

DEFINITION:

1) Definition of SAE/SAR (in the context of activities involving Scandiatransplant)

- a) Any undesired and unexpected/unforeseen event/reaction that occur in conjunction with, during or after:
 - i) The process of organ donation from deceased as well as living donors, including:
 - (1) Donor/organ evaluation, investigation and testing
 - (2) Organ harvesting, preservation and storage
 - (3) Organ allocation and transportation
 - ii) The transplantation of organs from living as well as deceased donors
- b) Any undesired and unexpected/unforeseen event/reaction that causes (or could have caused if remaining undiscovered and/or left untreated)
 - death
 - life threatening disease
 - transmission of disease from donor to recipient, such as
 - malignancy
 - infection
 - metabolic or genetic disorder
 - permanent damage, incapacity or disability
 - hospitalization, including prolonged hospitalization
 - disease or prolonged disease

EXAMPLES:

	Unexpected/unforeseen event, should be reported	Expected/foreseen event, should not be reported
Contagious diseases and Infections	Donor virus serology (such as HIV, or HCV) erroneously reported, or interpreted, as negative while actually being positive. Mistake discovered after transplantation	Known positive donor virus serology. Organs transplanted after careful evaluation of possible risks and benefits for the recipient
	Positive donor blood cultures not discovered or reported until after transplantation.	Positive donor blood culture discovered and reported before transplantation. Organs transplanted after careful evaluation of possible risks and benefits for the recipient
Tumors and Malignancies	Donor history of malignancy not discovered or reported until after transplantation.	Known donor history of malignancy. Organs transplanted after careful evaluation of possible risks and benefits for the recipient
	Unknown, possibly malignant tumor discovered during donor surgery	
	One or several recipients diagnosed with malignancy of possible/suspected donor origin	
Other	Retrieved organ dropped to the floor	Blood group incompatibility or positive HLA crossmatch accepted. Organs transplanted after careful evaluation of possible risks and benefits for the recipient
	Blood group, HLA type or cross-match erroneously reported	
	Wrong or outdated perfusion fluid used	
	Organ retrieved, but sent to the wrong place.	
	Organ cannot be used due to vascular lesions caused by the retrieval operation	