

Please send completed form to:
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Health Care Standards Directorate
 Superintendence of Public Health
 Ministry for Health

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Reference Number:

**SERIOUS ADVERSE REACTION INVESTIGATION REPORT FORM HUMAN
TISSUES AND CELLS**

Conclusions of Serious Adverse Reaction Investigation

Tissue/Cell Establishment		
Address		
Report identification <i>(unique identification number given at reporting site)</i>		
Confirmation date (dd/mm/yyyy)		
Date of serious adverse reaction (dd/mm/yyyy)		
Unique donation identification number		
Confirmation of serious adverse reaction	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Change of type of serious adverse reaction	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Clinical outcome (if known)		
Complete recovery		
Minor sequelae		
Serious sequelae		
Death		
Unknown		
Outcome of investigation and final conclusions		
Corrective measures taken (details)		

Reporter's Name	
Title	
Signature	
Email address	
Telephone number	

Supply of report forms required Yes No