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

IN CONFIDENCE

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 NEARMISS)

REPORTER DETAILS

Title:	**Name:**	**Date:**
Establishment/Organisation/Department:		
Address:		
E-mail:	**Telephone number:**	

REPORT INFORMATION

Report identification number*: (unique report identification number assigned at the reporting establishment)*
Involves: Donor ☐ Recipient ☐ Donor and recipient ☐ N/A ☐

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Type of donor: Deceased ☐ Living ☐
Type of organ involved: ☐ Liver ☐ Pancreas ☐ Heart ☐ Lung ☐ Kidney ☐ Other **If other, please specify:**
REPORT TYPE: SAR ☐ SAE ☐
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

Retrieval team/s (name of hospital/s):	
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:	

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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 the relevant sites been notified (e.g. transplant centre/procurement organisation and manufactures etc?) Yes ☐ No ☐ **If yes, provide details (site(s), date notified, relevant reference numbers etc:**

*Further information available from - Guide to Serious Adverse Reactions and Events Reporting for Human Organs for Transplantation

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 SAR & SAE: ☐ Rare ☐ Unlikely ☐ Possible ☐ Likely ☐ Almost Certain

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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/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 below)

Severity:
☐ Death ☐ Life-threatening ☐ Serious ☐ Non-serious

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SIGNATURE

Signature: _____

Print / type name: _____

Date: _____

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

Organ Donation Transplant Ireland 2nd Floor, Temple Theatre Hardwicke Place Temple St. Dublin 1. **Tel:** + 353 1 878 2629 **E-mail**: 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 **E-mail:** organsafety@hpra.ie

Please note that by your completion of this report form, you are consenting to the information provided, including your contact details, to be stored securely by HPRA. For the purposes of complying with our statutory and legal reporting requirements, details of this report may be shared with other bodies also involved in monitoring activities and in accordance with data protection requirements. This ensures that the information is available to all relevant parties. You have the right to request a copy of personal data held by the HPRA and to have any inaccuracies in such data corrected or deleted.