

STATUTORY INSTRUMENTS.

S.I. No. 251 of 2025

HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL EXAMINATION AND PUBLIC DISPLAY) (LIVING DONOR REIMBURSEMENT SCHEME) REGULATIONS 2025

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I, JENNIFER CARROLL MACNEILL, Minister for Health, in exercise of the powers conferred on me by section 3 of the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024 (No. 5 of 2024), hereby make the following regulations:

Citation and Commencement

- 1. (1) These Regulations may be cited as the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) (Living Donor Reimbursement Scheme) Regulations 2025.
 - (2) These Regulations shall come into operation on 17 June 2025.

Interpretation

2. In these Regulations –

"accommodation costs" means, subject to Regulation 9, the vouched cost of accommodation, which is incurred by a donor in respect of a transplantation activity or with the selection, assessment, evaluation, or preparation of the donor for the purpose of a transplantation activity;

"childcare costs" means, subject to Regulation 10, the vouched cost of childcare that would not have otherwise been incurred by the donor and that is incurred by a donor in respect of a transplantation activity or with the selection, assessment, evaluation, or preparation of the donor for the purpose of a transplantation activity;

"donation" for the purpose of these regulations, means in relation to transplantation activities, the donation of human organs for transplantation;

"donation process" means any clinical or logistical activity related to the donation and transplantation of human organs, including the selection, assessment, evaluation, preparation, and post-operative care of a living donor;

"donor" for the purpose of these regulations, means a person who donates human organs where that donation takes place during the lifetime of the person;

"Living Donor Programme" means the facility operated by Beaumont Hospital with responsibility for renal transplantation;

"Living Donor Reimbursement Office" means the facility operated by the Executive with responsibility for the administration of the Living Donor Reimbursement Scheme:

"loss of income" means, subject to Regulation 12, the loss of income from employment that would not have otherwise been incurred by the donor and that is incurred by a donor in connection with a transplantation activity or with the selection, assessment, evaluation, or preparation of the donor for the purpose of a transplantation activity;

"medical certificate" means a medical certificate in an official language of the State signed by a registered medical practitioner stating that the individual named in the certificate is unable to work;

"medical expenses" means the cost of medical care, and products and services ancillary to that care, including the cost of procuring a medical certificate, that are incurred by a donor in connection with a transplantation activity or with the selection, assessment, evaluation, or preparation of the donor for the purpose of a transplantation activity;

"Notice of Assessment" means a notice issued by the Revenue Commissioners pursuant to s.959E of the Taxes Consolidation Act, 1997 (as amended);

"Organ Donation and Transplant Ireland" means that part of the Executive known as the office for Organ Donation and Transplant Ireland;

"potential donor" means an individual invited to attend an assessment by the Living Donor Programme;

"suitable donor" means an individual whose organs meet the necessary clinical criteria and are deemed suitable for transplantation into an identified recipient;

"travel costs" means, subject to Regulation 9, the vouched cost of travel that would not have otherwise been incurred by the donor and that is incurred by a donor in connection with a transplantation activity or with the selection, assessment, evaluation, or preparation of the donor for the purpose of a transplantation activity;

"Treatment Abroad Scheme" means the scheme operated by the Executive that provides for access to medical treatment in another EU or EEA member state, the United Kingdom or Switzerland.

Payment of reimbursement

- 3. (1) Subject to the provisions of these regulations, the Executive may grant compensation, which shall be referred to as 'reimbursement' for the purposes of these Regulations, to an eligible donor in relation to the donation of an organ provided that such compensation is strictly limited to making good the reasonable expenses incurred by the eligible donor related to the donation process.
- (2) Reimbursement may not confer any financial incentive or financial reward on an eligible donor.
- (3) Consideration of a claim for reimbursement shall be limited to costs that are directly attributable to the donation process.
- (4) Notwithstanding the generality of Regulation 3, reimbursement shall not be paid in excess of an upper limit provided for in these regulations.
- (5) Reimbursement will not be permitted for any expense incurred where this expense is being or ought to be covered by another organisation, agency, or other body, whether in Ireland or abroad.

(6) Reimbursement will be net of any other reimbursement or other payment paid or due to the eligible donor through any other method or scheme.

Eligibility

- 4. (1) In these regulations, an eligible donor is a person who:
 - (a) has been selected as a potential donor by the Living Donor Programme,
 - (b) is under the clinical supervision of the National Renal Transplant Programme in Beaumont Hospital, and is travelling abroad for a paired kidney donation,
 - (c) travels abroad for a living liver donation under the Treatment Abroad Scheme, or
 - (d) is a non-directed altruistic donor.
- (2) An Irish resident travelling abroad to donate a kidney or lobe of liver to a person resident in another jurisdiction and is listed on a waiting list in the other jurisdiction shall not be eligible for reimbursement under these Regulations.
- (3) If a potential donor is subsequently deemed unsuitable to proceed to donation, the potential donor's travel and accommodation costs and medical expenses incurred up to the date where it is determined that the donation will not proceed may be considered eligible for reimbursement.

Donor Responsibility

- 5. (1) An eligible donor shall take all reasonable and necessary steps to ensure that financial losses in respect of the donation process are minimised.
- (2) A donor shall take personal responsibility for his or her own care and follow reasonable medical advice.
- (3) Failure to comply with Regulations 5(1) and 5(2) may result in expenses not being reimbursed.

Claims for Reimbursement

- 6. (1) The Scheme will be administered by the Living Donor Reimbursement Office.
- (2) The Living Donor Reimbursement Office shall maintain a record of all claims made by eligible donors for the purpose of validating, assessing, and determining each claim.
- (3) Travel and accommodation costs and medical expenses submitted for reimbursement will be strictly validated, subject to Regulation 7, to ensure that they are reasonable and appropriate.

Validation of claims

- 7. (1) Any claim for reimbursement must be approved by either the Living Donor Programme or the Treatment Abroad Scheme before the eligible donor may submit such a claim to the Living Donor Reimbursement Office.
- (2) Appropriate records must be kept by the Living Donor Programme and the Treatment Abroad Scheme to facilitate the validation of claims for reimbursement by the Living Donor Reimbursement Office.
- (3) All claims for reimbursement must be validated by the Living Donor Reimbursement Office, in consultation with the Living Donor Programme or the Treatment Abroad Scheme, as appropriate.
- (4) Organ Donation and Transplant Ireland shall be responsible for ensuring that claims are properly validated by the Living Donor Reimbursement Office and shall reimburse the Living Donor Reimbursement Office for payments made to eligible donors in accordance with these Regulations.

Supporting Documentation

- 8. (1) All claims by donors for reimbursement must be accompanied by relevant supporting documentation.
- (2) An eligible donor shall provide such information, including relevant supporting documentation, as the Living Donor Reimbursement Office may require, to support his or her claim for reimbursement.
- (3) The information required shall be furnished by the eligible donor when submitting a claim for reimbursement to the Living Donor Reimbursement Office.
- (4) The Living Donor Reimbursement Office may request any additional information it deems necessary and appropriate from the eligible donor or from third parties, to verify the claim for reimbursement.
- (5) An eligible donor is responsible for obtaining and retaining relevant supporting documentation which may be required during the course of the assessment of a claim for reimbursement.
- (6) Failure to provide such information, including relevant supporting documentation, when submitting a claim or in response to a request for additional information under Regulation 8(4) may result in expenses not being reimbursed.

Travel and Accommodation Costs

- 9. (1) Reimbursement of travel and accommodation costs shall be made in line with the Executive's National Financial Regulations.
- (2) Travel and accommodation costs may be reimbursed up to an upper limit of $\in 8,000$.
- (3) Subject to Regulation 9, reimbursement for travel and accommodation costs shall only be in respect of costs actually incurred during the donation process and on the provision of relevant supporting documentation.

- (4) The dates on any relevant supporting documentation must coincide with an appointment date during the donation process to be considered eligible for reimbursement.
- (5) Subject to Regulations 9(3) and 9(4), travel and accommodation costs incurred from when the donor has been selected as a potential donor through to the donation and for up to 12 weeks post-donation are eligible for reimbursement.
- (6) The donor shall take all reasonable steps to ensure that the most cost-effective mode of transport is used.
- (7) Reimbursement of travel costs shall not be in excess of the standard class fare, where applicable.
- (8) A donor must submit original receipts, coinciding with an appointment date during the donation process in the relevant hospital.
- (9) Where a donor travels by car, reimbursement will be calculated with reference to the fuel price comparison as prepared by the Sustainable Energy Authority Ireland, calculated on the day the claim is processed.
- (10) Where overnight accommodation is required for attendance for a hospital appointment during the donation process, this must be approved in advance by the Living Donor Programme or the Living Donor Reimbursement Office to be eligible for reimbursement.
- (11) Parking costs associated with pre-approved overnight accommodation may also be considered for reimbursement.
- (12) Reimbursement of accommodation costs may be considered up to \in 3.50205 per night, for a rate that includes bed and breakfast only.
- (13) Costs associated with any overnight stay beyond that directly connected with the donation process, shall not be eligible for reimbursement.

Childcare Costs

- 10. (1) Childcare costs that would not have otherwise been incurred by an eligible donor may be reimbursed up to an upper limit of ϵ 6,750.
- (2) Reimbursement for childcare costs will only be considered for children placed with childminders or centre based childcare providers who are registered with Tusla, the Child and Family Agency, in line with the Child Care Act 1991 (Early Years Services) Regulations 2016 and the Child Care Act 1991 (Registration of School Age Services) Regulations 2018.

Medical Expenses

11. (1) Reimbursement of the costs of medical certificates shall be limited to such medical certificates obtained in relation to the donation process.

Loss of Income - General

- 12. (1) Loss of income may be reimbursed up to an upper limit of $\in 15,000$ on the provision of relevant supporting documentation.
- (2) The maximum period for which a claim for reimbursement for loss of income can be made is 12 weeks.
- (3) Subject to Regulation 12(2), loss of income from when the donor has been selected as a potential donor through to the donation and for up to 12 weeks post-donation may be eligible for reimbursement
- (4) A claim for reimbursement for loss of income shall not exceed 12 weeks in total, which may include any period of absence prior to and following the donation.
- (5) Any loss of income incurred in excess of 12 weeks shall not be eligible for reimbursement.
- (6) A claim for reimbursement for loss of income must be supported by medical certificates from the donor's treating consultant or GP and shall include written confirmation of the date of return to work.
- (7) An eligible donor who is in receipt of a payment from any Department of Social Protection Scheme will continue to have this payment made, in line with the normal rules and regulations of such payments, for a period of up to 12 weeks from donation.
- (8) Where an eligible donor is in receipt of a payment under Regulation 12(7), the Living Donor Programme, or the Living Donor Reimbursement Office, as appropriate, shall make the necessary arrangements with the Department of Social Protection in consultation with the donor for such payment to continue.

Loss of income – salaried or waged donors

- 13. (1) An eligible donor who is in receipt of a salary or wage must submit a letter from his or her employer confirming the amount of salary or wages that will be paid to the eligible donor for the period connected to the donation, for which reimbursement may be payable.
- (2) Where a letter from an employer confirms that the eligible donor will be fully paid by his or her employer during this period, the eligible donor will not be entitled to reimbursement for loss of income.
- (3) Where a letter from an employer confirms that the eligible donor will not be paid by his or her employer during this period, or any portion thereof, the eligible donor must submit details from the Department of Social Protection of any payment that the eligible donor is in receipt of, or details of any income continuance plan or other similar policy, detailing what benefits, if any, the eligible donor is entitled to during the period connected to the donation.
- (4) Reimbursement for loss of income will be based on the difference between the eligible donor's average net pay and the total of any payments made to them by their employer, the Department of Social Protection, or on foot of any income continuance plan or other similar policy.

- (5) An eligible donor who is in receipt of a salary or wage shall obtain written confirmation of their date of return to work from his or her employer and shall provide such written confirmation in support of any claim made under these Regulations.
- (6) Overtime payments, shift allowances, or other similar payments may be eligible for reimbursement, where such payments comprise a regular portion of the eligible donor's salary, and this is supported by relevant supporting documentation.
- (7) For the purposes of determining a claim for reimbursement for loss of income in relation to an eligible donor in receipt of a salary or wage, relevant supporting documentation may include:
 - (a) most recent Employment Detail Summary,
 - (b) payslips relating to
 - (i) the 6 month period prior to the donation,
 - (ii) a comparable 6 month period as may be determined by the nature of the employment, or
 - (iii) in exceptional circumstances, the Living Donor Reimbursement Office may accept payslips relating to a period of 3 to 6 months,

and

(c) such other documentation as may be requested by the Living Donor Reimbursement Office to support consideration of the claim.

Loss of income – self-employed donor

- 14. (1) Self-employed eligible donors shall submit a Notice of Assessment and the Revenue Commissioner's Form 11 as relevant supporting information in any claim for reimbursement for loss of income.
- (2) Reimbursement for a 12 week period will be calculated as the proportion of the eligible donor's income corresponding to twelve weeks of the preceding 12 month tax period.
- (3) Written confirmation of the date of return to work for self-employed donor shall be provided by the donor's treating consultant or GP as relevant supporting information in any claim for reimbursement for loss of income.
- (4) A self-employed eligible donor may make a claim for the expense of a person to replace himself or herself in his or her business for a period of up to 12 weeks, up to an upper limit of $\in 15,000$.
- (5) Where a claim for the replacement of a self-employed eligible donor in his or her business is submitted, the claim shall include relevant supporting documentation.
- (6) Where a claim for the replacement of a self-employed eligible donor in his or her business is submitted, and the person replacing him or her is already an employee of the self-employed eligible donor, it will be necessary for the self-

employed eligible donor to demonstrate the additional hours that employee has incurred in his or her duties to replace the self-employed donor.

- (7) Only the additional hours worked by the employee of the self-employed eligible donor will be eligible for reimbursement.
- (8) A self-employed eligible donor can only make a claim for either loss of income or for the cost of engaging a replacement employee in his or her business, but not both.

Reimbursement for Donors from Outside the State

- 15. (1) Where a donor from another jurisdiction travels to the State for the purpose of donation under the clinical supervision of Beaumont Hospital, travel and accommodation costs may be reimbursed in accordance with the conditions set out in these regulations.
- (2) Where testing of a donor from another jurisdiction is conducted prior to donation, any associated costs or expenses incurred while present in the State during the donation process may be reimbursed in line with the conditions set out in these regulations.

Determination of Claims

- 16. (1) A decision of the Living Donor Reimbursement Office will set out in writing the claim(s) for reimbursement made by an eligible donor which have been approved or declined and the value of the reimbursement payment for any approved claim for reimbursement.
- (2) There is no discretion for reimbursement to be paid to an eligible donor outside the provisions of these Regulations.
- (3) There is no discretion for the grant of an *ex gratia* scheme or once off payment to an eligible donor outside of the provisions of these Regulations.

Exemption from tax

17. Payments for reimbursement made under these Regulations are exempt from income tax and are not reckoned in computing income for the purposes of the Income Tax Acts, in accordance with section 204B of the Taxes Consolidation Act 1997, as amended.

Limitation

18. The Minister, the Department of Health, or the Executive do not bear any responsibility for the loss by an eligible donor of any entitlement as a result of their becoming an eligible donor.

Appeal

- 19. (1) Where a claim for reimbursement or part thereof is not reimbursed, an appeal of the decision of the Living Donor Reimbursement Office may be made by the eligible donor to Organ Donation and Transplant Ireland.
- (2) Appeals will be determined under the procedure set out in Schedule 1 of these regulations.

Governance

- 20. (1) The Living Donor Reimbursement Scheme shall be administered by the Living Donor Reimbursement Office.
- (2) The Executive shall, in consultation with Organ Donation and Transplant Ireland, the Living Donor Reimbursement Office, and the Living Donor Programme, establish a governance structure for the purposes of administering the Living Donor Reimbursement Scheme.
- (3) The Living Donor Reimbursement Office shall establish appropriate procedures to ensure that all reimbursements are correct and legitimate and that appropriate records are kept.
- (4) All information, in whatever form, on the implementation of the Living Donor Reimbursement Scheme shall be made available to Organ Donation and Transplant Ireland and the Department of Health upon request.

Review

- 21. (1) The Minister shall, not later than 3 years following the commencement of these Regulations, carry out a review of the operation of the Living Donor Reimbursement Scheme.
- (2) In carrying out a review under Regulation 21(1), the Minister may consult with such persons as he or she considers appropriate.

Schedule

Regulation 19

Appeals procedure

- 1. An appeal of a determination of a claim for reimbursement may be made where a claim for reimbursement or part thereof is not reimbursed by the Living Donor Reimbursement Office.
- 2. An appeal shall be submitted to Organ Donation and Transplant Ireland for determination.
- 3. All communication relating to an appeal must be in writing with appropriate record-keeping by all parties.
- 4. The appeals officer in Organ Donation and Transplant Ireland shall, where possible, be of a grade higher on the Health Sector Consolidated Salary Scales than the decision-maker in the Living Donor Reimbursement Office.
- 5. Upon receipt of an appeal, Organ Donation and Transplant Ireland shall acknowledge receipt to the appellant and identify the appeals officer who will consider the appeal.
- 6. Any officer previously involved in the decision-making process regarding the claim for reimbursement which is the subject of the appeal shall not take part in the determination of any appeal concerning that claim.
- 7. The Living Donor Reimbursement Office shall provide a full copy of any file associated with the appellant to Organ Donation and Transplant Ireland to assist in considering the appeal.
 - 8. In considering an appeal, an appeals officer shall:
 - (a) act professionally and impartially;
 - (b) only consider the documentation available;
 - (c) not rely on non-documented evidence; and
 - (d) only consider the appeal within the conditions set out in these Regulations.
- 9. An appeals officer may request any information or clarification, as he or she deems necessary, to consider the appeal.
- 10. An appeals officer shall have ten working days from the date of receipt of an appeal to make a decision, unless otherwise notified in writing to the appellant.
- 11. An appeals officer shall issue the appeal decision to the appellant in writing.
 - 12. The decision letter shall include:
 - (a) the decision of the appeals officer;
 - (b) the rationale for the decision;

- (c) information as to their right to complain to the Office of the Ombudsman if they are dissatisfied with the outcome of the appeal.
- 13. Upon issuing the decision, the appeals officer shall send the appeal file, either in its original form or as a copy, to the Living Donor Reimbursement Office.



GIVEN under my Official Seal, 12 June, 2025.

JENNIFER CARROLL MACNEILL, Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations provide a statutory basis and conditions for the Living Donor Reimbursement Scheme as provided for in section 12 of the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024. These Regulations allow for the reimbursement of the costs and expenses incurred by an eligible donor as part of the donation process.

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