Government of Western Australia
Department of Health

Policy Frameworks
MP 0129/20
Effective from: 28 January 2020

Release of Human Tissue and Explanted Medical Devices Policy

1. Purpose

This Policy sets out the minimum requirements for responding to requests for the release of human tissue or an implantable medical device that has been removed (explanted) from an individual's body. Human tissue in the context of this Policy includes a human fetus or placenta. Accordingly, in all cases, reference to human tissue includes a human fetus or placenta unless stated otherwise.

This Policy is in accordance with the *Environmental Protection Act 1986* and *Environmental Protection (Controlled Waste) Regulations 2004* which regulate clinical waste; and the *Therapeutic Goods Act 1989* (Cth) which regulates medical devices supplied in Australia. Neither State nor Commonwealth legislation explicitly authorises or prohibits the release of human tissue or explanted medical devices to a requestor.

This Policy is a mandatory requirement under the *Public Health Policy Framework* pursuant to section 26(2)(c) of the *Health Services Act 2016*.

This Policy supersedes Operational Directive (OD) 0398/12 *Release of Human Tissue and Explanted Medical Devices*.

The Policy does not relate to actions concerning tissue or organs intended for donation, or teeth, hair and nails.

2. Applicability

This Policy is applicable to all Health Service Providers.

3. Policy requirements

The Executive Director or equivalent of the Hospital is responsible for investigating and resolving any disputes.

3.1. Overarching

In responding to a request for the release of human tissue or an explanted medical device, Health Service Providers must consider the risks associated with complying with the request and ensure the provision of requisite information to enable informed consent.

All requests must be assessed by a senior health professional, preferably the one who has been involved in the care of the patient concerned. The outcome of relevant discussions must be documented in the patient's health record, recording the final decision and the person (requestor) to whom the human tissue or explanted medical device was released.

Storage and/or disposal methods planned by the requestor must be in accordance with the OD 0651/16 *Clinical and Related Waste Management Policy* except where this Policy specifies minor alterations that do not adversely affect the risk mitigation process or procedure. For example, the use of sealed clear plastic bags and container, rather than yellow bag/container with black biological hazard marking, may be acceptable for the transport and storage.

A senior health professional must only release human tissue or an explanted medical device to a requestor if they are satisfied that the arrangements for transport, storage and disposal will not constitute a public health risk.

The appropriate patient information sheet and consent forms (provided at section 5) must be completed and signed prior to release. The form must then be filed in the patient's medical record along with documentation regarding the outcome of all relevant discussions. A copy of the form must also be provided to the requestor.

3.2. Human tissue (excluding a human fetus or placenta)

Exclusion criteria

Human tissue must not be released if:

- it is a component of laboratory waste, such as a biopsy or tissue culture
- it may include a related waste component, such as cytotoxic, pharmaceutical, chemical or radioactive waste
- it poses a risk of infectious disease transmission: including but not limited to, human immunodeficiency virus (HIV), hepatitis B, hepatitis C, or multi-resistant bacteria.

Preparation for the release of human tissue

If satisfied that the arrangements for the release of the human tissue will not constitute a public health risk, and in conjunction with using the *Patient Information Sheet and Consent Form – Authorisation and Release of Human Tissue* (provided at section 5), the senior health professional must ensure that:

- the human tissue is double-bagged and sealed to prevent leakage (the use of sealed clear plastic bags is acceptable)
- the bagged human tissue is placed in a rigid walled, leak-proof container for the purpose of storage and transport
- the container is dated and labelled '*Human tissue for collection by <insert name of requestor>*'
- the requestor is aware that the container should not be re-opened on Health Service Provider premises unless further clinical examination is required
- the requestor has received information about the safe disposal of the human tissue and completed the appropriate consent form before its release
- the consent form is signed by both the requestor and the senior health professional authorising release and is filed in the health record of the relevant patient.

Information relating to safe disposal and consent is contained within the relevant information sheet and consent form.

3.3. Human fetus or placenta

Exclusion criteria

A human fetus or placenta must not be released if:

- it poses a risk of infectious disease transmission including, but not limited to, human immunodeficiency virus (HIV), hepatitis B or hepatitis C, or multi-resistant bacteria
- there was confirmed maternal infection or suspected/confirmed chorio-amnionitis.

Preparation for the release of a human fetus of fewer than 20 weeks gestation, or a placenta

If satisfied that the arrangements for the release of the human fetus or placenta will not constitute a public health risk, and in conjunction with using the *Patient Information Sheet and Consent Form – Authorisation and Release of a Human Fetus or Placenta* (provided at section 5), the senior health professional must ensure that:

- the fetus/placenta is double-bagged and sealed to prevent leakage (the use of sealed clear plastic bags is acceptable)
- the bagged fetus/placenta is placed in a rigid walled, leak-proof container for the purpose of storage and transport
- the container is dated and labelled '*Human tissue for collection by <insert name of requestor>*'
- the container is refrigerated as soon as practicable until collection
- the requestor is aware that the container should not be re-opened on Health Service Provider premises unless further clinical examination is required
- the requestor has received information about the safe disposal of the human fetus or placenta and completed the appropriate consent form before its release
- the consent form is signed by both the requestor and the senior health professional authorising release and is filed in the health record of the relevant patient.

Information relating to safe disposal and consent is contained within the relevant information sheet and consent form.

3.4. Explanted medical devices

Exclusion criteria

An explanted medical device must not be released if it poses a public health risk, including if:

- it poses a risk of infectious disease transmission including, but not limited to, human immunodeficiency virus (HIV), hepatitis B, hepatitis C, or multi-resistant bacteria
- it poses a serious 'sharps' risk, or contains pharmaceutical, chemical or radioactive material
- the device is defective
- the device is associated with a suspected adverse event or near adverse event in this patient, or is subject to a Therapeutic Goods Administration (TGA) safety alert or recall notice. Adverse events related to the use of all medical devices must be reported to the TGA via its Medical Device Incident Reporting and Investigation Scheme (IRIS).

Assessment of explanted medical devices

The Bioengineering service[1] provides analysis of individual explanted medical devices as well as a state-wide collation of data to facilitate the identification of systemic medical device issues or failure. All explanted medical devices (not only those associated with fault or adverse events) are sought for assessment to provide an overview of device performance. Information collated as part of the state-wide medical device analysis service may be used for teaching, research and presentation.

When issuing an explanted medical device to the Bioengineering Division:

- the device must not be cleaned for transport
- theatre management system procedures must be followed with regard to the preparation for the transport of the device
- the transfer of the device must be documented appropriately.

Information on how to send the device can be obtained by contacting the Biomedical Engineer at: rph.mep@health.wa.gov.au

Preparation for the release of an explanted medical device

If satisfied that the arrangements for the release of the explanted medical device will not constitute a public health risk, and in conjunction with using the *Patient Information Sheet and Consent Form – Authorisation and Release of an Explanted Medical Device* (provided at section 5), the senior health professional must ensure that:

- the medical device is double-bagged and sealed to prevent leakage (the use of sealed clear plastic bags is acceptable)
- the bagged medical device is placed in a rigid walled, leak-proof container for the purpose of storage and transport
- the container is dated and labelled '*Explanted Medical Device for collection by <insert name of requestor>*'
- the container is not re-opened on Health Service Provider premises unless further clinical examination is required
- the requestor has received information about the safe disposal of the explanted medical device and completed the appropriate consent form before its release
- the consent form is signed by both the requestor and the senior health professional authorising release, and is filed in the health record of the relevant patient from whom the device was explanted
- appropriate records are maintained in accordance with Health Service Provider record keeping policy.

Information relating to the safe disposal and consent is contained within the relevant information sheet and consent form (provided at section 5).

[1] The Biomaterials and Implant Technology Section of the Bioengineering Division, located at Royal Perth Hospital – RPH - (Bioengineering), provides a state-wide medical device analysis service to all Health Service Providers to assess, investigate, record and archive explanted medical devices.

3.5. Recordkeeping

Each Health Service Provider must ensure a record of the following information is made in a searchable system for each episode of release of human tissue or an explanted medical device:

- patient name
- patient date of birth
- patient Unit Medical Record Number
- date of tissue/device removal
- description of the human tissue or device
- details (including name and contact) of person to whom the human tissue or device was released.

4. Compliance monitoring

Health Service Providers are required to monitor their compliance with this Mandatory Policy. The System Manager may request Health Service Providers submit evidence of compliance in relation to the requirements of this Policy. In such cases, the Office of the Chief Health Officer will work with Health Service Providers regarding the information required and the timeframes within which this is to be submitted.

5. Related documents

The following documents are mandatory pursuant to this Policy:

- Patient Information Sheet and Consent Form - Authorisation and Release of Human Tissue
- Patient Information Sheet and Consent Form - Authorisation and Release of a Human Fetus or Placenta
- Patient Information Sheet and Consent Form - Authorisation and Release of an Explanted Medical Device

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- Guideline for the Release of Human Tissue
- Guideline for the Release of a Human Fetus or Placenta
- Guideline for the Release of an Explanted Medical Device

7. Definitions

The following definition(s) are relevant to this Policy.

Term	Definition
Authorised delegate	The individual or senior next-of-kin may authorise another person (the authorised delegate), in writing, to exercise their function as requestor.
Explanted medical device	A medical or surgical device, such as a pacemaker, previously implanted and subsequently removed.

Human fetus	A fetus less than 20 weeks gestation of pregnancy, or of unknown gestation but under 400 grams body weight. Included in this definition is an intact or complete fetus and the remaining products of conception expelled from the mother's body or involving surgical intervention to be removed (i.e. dilatation and curettage).
Human Tissue	Includes an organ or part of the human body or a substance extracted from, or from a part of, the human body. A human fetus is included in this definition.
Individual	The person from whom the human tissue and/or medical device was removed.
Public health risk	The risk to persons outside the healthcare facility of infection, either directly or from contamination of drinking water sources.
Requestor	Patient, senior available next-of-kin or authorised delegate who makes the request for release.
Senior health professional	Senior medical officer, midwife or registered nurse.
Senior next of kin	The first in order of priority as listed in the *Human Tissue and Transplant Act 1982.*
Waste	The definitions of waste outlined below reflect those set out in the OD 0651/16 *Clinical and Related Waste Management Policy* and the Standards New Zealand (NZS) 4304:2002: Management of Healthcare Waste. **Clinical waste** Clinical waste is waste that has the potential to cause disease, sharps injury or public offence and includes sharps, human tissue waste, laboratory waste, animal waste, and any other relevant waste specific to an establishment. **Related waste** Related waste includes cytotoxic waste, pharmaceutical waste, chemical waste, and radioactive waste.

8. Policy contact

Enquiries relating to this Policy may be directed to:

Title: Medical Advisor

Directorate: Office of the Chief Health Officer

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9. Document control

Version	Published date	Effective from	Review date	Effective to	Amendment (s)
MP0129/20	28 January 2020	28 January 2020	January 2023	Current	Original version

10. Approval

Approval by	Nicole O'Keefe, Assistant Director General, Strategy and Governance Division, Department of Health
Approval date	23 January 2020

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