



REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Tissues and Cells - Directive 2006/86/EC

Instructions to complete the form:

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- 1) Be informed that you need to have at least the Adobe Reader version 9 or higher to fill and submit this form.
- 2) Please fill out this form according to the **definitions and recommendations** provided in the "Common approach document". Some definitions are also provided as mouse-overs.
- 3) Please fill out all the fields with the appropriate information.
 - When data are **not available**, please insert **NA**
 - When data are available, please provide a number **≥ 0**To verify your data entry while filling your form, you can use the "verify form" button at the top of each page.
- 4) When you have finished filling the form, verify that your internet connection is active and then click on the submit notification button below. If the form is properly filled, the notification will be submitted to the server and a Submission number will appear in the corresponding field.
- 5) IMPORTANT: Once you have received the Submission number, save the form on your computer.
- 6) If the form is not properly filled, an alert box will appear indicating the number of incorrect fields. Please check your form again and try to re-submit. Should you still have any difficulties, please contact SANTE-SARE@ec.europa.eu, describe the issue and mention the version of this document: 2018 2.8.2
- 7) Where a Member State has **two different competent authorities** responsible for SARE reporting for tissues and cells, it is not possible to submit two separate electronic forms. In these circumstances, one competent authority should enter their data on the electronic form and **save it without submitting**; the second competent authority should then add their data and **submit** the form.
- 8) Privacy statement (see last page)

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REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)
Tissues and Cells - Directive 2006/86/EC

Reporting country: CROATIA

This data collection refers to the period

1 Jan 2018 - 31 Dec 2018

Competent Authority responsible for the reported data * :
Ministry of Health of the Republic of Croatia

E-mail of Competent Authority responsible for the reported data * :
biomedicina@miz.hr

* = mandatory field

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Annual notification for Serious Adverse Reactions

NON-Reproductive T&C yes no

	Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipients for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR	Add row	Delete row
1	Skeletal tissues	yes											
1.1			GENERAL (to be filled out only if data for subcategories are not available)										
1.2			Bone	183	141	no							
1.3			Tendons/ligaments	0	0	no							
1.4			Cartilage	0	0	no							
1.5			Fascia	0	0	no							
1.6			Other (e.g. meniscus, ear, ossicles)	1	1	no							
2	Haematopoietic Stem Cells	yes											
2.1			GENERAL HPC (to be filled out only if data for subcategories are not available)										
2.2			Bone Marrow (auto-allo)	30	30	no							
2.3			Peripheral Blood Stem Cells (auto-allo)	344	193	no							
2.4			Cord Blood	0	0	no							
2.5			Donor lymphocyte infusions	58	19	no							
2.6			Other Haematopoietic Stem Cells	0	0	no							
3	Ocular Tissues (Cornea, Sclera, Other Ocular tissue)	yes											
3.1			General Ocular Tissues (to be filled out only if data for subcategories are not available)										
3.2			Cornea	332	334	no							
3.3			Sclera	8	4	no							

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipients for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR	Add row	Delete row
3.4		Other	0	0	no							
4	yes	Cardiovascular Tissues										
4.1		GENERAL CV/ta to be filled out only if data for subcategories are not available!										
4.2		Heart Valve	8	7	no							
4.3		Vessel	3	2	no							
4.4		Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	4	2	no							
5	yes	Skin (units)										
5.1		Skin (units)	21	5	no							
6	yes	Multiple T&C										
6.1		Multiple T&C	2	1	no							
7	yes	Other tissues or cells (units)										
7.1		Pancreatic Islets	0	0	no							
7.2		Hepatocytes	0	0	no							
7.3		Amniotic membrane	133	109	no							
7.4		Other (e.g. adipose tissue, tympanic membrane)	0	0	no							

Non-reproductive T&C SAR Totals

Total nr tissues&cells distributed	Total nr of recipients	Total nr of SAR	1. Nr SAR Transmitted of transmitted infections	2. Nr. SAR Transmitted malignant diseases	3. Nr. SAR Transmitted genetic diseases	4. Nr. Other SAR
1,127	848	0	0	0	0	0

Deaths Associated with SAR

Total number of SAR that resulted in recipient death: 0

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

General comments on SAR NON REPRODUCTIVE TISSUES AND CELLS :

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REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Reproductive T&C yes no

Order	Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipient s for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR
1	SPERM	yes									
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)								
1.2			Sperm - partner donation	1430	923	no					
1.3			Sperm - Non-partner donation	0	0	no					
2	EMBRYO	yes									
2.1			General embryos (to be filled out only if data for subcategories are not available)								
2.2			Embryos, partner gametes	8841	4607	no					
2.3			Embryos, donor sperm, partner oocyte	0	0	no					
2.4			Embryos, donor oocyte, partner sperm	0	0	no					
2.5			Embryos, donor sperm and oocyte	0	0	no					
3	Other Reproductive tissues an cells (e.g. ovarian or testicular tissue)	yes									
3.1			Ovarian tissue	4	4	no					
3.2			Testicular tissue	112	0	no					
3.3			Other	0	0	no					

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Reproductive T&C SAR Totals						
Total nr tissues&cells distributed	Total nr of recipients	Total nr of SAR	1. Nr SAR Transmitted of transmitted infections	2. Nr. SAR Transmitted malignant diseases	3. Nr. SAR Other disease transmissions	4. Nr. Other SAR
10,387	5,534	0	0	0	0	0

Deaths Associated with SAR

Total number of SAR that resulted in recipient death: 0

General comments on SAR REPRODUCTIVE TISSUES AND CELLS :

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Annual notification for Serious Adverse Events

NON-Reproductive Tissues and Cells processed yes no

	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE	Add row	Delete row
1	Skeletal tissues	yes										
1.1			GENERAL (to be filled out only if data for subcategories are not available)									
1.2			Bone	251	yes							
1.2.0						0. Transport	no					
1.2.1						1. Donor selection	no					
1.2.2						2. Procurement	no					
1.2.3						3. Testing	no					
1.2.4						4. Processing	no					
1.2.5						5. Storage	no					
1.2.6						6. Product selection (possible TE and CIRHA act)	no					
1.2.7						7. Issue (possible TE and CIRHA act)	yes					
1.2.7.4								4. Human error	Right humerus with rotator cuff was issued instead of a left humerus with rotator cuff.	1	+	X
1.2.8						8. Distribution	no					
1.2.9						9. Other	no					
1.3			Tendons/ligaments	0	no							
1.4			Cartilage	0	no							
1.5			Fascia	0	no							

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE	Add row	Delete row
1.6			Other (e.g. meniscus, ear, ossicles)	0	no							
2	Haematopoietic Stem Cells	yes										
2.1			GENERAL HPC (to be filled out only if data for subcategories are not available)									
2.2			Bone Marrow (auto-allo)	20	no							
2.3			Peripheral Blood Stem Cells (auto-allo)	662	no							
2.4			Cord Blood	1377	no							
2.5			Donor Lymphocyte Infusions	55	no							
2.6			Other Haematopoietic stem cells	0	no							
3	Ocular Tissues (Cornea, Sclera, Other Ocular tissue)	yes										
3.1			General Ocular Tissues (to be filled out only if data for subcategories are not available)									
3.2			Cornea	540	no							
3.3			Sclera	6	no							
3.4			Other	0	no							
4	Cardiovascular Tissues	yes										
4.1			GENERAL CV (to be filled out only if data for subcategories are not available)									
4.2			Heart Valve	8	no							
4.3			Vessel	14	no							
4.4			Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	0	no							
5	Skin (units)	yes										
5.1			Skin (units)	15	no							
6	Multiple T&C	yes										
6.1			Multiple T&C	0	no							
7	Other tissues or cells (units)	yes										

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7.1		Pancreatic islets	0	no			
7.2		Hepatocytes	0	no			
7.3		Amniotic membrane	106	no			
7.4		Other (e.g. adipose tissue, synaptic membrane)	0	no			

Non-reproductive SAE Totals						
Total nr tissues&cells processed	Total nr of SAE	1. Tissue or cell defect	2. Equipment failure	3. Materials	4. Human error	5. Other
3,054	1	0	0	0	1	0

General comments on SAE NON REPRODUCTIVE TISSUES AND CELLS :

Reproductive Tissues and Cells processed yes no

Order	Type of Tissues and Cells	yes/ no	Specification	Nr of Tec processed	SAE yes/no	Activity Step	yes/no SAE Specification	Description and Number of T&C affected	Number of SAE
1	SPERM	yes							
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)						
1.2			Sperm - partner donation	6308	yes				

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Order	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE
1.2.0						0. Transport	no			
1.2.1						1. Donor selection	yes			
1.2.1.1								1. Tissue or Cell Defect	Bacterial infection in medium after IVF due to active bacterial infection in semen (which has been later confirmed).	2
1.2.2						2. Procurement	no			
1.2.3						3. Testing	no			
1.2.4						4. Processing	no			
1.2.5						5. Storage	no			
1.2.6						6. Product selection (possible TE and ORHA activity step)	no			
1.2.7						7. Issue (possible TE and ORHA activity step)	no			
1.2.8						8. Distribution	no			
1.2.9						9. Other	no			
1.3			Sperm - Non-partner donation	0	no					
2	OVOCYTES	yes								
2.1			GENERAL Oocyte (to be filled out only if data for subcategories are not available)							
2.2			Ovocytes - Partner donation	28351	no					
2.3			Ovocytes - Non-partner donation	0	no					
3	EMBRYO	yes								
3.1			General embryos (to be filled out only if data for subcategories are not available)							
3.2			Embryos, partner gametes	20313	no					
3.3			Embryos, donor sperm, partner oocyte	0	no					

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3.4		Embryos, donor oocyte, partner sperm	0	no			
3.5		Embryos, donor sperm and oocyte	0	no			
4	Other Reproductive tissues an cells (e.g. ovarian or testicular tissue)	yes					
4.1		Ovarian tissue	4	no			
4.2		Testicular tissue	141	no			
4.3		Other	0	no			

Reproductive SAE Totals

Total nr tissues&cells processed	Total nr of SAE	1. Tissue or cell defect	2. Equipment failure	3. Materials	4. Human error	5. Other
55,117	2	2	0	0	0	0

General comments on SAE REPRODUCTIVE TISSUES AND CELLS :

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

Annual notification for Serious Adverse Reactions in DONORS

SAR in Donors - Non-reproductive tissues and cells yes no

General comments on SERIOUS ADVERSE REACTIONS in DONORS - Non-Reproductive tissues and cells :

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SAR in Donors - Reproductive tissues and cells yes no

Tissue and cell donor	Specification of SARs in DONORS (not influencing the quality and safety of tissues and cells)	Number	Add row	Delete row
6. Ovocytes - partner donation	Bleeding and laparoscopic operation after ovarian aspiration	6	+	X
6. Ovocytes - partner donation	Heterotopic pregnancy	1	+	X
6. Ovocytes - partner donation	Termination of pregnancy due to the wrong implantation in the uterus.	1	+	X

Total nr of SAR IN DONORS - Reproductive tissues and cells	8
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Deaths Associated with SAR in DONORS (REPRODUCTIVE)

Total number of SAR that resulted in donor death:	0
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General comments on SERIOUS ADVERSE REACTIONS in DONORS - Reproductive tissues and cells :

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Tissues and Cells - Directive 2006/86/EC

Privacy statement

Enforcement action – Communicators Network

Purpose and scope of personal data processing:

The reporting document is for the collection of national contributions to reports on enforcement actions. The information gathered includes two contact points:

- i) one which has been authorised by the reporting Member State to act as contact point for the press on the enforcement action concerned, and which can be published and*
- ii) a second which identifies a contact point for the Commission for any discussions with Member States on their reports; these contacts will not be published.*

The information collected and the purpose of a contact point in this context:

Your data are recorded and stored as long as follow-up actions are needed in the context of each enforcement action. Your data will be handled in conformity with Regulation (EC) N° 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data.

Right of rectification & personal data controller:

Should you require further information concerning the processing of your personal data or wish to exercise your rights (e.g. access or rectify any inaccurate or incomplete data) please contact the following mailbox:

SANTE-SARE@ec.europa.eu

*You have the right of recourse at any time to the European Data Protection Supervisor at ***edps@edps.europa.eu****

