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.

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** |
| SARSAE | [ ] [ ]  | **Donor:**MaleFemaleDate of birth: | [ ] [ ]       | **Recipient:**MaleFemaleDate 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.