

Human Tissue (Removal, Preservation and Transplant) (Importation and Use of Corneal Tissue) Regulations 2024

GN No. 51 of 2024

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THE HUMAN TISSUE (REMOVAL, PRESERVATION AND TRANSPLANT) ACT

Regulations made by the Minister, on the advice of the Tissue Donation, Removal and Transplant Board, under sections 22 and 28 of the Human Tissue (Removal, Preservation and Transplant) Act

1. These regulations may be cited as the **Human Tissue (Removal, Preservation and Transplant) (Importation and Use of Corneal Tissue) Regulations 2024**.
2. In these regulations -
"Act" means the Human Tissue (Removal, Preservation and Transplant) Act.
3. For the purpose of section 22 of the Act -
 - (a) an application to the Board for the importation and use of tissue shall be made in the form set out in Part I of the Schedule;
 - (b) an authorisation of the Board for the importation and use of tissue shall be granted in the form set out in Part II of the Schedule; and
 - (c) a refusal of the Board to authorise the importation and use of tissue shall be made in the form set out in Part III of the Schedule.
4. These regulations shall come into operation on 10 January 2024.

Made by the Minister, on the advice of the Tissue Donation, Removal and Transplant Board, on 5 January 2024.

SCHEDULE

[Regulation 3]

APPLICATION FOR THE IMPORTATION AND USE OF TISSUE

[under section 22 of the Human Tissue (Removal, Preservation and Transplant) Act]

PART I - APPLICATION FORM

Name of applicant

National Identity Card no./Passport no.

Occupation

Address

Telephone no..... Mobile no.....

Fax no. Email address.....

I, the above named, am hereby making an application for the importation of.
(number) of corneal tissue(s) from
(name of eye bank) of (name of country of origin).

I confirm that I am aware of the provisions of the Human Tissue (Removal, Preservation and Transplant) Act and I further confirm that -

- (a) I understand the offences referred to in the Act; and
- (b) no payment or gratification, as referred to in the Act, has been made to me or will be made to me or any other person.

I am enclosing the following documents, in support of my application -

- (a) copy of my National Identity Card/passport; and
- (b) original letter of authorisation from the health institution.

I undertake to comply with any conditions imposed by the Board if the application is granted.

I confirm that the particulars provided in this form are, to the best of my knowledge and belief, true and correct.

.....
Signature of Applicant

.....
Date

FOR OFFICIAL USE ONLY

.....
.....

Approved/not approved

.....
Signature of Registrar

.....
Date

PART II — LETTER OF AUTHORISATION

Further to your application dated, under section 22 of the Human Tissue (Removal, Preservation and Transplant) Act, I am directed by the Tissue Donation, Removal and Transplant Board (Board) to inform you that the Board' has authorised the importation of up to(number) corneal tissue(s) from(name of eye bank) of(name of country of origin).

This authorisation is subject to the following conditions -

- (a) all corneal tissue(s) imported shall be transplanted solely at the approved health institution importing the tissue, within a timeframe of 14 days from the date of retrieval of corneal tissue;
- (b) within 24 hours of receipt of the corneal tissue(s) at the approved health institution, you shall provide to the Board with the serial number/identification number of each corneal tissue imported;
- (c) within 21 days of receipt of the corneal tissue(s), the applicant shall provide to the Board with the following information in relation to each and every corneal tissue(s) transplanted -
 - (i) serial number/identification number;
 - (ii) name of eye bank;
 - (iii) country of origin;
 - (iv) date of tissue retrieval;
 - (v) expiry date;
 - (vi) name of recipient;
 - (vii) file number of recipient;
 - (viii) National Identity Card no. of recipient;
 - (ix) sex of recipient;
 - (x) date of transplant; and
 - (xi) indication for the corneal transplant.
- (d) Where any corneal tissue(s) is deemed improper for transplantation, the following information in relation to that tissue shall be provided to the Board -
 - (i) serial number;
 - (ii) name of eye bank;
 - (iii) country of origin;
 - (iv) date of tissue retrieval;
 - (v) expiry date; and

(vi) reason for corneal tissue(s) deemed improper for transplantation.

.....
Signature of Registrar

.....
Date

PART III - LETTER REFUSING AUTHORISATION

Further to your application dated, under section 22 of the Human Tissue (Removal, Preservation and Transplant) Act, I am directed by the Tissue Donation, Removal and Transplant Board (Board) to inform you that the Board has not approved the importation of(number) corneal tissue(s)from (name of eye bank) of
..... (name of country of origin) for the following reason(s) –

- (a)
- (b)
- (c)

.....
Signature of Registrar

.....
Date

.....
Office stamp