HUMAN TISSUE AND ORGAN DONATION (ETHICAL APPROVAL, ETC.) REGULATIONS 2025

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Statutory Document No. 20XX/XXXX

Human Tissue and Organ Donation Act 2021

HUMAN TISSUE AND ORGAN DONATION (ETHICAL APPROVAL, ETC.) 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), 15, 32(3), 32(4) and 33(1) of, and paragraphs 9(b) and 11(2) of Schedule 3 to, the Human Tissue and Organ Donation Act 2021.

PART 1

GENERAL

1 Title

These Regulations are the Human Tissue and Organ Donation (Ethical Approval, Etc.) 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;

"**the clinical trials regulations**" means—

(a) the Medicines for Human Use (Clinical Trials) Regulations 2004 (of Parliament)[2] and any other regulations replacing those regulations or amending them; and

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

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(b) any other regulations that are designated as clinical trials regulations by the Department, with the concurrence of the Director of Public Health, in regulations for the purposes of paragraph (7) of section 41 (research) to the Capacity Act 2023;

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

"**intrusive research**" means research of a kind that would be unlawful if it was carried out —

(a) on or in relation to a person who had capacity to consent to it, but

(b) without that person's consent;

"**IOMREC**" means the Isle of Man Research Ethics Committee that assesses the ethics of health and social care research involving individuals and is recognised for that purpose by the Department and is prescribed in paragraph 5A (the Isle of Man Research Ethics Committee) of, and paragraph 57 of Part 3 (Non-statutory tribunals and other bodies) of Schedule 1 (bodies whose members are entitled to attendance and travelling allowances) to, the Payment of Members' Expenses (Specified Bodies) Order 2017[3].

"**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

"**relevant commencement date**", in relation to any particular research, means—

(a) the date on which section 41 (research) of the Capacity Act 2023 comes into force, but

(b) if different dates are appointed for different purposes, means the date on which that section, in its application to that research, comes into force.

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[2] SI 2004 No. 1031.

[3] SD 2017/0290, as amended by SD 2018/0189, SD 2018/0317 and SD 2022/0041.

PART 2

REQUIREMENTS FOR ETHICAL APPROVAL WHERE DONOR CONSENT HAS NOT BEEN GRANTED FOR RESEARCH INVOLVING HUMAN ORGANS AND TISSUE

4 Ethical approval of research for scheduled purposes and paragraph 9(b) of Schedule 3 to the Act

(1) Research is ethically approved for the purposes of —

(a) paragraph (9)(a) of section 7 (authorisation of activities for scheduled purposes) of the Act; and

(b) paragraph 9(b) of Schedule 3 (section 68: supplementary) to the Act,

where ethical approval is granted in accordance with paragraph (2).

(2) The Director of Public Health may grant ethical approval for research after consulting with —

(a) the IOMREC; and

(b) any other person the Director of Public Health considers it appropriate to consult.

PART 3

REQUIREMENTS FOR ETHICAL APPROVAL FOR DEEMED CONSENT FOR STORAGE, USE AND RESEARCH INVOLVING HUMAN ORGANS, TISSUE AND DNA

5 Deemed consent to storage and use of organs and tissue

(1) This regulation applies in any case falling within paragraph (a) and (b) of section 13 (activities involving organs or tissue from adults who lack capacity to consent) of the Act.

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in paragraph (1)(d) of section 7 (authorisation of activities for schedule purposes) to the Act which involves material from P's body, is deemed to have consented to the activity where —

(a) the activity is done for a purpose specified in paragraph 4 or 7 of Schedule 1 (scheduled purposes) to the Act (the purposes of obtaining information relevant to another person and of transplantation) by a person who is acting in what that person reasonably believes to be P's best interests;

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(b) the activity is done for the purpose of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the activity is done on or after the relevant commencement date for the purpose of intrusive research which is carried out in accordance with the requirements of section 41 (research) of the Capacity Act 2023 and regulations made under paragraph (7) of section 41 (research) of the Capacity Act 2023;

(d) the activity is done on or after the relevant commencement date for the purpose of intrusive research and is carried out in accordance with regulations made under paragraph (7)(h) of section 41 (research) of the Capacity Act 2023 relating to the circumstances in which intrusive research may be continued notwithstanding a loss of capacity on P's part;

(e) the activity is done before the relevant commencement date for the purpose of research which, before that date, is ethically approved within the meaning of regulation 7 (ethical approval for the purposes of regulation 5).

6 Purposes for which DNA obtained from bodily material may be analysed without consent

(1) This regulation applies for the purposes of paragraph 11 (purposes relating to DNA of adults who lack capacity to consent) of Schedule 3 (section 68: supplementary) to the Act.

(2) In any case falling within paragraph (1)(a) and (b) of that paragraph, the purposes for which DNA manufactured by the body of a person ("P") who lacks capacity to consent to analysis of the DNA may be analysed are —

(a) any purposes which the person carrying out the analysis reasonably believes to be in P's best interests;

(b) the purposes of a clinical trial which is authorised and conducted in accordance with the clinical trials regulations;

(c) the purposes of intrusive research which is carried out on or after the relevant commencement date in accordance with the requirements of section 41 (research) of the Capacity Act 2023 and regulations made under paragraph (7) of section 41 (research) of the Capacity Act 2023;

(d) the purposes of intrusive research —

(i) which is carried out on or after the relevant commencement date;

(ii) in relation to which regulations made under paragraph (7)(h) of section 41 (research) of the Capacity Act 2023, relating to the circumstances in which intrusive research

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may be continued notwithstanding a loss of capacity on P's part, apply; and

(e) research which is carried out before the relevant commencement date and which, before that date, is ethically approved within the meaning of regulation 6 (ethical approval for the purposes of regulation 4 and 5).

7 Ethical approval for the purposes of regulations 5 and 6

(1) Research using defined material is ethically approved within the meaning of this regulation if approval is given by, or on behalf of, the Director of Public Health in the circumstances specified in paragraph (2).

(2) The circumstances are that —

(a) the research is in connection with disorders, or the functioning, of the human body;

(b) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the research has to be confined to, or relate only to, persons who have capacity to consent to taking part in it;

(c) there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out in circumstances such that the person carrying out the research is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified;

(d) the Director of Public Health has consulted with the IOMREC and any other person the Director of Public Health considers it appropriate to consult.

(3) In this regulation, "defined material" —

(a) in relation to ethical approval for the purposes of regulation 5 (deemed consent to storage and use of organs and tissue), means organs and tissue involved in an activity of a kind mention in section 7(1)(d) or (f) of the Act;

(b) in relation to ethical approval for the purposes of regulation 6 (purposes for which DNA may be analysed without consent), means the bodily material that is the source of the DNA being analysed.

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PART 4

QUALIFYING PURPOSES FOR ACTIVITIES IN RELATION TO DONATED MATERIAL

8 Qualifying purposes for activities in relation to donated materials

Further to the requirements of subsection (3)(d) of section 15 (restriction of activities in relation to donated material) references to qualifying purpose include any activities —

(a) involving organs or tissue for purposes related to —

(i) the prevention or detection of crime; or

(ii) the conduct of a prosecution,

within the meaning of section 38 (criminal justice purposes) of the Act; and

(b) involving bodily material that is excepted under subsection (2) of section 68 (non-consensual analysis of DNA) of the Act.

PART 5

MEANING OF TRANSPLANTABLE MATERIAL FOR THE PURPOSES OF SECTIONS 32 AND 33 OF THE ACT.

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

(1) Subject to paragraphs (2) and (3), for the purposes of section 32 (restriction on transplants involving a live donor), "transplantable material" means blood other than —

(a) bone marrow; and

(b) peripheral blood stem cells,

where that material is removed from the body of a living person with the intention that it be transplanted into another person or stored for transplantation into another person.

(2) The material referred to in paragraph (1) is not transplantable material for the purposes of section 32 (restriction on transplants involving a live donor) of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1) is transplantable material for the purposes of section 32 (restrictions on transplants involving a live

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donor) and section 33 (information about transplant operations) of the Act when no reward has been or is to be given in contravention of section 31 of the Act (prohibition of commercial dealings in human material for transplantation) and —

(a) consent for its removal for the purpose of transplantation has been given, or

(b) its removal for that purpose is otherwise lawful.

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DAVID ASHFORD
Minister for the Cabinet Office

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set out supplementary provision relating to ethical approval, qualifying purposes and transplantable materials necessary to support the operation of the Human Tissue and Organ Donation Act 2021 (the Act).

The Regulations are set out in five parts.

- Part 1 (general) sets out the title, commencement and interpretation provisions of these Regulations.

- Part 2 (requirements for ethical approval where donor consent has not been granted for research involving human organs and tissue) sets out the process the Director of Public Health must follow when granting ethical approval for research for scheduled purposes and paragraph 9(b) of Schedule 3 to the Act.

- Part 3 (requirements for ethical approval for deemed consent for storage, use and research involving human organs, tissue and DNA) sets out the process the Director of Public Health must follow when granting ethical approval for the purposes of —

    - section 13 (activities involving organs or tissue from adults who lack capacity to consent) of the Act; and

    - paragraph 11 (purposes relating to DNA of adults who lack capacity to consent) of Schedule 3 (section 68: supplementary) to the Act.

- Part 4 (qualifying purposes) prescribes that activities involving human tissue for criminal justice purposes or DNA analysis are qualifying purposes for section 15 (restriction of activities in relation to donated material) of the Act.

- Part 5 (meaning of transplantable material for the purposes of sections 32 and 33 of the Act) specifies that blood (other than bone marrow and peripheral blood stem cells) is a transplantable material when it is removed from the body of a living person with the intention that it be transplanted into another person.

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