



**EYE BANK OF
BRITISH COLUMBIA**

EYE DONATION AND TRANSPLANT

INFORMATION MANUAL

FOR THE HEALTH CARE PROFESSIONAL

Revised: July 2009

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INTRODUCTION

In British Columbia today, approximately 400 individuals of all ages and walks of life are waiting for a corneal transplant. The demographic trends in our province indicate that the waiting list will continue to grow and as our aged population increases so will the need for corneal transplants.

To meet this growing demand for corneal tissue, the Eye Bank of British Columbia was established in 1983 as the provincial referral centre, supported by the Government of British Columbia and BC Hospital Programmes. The Eye Bank of BC is located in the VGH/UBC Eye Care Centre on the Vancouver General Hospital site, a part of the Vancouver Coastal Health Authority.

The success of the Eye Bank, to meet the needs of those who are waiting relies on the cooperation of hospital administrators, physicians, nurses, ancillary staff, and the donor families who give consent for donation.

By assisting the Eye Bank in acquiring tissue, hospital personnel can have a direct role in reducing the waiting list. The Eye Bank acts as a liaison between the donor, next-of-kin, and recipient to coordinate ocular tissue transplantation. We rely on members of the medical profession at all levels to take the first step with the gift of sight by referring potential donors to the Eye Bank.

In this presentation, we will delineate the structure and role of the Eye Bank. It is intended as a reference for hospital and medical staff. Please note that this information manual is updated on a regular basis. Check our website (www.eyebankofbc.com) to ensure that you have the most current edition. If further copies are needed at any time, please contact us at:

**Eye Bank of BC
2550 Willow Street
Vancouver, BC V5Z 3N9**

**Phone: 604-875-4567 Toll Free (in Canada): 1-800-667-2060
Fax: 604-875-5316**

**Web: www.eyebankofbc.com
Email: eyebankofbc@vch.ca**

EYE BANK OF BRITISH COLUMBIA

Medical Director J. Martin McCarthy, M.D.
Deputy Medical Director..... Simon Holland, M.B.

Advisory Board

VGH/UBC Head of Ophthalmology..... Fred Mikelberg, M.D.

Eye Bank Staff

Manager..... Dermot Kelly
Transplant Coordinators Ivan Yan, Rick Farrer, Chris Frketich, Brian Ha, Teresa Mizban
QA Coordinator Janet Bristeir
Administrative Secretary..... Catherine Millard-Saadi
Nurse Educators..... Jane Slingsby

As well, the Eye Bank has several on-call technicians who perform the donor screening and eye retrieval procedure in the Greater Vancouver area and coordinate the eye donation process for the province.

The Eye Bank of British Columbia became a certified member of the Eye Bank Association of America in 1984 and has been re-accredited in 1988, 1991, 1994, 1997, 2001, 2004, and 2007.

MISSION STATEMENT:

The mandate of the Eye Bank of British Columbia (EBBC) is to maximize the availability of transplantable ocular tissue in British Columbia. The EBBC's purpose is to acquire, evaluate, process, preserve, store, and distribute human donor eye tissue for transplant procedures primarily for the residents of British Columbia, as well as for medical research and medical educational purposes.

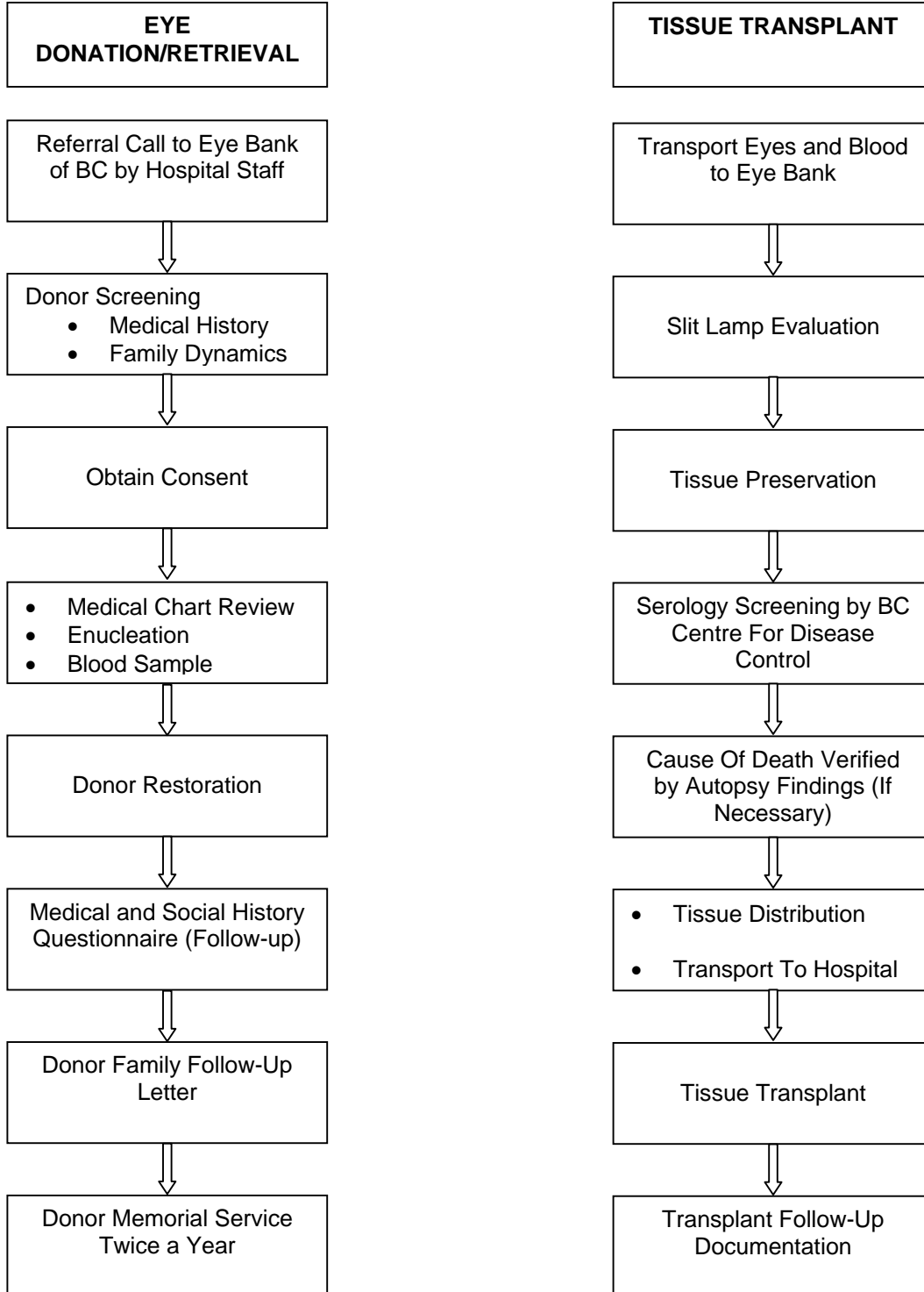
PURPOSE:

- 1) To obtain human donor eye tissue for:
 - a) Corneal transplantation
 - b) Scleral grafts
 - c) Scientific research
 - d) Medical education
- 2) To act as a liaison between donor families, the medical community, and corneal recipients.
- 3) To preserve and store eye tissue.
- 4) To distribute eye tissue.

GOALS:

- 1) To establish and implement high standards for the collection and evaluation of eye tissue used for transplant.
- 2) To maintain fair tissue distribution.
- 3) To reduce the waiting list for corneal transplants.

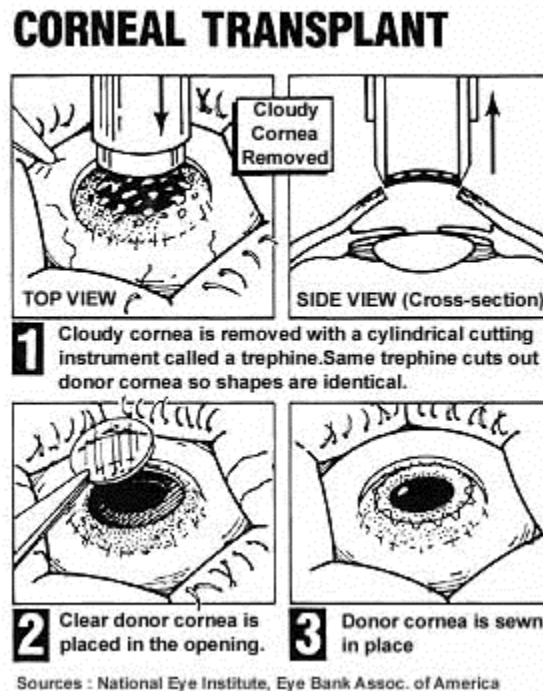
FLOWCHART



CORNEAL TRANSPLANTS

Modern advances have made possible the successful transplantation of a number of tissues of the body. The cornea is considered a privileged site and is a tissue that can be transplanted with a high percentage of success. Generally blood and tissue typing is not required.

The cornea is the clear tissue at the front of the eye and may be compared to a "watch crystal". The cornea is the major focusing structure of the eye. When injury, degeneration, infection, or scarring affect this clear membrane, it can become cloudy, impairing the transmission of light to the retina, resulting in decreased vision. If vision is impaired significantly, the diseased portion of the cornea can be removed and replaced with new tissue from a donor. An ophthalmologist determines whether a corneal transplant would be beneficial to the patient.



OTHER PROCEDURES

Lamellar keratoplasty and other similar procedures use a thin portion of the cornea for a partial thickness graft. These may be used to produce a better refractive result. Sclera is used for several different kinds of reconstructive surgical procedures. Tissue not suitable for transplant can be used for research and education according to the consent from the next of kin.

The potential benefits of one eye donor are:

1. Up to two patients may receive corneal transplants.
2. Up to six patients may receive scleral grafts.
3. Remaining portions of tissue may be used for research and education.
4. Some comfort to the donor family who gave the Gift of Sight.

EYE DONOR IDENTIFICATION AND REFERRAL

The attending physician's first responsibility is to maintain the life and well-being of the patient. If death occurs, the following steps may be taken:

Identify the deceased as a potential donor.	Any death from age 2 to 75 (donors younger than 2 may be used for certain specialized procedures - please consult with the Eye Bank).
Notify the Organ Donor Referral Line.	1-877-366-6722 (24 hrs).
Obtain consent from the next of kin for eye donation (enucleation) if deemed medically suitable by the Eye Bank.	Document consent.
Care of the Potential Donor: a) Instill eye drops (Optimyxin, artificial tears, or normal saline) b) Tape eyelids closed. c) Place bag of crushed ice over eyes.	10 drops per eye. Protect cornea. Keep eyes cool.
Perform enucleation procedure if certified*, or the Eye Bank will arrange to have this done.	Eye Bank Technician or physician.

* Education will be offered by the Eye Bank regarding the procurement procedure to those interested in participating.

Nursing staff can play a vital role in identifying potential donors by being familiar with the guidelines of tissue suitable for donation. The Eye Bank is willing to provide in-service seminars regarding the eye donation process, for identifying potential donors, and approaching for consent.

Note to Physicians: Payment of fee item (MSP 0050) is limited to:

(a) enucleations yielding tissue which is confirmed by the Eye Bank of British Columbia as falling within its guidelines for enucleations, and (b) enucleations where the donors were insured by the Medical Services Plan at the time of death.

DONOR SCREENING

Under the *Human Tissue Gift Act of British Columbia - Consent to Donation Regulation* (Appendix C), any death that occurs in any hospital in BC is required to be reported to an organ donor agency (e.g. Eye Bank of BC). The Eye Bank, in conjunction with the hospital, then determines donor suitability.

To report a death, please call the Donor Referral Line at 1-877-366-6722 (24 hrs). Please be prepared to answer the following questions:

- Name and title of person calling
- Location and phone number
- Date of birth and age of potential donor
- Specifics of the death (*i.e.* date and time of death, cause of death, medical history, and most recent WBC and temperatures)

Please be sure to record the referral number given to you, as this number will be used by the Eye Bank for follow up.

The Donor Referral Line then forwards the information to the Eye Bank. A member of the Eye Bank will then contact the hospital to do the following:

- Obtain the patient's name
- Verify the information given
- Determine suitability
- Determine family dynamics
- Consult with hospital regarding consent for donation

GUIDELINES:

1. Potential eye donor suitability must be determined prior to enucleation. Contact the Eye Bank via the Donor Referral Line at 1-877-366-6722 (24 hrs).
2. Age limit: 2 to 75 (donors younger than 2 **may** be used for certain specialized procedures - consult with the Eye Bank).
3. Time of death to enucleation equal to or less than 8 hours.
4. One blood sample is required for serology.
5. Some form of legal consent is mandatory.
6. Cause of death **must** be determined before tissue is used for transplant.

CONTRAINDICATIONS:

The following is a general list of contraindications to eye donation. **Please report ALL deaths to the Eye Bank, since the Eye Bank requires the information for statistical purposes.**

- Infectious or potentially infectious diseases
 - HIV/AIDS
 - Hepatitis B/C or active Hepatitis A
 - Syphilis
 - Active viral encephalitis
 - Creutzfeldt-Jacob Disease
 - Rabies
 - Rubella
 - Reyes Syndrome
 - Subacute sclerosing panencephalitis (measles)
 - Septicemia (bacteremia, viremia, fungemia)
 - Progressive multifocal leukoencephalopathy

CONTRAINDICATIONS (cont.):

- Central Nervous System Disorders
 - Alzheimer's Disease
 - Multiple Sclerosis (MS)
 - Parkinson's Disease
 - Amyotrophic lateral sclerosis (ALS, Lou Gehrig's Disease)
 - Other CNS diseases of unknown etiology

- Malignancies
 - Leukemia
 - Lymphoma
 - Lymphosarcoma
 - Hodgkin's Disease
 - MOST OTHER TYPES OF CANCER ARE ACCEPTABLE FOR EYE DONATION

- Intrinsic Eye Disorders
 - Ocular inflammation (infection)
 - Corneal scarring
 - Prior refractive surgery (RK, PRK, LASIK) – OKAY for certain types of transplants
 - Congenital or acquired eye disorders
 - Retinoblastoma
 - Malignant tumours of the anterior segment
 - CATARACTS AND GLAUCOMA ARE ACCEPTABLE FOR EYE DONATION

If the potential donor is suitable by age, cause of death, and medical history, the family may be approached for consent by:

- a) Physician
- b) Registered Nurse
- c) Social Worker
- d) Pastoral Care Worker
- e) Eye Bank Technician

CONSENT FOR EYE DONATION

LEGAL AUTHORITY FOR DONATION OF EYES

- Ensuring legal consent in tissue donation is of the utmost importance. *The Human Tissue Gift Act of British Columbia* (Appendix D) addresses the issue of consent.
- Legal consent may be:
 - a) Consent form signed by legal next of kin and witnessed, or
 - b) Verbal consent from next of kin and witnessed by two other individuals
- The Eye Bank of BC recommends the use of the standard consent form (see appendix A) and the protocols included on the reverse of that form.
- Who may give consent?
 - a) The patient of legal age (19 years or older)
 - b) Patient's spouse of any age
 - c) Any of the patient's children of legal age
 - d) Either of patient's parents
 - e) Any of patient's siblings of legal age
 - f) Any other next of kin of legal age
 - g) Executor (Power Of Attorney)

THE CONSENT PROCESS

Why Ask? We believe that:

1. By asking, you give the families the chance to take control at a time when everything in their world seems out of control.
2. Everyone deserves the opportunity to consider giving; to do something noble at their time of sorrow.
3. Consenting to THE GIFT OF SIGHT can be a positive experience for families; it can provide comfort and may even lessen the sense of finality.
4. **If you don't ask, you are really making the decision for them.**

About Asking for Consent

Approaching potential donor families is never an easy task but this does not lessen the importance of asking. Potential donor families need to know:

1. That their loved one can be a donor and help others in need.
2. That their decision is a private one and will be supported by you.
3. Recovery of donated eye tissue is a surgical procedure performed by Eye Bank professionals.
4. Donated eye tissue will be used for transplant if at all possible.

**THE SINCERITY OF THOSE WHO ASK IS APPRECIATED BY FAMILIES;
TRUST THAT THEY WILL KNOW YOU CARE!**

COMPLETING THE CONSENT FORM

Please ensure that the consent form is properly completed (refer to Appendix A):

1. Please use the Addressograph or labels, if available.
2. Determine if the patient is registered with the Organ Donor Registry (ODR).
3. If the patient was listed on the ODR, please attach a copy to the consent form - **please note: even if the patient is listed on the ODR, you should verify with the family that the patient did not change his/her mind about organ donation.**
4. Complete the form with: a) name of next of kin giving consent, b) the next of kin's relationship to the donor, and c) the donor's name.
5. Ensure that either the "Any organs or tissues" field or the "Limit donation to the following" field is initialled by the next-of-kin. If "Limit donation to the following" is initialled, "Eyes" must also be initialled. If this is a verbal consent, ensure that the two witnesses initial all the appropriate fields. Please note: The Eye Bank of BC retrieves whole eyes AND NOT JUST THE CORNEAS - **THEREFORE THE CONSENT FORM MUST STATE "EYES" AND NOT "CORNEAS"!**
6. Please have the family specify their wishes with regards to "Medical Education" and "Scientific Research," by initialling the appropriate field. The Eye Bank of BC's primary goal is to use donated tissue for transplantation purposes.
7. The Eye Bank of BC routinely performs medical/social history interviews. If there is anyone other than the next-of-kin that may be contacted to discuss the donor's history, this can be specified on the field following "In conjunction with the patient's physician and/or family member..."
8. Ensure that the next-of-kin information is completed - if this is a verbal consent, write "verbal consent" in the signature space.
9. If this is a *signed consent* by the next-of-kin, ensure that the person who obtained the consent witnesses the consent in the space provided.
10. If this is a *verbal consent*, ensure that two witnesses complete the "witness" section of the consent form.

Ensure that a copy of the consent form is attached to the donor's medical chart.

THE ENUCLEATION PROCEDURE

If the family decides to donate, an Eye Bank staff member or designee will perform the procedure once the family has said their final goodbye. The entire procedure takes about one hour to complete.

Prior to the actual procedure, a thorough medical chart review is completed. The enucleator will review the chart for past and current medical history, as well as lab results, medications, nurses' and doctors' notes, consult reports, *etc.* The enucleator then completes the appropriate paperwork and proceeds with the rest of the enucleation procedure.

The enucleation procedure takes place using standard aseptic techniques. The enucleator will wear a bouffant cap, surgical mask, eye protection, fluid impermeable lab gown, and gloves. Before beginning the surgical technique, the donor's identity is verified, a body examination is performed and any findings documented, and the eyes are evaluated using a penlight.

The enucleation procedure **requires that the whole eyes be retrieved and replaced with conformer caps, which retain the shape of the eyes.** As well, a small amount of blood is taken for testing. Once the procedure is completed, there are usually no obvious signs that the donation took place, and viewing of the donor can take place afterwards.

TISSUE PROCESSING AND RELEASE

Once the eyes are back at the lab, they are evaluated. If they can be used for transplants, they are processed and preserved in a storage medium. If the eyes cannot be used for transplantation, they then can be used for research, if allowed for in the consent.

Once the ocular tissues have been preserved, the blood sample obtained is sent off for testing. These tests currently include:

- HIV 1 and 2
- HTLV I and II
- Hepatitis B and C
- Syphilis

The blood tests must be negative in order for the tissue to be used for transplants.

The donor's family doctor and/or family is contacted to answer a standard questionnaire about the donor's medical and social history.

Once the questionnaire and blood tests are suitably completed, and the autopsy results obtained (if applicable), the tissue can then be used for transplantation.

FOR MORE INFORMATION

For further information regarding the Legacy of Sight Program, please contact the Eye Bank of BC at 604-875-4567 or toll free (in Canada) at 1-800-667-2060 (24 hrs), or on the web at www.eyebankofbc.com.

An Eye Bank technician is available 24 hours a day to perform the eye removal procedure in the Greater Vancouver area. For hospitals outside this area, individuals trained in the enucleation procedure are utilized. If you are interested in becoming trained, please contact the Eye Bank.

APPENDIX A - SAMPLE COMPLETED CONSENT FORMS

(Refer to Completing the Consent Form (page 11) for legend):

Consent For Donation of Organs and/or Tissues (See reverse for instructions for obtaining consent)	
FOR COMPLETION BY HEALTHCARE PROVIDER Referral call placed to 1-877-DONOR BC <input type="checkbox"/> YES Has a Consent Record been obtained from the Organ Donor Registry (ODR) <input type="checkbox"/> YES – attached <input checked="" type="checkbox"/> NO (no ODR record)	ADDRESSOGRAPH/PATIENT LABEL

Having attained the age of 19 years, I, Jane Doe (name of person providing consent/affirming patient's consent), being wife (self/relationship to patient) of John Doe (name of patient) who has died or whose death is imminent, do hereby consent under the Human Tissue Gift Act of British Columbia to the removal of the organs/tissues specified in this consent for the purposes of transplantation.

MW/MB (initial) **Any organs or tissues (see complete listing below)**

MW/MB (initial) **Limit donation to the following (please INITIAL organs/tissues to be donated):**

Heart _____ (initial)	Kidneys _____ (initial)	Pancreas _____ (initial)	Small Bowel (pediatric only) _____ (initial)
Liver _____ (initial)	Lungs _____ (initial)	Eyes <u>MW/MB</u> (initial)	

I agree that if any organ or tissue retrieved for the purpose of transplantation is determined not to be suitable for transplantation, it may be used for (please INITIAL both questions):

Used for Medical Education? YES MW/MB (initial) NO _____ (initial) Used for Scientific Research? YES MW/MB (initial) NO _____ (initial)

I understand and agree that for the purposes of determining suitability:

- Blood tests for infectious diseases, including but not limited to human immunodeficiency virus (HIV), human T-cell lymphotropic virus (HTLV), hepatitis B and C, West Nile virus (WNV), and syphilis will be performed;
- Blood and splenic samples may be retained for future testing for infectious diseases and tissue typing;
- The retrieval agency may perform examinations and receive medical records relevant to the transplant;
- The patient's physician and/or family member may be contacted by the retrieval agency to discuss relevant medical/social history;
- In conjunction with the patient's physician and/or family member, a friend(s) _____, (insert name) _____, (insert name) may be contacted by the retrieval agency to discuss relevant medical/social history;

I understand that this information will be kept confidential to the extent permitted by law. I am aware that certain infectious diseases must be reported to the Medical Health Officer, who may trace contacts as permitted by legislation.

I consent to the transfer of the deceased to the retrieval/transplant centre for the removal of said organs or tissues if necessary.

I agree that I have read and fully understood the above consent, that I have had the opportunity to ask questions and that the explanations referred to in this document were made.

Person providing consent/affirming patient's consent Date consent provided: January 1, 2007

Jane Doe (Print Name) Verbal Consent (Signature) 604-555-5555 (Telephone #)

1234 Main Street, Vancouver, BC V1V 1V1 (Address, city, province, postal code)

Witness(es) (Note two witnesses are required for telephone/verbal consent)

Marcus Welby (Print Name) M Welby (Signature) 604-875-4111 (Telephone #)

Mark Green (Print Name) Mark Green (Signature) 604-875-4111 (Telephone #)



3 copies of this form are required: 1 copy for the Patient Chart 1 copy for the BC Transplant Society 1 copy for the Eye Bank of BC.

Instructions for Obtaining Consent for Donation of Organs and/or Tissues

Prior to approaching family for consent

- Prior to approaching the family for consent, call 1-877-DONOR BC to determine patient donation potential.
- Following determination of patient suitability/potential for organ and/or tissue donation, access the Organ Donor Registry (see instructions below) to determine whether a decision record already exists for the patient.

Organ Donor Registry (ODR) access procedure

1. Dial ODR number 1 604-877-1693
2. Enter 4-digit access code number
3. Enter Personal Health Number (PHN) of the potential organ/tissue donor
4. If a decision record exists, it will be faxed back to the facility
5. Call BCTS at 1-800-663-6189 if you encounter difficulties.

DO approach family if no decision record exists.

DO approach family if decision record **indicates consent** for donation.

If the ODR decision record indicates the patient did not want to be a donor, the family may be approached to see if a record of a revised decision regarding donation exists.

1) How to document consent

Consent for Donation may be documented in any one of the following three ways:

- i. The decision record from the Organ Donor Registry (ODR) plus this “Consent” form, duly completed, and signed by the person affirming consent and one witness (see “*Who may give consent*” below).
- ii. *In the absence of an ODR record*, this “Consent” form, duly completed, and signed by the person giving consent and one witness (see “*Who may give consent*” below).
- iii. *In the absence of an ODR record and in the case where consent/affirmation is obtained over the telephone*, this “Consent” form, duly completed and documenting the person giving consent and **two** witnesses (see “*Who may give consent*” below).

2) Who may give consent?

Consent may be given by the following persons of **nineteen years of age or over** in this order: spouse, child, parent, sibling, grandchild, grandparent or nearest” blood relative” **or by the person lawfully in possession of the body** other than the administrative head of the hospital or the coroner.

3) What are they consenting to?

Consent may be given for “any” organs or tissues, or may be given for a specific organ(s) or tissues. The specific organs are listed on this “*Consent*” form. In the case of consent for a specific organ(s) or tissues, the person giving consent (see “*Who may give consent*” above) must indicate their decision by placing an initial in the space(s) provided.

“Any” organ or tissue could include all or any combination of the following, pending suitability: heart, lungs, liver, pancreas, kidneys, small bowel and eyes. Consent may also be given for:

- i. organ/tissue donation for the purposes of “**Scientific Research**” . “Scientific Research” refers to transplantation research carried out in accordance with the Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* by any UBC affiliated staff members; and
- ii. eye donation for the purposes of “**Medical Education**”.

This “*Consent*” form is **not** applicable to the *donation of bodies to science*.

4) What fields must be completed on this “Consent” form?

- Name and signature of the person giving consent or affirming patient’s consent
- Name of patient
- Relationship between the patient and the person giving consent/affirming patient’s consent
- Date of consent
- Name and signature of witness(es)
- Details of what they are consenting to (see “*What are they consenting to?*” above)

5) Must the form be witnessed?

Yes. See “*How to document consent*” above.

For further information regarding:

Solid organ donation, please contact the British Columbia Transplant Society (1-800-663-6189).

Eye donation, please contact the Eye Bank of British Columbia (604-875-4567 or 1-800-667-2060).

APPENDIX B - FREQUENTLY ASKED QUESTIONS

Whom do corneal transplants benefit?

There are several different reasons for requiring a corneal transplant. Some of the more common are as follows:

- Keratoconus – a disease where the central cornea thins and bulges forward
- Fuch's Dystrophy – an hereditary disease in which the cells that maintain corneal clarity are gradually lost
- Aphakic and Pseudophakic bullous keratopathy – conditions where the cells that maintain corneal clarity are damaged as a result of cataract surgery
- Chemical/Physical injuries to the cornea

What is sclera used for?

There are a few reasons for requiring a scleral transplant. The major ones are as follows:

- Ocular implantation after enucleation – a synthetic eye implant is wrapped in sclera. The muscles are then attached to the sclera, which allows the artificial eye to move with the companion eye.
- Lid retraction – the sclera is used to reconstruct the eyelid
- Glaucoma surgery – a Ahmed valve is inserted into the eye to reduce intraocular pressure. The valve is covered with a piece of sclera to allow movement of the eyelids across the implant.

Is the whole eye transplanted?

- No, only the cornea (the clear, front part of the eye) is used for corneal transplants. The sclera (white part) is sometimes used for procedures such as glaucoma surgery and lid reconstruction. The rest of the eye can be used for research (if allowed from the consent) to aid in future treatment of eye disease.

Will a person be able to have an open-casket funeral?

- Yes – no one will know there has been an eye donation unless you tell them. In very few instances there may be a bit of bruising or swelling, but otherwise there should be no visible signs following donation.

Is the family told who will receive the eyes?

- No. A letter of appreciation is sent to the family. The actual identities of the donor and recipients are kept confidential under present laws. However, recipient and donor families can communicate with each other anonymously via the Eye Bank.

Can all blind people benefit from a corneal transplant?

- No, only those whose eyes have a defective cornea.

Can patients who wear glasses and/or who suffer from cataracts/glaucoma donate?

- Yes. Even totally blind people with healthy corneas can donate their eyes because there is no relationship between poor eyesight and donor eligibility.

Can cancer patients donate their eyes?

- Yes, most cancer patients can donate. Only those who have leukemia, lymphoma, or ocular cancers are ruled out.

I have an ethical/moral issue with eye donation.

- Although we appreciate that some are individually uncomfortable with the idea of eye donation, we emphasize that **the decision for eye donation is personal**. Please remember that if you do not refer any donors to us or refuse to approach the next of kin, you've taken that choice away from the family. In our experience, many donor families are unaware that they can donate and are grateful that they are able to help someone.

IN ORDER TO ALLOW US TO HELP OTHERS, WE REQUIRE YOUR PARTICIPATION IN THE LEGACY OF SIGHT PROGRAM!

Please note that your involvement in the program is essential for a variety of reasons:

- We need to increase the number of donors in order to reduce the cornea wait list - please remember to notify us regarding all deaths
- Studies suggest that consent rates approximately *double* when the next of kin are approached by a hospital staff member in person versus a "stranger" contacting them via telephone; as well, the next of kin often do not go home immediately afterwards, making a telephone consent much more difficult to achieve

If you have any more questions regarding eye donation, please call the Eye Bank of British Columbia at 604 875-4567 or toll free (in BC) 1-800-667-2060, or on the web at www.eyebankofbc.com.

APPENDIX C - *The Human Tissue Gift Act - Consent to Donation Regulation*

CONSENT TO DONATION REGULATION

[includes amendments up to B.C. Reg. 229/99]

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Definitions

1 In this regulation:

"**agency**" means the British Columbia Transplant Society;

"**consent**" means consent to the use of a patient's body, or the removal and use of specified parts of it, after death for therapeutic purposes, medical education or scientific research;

"**decision record**" means the written or electronic record of the decision, made by the patient in accordance with section 4 of the Act, either

- (a) to give consent, or
- (b) to refuse consent;

"**facility**" means a hospital, licensed hospital or community care facility;

"**next of kin**" means a relative of the patient determined in accordance with section 5 (1) (a) to (e) of the Act;

"**patient**" means a person admitted to a facility and includes a person who is dead on arrival at a facility;

"**registry**" means the Provincial Organ Donor Registry operated by the agency.

Purpose

2 The purpose of this regulation is to facilitate increased levels of organ donation and transplantation.

Notification

3 (1) A facility must notify the agency immediately in the event of the death, or impending death, of a patient 75 years of age or younger, in its care.

(2) Notification under subsection (1) must be by telephone or by electronic means and must include the following information about the patient:

- (a) name;
- (b) personal health number;
- (c) age;
- (d) cause, or expected cause, of death;
- (e) any past and current medical history which is relevant to organ transplantation which is available.

Medical suitability

4 (1) At the time of giving a notification under section 3, the facility must contact the agency, or a person designated by the agency, and the agency must determine and advise the facility whether

(a) the existence of a medical or other condition will make the tissue of the patient unsuitable for use in another person, or

(b) the tissue of the patient may be suitable for use in another person because paragraph (a) does not apply.

(2) If a determination is made that subsection (1) (a) applies, the facility must take no further action under this regulation in relation to the patient.

Search by facility for decision record

5 (1) If the facility has given a notification under section 3 and has not been advised of a determination under section 4 (1) (a), the facility must immediately search the registry to determine whether a decision record exists for that patient.

(2) The facility must advise the agency of the results of its search under subsection (1) and, if there is a decision record,

(a) the facility must immediately place a copy of the decision record in the medical record of the patient, and

(b) provide the next of kin with a copy of the decision record.

(3) If the decision record indicates a refusal to give a consent, the facility is to take no further action under section 6 or otherwise to obtain a consent.

Notification of patient's next of kin

6 (1) If the facility has obtained a copy of a decision record for a patient from the registry, the decision record contains a consent and section 4 (1) (b), if applicable, applies, the facility must advise the next of kin whether it intends that the body is to be used or specified parts are to be removed as authorized by the consent.

(2) If no decision record for a patient is found in a search under section 5 (1), the facility must, in accordance with the facility protocol which has been implemented under section 9,

(a) approach the next of kin and advise that no decision record exists,

(b) provide the next of kin with any evidence the facility has of the intentions of the patient in relation to giving or refusing consent, and

(c) determine whether the next of kin will give consent.

(3) If a decision is made by the next of kin under subsection (2) to refuse consent to any use of the body after death, for any purpose, the facility must take no further action to obtain a consent in relation to the patient.

Review of records by minister

7 (1) A facility must establish and maintain, in consultation with the agency, a system of record keeping, satisfactory to the minister, for the purposes of:

(a) monitoring the effectiveness of this regulation;

(b) preparing annual or other reports that may be required from time to time;

(c) auditing the compliance of facilities with this regulation.

(2) A system of record keeping under subsection (1) must

(a) include a copy of the notification given under section 3,

(b) include information respecting determination of medical unsuitability, and

(c) be updated promptly upon the death of a patient in a facility.

(3) Records under this section must be available, on reasonable notice, on request by the minister.

(4) Records maintained under the system referred to in subsection (1) must be available for inspection, on reasonable notice, by persons specified for the purpose by the minister.

Application of this regulation to health professionals

8 (1) The health care professionals who may be designated, on behalf of a facility, to seek a consent under section 6 (2) are:

(a) medical practitioners;

(b) registered nurses;

(c) hospital social workers;

(d) hospital pastoral care workers;

(e) other facility employees or agency employees who are specifically identified by a facility or the agency because of their special training and experience.

(2) A health care professional designated in accordance with subsection (1) must meet the training requirements specified in the facility protocol, referred to in section 9 (e).

Facility protocols

9 A facility must implement, in consultation with the agency, a protocol satisfactory to the minister, that includes specific provision for these matters:

- (a) how notification under section 2 can occur in the most expeditious manner possible;
- (b) who will advise the next of kin of the death or impending death of a patient;
- (c) the process for advising the patient's medical practitioner at the earliest reasonable opportunity of any action taken by the facility under section 6 (2);
- (d) who, ordinarily not the person providing advice under paragraph (b), will seek consent under section 6 (2);
- (e) the training necessary for a person referred to in paragraph (d);
- (f) the timeliness and mechanisms for reporting notifications under this regulation;
- (g) other terms and conditions necessary for the administration of this regulation in the most sensitive and appropriate manner possible.

[Provisions of the *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211, relevant to the enactment of this regulation: section 15]

APPENDIX D - *The Human Tissue Gift Act of British Columbia*

HUMAN TISSUE GIFT ACT

[RSBC 1996] CHAPTER 211

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Definitions

1 In this Act:

"**consent**" means a consent given under this Act;

"**tissue**" includes an organ, but does not include skin, bone, blood, blood constituent or other tissue that is replaceable by natural processes of repair;

"**transplant**" means the removal of tissue from a human body, whether living or dead, and its implantation in a living human body;

"**writing**" for Part 2 includes a will and any other testamentary instrument, whether or not probate has been applied for or granted and whether or not the will or other testamentary instrument is valid.

Part 1 — Gifts for Transplants While Donor Alive

Transplants under Act are lawful

2 A transplant from one living human body to another living human body may be done in accordance with this Act, but not otherwise.

Consent for transplant

3 (1) A person who has reached age 19, is mentally competent to consent, and is able to make a free and informed decision, may sign a consent to the removal at once from the person's body of the tissue specified in the consent and its implantation in the body of another living person.

(2) Despite subsection (1), consent given by a person who had not reached age 19, was not mentally competent to consent, or was not able to make a free and informed decision is valid for this Act if the person who acted on it had no reason to believe that the person who gave it had not reached age 19, was not mentally competent to consent, and was not able to make a free and informed decision, as the case may be.

(3) Consent given under this section is full authority for a medical practitioner to

(a) make any examination necessary to assure medical acceptability of the tissue specified, and

(b) immediately remove that tissue from the body of the person who gave the consent.

(4) If for any reason the tissue specified in the consent is not removed in the circumstances to which the consent relates, the consent is void.

Part 2 — Gifts for Transplants When Donor Dies

Consent by person for use of body after death

4 (1) A person who has reached age 19 may consent,

(a) in writing signed by the person at any time, or

(b) orally in the presence of at least 2 witnesses during the person's last illness, that the person's body or parts of it specified in the consent be used after the person's death for therapeutic purposes, medical education or scientific research.

(2) Despite subsection (1), consent given by a person who had not reached age 19 is valid for this Act if the person who acted on it had no reason to believe that the person who gave it had not reached age 19.

(3) On the death of a person who has given a consent under this section, the consent is binding and is full authority for the use of the body or the removal and use of the specified parts for the purpose specified.

(4) Despite subsection (3), a person must not act on a consent given under this section if the person has reason to believe that it was subsequently withdrawn, unless the consent was contained in a valid will of the deceased.

Consent by spouse or others for use of body after death

5 (1) If a person of any age who has not given a consent under section 4 dies, or in the opinion of a medical practitioner is incapable of giving a consent by reason of injury or disease and the person's death is imminent,

(a) the person's spouse of any age,

(b) if none or if the person's spouse is not readily available, any one of the person's children who has attained the age of majority,

(c) if none or if none is readily available, either of the person's parents,

(d) if none or if neither is readily available, any one of the person's brothers or sisters who has attained the age of majority,

(e) if none or if none is readily available, any other of the person's next of kin who has attained the age of majority, or

(f) if none or if none is readily available, the person lawfully in possession of the body other than, if the person died in hospital, the administrative head of the hospital, may consent,

(g) in writing signed by the spouse, relative or other person,

(h) orally by the spouse, relative or other person in the presence of at least 2 witnesses, or

(i) by the telegraphic, recorded telephonic or other recorded message of the spouse, relative or other person,

to the body or the parts of it specified in the consent being used after death for therapeutic purposes, medical education or scientific research.

(2) A person must not give a consent under this section if the person has reason to believe that the person who died or whose death is imminent would have objected to it.

(3) On the death of a person for whom a consent was given under this section, the consent is binding and is, subject to section 6, full authority for the use of the body or for the removal and use of the specified parts for the purpose specified.

(4) Despite subsection (3), a person must not act on a consent given under this section if the person has actual knowledge of an objection to it by the person for whom the consent was given or by a person of the same or closer relationship to the person for whom the consent was given than the person who gave the consent.

(5) In subsection (1), "**person lawfully in possession of the body**" does not include

(a) the supervising coroner or a coroner in possession of the body under the *Coroners Act*,

(b) the Public Guardian and Trustee in possession of the body for its burial under the *Public Guardian and Trustee Act*,

(c) an embalmer or funeral director in possession of the body for its burial, cremation or other disposition, or

(d) the superintendent of a crematorium in possession of the body for its cremation.

Coroner's direction

6 If, in the opinion of a medical practitioner, the death of a person is imminent by reason of injury or disease and the medical practitioner has reason to believe that section 9 of the *Coroners Act* may apply when death does occur and a consent under this Part has been obtained for a post mortem transplant of tissue from the body, a coroner having jurisdiction, even though that death has not yet occurred, may give directions the medical practitioner thinks proper for the removal of that tissue after the death of the person, and every direction given has the same effect as if it had been made after death under section 38 (3) of the *Coroners Act*.

Determination of death

7 (1) For a post mortem transplant, the fact of death must be determined by at least 2 medical practitioners in accordance with accepted medical practice.

(2) A medical practitioner who has had any association with the proposed recipient of the post mortem transplant that might influence the medical practitioner's judgement must not take any part in the determination of the fact of death of the donor.

(3) A medical practitioner who took any part in the determination of the fact of death of the donor must not participate in any way in the transplant procedures.

(4) Nothing in this section in any way applies to a medical practitioner in the removal of eyes for cornea transplants.

If specified use fails

8 If a gift under this part cannot for any reason be used for any of the purposes specified in the consent, the subject matter of the gift and the body to which it belongs must be dealt with and disposed of as if no consent had been given.

Part 3 — General

Civil liability

9 No action or other proceeding for damages lies against a person for an act done in good faith and without negligence in the exercise or intended exercise of any authority conferred by this Act.

Sale of tissue prohibited

10 A person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research.

Dealing contrary to public policy

11 Any dealing prohibited by section 10 is invalid as contrary to public policy.

Disclosure of information

12 (1) Except if legally required, a person must not disclose or give to any other person any information or document by which the identity of any person

(a) who has given or refused to give a consent,

(b) with respect to whom a consent has been given, or

(c) into whose body tissue has been, is being, or may be transplanted, may become known publicly.

(2) If the information or document disclosed or given pertains only to the person who disclosed or gave the information or document, subsection (1) does not apply.

(3) Despite subsection (1), if

(a) a recipient of body tissue consents in writing to the publication of the recipient's identity,

(b) in the case of a recipient who is under the age of majority, the recipient's parent or guardian consents in writing to the publication of the recipient's identity,

(c) a donor of body tissue consents in writing to the publication of the donor's identity, or

(d) in the case of a donor who is dead or under the age of majority, any one of the persons referred to in section 5 (1) (a) to (d) consents to the publication of the donor's identity,

the identity may be published by any person not sooner than one month after the date of the transplant.

Application of other Acts

13 (1) Except as provided in section 6, nothing in this Act affects the *Coroners Act*.

(2) The *Health Care (Consent) and Care Facility (Admission) Act* does not affect anything in this Act.

Offence

14 A person who knowingly contravenes this Act commits an offence and is liable, on conviction, to a fine of not more than \$1 000, or to imprisonment for a term of not more than 6 months, or to both a fine and imprisonment.

Regulations

15 (1) The Lieutenant Governor in Council may make regulations that establish standards, practices, protocols or procedures

(a) requiring notification of an agency described by subsection (2) (d), patients or relatives of patients so that consideration can be given in a timely manner to the giving of a consent in appropriate circumstances,

(b) facilitating the giving of consents if patients or their relatives wish these consents to be given, or

(c) expediting the effective use of consents.

(2) Regulations under subsection (1) may be made to apply to

(a) health care professionals specified in those regulations,

(b) a hospital as defined in section 1 of the *Hospital Act* or a licensed hospital as defined in section 5 of that Act,

(c) a community care facility as defined in section 1 of the *Community Care Facility Act*, or

(d) an agency specified in those regulations that facilitates and coordinates transplants in British Columbia.