Serious Adverse Event or Reaction Notification Form
The Serious Adverse Event or Reaction Notification (SAEN) form and guideline facilitates a measure for the donation and transplantation sectors to report serious adverse events and reactions (SAERs) related to donation and transplantation at a national level. Data reported is de-identified and incident based only.

The process has been developed by the Organ and Tissue Authority (OTA) and DonateLife Network in consultation with states and territories, the Transplantation Society of Australia and New Zealand, and the Australasian Transplant Coordinators Association to ensure there is a system in place to facilitate national reporting of SAERs to identify trends and inform clinical practice, organ donation and transplantation management, and future health policy.

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.

Who completes the Serious Adverse or Reaction Event Notification form?
SAERs are to be verbally notified to the DonateLife State Medical Director of Organ and Tissue Donation (SMD) in the jurisdiction where the incident occurred (contact details below). The SMD will complete the SAEN form and will notify the OTA National Medical director (NMD) as soon as practicable. The SMD will follow up with a completed SAEN form as soon as possible to the NMD 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 (OTA) Clinical Governance Committee will discuss de-identified SAERs at quarterly meetings for the purposes of shared learnings. Extraordinary events will be communicated to all SMDs as soon as practicable with subsequent agreed course of action. Vigilance and surveillance discussions will also take place at meetings of the OTA's Transplant Liaison Reference Group and jurisdictional Transplant Advisory Committee meetings (or equivalent).

The process will be revised on formal implementation of the *Australian Vigilance and Surveillance Framework for Organ Donation and Transplantation.*

Jurisdiction	State Medical Director	Email
QLD	Leo Nunnink	leo.nunnink@health.qld.gov.au
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