AUSTRALASIAN TRANSPLANT COORDINATORS ASSOCIATION

AND

THE TRANSPLANTATION SOCIETY OF AUSTRALIA AND NEW ZEALAND

NATIONAL STANDARD OPERATING PROCEDURES

ELECTRONIC DONOR RECORD UTILISATION FOR: ORGAN OFFER PROCESS ORGAN TRANSFER DOCUMENTATION

Version 1.0

ATCA-TSANZ SOP 002/2014

Australian Government
Organ and Tissue Authority

donatelife

CONTENTS

INTRODUCTION

The introduction of the Electronic Donor Record (EDR) required modification and adaptation of current ATCA/TSANZ national practice to allow for optimal utilisation of the EDR. The practice changes will both optimise the advantages of an electronic system and ensure identified potential practical and logistical issues have standardised resolutions. This SOP was developed by the members of the EDR National Standard Operating Procedure Development Working Group.

The TSANZ Council and the ATCA Committee have approved this SOP and the Organ and Tissue Authority through the State Medical Directors and Jurisdictional Health Department Representatives committee have endorsed it.

PURPOSE

The purpose of the Standard Operating Procedure is to ensure clinical practice allows for optimal utilisation of the EDR.

SCOPE

The SOP contains new processes that have been developed for utilisation of the EDR and existing practice that remains unchanged.

This document pertains to donation cases that have been entered into the EDR. New Zealand does not utilise the EDR and therefore New Zealand donor information will be provided in hard copy only.

RESPONSIBILITY

ATCA/TSANZ
It is the responsibility of ATCA and TSANZ to maintain clinical currency of this SOP. ATCA is responsible for ensuring the SOP is available on the ATCA Website and for notification to the relevant parties of when an updated version is released.

DONATELIFE AGENCY
It is the responsibility of each DonateLife Agency to ensure relevant staff have access to the SOP and follow the agreed national practice.

OTA
The OTA are responsible for ensuring the SOP is available to DonateLife Agencies via the CONNECT Website.

1. DOCUMENTATION OF DONOR BLOOD GROUP, SEROLOGY, NAT

Formal documentation of donor blood group, validated serology results and NAT results (when applicable) are routine requirements for all donors. Both paper and electronic versions of this donor information are required for the donation coordination and organ transplantation process. The standard operating procedures for recording and providing this information are as follows.

Standard "identifiers" for documentation are to be followed:

- **Identified:** First and last name, date of birth, medical record number
- **De-identified:** Donor ID, date of birth, medical record number

1.1 DONOR BLOOD GROUP

The Donation Specialist is responsible for ensuring an identified copy of the donor blood group is sourced from the appropriate laboratory. Once the blood group is confirmed the Donation Specialist will enter this data into the EDR Case File. The donor blood group will then appear at the header of each page of the donor's EDR Case File.

The Donation Specialist will be responsible for ensuring the following electronic and paper copies are provided:

a. Identified Donor Blood Group

- An electronic copy uploaded as an attachment to the donor's EDR Case File as a permanent record.
- A paper copy for formal identification review in the donor operating theatre.

b. De-Identified Donor Blood Group

- An electronic copy uploaded as an attachment to the donor's EDR Case File to be included in organ referrals.
- A paper copy to include in the organ documentation envelope that will accompany any organ.

1.2 SEROLOGY AND NAT RESULTS

The Donation Specialist will ensure a validated copy of the donor serology results and NAT results (when applicable) is sourced from the appropriate laboratory. Once the results are available the Donation Specialist will enter this data on the *Serology Page* of the EDR. However, the **validated laboratory results MUST** be used when providing the identified and de-identified electronic and paper copies **NOT** the PDF *Serology Page* of the EDR.

The Donation Specialist will be responsible for ensuring the following electronic and paper copies are provided:

a. Identified Serology and NAT results

- An electronic copy uploaded as an attachment to the donor's EDR Case File as a permanent record.
- A paper copy for formal review in the donor operating theatre.

b. De-Identified Serology and NAT results

- An electronic copy uploaded as an attachment to the donor's EDR Case File to be included in organ referrals.
- A paper copy to include in the organ documentation envelope that will accompany any organ.

2. ORGAN OFFER PROCESS

The ATCA/TSANZ SOP 001/2013 provides the standard operating procedures in regards to organ allocation and use of the organ allocation rotations. These procedures remain unaffected by the introduction of the EDR.

The method of providing donor information relevant to the organ offer has been adapted to optimise the advantages of an electronic system. The standardised process provides efficient practice methods while minimising potential errors and is applicable to all organ offers.

Note: *Depending on the organ and jurisdiction, the initial contact person to receive an organ referral may be a transplant coordinator, transplant consultant or donation specialist. For the purpose of this document the initial contact person will be referred to as a Transplant Coordinator.*

a. The Donation Specialist will contact the appropriate on-call Transplant Coordinator to receive the organ offer as per current process, resulting in a telephone conversation.

b. The Donation Specialist will provide a verbal "Donor Brief" to the Transplant Coordinator. The briefing will be limited to the following:
   - Donor identifiers: Donor ID, DOB and MRN
   - Confirm organ/s being offered
   - Donation pathway: DBD or DCD
   - Donor blood group, weight, height, girth and build
   - Donor location
   - Highlight/flag relevant medical-social history and/or clinical information being sure to include risk information. (Brief review only, as details are contained in electronic referral)
   - **When providing an interstate referral include:**
   - Reason home state and any other states have declined organ offer
   - Number (1st, 2nd etc) state to receive offer
   - Relevant logistic retrieval information (ie: home state can provide retrieval surgeons or time restrictions)

c. The donor information for the organ referral is provided electronically via email. All authorised Transplant Coordinators and Transplant Consultants email addresses are pre-populated in the EDR. The Donation Specialist will select the appropriate email address from the contact list on the EDR Transmit page. The Donation Specialist will confirm the email address with the Transplant Coordinator prior to sending the electronic organ referral.

d. The organ referral email will contain the following de-identified documents in a PDF format. All PDF files must be labelled in the naming convention described in the EDR User Guide.

   - EDR Donor Chart (Appendix 1)
   - ABO
   - Serology and NAT results (if available)
   - Relevant attachments for organ being offered. (ie: CXR, Echocardiogram, ECG)

e. The email will have the sender as "support@itransplant.net"" with the Subject as: "EDR iTransplant Confidential Donor Data Donor ID xxxxxx".

f. The Transplant Coordinator is required to confirm with the Donation Specialist the email has arrived and PDF attachments are readable. The confirmation must be done verbally. Email and/or SMS confirmation is not acceptable.

g. The Transplant Coordinator will then contact the appropriate Transplant Consultant as per local process and forward the PDF Donor Data to the Consultant for review and assessment.

h. The 30 minute response time for accepting or declining an organ offer will begin from when the Transplant Coordinator has confirmed receipt of the organ referral email.

i. The Transplant Coordinator will then contact the Donation Specialist by telephone with a formal "ACCEPT" or "DECLINE" of the organ offer. The organ offer response must be done verbally. Email and/or SMS response is not acceptable.

3. DOCUMENTATION PROCESS FOR ORGAN TRANSFERS

Note: *Depending on organ and jurisdiction, the person responsible for the packaging of organs and accompanying documentation in the donor theatre may be a transplant coordinator, perfusionist or donation specialist. For the purpose of this document, the person responsible will be referred to as a Retrieval Coordinator.*

3.1 PROCEDURES IN DONOR THEATRE

a. The **mandatory** documentation that must accompany any organ from the donor theatre to the transplant hospital is listed below. **All documentation must be de-identified paper copies.**

    1. Donor blood group
    2. Donor Serology
    3. Donor NAT (when applicable/available)
    4. HLA + Cross match results (when applicable/available)
    5. EDR Organ Data page (organ specific)
    6. EDR Intraoperative Management page
    7. EDR DCD Flow Sheet (when applicable)
    8. Donor Vessel Tracking Form (when vessels sent with abdominal organs)
    9. Donor Vessel Documents Sticky Label (when vessels sent with abdominal organs)
    10. Organ Retrieval Report Form (when applicable)

b. The EDR Donor Chart is provided electronically in PDF format in the initial organ offer process to the transplant unit. Hard copy of this donor information will not be included in the documentation that accompanies the organ. It is the responsibility of the Transplant Coordinator to ensure the transplanting surgeon has access to the EDR Donor Chart. Local process will determine the method of providing the donor information to the appropriate transplant surgeon.

c. All of the listed documentation will be enclosed in an ATCA/TSANZ envelope pre-labelled with: **Donor/Organ Documentation – Confidential Information for Transplant Surgeon.** (Appendix 2)

d. During organ labelling and packaging in the donor theatre, the Retrieval Coordinator and a member of the surgical retrieval team must verify the Donor ID and the Donor Documentation that will accompany the organ.

e. The Donor/Organ Documentation envelope is sealed in a zip-lock bag (to prevent moisture) then placed inside the organ transport container.

f. An **ATCA/TSANZ Urgent Delivery** address label is completed and affixed to the outside lid of the organ transport container. (Appendix 3)

3.2 IDENTIFIED POTENTIAL LOGISTICAL ISSUES IN DONOR THEATRE

a. The Donation Specialist is responsible for entering the relevant data in the EDR for each applicable Organ Data page and the Intraoperative Management page. This data entry is required to occur intra-operatively. The main challenge identified with this process is inadequate internet connectivity for real time data entry and connection to printers in the operating theatre.

b. The Donation Specialist has the following options to record the required intra-operative data and provide this information to the transplant team. To provide a standardised approach the following options are listed in order of preference, option one being the optimal process.

1. Ability to access EDR and print pages in the donor theatre
Data is entered directly into the EDR Organ Specific Data and Intraoperative Management pages. The PDF version of the page is printed and included in the Donor/Organ Documentation envelope.

2. Ability to access EDR and but unable to print pages in the donor theatre
Data is entered directly into the EDR Organ Specific Data and Intraoperative Management pages. The PDF of the page is transmitted to the Transplant Coordinator. The Transplant Coordinator is responsible for ensuring the transplanting surgeon has access to the Organ Specific Data and Intraoperative Management pages.

3. Inability to access EDR in donor theatre
In the situation that the EDR is unable to be accessed during the retrieval surgery the Donation Specialist will utilise the EDR Paper Form to record the required intra-operative data. Hard copy of the relevant pages will be included in the Donor/Organ Documentation envelope. The Donation Specialist will then be responsible for ensuring the collected data is accurately entered as soon as possible in the EDR once internet connectivity is established.

3.3 PROCEDURES IN RECIPIENT THEATRE

a. The information provided in the Donor/Organ Documentation envelope is confidential and is utilised by transplant centre staff for the purpose of accurate organ identification and verification of donor and recipient details.

b. The confidential donor information provided **MUST NOT** be filed in the recipient medical record.

c. If there are vessels accompanying the organ, then the documentation will be handled as per the ATCA-TSANZ SOP 003/2012, Packaging, Labelling and Documentation of Deceased Donor Vessels.

d. If there are no vessels accompanying the organ, the transplant centre staff will be responsible for returning the documents to the local Transplant Coordinator or as per the local jurisdictional guidelines decided by the transplanting units as to the safe storage or disposal of confidential documentation.

APPENDIX 1

The EDR Donor Chart is a preset group of pages from the EDR that is exported in a de-identified PDF format. The selection of pages contained in the EDR Donor Chart can not be edited by the Donation Specialist.

The table displays the pages contained in the EDR Donor Chart in order of appearance in the PDF.

EDR TAB	EDR Page
Organ pre-OR	Donor Information
Organ pre-OR	Authorisation Info
Organ pre-OR	Admission Course
Organ pre-OR	Physical Assessment
Organ pre-OR	Physical examination
Organ pre-OR	Biochemistry
Organ pre-OR	Haematology
Organ pre-OR	Serology
Organ pre-OR	Plasma Dilution
Organ pre-OR	Arterial Blood Gases
Organ pre-OR	Culture Results
Organ pre-OR	Flow sheet
Organ pre-OR	Medications/other drugs
Organ pre-OR	ECG
Organ pre-OR	Echocardiogram
Organ pre-OR	Angiography
Organ pre-OR	CXR
Organ pre-OR	Bronchoscopy
Organ pre-OR	Lung Measurements
Organ pre-OR	Diagnostic Tests
Organ pre-OR	Fluid balance
Organ pre-OR	Blood Products/ Colloid admin
Organ pre-OR	Urinalysis
Tracking	Med Soc Questionnaire

APPENDIX 2

Donor / Organ Documentation

Confidential Information for Transplant Surgeon

Donor No: _____

Donor State: _____

Organ: _____

Retrieval Date: _____

Retrieval Coordinator: _____

Contact No: _____

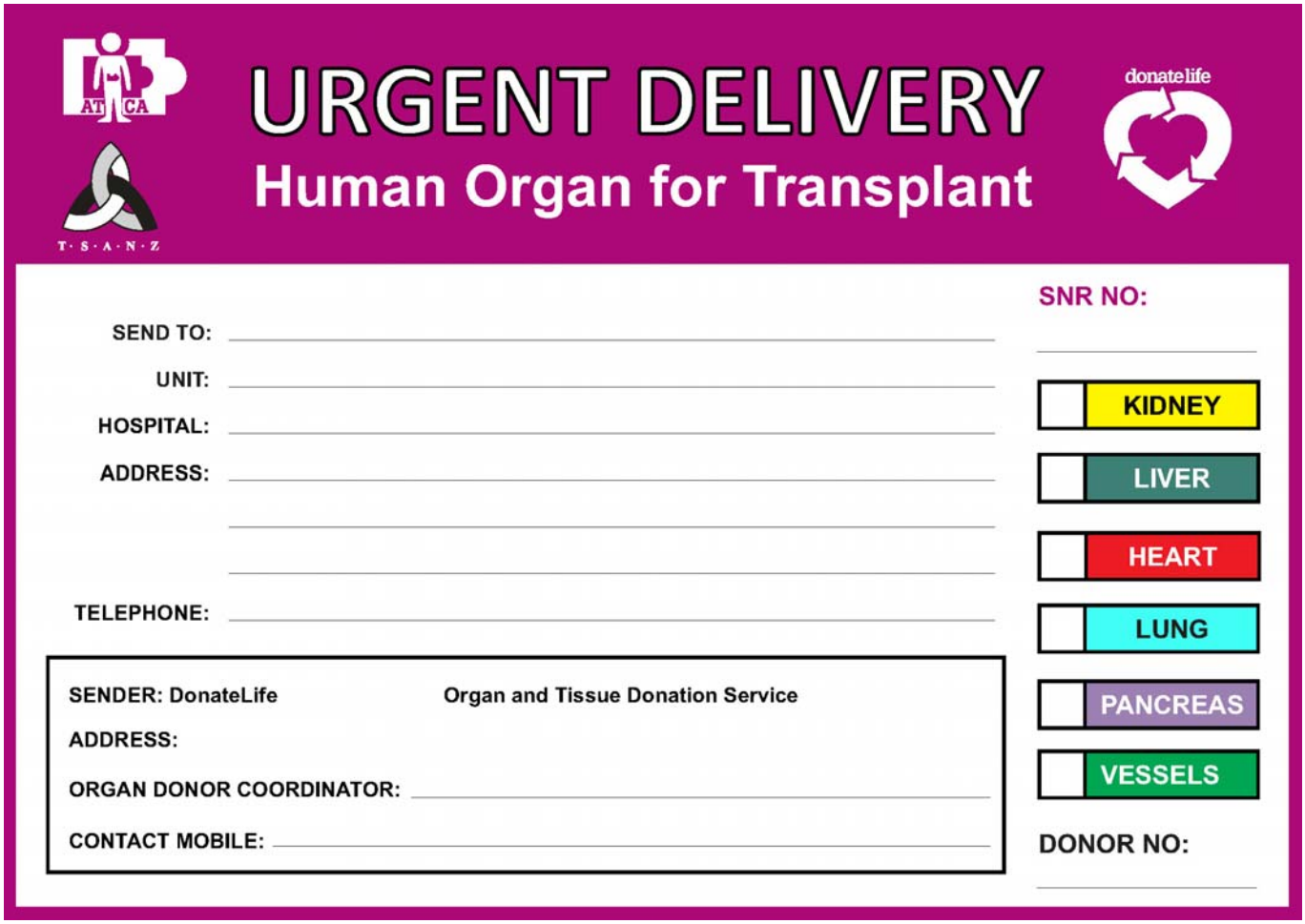
This envelope contains: ☑

- ☐ Donor blood group
- ☐ Donor serology
- ☐ Donor NAT
- ☐ HLA + Crossmatch
- ☐ EDR Organ Data Page
- ☐ EDR Intraoperative Management page
- ☐ EDR DCD Flowsheet
- ☐ Donor Vessel Tracking Form
- ☐ Donor Vessel Documents Sticky Label
- ☐ TSANZ Organ Retrieval Report Form

IF THERE ARE NO VESSELS ACCOMPANYING THIS ORGAN, RETURN THIS ENVELOPE AND CONTENTS TO YOUR HOSPITAL TRANSPLANT/DONOR COORDINATOR OR SHRED

DO NOT FILE THESE DOCUMENTS IN THE RECIPIENT RECORD

APPENDIX 3


URGENT DELIVERY
Human Organ for Transplant
donatelife
T·S·A·N·Z
SNR NO:
SEND TO:
UNIT:
HOSPITAL:
ADDRESS:
TELEPHONE:
KIDNEY
LIVER
HEART
LUNG
PANCREAS
VESSELS
SENDER: DonateLife
Organ and Tissue Donation Service
ADDRESS:
ORGAN DONOR COORDINATOR:
CONTACT MOBILE:
DONOR NO:

APPENDIX 4

The TSANZ and ATCA established standards for packaging and labelling organs being transported interstate for use by another transplant unit remain unchanged. The procedure is as follows:

a. Organ is triple bagged with at least 500mls of preservation solution surrounding the organ in the first bag

b. Slush is placed in the second bag

c. The third bag is dry

d. The outer bag is labelled with type of organ, donor blood group and donor identifiers

e. The transport container is lined with a large plastic bag to prevent leakage of wet ice during transportation. Note: this is an airline standard requirement

f. The organ is completely submerged in wet ice with the organ ID tag exposed

g. The ATCA/TSANZ Donor/Organ Documentation envelope is sealed in a zip-lock bag (to prevent moisture) then placed inside the organ transport container

h. Transport container sealed with airline tape around openings and transversely

i. Appropriate labels applied (e.g. Wet Ice label)

j. An ATCA/TSANZ Urgent Delivery address label is completed and affixed to the outside lid of the organ transport container.

APPENDIX 5

Members of the EDR National Standard Operating Procedure Development Working Group

Clinical Members

Ms Francesca Rourke	Donation Specialist Coordinator (QLD) (Chair)
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Version Control

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