CANADIAN TRANSPLANTATION ADVERSE EVENT (TAE) REPORTING FORM FOR TISSUES

1. RECIPIENT IDENTIFICATION

Date of Birth: Day | Month | Year

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	QUANTITY TRANSPLANTED	DATE OF TRANSPLANT/ IMPLANT	PRE-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT	POST-TRANSPLANT/ IMPLANT CULTURE DATE AND RESULT
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	Day Month Year
				Day Month Year		Day Month Year	Day Month Year	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)