VICTORIAN INSTITUTE OF FORENSIC MEDICINE

ALRC REVIEW OF HUMAN TISSUE LAWS

About the VIFM and the DTBV

The Victorian Institute of Forensic Medicine (VIFM) is a statutory agency established under the *Victorian Institute of Forensic Medicine Act 2024* (VIFM Act).

The VIFM exists to provide quality-driven, ethically grounded, independent forensic medical and scientific services for the justice system; to expand and share our knowledge locally and globally; and to make a positive contribution to the health and safety of our community.

Our statutory responsibilities are to provide independent forensic medical and scientific expertise to the justice system, tissue for transplantation, and to both teach and undertake research that will benefit the community.

Donor tissue banking at the VIFM is undertaken by the Donor Tissue Bank of Victoria (DTBV). The DTBV is a multi-tissue bank, operating from a purpose-built Therapeutic Goods Administration (TGA) licensed facility with specialised human tissue processing and storage facilities.

The DTBV screens, processes, stores, tests and distributes heart valves, skin and musculoskeletal tissue (bones and tendons) to Australian hospitals and surgeons. The DTBV's human tissue products are known as "allografts".

Since its establishment, the DTBV has provided over 40,000 high-quality allografts retrieved from over 4,000 donors and transplanted to approximately 18,000 recipients in the community.

The DTBV allografts are life-enhancing and, in the case of cardiac and skin tissue, life-saving. Human tissue is used in a wide range of reconstructive surgeries:

- skin and cardiac allografts are used for burns and cardiac patients
- bone can be manufactured to be a 'biological scaffold' and even a 'stimulant' to enable growth of a patient's own tissue in the recovery process from orthopaedic or spinal surgery
- tendons assist in restoring mobility for orthopaedic patients. 1.8. The DTBV also facilitates retrieval of corneas by the Lions Eye Donation Service, used to restore eyesight.

The DTBV donation program operates in collaboration with partners through the DonateLife Network. Partners include DonateLife Victoria, DonateLife Tasmania and the Lions Eye Donation Service in Melbourne. The Living Donor Program also collects tissue from patients undergoing routine hip replacements at several hospitals across Victoria and collaborates with The Royal Children's Hospital to collect cardiac valves from heart transplant recipients.

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VIFM Response to Discussion Paper

1. A nationally harmonised regulatory framework

Key points

- The VIFM supports consistent human tissue legislation and consistent criteria for human tissue donation across jurisdictions.
- The VIFM supports a single national regulator, provided consideration is given to avoiding duplication and the regulator can effectively support both tissue and organ donation.

- The VIFM supports consistent human tissue legislation across jurisdictions. The legislation should include consistent criteria for human tissue donation across jurisdictions in order to promote equitable access, which includes equitable access to the opportunity to donate.
- The VIFM supports the establishment of a single national regulator as a means of ensuring proper coordination of human tissue donations across jurisdictions.
- The VIFM has reservations about the incorporation of the Organ and Tissue Authority (OTA) into the model for the national regulator. In the VIFM's experience, OTA has had to focus its limited resources on organ retrieval and allocation as a higher priority ahead of tissue. A new national regulator should take a consistent approach to all human tissue donations.
- The model for a new national regulator should also take into account the significant differences in the way tissue and organ processes are regulated due to the way products are processed, priced and used, and be able to support all sectors effectively.
- The VIFM supports a model for a national regulator that avoids duplication or overlapping regulation, particularly for bodies that are involved in tissue selection and retrieval, as well as processing. For example, there is an existing Therapeutic Goods Order (TGO 108) in relation to minimising risk for the transfer of infectious disease in tissue, which impacts on donor selection. It would be an overlap if a national regulator also has a role in setting standards in relation to donor selection criteria.

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2. The objects of human tissue laws

Key points

- The VIFM supports the inclusion of objects in human tissue legislation. It is important that the meaning of objects is clear.
- The VIFM considers that the objects should more clearly articulate the ethical framework intended by the human tissue legislation, which should be consistent with existing guidelines, such as the *NMHRC Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation 2025.*
- The objects should also specify the intended role of human tissue legislation in relation to the import and export of human tissue in and out of Australia.

- The VIFM supports the inclusion of objects in human tissue legislation and broadly supports the objects set out in Proposal 5.
- If there is to be reference in the objects to Australia's international human rights obligations (as proposed by item (c) in Proposal 5), it would be useful to articulate the content of the human rights or provide further guidance about the meaning of the human rights, as human rights may be competing or in conflict in the context of human tissue processes.
- The object proposed by item (f) in Proposal 5 does not sufficiently articulate the ethical framework intended by the human tissue legislation. The ethical framework should include that human tissue processes are not driven by profit and that there is proper consent for tissue donations, unless the requirement for consent for the use of tissue in research has been waived by a Human Research Ethics Committee[1].
- The VIFM notes the principles in the *National Health and Medical Research Council Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation 2025* and suggests that referencing compliance with these Guidelines in the objects (or elsewhere in the legislation) may avoid duplicating frameworks and allow principles to be updated in line with community values from time to time.
- It would also be helpful for the objects to set out the intended role of the human tissue legislation in relation to the import and export of human tissue in and out of Australia

[1] In accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (NHMRC National Statement 2025)

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3. Removing barriers and promoting equitable access to human tissue

Key points

- The VIFM defines 'equitable access' to include equitable access to the opportunity to donate. This includes equity between jurisdictions in Australia and between metropolitan areas and regional and remote areas.
- There are a range of measures that could be taken to improve access to donation in Victoria.
- Any costs associated with implementation of these measures and any requirements to provide equitable access to donation between metropolitan areas and regional and remote areas should be appropriately funded by the Commonwealth or relevant health portfolio and take into account the differences in operation between the organ and tissue markets.

- The VIFM defines 'equitable access' to include equitable access to the opportunity to donate. This includes equity between jurisdictions in Australia and between metropolitan areas and regional and remote areas.

- Currently in Victoria, only deaths reported to the coroner are routinely assessed for suitability for tissue donation. There are a large number of people who die in hospital who are not considered for tissue or eye donation unless this is considered in conjunction with organ donation. This is different from other jurisdictions, where deaths in public hospitals are notified to tissue banks. A similar requirement for automatic notification in nationally consistent legislation would address the current inequity in Victoria.
- In addition to automatic notification, current barriers to donations in Victoria would be assisted by:
    - the development of a uniform set of donor selection criteria and tissue banking procedures, applied consistently across jurisdictions and overseen by a national regulator: see Chapter 1
    - broadening the category of health professionals who can verify that a person is deceased so that donation retrieval can commence: see Chapter 5
    - improved access to information from hospitals in order to assess suitability for tissue donations, including information about the donor and about the donor's senior next of kin (or authorised decision maker): see Chapter 12.
- Any costs associated with implementation of these measures should be appropriately funded by the Commonwealth or relevant health portfolio.
- The VIFM notes that if legislation is to provide for geographical equity for donation, there will be additional costs for tissue and organ donation and transplantation services under the current funding model. Unless additional government funding is provided, tissue retrieval in particular may become cost prohibitive, as it operates on a cost recovery basis in a competitive market, whereas organ donation is centrally publicly funded and operates as a monopoly.

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4. Reforms relating to the definition of tissue

Key points

- The VIFM supports a nationally consistent definition of human tissue that is relatively broad and provides for a flexible mechanism to adjust the definition.
- The VIFM notes the broad range of material that may be included by a definition that refers to material that consists of, includes or derives from human cells and supports a mechanism such as regulations to appropriately exclude certain material.

- The VIFM supports a nationally consistent definition of human tissue that is relatively broad and provides for a flexible mechanism to adjust the definition.
- The definition of human tissue is fundamental to the range of the VIFM's forensic medical and scientific services (in addition to its tissue banking services) in which human tissue is removed and stored, including:
  - medico-legal death investigations
  - provision of tissue for genetic testing for family members of a person who has died and whose death has been reported to the coroner
  - product validation and equipment qualification
  - research.
- The Discussion Paper sets out options for a definition of human tissue that refer to material that consists of, includes or derives from human cells. The VIFM notes that such a definition:
  - would capture a range of material removed from the body in the course of the medico-legal death investigation (urine, mucus, stomach contents, bile, cerebrospinal fluid, swabs from the surface of the body or bladder, fingernail scrapings, maggots). We query whether this material should be regulated in the same way as, for example, whole organs and note that there could be a mechanism to exclude these items through regulations.
  - would not include plasma, as plasma is not derived from human cells and does not contain cells, and so the utility of the definition will depend on whether plasma is to be regulated by human tissue laws
  - would include hair and nails, which will necessitate adjustments for actions such as those by hairdressers, barbers and beauticians etc.
- Adjustments might also need to be considered in relation to museum or art exhibits that include human tissue, for example mummies or plasticised bodies and body components.

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5. Reforms relating to the determination of death

Key points

- The VIFM supports nationally consistent legislation regarding the determination of death.
- The VIFM proposes that, in circumstances where a person has died in the community, formal verification of death by a medical practitioner is either not required or a broader range of health practitioners be able to verify death to enable tissue to be removed from the deceased for donation.

- The VIFM supports nationally consistent legislation regarding the determination of death.
- The VIFM proposes a modification to the articulation of the "Dead Donor Rule" in Proposal 13. Like current Victorian legislation, Proposal 13 continues to require that a person's death be verified by a registered medical practitioner before tissue can be removed for a donation. The VIFM accepts that this verification requirement is necessary when the deceased person has had their respiration maintained by artificial means or has been under treatment in hospital. However, the verification requirement is impractical for deaths that occur in the community.
- Medical verification of death is not required for admission and management of the deceased person's body in the coronial process. However, the verification requirement before donation acts as a barrier to tissue donation through the VIFM's DTBV, where a registered medical practitioner is not necessarily onsite 24/7 but tissue must be retrieved within 24 hours after death to be viable (subject to applicable consents).
- The VIFM proposes that, in circumstances where a person has died in the community, formal verification of death by a medical practitioner is either not required or a broader range of health practitioners be able to verify death to enable tissue to be removed from the deceased for donation. For example, a registered nurse or paramedic who would otherwise have the expertise to establish that a death has occurred in the community.

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6. Reforms related to the donation of tissue by living persons

Key points

- The VIFM supports nationally consistent legislation regarding the requirement for 'valid consent' by a living person for the 'collection' of their tissue. The valid consent process should include informing the person of commercial factors if commercial donation of human tissue is not prohibited.
- The consent process should also provide for consent to be given for any intended alternative use of the collected tissue, in the event that the primary intended use is not possible.
- A person's decision to withdraw consent should be respected up to the point where the tissue can no longer be prevented from being used.
- Approval of a Committee should not be required for donation of tissue by a living child in a situation where the removal is undertaken as part of a medically necessary procedure.

- The VIFM supports nationally consistent legislation regarding the requirement for 'valid consent' by a living person for the donation of their tissue for the purpose of transplantation or for other medical, educational or scientific purposes (noting that a separate consent process is proposed for consent by living persons to tissue collection for research purposes).
- The VIFM recommends that the consent by the person be for the 'collection' of their human tissue, rather than for the 'removal of tissue' from their body, as certain human tissue is not removed per se, for example, breast milk or faecal tissue.
- If the proposed national legislation does not prohibit commercial donation of human tissue, the 'valid consent' process should include informing the donor about these commercial factors.
- The VIFM supports the position taken in the Discussion Paper that 'medical, educational or scientific purposes' is an overlapping term that includes, among other things:
    - use of human tissue or bodies to help medical students learn about anatomy
    - removal of tissue from one person's body and the transplantation of the tissue into the body of another person
    - use of tissue in therapeutic products
    - use of tissue for training, quality control, equipment calibration, or process validation in connection with a medical, educational or scientific purpose.
- The 'valid consent' process in Proposal 14 provides that valid consent is given after the adult who is consenting has been informed about the intended use of the tissue after it has been removed (collected). The consent process should also provide for consent to be given for any intended alternative use of the collected tissue in the event that the primary intended use is not possible, for example, if the collected tissue is ultimately not suitable for transplantation but it is proposed to use the tissue for a medical, educational, scientific or research purpose so that the donation can still be utilised for the benefit of public health.

- The 'valid consent' process in Proposal 14 also provides that valid consent is able to be withdrawn at any time before the removal (collection) of the tissue. In the VIFM's experience, donors or their representatives sometimes withdraw their consent after tissue has been collected but before the tissue has been transplanted. The VIFM considers that a person's decision to withdraw consent should be respected up to the point where the tissue can no longer be prevented from being used (for example, because the tissue or tissue product has been provided on consignment to a health service or transplanted).
- In relation to donation of tissue by living children, the VIFM considers that approval of a Committee should not be required in a situation where the removal is undertaken as part of a medically necessary procedure, for example a paediatric living heart donor where the native heart is removed as part of heart transplant surgery and is donated to a tissue bank for heart valve donation. It should be sufficient to have parental consent or individual consent where the child has decision-making capacity.
- Further, this model raises the possibility of requiring Committee consent where placental tissue and cord blood are removed as these could be considered tissue belonging to the baby. This would be operationally impractical.

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7. Reforms relating to deceased donation

Key points

Consent and authorisation for removal of tissue after death

- The VIFM supports nationally consistent legislation regarding the requirement for 'valid consent' for deceased donation of tissue.
- The proposed authorised decision-maker hierarchy would necessarily require consideration of how the hierarchy operates with the decision-maker hierarchy for coronial process purposes. As the timeframe for removing tissue for a viable donation after death is very limited, it is important that the identification of the person authorised to consent to tissue donation be as easy and certain as possible.
- The VIFM notes that DonateLife do not operate in all hospitals so it may not be appropriate to remove Designated Officers.

Pre-mortem interventions

- The VIFM supports the proposed definition of pre-mortem intervention but suggests that the definition be extended to include preserving the opportunity to donate, as the interventions may not actually result in a donation event.
- The VIFM proposes that consent not be required for procedures that can be carried out without adversely interfering with current medical interventions.
- Where a person has consented in life to organ donation, consideration could also be given to not requiring additional consent for procedures that do not affect their death outcome, but which would enable the donation to occur.

Respectful and dignified treatment of deceased body

- The VIFM supports a mechanism, such as regulations, that enables medical practitioners and other authorised classes of people to remove certain types of tissue from deceased bodies. Authorised classes of people should include practitioners with relevant qualifications for types of tissue removal and technicians or other practitioners who are employed by bodies that have human tissue services as a statutory role and whose duties include the removal of tissue from deceased persons.

Coronial consent to donation

- Human tissue laws should reflect the importance of tissue donation to the community in the granting of coronial consent relating to donation.

Use of tissue removed during a post-mortem examination

- The VIFM supports Proposal 31 subject to exceptions that allow for small samples of tissue to be used for scientific, medical, educational purposes or research (and/or destroyed) without the need for consent.

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Consent and authorisation for removal of tissue after death

- The VIFM supports nationally consistent legislation regarding the requirement for 'valid consent' for deceased donation of tissue for the purpose of transplantation or for other medical, educational or scientific purposes (noting that a separate process is proposed for consent to tissue donation for research purposes after death).
- The 'valid consent' process in Proposal 23 includes consent by a deceased adult's 'authorised decision-maker' and proposes a new hierarchy of decision-makers modelled on the NT *Health Care Decision Making Act 2023*. The VIFM acknowledges that this model is an updated hierarchy of decision-makers that recognises culturally diverse understandings of kinship and those in close and continuing relationships. However, the new authorised decision-maker hierarchy for human tissue legislation would necessarily require consideration of how the hierarchy operates with the decision-maker hierarchy for coronial process purposes, noting:
    - the additional complexity that would be created by having two different decision-makers in the in the context of deceased donations from a coronial case
    - in relation to a coronial case, the ability for a coroner to determine who is the senior next of kin in the event of unavailability or dispute.
- In the context of sudden or unexpected deaths reported to the coroner, the timeframe for removing tissue for a viable donation after death is very limited. It is important that the identification of the person authorised to consent to tissue donation be as easy and certain as possible.
- In this time-sensitive context, it is also important to allow consent to be given verbally.
- The VIFM understands that the proposal to remove Designated Officers (Proposal 23) is premised on the assumption that DonateLife primarily undertakes the role of the Designated Officer. The VIFM notes that DonateLife does not operate in all hospitals, nor are they routinely involved in donation processes not involving organ donation (e.g. eye or tissue donation), so it is not clear who will undertake the role in these circumstances. We further note that a Designated Officer role provides a safeguard against any potential conflict of interest in relation to any performance targets for tissue donation (not just organ donation).

Pre-mortem interventions

- The VIFM supports Proposal 26 for human tissue legislation to define pre-mortem interventions to mean any activity, procedure or investigation that is performed on a living person solely for the purpose of tissue donation after death, including to assess, maintain, or improve the viability of organs for transplantation. The VIFM suggests that the definition be extended to include preserving the opportunity to donate, as the interventions may not actually result in a donation event.
- The VIFM agrees that there are circumstances in which it is difficult or impractical to obtain prior consent for minor procedures that are needed to determine a person's suitability to donate tissue after their death. The VIFM proposes that consent not be required for procedures that can be carried out without adversely interfering with current medical interventions, for example, taking a temperature, taking a blood sample where there is

already a canula, doing a biopsy on an incidental tumour finding where already operating.

- Consideration could also be given to not requiring additional consent where a person has consented in life to organ donation and this is taken to also being consent to any additional procedures that do not affect their death outcome but which enable their wish for donation to occur.

Respectful and dignified treatment of deceased body

- The VIFM supports human tissue legislation providing a mechanism, such as regulations, that enables medical practitioners and other authorised classes of people to remove certain types of tissue from deceased bodies (Proposal 29).
- Proposal 29 refers to the mechanism/regulations authorising 'technicians' with relevant qualifications. The mechanism/regulations could also recognise:
    - other practitioners with relevant qualifications for types of tissue removal, such as nurses
    - technicians or other practitioners who are employed by bodies that have human tissue services as a statutory role (for example, VIFM under sections 8(a) and 9(1)(m)(iii) of the VIFM Act) and whose duties include the removal of tissue from deceased persons.

Coronial consent to donation

- Successful tissue donation relies on close cooperation between tissue banks and the coronial system. The VIFM and the Coroners Court of Victoria work effectively together to support tissue donation. Human tissue laws should reflect the importance of tissue donation to the community in the granting of coronial consent relating to donation.

Use of tissue removed during a post-mortem examination

- The VIFM supports Proposal 31 - that tissue removed during a post-mortem examination cannot be used for a purpose other than the post-mortem examination unless consent has been given for the other purpose – subject to exceptions that allow for small samples of tissue to be used for scientific, medical, educational purposes or research (and/or destroyed) without the need for consent.
- The VIFM notes that, under the current legislative regime in Victoria, the VIFM has the authority to use tissue removed during a post-mortem examination for therapeutic, medical or scientific purposes, subject to two qualifications:
    - any order to the contrary by a coroner
    - if that use would impair or detract from the discharge by the VIFM of its functions under and in connection with the Victorian *Coroners Act 2008*.
- For example, the VIFM would not be authorised to use certain tissue for a therapeutic purpose if the tissue were necessary for the VIFM to complete a forensic medical examination, and by being used for the therapeutic purpose the tissue became unavailable for use in that examination.
- The small samples of tissue that the VIFM currently uses for a medical, scientific, or therapeutic purpose under the authority of the *Human Tissue Act 1982* (Vic) include samples taken during the preliminary examination of the body (bodily fluids such as blood, urine, vitreous humour, mucus, as well as swabs from the surface of the body or

wounds, fingernail scrapings and hair) as well as small tissue samples during the autopsy for further analysis, such as histology.

- Subject to the above qualifications, the VIFM can and wishes to continue to be able to:
  - use tissue removed under the authority of the Coroners Act 2008 to validate scientific laboratory equipment (such as for toxicology and molecular biology analysis) to ensure that the equipment performs accurately in conducting post-mortem analyses of tissue
  - with the consent of affected family members, provide the tissue for genetic analysis in circumstances where the coronial investigation process has uncovered a previously unknown medical condition of the deceased that might have a genetic basis and that may be relevant to the healthcare of surviving family members
  - with the consent of the senior next of kin, issue tissue to a third party for use in an assisted reproductive procedure
  - use the tissue to conduct research in accordance with the VIFM's statutory objects and subject to a decision of the VIFM Human Research Ethics Committee in relation to any required consent in accordance with the National Statement on Ethical Conduct in Human Research, and
  - destroy tissue removed during the post-mortem examination, which then becomes hazardous or unusable.

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8. Reforms relating to tissue donation for research

Key points

- The VIFM supports a requirement that tissue removed (collected) for research must be collected and the research conducted in a manner that is consistent with the National Statement on Ethical Conduct in Human Research.

- The VIFM notes that it is proposed to have separate processes for consent for collection of tissue for transplantation or other medical, scientific or educational purposes, and collection of tissue for research (Proposal 32).
- The VIFM also notes that the 'valid consent' process in Proposal 32 and Proposal 36 provides that valid consent is able to be withdrawn at any time before the removal (collection) of the tissue. As discussed in relation to Chapter 6, the VIFM considers that a person's decision to withdraw consent should be respected up to the point where the tissue can no longer be retrieved or treated separately.
- The VIFM supports Proposal 34 - that new human tissue legislation should provide that tissue removed (collected) for research must be collected and the research conducted in a manner that is consistent with the National Statement on Ethical Conduct in Human Research.

9. Reforms relating to donation and use of deceased bodies, including for research

- The VIFM has no specific comments on this Chapter.

10. Reforms relating to stored tissue collections

Key points

- Any legal requirement to obtain consent from the senior next of kin for the use of stored tissue samples for a research purpose should include an exception when a HREC registered with the NHMRC waives the requirement for consent in accordance with the National Statement.
- The VIFM supports the regulation of tissue collections held for educational purposes under a School of Anatomy licence without unnecessary or overly burdensome administrative requirements.
- The VIFM supports a regulatory regime that would allow legacy collections to be retained for a teaching or case-work purpose, even where there is not full documentation regarding the acquisition of the skeletal items, provided reasonable attempts have been made to document the remains.
- Reform to human tissue legislation should clarify the purposes for which individuals could seek access to stored tissue from their deceased relative, in particular in relation to legal purposes such as paternity testing.

- The VIFM has a statutory function to conduct research and to support research undertaken by other entities where that research is consistent with VIFM's statutory objects. Much of VIFM's research is aimed at improving the forensic medico-legal death investigation and tissue banking services, increasing our understanding of causes of death, improving processes for the identification of deceased persons, drug surveillance, and contributing to the reduction in the number of preventable deaths.
- The VIFM stores tissue samples removed during the preliminary examination of a deceased person and during the autopsy, including blood samples (toxicology laboratory), bone samples (molecular biology laboratory) and histology blocks and slides. These samples are made available to researchers (internal and external to VIFM) when a research application has been approved by the VIFM's Research Advisory Committee and the VIFM's HREC.
- The *Human Tissue Act 1982* (Vic) currently authorises the use of tissue removed under the authority of the *Coroners Act 2008* for a scientific purpose, without the legal requirement for consent from the deceased persons' senior next of kin. However, the NHMRC National Statement creates an ethical requirement for obtaining consent for the use of these tissue samples for a research purpose, unless a HREC has waived the requirement for consent in accordance with paragraph 2.3.10.
- The VIFM HREC routinely waives the requirement for consent for the use of stored tissue samples for a research purpose, balancing the requirements of the National Statement and taking into consideration the potential upset caused by contacting the next of kin of a deceased person to seek consent, possibly years after the death of their loved-one.
- As stated above, the VIFM wishes to continue to be able to use stored tissue samples removed under the authority of the *Coroners Act 2008* for a research purpose without the consent of the senior next of kin, where the VIFM HREC has waived the requirement for consent in accordance with the National Statement.
- Any legal requirement to obtain consent from the senior next of kin for the use of stored tissue samples for a research purpose, should include an exception when a HREC registered with the NHMRC waives the requirement for consent in accordance with the National Statement.
- The VIFM supports the regulation of tissue collections held for educational purposes under a School of Anatomy licence, without unnecessary or overly burdensome administrative requirements.
- It is important to acknowledge the value of legacy collections for teaching and for VIFM's case work. Forensic anthropology requires human reference samples to assist in identifying whether skeletal remains admitted to the mortuary following the report of a death to the coroner are human, or whether they have been damaged, burnt, submerged in water etc. Given the subtleties in colour, weight and texture, these skills of analysis can only be effectively taught using real human skeletal elements.
- The VIFM supports a regulatory regime that would allow legacy collections to be retained for a teaching or case-work purpose, even where there is not full documentation regarding the acquisition of the skeletal items, as long as reasonable attempts have been made to document the remains and noting that all human remains that are, or are likely to be, Aboriginal ancestral remains must be reported

and transferred to the Aboriginal Heritage Council (*Aboriginal Heritage Act 2006*).

- It is also important to acknowledge that many members of the community have unprovenanced human tissue (medical reference teaching skeletons) in their possession. In Victoria, the VIFM/Coroners Court is the first point of contact for this tissue. Sometimes these teaching skeletons are found in less than respectful circumstances and other times it is the member of the community who wishes to dispose/donate the remains in line with modern ethical standards. Currently, the only options for ethical and respectful care of medical reference teaching skeletons are either cremation (noting not all cultures embrace this practice and as these remains are unprovenanced their cultural belief is unknown), or respectful curation (preferred option given they are unprovenanced) within the Schools of Anatomy such as VIFM and the universities.
- The VIFM and the Coroners Court of Victoria often receive requests from families for access to stored tissue for a variety of purposes, including for research projects being conducted by external institutes, paternity testing in relation to legal disputes, or as a memento of the deceased.
- Current legal authority limits the use of tissue retrieved under the authority of the *Coroners Act 2008*, to a scientific, therapeutic or medical purpose. Reform to human tissue legislation should clarify the purposes for which individuals could seek access to stored tissue from their deceased relative, in particular in relation to legal purposes such as paternity testing.

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11. Reforms relating to the prohibition of trade

Key points

Prohibiting the exchange of human tissue for reward

- The VIFM supports new human tissue legislation that prohibits the offering, giving or receiving in Australia of any reward in exchange for human tissue. The proposed prohibition should extend to manufacturers and processors whose primary role is tissue provision.
- The VIFM agrees that the prohibition should not apply to the reimbursement of expenses or the direct and indirect costs involved in tissue banking.
- The VIFM does not support the proposed automatic exceptions from the general prohibition. While the products that would be excepted would have been approved by the Therapeutic Goods Administration, they would not have been subject to the same ethical regulation as required under human tissue legislation.
- The VIFM supports a mechanism for the exemption of exchanges, or categories of exchanges of human tissue from the general prohibition instead of an exception, provided the exemption process is transparent.
- In considering an exemption the national regulator should also be required to consider how a decision to allow the import of tissue will affect local tissue banks.

Prohibiting advertising

- The VIFM supports the prohibition on advertising for the prohibited exchange of human tissue, noting what is meant by 'prohibited exchange' should be clear. It would also be useful to have a positive statement about what activities are allowed.
- The VIFM supports a mechanism to help make sure that imported tissue has been ethically sourced. This could be both a prohibition on the importation of tissue obtained without consent or in exchange for reward or profit, and a licensing or reporting scheme. The mechanism should apply to all places that hold or handle tissue, including for-profit manufacturers or entities that may or may not be suppliers.

Improving access to data

- The VIFM agrees that there is a need for data to better understand the demand for tissue and to inform future policy development.
- The reporting of data should only be mandatory if it includes all import data.

Prohibiting the exchange of human tissue for reward

- The VIFM supports new human tissue legislation that prohibits the offering, giving or receiving in Australia of any reward in exchange for human tissue (Proposal 40). The proposed prohibition should extend to manufacturers and processors whose primary role is tissue provision. This would prevent for-profit tissue manufacturing and processing businesses using not-for-profit entities for collection, donation and/or distribution

to avoid the "no reward" prohibition. Allowing such an arrangement significantly disadvantages the viability of not-for-profit tissue banks.

- It is also proposed that the prohibition not apply to "the reimbursement of any expense or cost". The VIFM agrees that the prohibition should not apply to the reimbursement of expenses or costs involved in tissue banking[2]. This includes both direct and indirect costs, such as a tissue bank's general operational need to comply with regulatory requirements, capital equipment, facility management, and research and development services (not just cost recovery for managing individual donations).
- The VIFM does not support the proposed automatic exceptions from the general prohibition, which are set out in Proposal 42. While the proposed exceptions concern products that have been approved by the Therapeutic Goods Administration, the products have not been subject to the same ethical regulation as required under human tissue legislation.
- The VIFM supports human tissue legislation having a mechanism to allow for the exemption of exchanges, or categories of exchanges, of human tissue from the general prohibition instead of the exceptions in Proposal 42.
- As set out in Proposal 43, this could be to allow the national regulator to grant exemptions from the prohibition provided that the application and decision-making processes of the national regulator are transparent.
- In making a decision to exempt exchanges or categories of exchanges in addition to the factors set out in Proposal 43, the national regulator should also be required to consider how a decision to allow the import of tissue will affect local tissue banks, for example, whether allowing the import of a particular tissue for one provider/sector would affect the viability of local tissue banks.

Prohibiting advertising

- The VIFM supports the proposed prohibition on the public dissemination of information that invites, promotes or seeks to induce a person to engage in a prohibited exchange of human tissue. The VIFM considers that the prohibition would be most effective if what is meant by a 'prohibited exchange' of human tissue is clear on the face of the prohibition.
- The VIFM would also support clarity in the legislation (or other guidance material) about what tissue donation-related activities can be promoted and/or advertised. That is, it would be useful to have a positive statement about what activities are allowed rather than this being based on an understanding of what activities are not prohibited.
- The VIFM supports new human tissue legislation that includes a mechanism to help make sure that imported tissue has been ethically sourced (Question 40). The VIFM considers that the mechanism could be both a prohibition on the importation of tissue obtained without consent or in exchange for reward or profit, and a licensing or reporting scheme. The mechanism should apply to all places that hold or handle

[2] VIFM Act, section 3, definition of "human tissue services" means the removal, receipt, processing, storage or supply of human tissue; and any other service provided in connection with the removal, receipt, processing, storage or supply of human tissue.

tissue, including for-profit manufacturers or entities that may or may not be suppliers. Without such a mechanism, there will not be a level playing field for Australian tissue banks that operate on a cost recovery basis.

Improving access to data

- The VIFM agrees that there is a need for data to better understand the demand for tissue and to inform future policy development (Question 42). This includes data in relation to:
    - number of deaths in hospital
    - number of referrals to local tissue banks and the tissue involved
    - number of successful transplants from local donations of tissue and the tissue involved
    - number and type of tissue imported and supplied from where (including the country origin of the donor) and including number and type of tissue imports for further processing.
    - number and type of tissue transplants in Australia from imported tissue products (including those manufactured from imported tissues).
- The reporting of data should only be mandatory if it includes all import data, supported by inspection of records by the national regulator, so that there is an accurate and reliable source of information about human tissue markets in Australia.

VICTORIAN INSTITUTE OF FORENSIC MEDICINE

12. Reforms relating to how information can be disclosed and shared

Key points

- The VIFM supports prohibiting the public disclosure of a human tissue donor's or human tissue recipient's 'personal information' unless consent to disclosure has been provided.
- The VIFM supports allowing medical practitioners to disclose a human tissue donor's personal information to a potential human tissue recipient in specified circumstances.
- The VIFM supports allowing human tissue donors or recipients (or their authorised decision-maker if the donor or recipient is deceased) to consent to the disclosure of their personal information.
- The VIFM supports new human tissue legislation that explicitly allows medical practitioners, health authorities and other donation agencies (not just DonateLife) to share information that identifies a potential donor and their authorised decision-maker before a donation decision is made.
- Donation agencies like the VIFM could also be allowed to directly access specific medical information to assist donation purposes.

- The VIFM supports new human tissue legislation that prohibits the public disclosure of a human tissue donor's or human tissue recipient's 'personal information' unless consent to disclosure has been provided (Proposal 46). However, consideration should be given to how any such prohibition will operate with other legislative requirements to protect personal and health information, such as requirements that apply to public entities under privacy legislation.
- The VIFM supports new human tissue legislation that provides that it is permissible for medical practitioners to disclose a human tissue donor's personal information to a potential human tissue recipient in specified circumstances (Proposal 47).
- The VIFM supports new human tissue legislation that provides that consent to the disclosure of a human tissue donor's or human tissue recipient's personal information may be given by the human tissue donor or recipient themselves, or their authorised decision-maker if the donor or recipient is deceased (Proposal 48). However, as noted in relation to the proposed new authorised decision-maker hierarchy discussed in Chapter 7, further consideration must be given to how the hierarchy will operate with the decision-maker hierarchy for coronial process purposes, including:
    - the additional complexity that would be created by having different decision-makers for different stages/processes, particularly if there is a dispute between the decision-makers

  - how the hierarchy might operate over time, such that the decision-maker at the time of donation is not the same person at the time of information disclosure
  - the possible need for a process to determine the decision-maker when there is no one in the hierarchy who is available.

- Proposal 49 is for new human tissue legislation to use section 45(4)-(6) of the Victorian *Human Tissue Act 1982* as a model to ensure that medical practitioners and DonateLife staff can access and share with each other relevant information for donor identification and screening. The VIFM accepts the proposed intention of the current Victorian provisions but recommends that the drafting approach be reviewed for new human tissue laws to ensure clarity in the operation of the provisions.
- In the VIFM's experience, the Human Tissue Act sections do not provide sufficient clarity to enable the required information sharing. Hospital staff continue to express concerns about sharing information with donation agencies about a potential donor or their next of kin before formal consent for donation has been obtained. As a consequence, patients who die outside the required circumstances for organ donation (which has dedicated on-site staff) are rarely referred to local donation agencies for eye or tissue donation.
- As hospitals are concerned about sharing information prior to obtaining a family's consent, approaches to families are often made by non-specialised practitioners, resulting in poorer donation outcomes and family experiences.
- The VIFM seeks a policy setting that promotes the public good of tissue and organ donation and encourages open discussions with individuals and families.
- The Human Tissue Act sections are premised on an initial and broad prohibition of sharing information. The sections would be improved by positive re-drafting that explicitly allows medical practitioners, health authorities and other donation agencies (not just DonateLife) to share information that identifies a potential donor and their authorised decision-maker before a donation decision is made.
- Donation agencies like the VIFM would also be assisted by being able to directly access specific medical information for this purpose. There are a range of medical reasons why a person will not be able to donate tissue and early identification of relevant medical information would avoid unnecessary distress to families regarding potential donation.
- Donation agencies must have access to this information so that trained donation requestors can undertake the important conversations about donation. Both the medical information about the potential donor, and the social history information provided by family members, is necessary to assess whether a person's tissue is suitable for donation.