2 to the Act

(1) This procedure applies when the Licensing Officer issues a notice under paragraph 11 (notification of licensing decisions) of Schedule 2 (licenses for the purposes of section 20) to the Act.

(2) When giving a notice under sub-paragraph (1) of paragraph 11 of Schedule 2 to the Act, the Licensing Officer must —

(a) specify in the notice which activity a person may undertake under the licence.

(b) provide, in relation to that licence, a certificate of authority in such form as the Department considers appropriate;

(c) provide, in relation to that licence, a copy of the conditions to be imposed by the licence;

(d) provide a statement setting out —

(i) the reasons (if any) for the conditions to be imposed by the licence;

(ii) the right, within 28 days of receiving a copy of the conditions imposed by the licence, to request in writing that the Department reconsider those conditions, stating the grounds on which the reconsideration is requested.

(3) When giving a notice under sub-paragraph (2), (4) or (5) of paragraph 11 of Schedule 2 to the Act, the Licensing Officer must provide a statement setting out the right of the person receiving that notice to submit a written representation that the Department reconsider the decision.

(4) Any written representation submitted to the Department further to paragraph (3) must —

(a) be submitted before the end of the period of 28 days beginning with the day on which the notice under sub-paragraph (1), (2) (3), (4) or (5) of that paragraph was given;

(b) state the grounds on which the reconsideration of the decision is requested;

(c) indicate whether or not the person submitting the written representation would wish to have either a written review or an oral review as defined in regulation 10 (procedure to reconsider a decision by the Department).

10 Procedure to reconsider a decision by the Department

(1) Upon receiving a written request for reconsideration further to —

(a) regulation 8 (additional procedures in relation to paragraph 10 of Schedule 2 to the Act); or

(b) regulation 9 (additional procedures in relation to paragraph 11 of Schedule 2 to the Act),

the Department must, subject to paragraph (2), appoint an officer of the Department to reconsider the decision ("the Review Officer").

(2) The Review Officer must —

(a) be appointed by the Department as soon as is practicable on receiving the written request for reconsideration;

(b) have had no involvement in the original application; and

(c) be informed as to any direction issued by the Department under the Act that is relevant to that written representation.

(3) As soon as practicable after being appointed the Review Officer must request that the Licensing Officer supply the Review Officer with a copy of any information relating to the written request for reconsideration.

(4) Before conducting a written review under paragraph (6), or an oral review under paragraph (6), the Review Officer must supply the appellant with —

(a) a list of the information supplied by the Licensing Officer under paragraph (3); and

(b) a copy of any information that the appellant does not already possess.

(5) The Review Officer may receive or request further written representations from the appellant or the Licensing Officer, on the condition that a copy of the written representation be supplied to all other parties.

(6) If the appellant indicated that they wished to have a written review the Review Officer must consider —

(a) the Act, and secondary legislation made under the Act, and any relevant directions issued by the Department under the Act;

(b) the written request for reconsideration and the information supplied by the Department under paragraph (3); and

(c) any further written representations supplied under paragraph (5).

(7) If the appellant indicated that they wished to have an oral review the Review Officer must —

(a) arrange a review meeting at a time suitable for the appellant and the Licensing Officer;

(b) notify the appellant and the Licensing Officer of the date, time and place of the review meeting at least 14 days before the date of the review meeting;

(c) inform the appellant and the Licensing Officer of the procedures to be followed at the review meeting, including that —

(i) the oral review may receive oral representations from a person acting on behalf of the appellant or a person acting on behalf of the Licensing Officer (or both); and

(ii) the Review Officer may ask questions of the appellant or the Licensing Officer (or both).

(8) Within 60 days of being appointed the Review Officer must —

(a) conduct a written review or an oral review;

(b) determine as to whether or not, on the balance of probabilities, that the decision of the Licensing Officer was either reasonable or unreasonable;

(c) give written notice to the appellant and the Licensing Officer setting out the —

(i) the decision of the Review Officer;

(ii) the reason, or reasons, for that decision;

(iii) any actions the Department must undertake as a consequence of that decision; and

(iv) the right to submit an appeal to the High Court, on a point of law, as to the decision of the Review Officer within 30 days of receiving that written notice.

(9) For the purposes of this regulation, "appellant" means the person who submitted a written request for reconsideration further to paragraph (1).

MADE

DAVID ASHFORD
Minister for the Cabinet Office

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations made additional provision about procedure in relation to the Department carrying out its functions under section 20 (licence requirement) of, and Schedule 2 (licenses for the purposes of section 20) to, the Human Tissue and Organ Donation Act 2021 (the Act).

These Regulations are set out in three parts —

- Part 1 (general) provides for regulations specifying the necessary title, commencement and interpretation provisions of these Regulations.

- Part 2 (exceptions from licensing requirements) sets out when exceptions from the licensing requirements apply in relation to the storage of organs or tissue by a person who intends to use them for a scheduled purpose.

- Part 3 (applications for licence) of the Regulations provides for the additional procedures the Department must follow when processing applications for licences. This includes —

    - making provision for a Licensing Officer (regulation 5);

    - specifying where application may be found and how application may be submitted (regulation 6);

    - setting out the criteria for a person to be considered a suitable person for purposes of a licence application under paragraph 6 of Schedule 2 to the Act (regulation 7);

    - detailing what arrangements must be made to receive oral representation in relation to a licence application under paragraph 10 of Schedule 2 to the Act (regulation 8); and

    - stating the additional procedures to be followed when a person requests a review of a decision by the licensing officer following a notification of a licensing decision under paragraph 11 of Schedule 2 to the Act (regulation 9).