Australian Government
Organ and Tissue Authority

donatelife
discover...decide...discuss
organ & tissue donation
www.donatelife.gov.au

DonateLife Network
Serious Adverse Event Notification Form

If a serious adverse event or reaction occurs it should be reported to the State Medical Director (or delegate). The State Medical Director (or delegate) will notify the National Medical Director as soon as possible.

The National Medical Director in consultation with the State Medical Director will decide on the immediate action required which could include but is not limited to notifying other jurisdictions.

This form does not take the place of jurisdictional adverse event reporting processes but is complementary to them. Serious adverse events and reactions (SAERs) related to organ donation for transplantation must be reported in accordance with hospital and jurisdictional reporting requirements as well as national reporting requirements.
Investigation of SAERs remains the responsibility of the hospital and jurisdiction.

Once completed by the State Medical Director the form should be forwarded as soon as possible to:

National Medical Director,
currently Dr Helen Opdam
helen.opdam@austin.org.au
Mob: 0438 161 166

Director Clinical Programs OTA,
currently Ms Eva Mehakovic
eva.mehakovic@donatelife.gov.au
Mob: 0431 659 796

This section to be completed by the State Medical Director:

Date of serious adverse event or reaction:

Time of serious adverse event or reaction:

Date/Time of notification:

Event reported to jurisdictional incident management system: **Yes** ☐ **No** ☐

Jurisdictional donor identifier *(for jurisdictional trace back purposes only)*:

Was this incident related to (tick relevant boxes):

Donor		**Recipient**			
Donor management	☐	**Pre-transplant**	☐	**Information/data transcription issues**	☐
Donor assessment	☐	**Transplant surgery**	☐		
Offer and allocation	☐	**Post-transplant**	☐		
Retrieval	☐				
Perfusion/Preservation	☐				
Storage/Transport	☐				

Other (please explain):

1. Nature of the serious adverse event or reaction:

DonateLife Network
Serious Adverse Event Notification Form

2. What action was taken:

2.1: At the time of detection of the serious adverse event or reaction?

2.2: By the State Medical Director (or delegate)?

2.3: Outcome of serious adverse event or reaction (if known):

State Medical Director **Signature** **Date**

This section to be completed by the National Medical Director:

3. What action was taken by the National Medical Director?

National Medical Director **Signature** **Date**

DonateLife Network
Serious Adverse Event Notification Form

GUIDELINES FOR USING THE SERIOUS ADVERSE EVENT NOTIFICATION FORM

The Serious Adverse Event or Reaction Notification form has been developed to ensure that the DonateLife Network has an established system in place to facilitate national reporting of serious adverse events or reactions (SAERs) specifically related to donation and transplantation.

Note: *This form does not take the place of jurisdictional adverse event reporting processes but is complementary to them. SAERs related to organ donation for transplantation must be reported in accordance with hospital and jurisdictional reporting requirements as well as national reporting requirements. Investigation of SAERs remains the responsibility of the hospital and jurisdiction.*

Serious adverse events/reactions[1] involving organ donation and transplantation can include (but are not limited to) incidents related to:

- avoidable loss of a potential donor or donor organ for transplantation due to inadequate resources, including shortage of surgical retrieval, transportation, donation or transplantation services;
- retrieval and perfusion of organs;
- storage and transportation of organs and vessels;
- identification and labelling of organs and vessels;
- donor screening and assessment of the risk of disease transmission and/or infection from donor to recipient;
- intra-operative or post-transplant discovery of potential/actual transmission of disease and/or infection from donor to recipient;
- death unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management; or
- major permanent loss of function (sensory, motor, physiologic or psychologic) unrelated to the natural course of the illness and differing from the expected outcome of patient management.

Incidents may be donor or recipient related, and may occur during donor management, donor assessment, offer and allocation, retrieval, perfusion/preservation, storage and transport, pre-transplant, transplant surgery or post-transplant.

[1] **Serious adverse event** - an 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, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.
Serious adverse reaction - an unintended response, including a communicable disease, in the donor or 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.
'chain from donation to transplantation' - The chain includes procurement, testing, processing, storage, distribution, transplantation and post transplantation management.

Interim

DonateLife Network
Serious Adverse Event Notification Form

Who completes the Serious Adverse or Reaction Event Notification form?
SAERs are to be reported to the State Medical Director (SMD) (or delegate) in the jurisdiction in which the incident occurred. The SMD (or delegate) will notify the National Medical director (NMD) (or delegate) as soon as practicable and will complete the SAEN form. The SMD (or delegate) will send the completed SAEN form as soon as possible to the NMD (or delegate) and the Director, Clinical Programs at the Organ and Tissue Authority.

Clinical judgement should be applied regarding the urgency of submitting the SAEN, however this should occur as soon as possible and preferably within two days of the event being identified.

What happens to the information?
The Organ and Tissue Authority's Clinical Governance Committee will discuss reported events at quarterly meetings for the purposes of shared learnings. Extraordinary events will be communicated to all SMDs as soon as practicable with subsequent course of action.