Case ID: _____

CANADIAN TRANSPLANTATION ADVERSE EVENT (TAE) REPORTING FORM FOR TISSUES

1. RECIPIENT IDENTIFICATION

LAST NAME	FIRST NAME	Date of Birth: Day / Month / Year
HEALTH CARD NUMBER	HOSPITAL CARD NUMBER	
PROVINCE/TERRITORY OF RESIDENCE		Sex: ☐ MALE ☐ FEMALE ☐ UNKNOWN

2. GENERAL INFORMATION

Transplanting/Implanting Facility	Source Establishment
NAME	NAME
ADDRESS	ADDRESS
CITY / PROVINCE	CITY / PROVINCE
NAME OF TRANSPLANTING/IMPLANTING PHYSICIAN	CONTACT PERSON
TELEPHONE / FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day / Month / Year
REPORTER	ADDITIONAL SOURCE ESTABLISHMENT (IF APPLICABLE)
☐ SAME AS ABOVE IF DIFFERENT, PLEASE SPECIFY BELOW:	NAME
NAME OF REPORTER	ADDRESS
ADDRESS	CITY / PROVINCE
CITY / PROVINCE	CONTACT PERSON
TELEPHONE / FAX	HC REGISTRATION #
EMAIL	NOTIFIED: ☐ YES ☐ NO DATE: Day / Month / Year

3. DATE AND LOCATION OF THE TAE

DATE OCCURRED:	Day	Month	Year	DATE REPORTED:	Day	Month	Year

LOCATION WHERE THE TAE WAS RECOGNIZED:

- ☐ HOSPITAL WHERE GRAFT TRANSPLATED/IMPLANTED;
- ☐ OTHER FACILITY, E.G. WALK-IN CLINIC, HOME _____
- ☐ OTHER HOSPITAL;
- ☐ MEDICAL OFFICE OF PHYSICIAN/SURGEON WHO PERFORMED TRANSPLANTATION/IMPLANTATION
- ☐ MEDICAL OFFICE OF OTHER PHYSICIAN WHO RECOGNIZED THE TAE.

4. SUSPECTED TRANSPLANTED/IMPLANTED TISSUE(S)

(NOTE: PRE AND POST TRANSPLANT/IMPLANT CULTURE DATES AND RESULTS ARE TO BE COMPLETED BY SOURCE ESTABLISHMENTS ONLY)

TISSUE TYPE	PRODUCT CODE	SUPPLIER NAME	DONOR ID CODE	EXPIRY DATE (Day / Month / Year)	QUANTITY TRANSPLANTED	DATE OF TRANSPLANT/ IMPLANT (Day / Month / Year)	PRE-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT (Day / Month / Year)	POST-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT (Day / Month / Year)

COMMENTS (INCLUDING TYPE OF PATHOGEN AND COLONY COUNT):

5. CLINICAL HISTORY

TYPE OF GRAFT: ☐ MUSCULOSKELETAL ☐ OCULAR ☐ CARDIAC ☐ VASCULAR ☐ SKIN ☐ OTHER: _____

ANTIBIOTIC PROPHYLAXIS: ☐ YES ☐ NO
DESCRIBE:

UNDERLYING DIAGNOSIS/INDICATION FOR TRANSPLANT/IMPLANT:
DESCRIBE:

CONCOMITANT MEDICATION:

DESCRIBE/SPECIFY THE PROCEDURE PERFORMED:

IMMUNE COMPROMISED: ☐ YES ☐ NO
IF YES, DESCRIBE:

ADDITIONAL COMMENTS:

OTHER CLINICAL HISTORY: ☐ YES ☐ NO

6. CLINICAL SIGNS

CLINCAL SIGNS AND SYMPTOMS:

☐ FEVER (Describe): _____
☐ CHILLS/RIGORS
☐ URTICARIA
☐ OTHER SKIN RASH
☐ SHOCK
☐ WOUND REDNESS/SWELLING
☐ PUS
☐ PAIN (Location): _____
☐ DEHISCENCE
☐ DEATH
☐ OTHER (Describe): _____

6A. RELEVANT TESTS/LABORATORY RESULTS

LABORATORY TEST	DATE SPECIMEN TAKEN			RESULTS		
	DAY	MONTH	YEAR	NORMAL	ABNORMAL	DETAILS
				☐	☐	
				☐	☐	
				☐	☐	
				☐	☐	
				☐	☐	
				NEGATIVE	POSITIVE	
BLOOD CLUTURE				☐	☐	
WOUND CULTURE (POST-TRANSPLANT)				☐	☐	

X-RAY RESULTS:

COMMENTS:

6B. DESCRIPTION OF TAE AND ACTION TAKEN

DESCRIBE:

7. DIAGNOSIS OF TAE

INFECTION

☐ NOT APPLICABLE

BACTERIAL: _____

VIRAL: _____

FUNGAL: _____

OTHER: _____

TISSUE SPECIFIC EVENTS

☐ NOT APPLICABLE

OCULAR	CARDIAC	MUSCULOSKELETAL
☐ PRIMARY GRAFT FAILURE	☐ VALVE THROMBOSIS	☐ OSTEOLYSIS
☐ ENDOTHELIAL REJECTION	☐ VALVE FAILURE	☐ FRACTURE
☐ DISLODGING OF GRAFT	☐ ENDOCARDITIS	☐ NON-UNION
☐ OTHER:	☐ OTHER:	☐ OTHER:

OTHER TAE

☐ NOT APPLICABLE

☐ ALLERGIC REACTION

☐ MALIGNANCY: _____

- ☐ AT SITE OF TRANSPLANT
- ☐ AT REMOTE SITE: _____

☐ OTHER:

COMMENTS:

7A. SEVERITY OF TAE

☐ GRADE 1 (NON-SEVERE) ☐ GRADE 2 (SEVERE) ☐ GRADE 3 (LIFE THREATENING) ☐ DEATH ☐ NOT DETERMINED

DID THE TAE RESULT IN HOSPITALIZATION OR PROLONGATION OF HOSPITALIZATION? ☐ YES ☐ NO

NUMBER OF EXTRA DAYS: _____

DID THE TAE REQUIRE REMOVAL OF IMPLANT? ☐ YES ☐ NO

7B. IMPUTABILITY

☐ DEFINITE ☐ PROBABLE ☐ POSSIBLE ☐ DOUBTFUL ☐ RULED OUT ☐ NOT DETERMINED

ARE THERE ANY TAE IN OTHER RECIPIENTS RESULTING FROM IMPLICATED DONOR(S)?

☐ YES … Please specify: _____

☐ NO

☐ UNKNOWN

7C. OUTCOME

☐ MINOR/NO CONSEQUENCE ☐ MAJOR CONSEQUENCE ☐ DEATH ☐ NOT DETERMINED

IF DEATH OCCURRED, DESCRIBE THE CIRCUMSTANCES RELATED TO THE DEATH:

IMPUTABILITY OF DEATH:

☐ DEFINITE ☐ PROBABLE ☐ POSSIBLE ☐ DOUBTFUL ☐ RULED OUT ☐ NOT DETERMINED

7D. STATUS OF INVESTIGATION

INVESTIGATION BY:

☐ SOURCE ESTABLISHMENT ☐ TRANSPLANTATION/IMPLANTATION FACILITY ☐ OTHER

☐ IN PROGRESS ☐ CONCLUDED (please specify): _____

☐ CANNOT BE CONDUCTED, REASON _____

DATE: ____ ____ ____ (Day Month Year)

SIGNATURE: _____

8. CONCLUSION (TO BE COMPLETED BY THE HOSPITAL WHERE THE TRANSPLANTATION/IMPLANTATION OCCURRED OR WHERE TAE WAS TREATED)

DATE REPORT RECEIVED: Day Month Year

DATE INVESTIGATION INITIATED: Day Month Year

HOSPITAL REPORTING PERSON:

SIGNATURE:

TELEPHONE NUMBER:

DATE AND TIME: Day Month Year Time (hh:mm)

9. CONCLUSION (TO BE COMPLETED BY SOURCE ESTABLISHMENT, OR IN THE CASE OF IMPORT TISSUES, SUPPLIER)

DATE REPORT RECEIVED: Day Month Year

DATE INVESTIGATION INITIATED: Day Month Year

MEDICAL DIRECTOR OR DESIGNATE:

SIGNATURE:

TELEPHONE NUMBER:

DATE AND TIME: Day Month Year Time (hh:mm)