Serious Adverse Reaction/Event Report Form – Human Tissues and Cells

IN CONFIDENCE (FOR COMPLETION BY HEALTHCARE PROFESSIONALS)

Please complete this form in confidence and send by email to [btosafety@hpra.ie](mailto:btosafety@hpra.ie).

Alternatively, hard copies can be submitted to Freepost, Tissues and Cell, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2. Telephone 353-1-6764971, Fax 353-1-6762517.

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 the ‘privacy and data protection’ and by clicking on ‘privacy notice for reporting a serious adverse reaction/event for tissues and cells’. **Do not include any personal data which may identify a patient, e.g. their name, patient ID number, etc. No staff member’s name other than the reporter’s name should be included in this report.**

Additional information may be provided in attachments, please ensure that the identification number is included on any attachments.

A Guide to Reporting Serious Adverse Reactions and Serious Adverse Events Associated with Human Tissues and Cells is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)).

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| **Report Case Identification Number:**  *(unique identification case number assigned at reporting site)* | | | | | | | |
| **Reporter Information** | | | | | | | |
| Name: | | | | | | Date: | |
| Establishment/Organisation: | | | | | | | |
| EU Tissue Establishment Code *(assigned on the EU Tissue Establishment Compendium)*: | | | | | | | |
| Title: | | | | | | | |
| Department: | | | | | | | |
| Email:       Telephone/mobile: | | | | | | | |
| **Serious adverse reaction (SAR) / Serious Adverse Event (SAE) Details** | | | | | | | |
| SAR  SAE |  | **Donor:**  Male  Female  Date of birth: |  | | **Recipient:**  Male  Female  Date of birth: | |  |
| Unique donation identification number | | | |  | | | |
| Single European Code (if applicable) | | | |  | | | |
| Date and place of event/reaction | | | |  | | | |
| Date and place of procurement | | | |  | | | |
| Date and place of human application | | | |  | | | |
| All relevant sites notified (manufacturer/establishment, etc.): Yes No  Specify site and date notified: | | | | | | | |
| Please describe the event/reaction (include details of any sequelae for the patient or treatment administered): | | | | | | | |

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| **Implicated tissues/cells (select all that apply)** | | | | | |
| **Non-ART** | | | | | |
| **Autologous  Allogeneic** | | | | | |
| Heart valves | | Other cardiovascular, please specify: | | Vessels | |
| Bone | | Tendons | | Demineralised bone | |
| Ligaments | | Other musculoskeletal, please specify: | | Skin | |
| Cornea | | Sclera | | Other ocular, please specify: | |
| Bone marrow | | Peripheral blood stem cells | | Umbilical cord blood | |
| Donor lymphocyte infusions | | Other stem cells, please specify: | | Amniotic membrane | |
| Hepatocytes | | Pancreatic islets | | Others, please specify: | |
| **ART** | | | | | |
| **Partner  Non-Partner** | | | | | |
| Sperm | Oocytes | | Embryo: partner gametes  Embryo: donor, sperm partner oocyte  Embryo: donor, oocyte partner sperm  Embryo: donor sperm and oocyte  Embryo unknown | | Ovarian tissue |
| Testicular tissue | Other reproductive tissue (specify): | | | | |

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| **For SARs Only** | | | | | | | | |
| **SAR Categorisation** | | | | | | | | |
| Transmitted bacterial infection | | | | Transmitted viral infection | | | | |
| Transmitted parasitical infection | | | | Transmitted malignant disease | | | | |
| Other disease transmissions | | | | Other, *(not involving a disease transmission*) please specify: | | | | |
| Suspected/confirmed genetic condition in an offspring | | | |  | | | | |
| **Severity of the reaction** | | | | | | | | |
| Non-Serious | | | Serious | | | Life threatening | | |
| **provide clinical outcome (if known)** | | | | | | | | |
| Complete recovery | | Minor sequelae | | | Serious sequelae | | | Death |
| **Imputability** | | | | | | | | |
| Unlikely | Possible (1) | | | Likely (2) | | | Certain (3) | |

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| --- | --- | --- | --- | --- | --- |
| **FOR SAES ONLY** | | | | | |
| **SAE Categorisation** | | | | | |
| Did the event occur at: | | | | | |
| Procurement | Testing | | Transport | | Processing |
| Distribution | Donor selection | | Product selection | |  |
| Storage | Issue | | Other, please specify: | | |
| Specification: | | | | | |
| Tissue and cells defect | | Equipment failure | | Human error | |
| Material | | System failure | |  | |
| Other, please specify: | | | | | |

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| **Root Cause Analysis SAR/E** |
| Please provide details: |
| **Additional details SAR/e (Including Corrective and Preventative Actions)** |
| Please provide details: |

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thank you for taking the time to complete this form.