**Serious Adverse Reaction / Event Report Form for Human Organs Intended for Transplantation**

IN CONFIDENCE

A privacy notice in relation to the personal data collected on this form is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) under ‘Report an Issue’, ‘Download/Print Forms’, ‘Serious Adverse Reaction / Event Report Form for Human Organs Intended for Transplantation’, ‘Privacy Notice’.

The aim of your report is to ensure the safety of organ donation and transplantation.

A SERIOUS ADVERSE REACTION (SAR) is an unintended response including a communicable disease in the living donor or in the recipient, that might be associated with any stage of the chain from donation to transplantation, that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

SAR = PATIENT AFFECTED

A SERIOUS ADVERSE EVENT (SAE) is any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation, that might lead to the transmission of a communicable disease, that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

SAE = EVENT HAPPENED, PATIENT NOT AFFECTED (INCLUDING NEAR MISS)

Reporter Details

|  |  |  |
| --- | --- | --- |
| Title:       | Name:       | Date:       |
| Establishment/Organisation/Department:       |
| Address:      |
| Email:        | Telephone number:       |

Report information

|  |
| --- |
| Report identification number (unique report identification number assigned at the reporting establishment):       |
| Involves: Donor [ ]  Recipient [ ]  Donor and recipient [ ]  N/A [ ]  |
| Type of donor: Deceased [ ]  Living [ ]  |
| Type of organ involved: Liver [ ]  Pancreas [ ]  Heart [ ]  Lung [ ]  Kidney [ ]  Other [ ]  If other, please specify:       |
| Report type: SAE [ ]  SAR [ ]  |
| Risk Stratification (provide details of known risk factors for the donor or the recipient):      Extended Donor Criteria Yes [ ]  No [ ] High Risk Recipient Yes [ ]  No [ ] Details:      |

SERIOUS ADVERSE REACTION /EVENT (SAR/SAE) DETAILS

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| --- |
| Retrieval team (name of hospital):       |
| Donor hospital:       | Transplant centre:       |
| Donor medical record number(s):       | Recipient medical record number(s):       |
| National donor number(s):        |
| Date of retrieval (dd/mm/yy):       | Transplant date (dd/mm/yy):       |
| Does the report relate to an organ received from or provided to another Member State?Yes [ ]  No [ ]  If yes, provide details:       |
| Date and time of occurrence of SAR/SAE:       |
| Date and time of SAR/SAE detection:       |
| Place of event/reaction if different from the reporting establishment:       |
| Could this incident have implications for other recipients/potential recipients? Yes [ ]  No [ ] If yes, provide details of other organs or tissue/cells obtained from this donor, and confirm if transplanted, if known:       |
| Have all relevant sites been notified (e.g. transplant centre / procurement organisation and manufacturers, etc.?) Yes [ ]  No [ ]  If yes, provide details (site(s), date notified, relevant reference numbers, etc.):       |
| Provide a brief description of the suspected SAR or SAE: (*For SAR include any treatment administered and the outcome for the patient. In the case of SAE details of the root cause analysis and corrective and preventative actions taken if available, and the status of the investigation i.e. complete or pending.)*       |
| Probability of recurrence of SAR/SAE: Rare [ ]  Unlikely [ ]  Possible [ ]  Likely [ ]  Almost certain [ ]   |
| Stage at which the SAR/SAE occurred:[ ]  Donation (coordination, consent procedures, etc.)[ ]  Testing (testing of samples for donor suitability, donor/recipient compatibility, organ function, etc.)[ ]  Characterisation(donor and organ*)*[ ]  Procurement/Retrieval (surgical retrieval of organ(s))[ ]  Preservation (including perfusion, packaging and interim storage)[ ]  Transport (transportation, delivery and handover of an organ, tissue or sample)[ ]  Transplantation (transplant surgery, including pre-transplant preparation)[ ]  Other (please specify):       |
| Specification SAR/SAE:Organ defect [ ]  Equipment failure [ ]  Human error [ ]  Other [ ] If other, please specify:        |
| Type of suspected SAR/SAE (that may be connected to the testing, characterisation, procurement, preservation transport or transplantation of the organ):[ ]  Transmission of infectious agent [ ]  Transmission of malignancy (unknown prior to transplant) [ ]  Any unexpected consequence for the recipient (including early graft failure, delayed graft function)[ ]  Unanticipated immunological reaction [ ]  Transplant aborted due to issues identified with organ supplied after recipient anaesthetised [ ]  Organ not used[ ]  Other (please specify):       |
| Severity: [ ]  Death [ ]  Life-threatening [ ]  Serious [ ]  Non serious |

Signature

|  |
| --- |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print/type name: Date:  |

Further information available from - [Guide to Serious Adverse Reactions and Events Reporting for Human Organs for Transplantation](http://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/sur-g0035-guide-to-sar-sae-reporting-for-human-organs-for-transplantation-v1.pdf?sfvrsn=19).

**Please return the completed form simultaneously to both HPRA and ODTI by email or post:**

Organ Donation Transplant Ireland

Ground Floor, Bridgewater House

Bridgewater Business Centre

Conyngham Road

Islandbridge

Dublin 8

D08 T9NH

Tel: + 353 1 778 4361

Email: odti@hse.ie

Organ Pharmacovigilance Section

FREEPOST

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: + 353 1 676 4971

Fax: + 353 1 676 2517

Email: btosafety@hpra.ie

Please also consider if this report needs to be included on the hospital’s Risk Register and if so, please provide the risk register reference number: