

**Bills Committee on
Human Organ Transplant (Amendment) Bill 2001**

Part I : Information requested by members

(a) Types of payment falling within the meaning of “administrative cost incidental to the removal, transportation or preservation of the organ to be supplied” referred to in clause 4(b)(ii) of the Bill, and the person(s) / organisations to whom/which the payment(s) would be made;

It is difficult to isolate the “administrative costs incidental to the removal, transportation or preservation of the organ” from the cost for removal, transportation or preservation of the organs, as these costs are usually associated.

In practice, the payments are usually made to organ / tissue banks. As an illustration, before management take-over of the Lions Eye Bank (Eye Bank) by the Hospital Authority, the Eye Bank charged HA and private practitioners for supply of eye tissues to recover partially its operating cost. At present, the Eye Banks continues to charge private practitioners for supply of eye tissues at HK\$3,500 per cornea. The calculation of the cost is usually based on the followings: -

(1) Costs of Procurement

- The salaries of the eye coordinators, technicians, and the proportionate share of the salaries of the eye bank administrator and clerical staff will be included in the calculation. The staff provide administrative support including: -
 - Screening and assessment of potential eye donors to determine if the deceased is suitable to be a cornea donor
 - Counseling the donor’s next of kin and providing bereavement support
 - Collection of data and maintaining a registry for the eye bank
 - Liaison with clinical units pathologists and other government departments

- Conducting quality assurance activities
- General administrative support to operations of the tissue bank

(2) Costs of Laboratory tests and transport medium

(3) Expenditure on transportation for processing and delivery of tissues

Apart from local organ / tissue banks, it is common that overseas organ / tissue banks requires payment of the charges before supplying organs to local organizations to cover their administrative overheads. According to information provided by HA, the Florida Eye Bank charges HA about US \$950 for each cornea.

(b) Number of cases handled by the Human Organ Transplant Board (the Board) each year since its formation.

Please refer to Table 1 and 2 at Annex A for the number of applications for living non-related transplant handled by the Board and the statistics on organ removal, transplant and disposal. You may wish to note that while the Board was established in February 1996, the Human Organ Transplant Ordinance first came into operation on 1 April 1998. Thus, the statistics for the 1998 cover only the period from 1 April to 31 December 1998.

(c) Number and types of organs imported into Hong Kong for transplant purposes each year for the past two years.

Please refer to Table 3 at Annex A for the number and types of organs imported into Hong Kong for transplant purpose for the past two years.

Part II: Administration's comments on suggestions made by members

(a) DNA testing should be used as a means of establishing genetic relationship for transplant of an organ from a live donor, in the event that the means of establishing the same as stipulated in section 2 of the Human Organ Transplant Regulation should fail.

It should be noted that there are certain limitations in utilizing DNA testing as a means for established genetic relationships. First, DNA sequencing can only give a mathematical theory or probability that two persons are related. Although the degree of certainty for verification of close genetic relationships, such as natural parents and children, is high, it is low for half blood relationships. Therefore, even if DNA tests were to be allowed, they could only be used for establishing relationships specified in Section 5(2)(a) and possibly (b) of the Ordinance, but would have little use for establishing relationship specified in Section 5(2)(c) and (d) of the Ordinance.

Second, it is also difficult to estimate the time required for DNA tests as different relationships require different number of tests and techniques. Generally, it takes about a week for relationship between natural parents and children which requires a relatively simple technique. Thus, DNA tests will not be useful for urgent cases.

(b) Donor should be required to make a declaration that there is no commercial dealing in donating his organ for transplanting into another person.

At present, for organ transplants between living persons who are neither genetically related nor a couple whose marriage has subsisted for not less than three years, when applying for approval of the Board, the donor has to declare that, to his best knowledge, no payment prohibited by the Ordinance have been, or is intended to be made. Please refer to Annex B for the Declaration Form to be signed by the intended donor.

Besides, a medical practitioner who, in Hong Kong, removed an organ from a donor, whether living or dead, for the purpose of its being transplanted into another person is required to fill in and supply to the

Board the Form 1 (at Annex C), in which the medical practitioner has to indicate his satisfaction to the requirements set out in the Ordinance, including that no payment prohibited by the Ordinance is made or intended to be made. Thus, the principle of prohibiting commercial dealings in human organs intended for transplant is upheld in all transplant cases.

- (c) Amendment to the proposed Schedule setting out organs not to be covered by the Human Organ Transplant Ordinance (the Ordinance) should be subject to positive vetting by the Legislative Council.*

The Administration accepts the Members' suggestion that the proposed Schedule setting out organs not to be covered by the Ordinance should be subject to positive vetting by the LegCo.

- (d) Two persons from the non-medical sector should be retained as members of the Board (wordings amended).*

The proposed composition of the Board shall continue to have nine substantive members, which is the same as present. The administration is not of the view that the proposed composition will not in any way diminish the representation or power of members under the "other person" category. In fact, the proposed composition would lead to an elevation of their status and influence as members under the 'other person' category are eligible to be appointed as the vice-chairman of the board.

- (e) Registered medical practitioners who are to transplant organs previously removed for therapeutic purposes should not be required to make a statement that no payment prohibited by the Ordinance has been or is intended to be made, and that the organs were removed for the therapy of the donors, having regard to the fact that the registered medical practitioners concerned do not have direct knowledge of the matter.*

The Administration is prepared to request the medical practitioner who removed the organ which was subsequently stored in the organ / tissue bank to declare that the organ / tissue, at the time when it was removed from the donor, was originally intended for therapy of the patient.

Nevertheless, we remain the view that it is necessary to require the medical practitioner, who is to transplant organs previously removed for therapeutic purpose, to declare, to his best knowledge, the following before proceeding with the organ transplant: -

- (1) no payment prohibited by the Ordinance has been or is intended to be made; and
- (2) the organ was originally removed for therapeutic purpose and not for transplanting into any specific recipient

The above is deemed necessary as a safeguard against the possibility of commercial dealings and that the medical practitioner, who is to carry out the transplant, is satisfied that the source of the organ / tissue is legitimate.

- (f) *Legal liability of the registered medical practitioner for performing an organ transplant on a patient without first obtaining the latter's consent under clause 5D of the Bill because of his illness or impaired state of consciousness or his being a minor, a mentally disordered or handicapped person; whether relatives of a patient who cannot give consent may give consent on behalf of the patient; and what would happen if the relatives have no consensus on whether to give consent.*

In the context of medical treatment in general, under common law, if a medical practitioner had treated a patient without his consent or despite a refusal of consent, it would constitute the civil wrong of trespass to the person and might constitute a crime. Nonetheless, if the patient had made no choice, and is in no position to make one when the need for treatment arises, the medical practitioner can lawfully treat the patient in accordance with his clinical judgment of what is in the patient's best interests.

In the case of an organ transplant, if a patient has expressly indicated his unwillingness for organ transplant before he has become unconscious, the medical practitioner cannot act against his wish. Since no one can give proxy consent on behalf of a competent adult who is rendered incompetent through illness or impaired consciousness, and if he has not made any advance directives regarding his wish, the medical practitioner can act in accordance with his clinical judgment of what is in the

patient's best interest.

Regarding mentally incapacitated adults within the meaning of the Mental Health Ordinance without guardians, the medical practitioner can also act in accordance with his clinical judgment in the best interest of the patient. However, where guardians have been appointed and vested with the power to consent to medical treatment on behalf of the mentally incapacitated adults, consent can be obtained from the guardians to the extent that the mentally incapacitated adults are incapable of consent. Applications can be made to the court to override the guardian's refusal.

As for minors, they can also consent if they can understand the nature and consequences of the operation. For children who cannot so understand, the power of consent is vested with the parents who must exercise such powers reasonably failing which an application can be made to the court.

Annex A

Table 1

Applications for Living Non-related Transplant Handled by the Board (as at 31 December 2001)

| Year | Total Number of Applications | Renal Transplant Applications | | | Liver Transplant Applications | | |
|-------|------------------------------|-------------------------------|----------|----------------|-------------------------------|----------|----------------|
| | | Approved | Rejected | Case withdrawn | Approved | Rejected | Case withdrawn |
| 1998 | 4 | 2 | 0 | 0 | 1 | 1 | 0 |
| 1999 | 10 | 4 | 0 | 0 | 6 | 0 | 0 |
| 2000 | 20 | 4 | 0 | 0 | 16 | 0 | 0 |
| 2001 | 17 ^(a) | 2 | 0 | 1 | 13 | 0 | 0 |
| Total | 51 | 12 | 0 | 1 | 36 | 1 | 0 |

^(a) Including 1 renal transplant application from Tuen Mun Hospital being processed (on 12 December 2001). A decision has yet to be made.

Table 2

Statistics on Organ Removal (R), Transplant (T) and Disposal (D)

(from information stated in statutory forms received in each year) (as at 31 December 2001)

| Types of organ/tissue | 1998 | | | 1999 | | | 2000 | | | 2001 | | |
|------------------------------|------------|------------|-----------|------------|------------|-----------|------------|------------|-----------|------------|------------|-----------|
| | R | T | D | R | T | D | R | T | D | R | T | D |
| Kidney | | | | | | | | | | | | |
| Living – genetically related | 19 | 19 | 0 | 16 | 16 | 0 | 8 | 8 | 0 | 11 | 11 | 0 |
| Living – married couple | 7 | 7 | 0 | 2 | 2 | 0 | 3 | 3 | 0 | 0 | 0 | 0 |
| Living – non-related | 2 | 2 | 0 | 4 | 4 | 0 | 4 | 4 | 0 | 2 | 2 | 0 |
| Cadaveric | 28 | 27 | 1 | 46 | 46 | 1 | 45 | 38 | 6 | 44 | 43 | 0 |
| Liver | | | | | | | | | | | | |
| Living – genetically related | 6 | 6 | 0 | 8 | 8 | 0 | 14 | 14 | 0 | 14 | 14 | 0 |
| Living – married couple | 2 | 2 | 0 | 6 | 6 | 0 | 9 | 9 | 0 | 10 | 10 | 0 |
| Living – non-related | 1 | 1 | 0 | 3 | 3 | 0 | 12 | 12 | 0 | 11 | 11 | 0 |
| Cadaveric | 12 | 12 | 0 | 19 | 19 | 1 | 16 | 16 | 1 | 25 | 25 | 0 |
| Cornea | 175 | 134 | 31 | 160 | 113 | 48 | 152 | 133 | 24 | 243 | 219 | 18 |
| Sclera | 26 | 6 | 6 | 40 | 7 | 8 | 10 | 12 | 18 | 22 | 15 | 11 |
| Lung | 2 | 1 | 0 | 4 | 4 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |
| Heart | 2 | 1 | 0 | 6 | 6 | 0 | 5 | 5 | 0 | 9 | 9 | 0 |
| Skin | 21 | 35 | 3 | 37 | 47 | 10 | 40 | 81 | 10 | 43 | 61 | 7 |
| Bone | 2 | 27 | 0 | 11 | 32 | 0 | 5 | 34 | 0 | 5 | 48 | 0 |
| Tendon | 2 | 3 | 0 | 5 | 9 | 0 | 3 | 6 | 0 | 5 | 15 | 0 |
| Others | 2 | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 309 | 284 | 43 | 367 | 322 | 68 | 326 | 375 | 59 | 445 | 484 | 36 |

Table 3

Organs Imported for Transplant Purposes

(as at 31 December 2001)

| | 2000 | | 2001 | |
|--------|------------------------|-------------------------|------------------------|-------------------------|
| | No. of <u>Cert.</u> | No. of <u>Organs</u> | No. of <u>Cert.</u> | No. of <u>Organs</u> |
| Liver | 0 | 0 | 0 | 0 |
| Cornea | 0 | 0 | 4 | 9 |
| Skin | 1 | 1 | 0 | 0 |
| Total | 1 | 1 | 4 | 9 |

附件 B

Declaration
聲明書

Application for Transplant Involving Live Donor
申請進行涉及在生的器官捐贈人的移植

(Declaration to be completed by the intended donor)
(由預定的器官捐贈人填寫)

I declare that
本人現謹聲明

- (a) I have reached the age of 18 years/ I have reached the age of 16 years and am married*;
本人年齡已達 16 歲/本人年齡已達 16 歲，並且已婚*；
- (b) A registered medical practitioner, _____ (name in block letters) who will not be the medical practitioner to remove the organ(s) from me, has explained to me and I have understood the procedure, the risk involved and my entitlement to withdraw consent at any time;
一名註冊醫生 _____ (姓名)，但並非將會自本人身上切除器官的醫生，已向本人解釋，而本人亦已明白有關的程序；所涉及的危險及本人可隨時撤回同意的權利。
- (c) I have given my consent to removal of my _____ (description of organ(s)) for transplant to _____ (name of recipient if known)* without coercion or the offer of inducement and have not subsequently withdrawn my consent; and
本人並非於威迫或利誘的情況下同意切除本人的 _____ (器官的類別) 予 _____ (器官受贈人姓名，如知道的話)* 作移植用。本人其後亦無撤回同意；
反
- (d) To the best of my knowledge, no payment for the supply of the organ(s) as prohibited by the Human Organ Transplant Ordinance (Cap 465) has been, or is intended to be, made.
就本人所知，沒有或不擬作出人體器官移植條例 (第 465 章) 所禁止為提供該器官而作出 / 接受的付款。

Signature of
Intended Donor
預定的器官捐贈人簽署 _____

Name of
Intended Donor
預定的器官捐贈人姓名 _____

Date 日期 _____

Signature of
Witness
見證人簽署 _____

Name of
Witness
見證人姓名 _____

HKIC No.
身分證號碼 _____

Date 日期 _____

* Delete whichever is inapplicable 刪去不適用者

附件 C

FORM 1
表格 1

[s. 3(1) & (5)]
[第 3(1)及(5)條]

HUMAN ORGAN TRANSPLANT ORDINANCE (CHAPTER 465)

《人體器官移植條例》(第 465 章)

HUMAN ORGAN TRANSPLANT REGULATION

《人體器官移植規例》

INFORMATION ON ORGAN REMOVAL FOR DONATION

為捐贈而切除器官的資料

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------|
| I. Particulars of the Donor 器官捐贈人的個人詳情 | | Serial Number 編號: (for internal use 供內部使用) |
| Full name 全名: _____ (in BLOCK letters, Surname first 請用正體, 先寫姓氏) | | |
| HKIC 香港身分證 / Passport 護照 No. 號碼: _____ | | |
| Age 年齡: _____ | | |
| Sex 性別: M 男 / F 女 | | |
| Marital status 婚姻狀況: Single 單身 / Married 已婚 | | |
| ----- | | |
| (a) <input type="checkbox"/> The donor was LIVING at the time of the removal of the organ(s) - 在器官切除時, 器官捐贈人是在生的 | | |
| (i) <input type="checkbox"/> The donor and the recipient are genetically related. They are _____ (please state the genetic relationship) and a copy of proof is enclosed. I am satisfied that the requirements in section 5(4)(b) - (e) of the Human Organ Transplant Ordinance have been complied with. 器官捐贈人與器官受贈人有血親關係。他們是 _____ (請述明該血親關係), 現附上證明文本一份。本人信納《人體器官移植條例》第 5(4)(b) - (e) 條的規定已獲遵從。 | | |
| (ii) <input type="checkbox"/> The donor and the recipient are a married couple. Their marriage has subsisted for not less than 3 years and a copy of proof is enclosed. I am satisfied that the requirements in section 5(4)(b) - (e) of the Human Organ Transplant Ordinance have been complied with. 器官捐贈人與器官受贈人是一對已婚夫婦。他們的婚姻已持續不少於 3 年, 現附上證明文本一份。本人信納《人體器官移植條例》第 5(4)(b) - (e) 條的規定已獲遵從。 | | |
| (iii) <input type="checkbox"/> The donor and the recipient are neither genetically related nor a married couple whose marriage has subsisted for not less than three years. Approval has been given by the Human Organ Transplant Board for the removal and transplant through File Reference _____ dated _____. 器官捐贈人與器官受贈人既非有血親關係, 亦非一對婚姻已持續不少於 3 年的已婚夫婦。人體器官移植委員會已就該項切除及移植透過文件檔案編號 _____ (日期為 _____), 發出批准。 | | |
| (b) <input type="checkbox"/> The donor was DEAD at the time of the removal of the organ(s) - 在器官切除時, 器官捐贈人已去世 | | |
| Time and date of death: _____ am 上午 / pm 下午; _____ / _____ / _____ 死亡的時間及日期 Day 日 Month 月 Year 年 | | |
| Cause of death 死因: _____ | | |
| ----- | | |
| II. <input type="checkbox"/> Organ(s) removed 被切除的器官 | | |
| Description of the organ(s) removed 被切除器官的類別: _____ | | |
| Date of the removal 切除日期: _____ / _____ / _____ Day 日 Month 月 Year 年 | | |
| Name of the hospital/clinic/institution where the removal of the organ(s) took place: 進行器官切除所在的醫院/診所/機構的名稱: (Also state the address if the removal of the organ(s) took place in clinic/institution 如於診所/機構進行器官切除, 亦請述明其地址) | | |
| ----- | | |
| III. <input type="checkbox"/> Organ(s) not removed within 30 days after approval given by Human Organ Transplant Board 器官沒有在人體器官移植委員會發出批准後的 30 天內切除 | | |
| Description of organ 器官的類別: _____ | | |
| Approval was given by the Human Organ Transplant Board through File Reference _____ dated _____ but no removal subsequently took place because (please state reasons): 人體器官移植委員會已透過文件檔案編號 _____ (日期為 _____) 發出批准, 但後來器官切除沒有進行, 因為 (請述明理由): | | |

The organ(s) was/were removed but no transplant subsequently took place within 30 days after the removal because:
 器官雖已切除，但沒有在切除後的 30 天內進行移植，因為：
 (please tick as appropriate 請於適當方格內加上“✓”號)

(a) The organ(s), after removal, was/were considered to be unusable -
 該/該等器官在切除後被認為不能使用

Description of unusable organ(s):
 不能使用的器官的類別:

(Complete ONLY if more than one organ has been removed as stated in Part II 在 Part II 部述明多於一個器官已於切除時填填單)

Reason(s) why organ(s) was/were unusable 器官不能使用的理由:

Manner of disposal 處置方式:

Date of disposal 處置日期: _____
 Day 日 / Month 月 / Year 年

(b) #The organ(s) removed is/are being kept in 被切除的器官現存放於:

(i) The hospital/clinic/institution stated in Part II above 在本表格第 II 部述明的醫院/診所/機構

(ii) Other institution 其他機構 (please specify name and address 請指明名稱及地址):

V. Extension of Deadline 期限的延長

A request for extending the deadline for submission of the Form has been made and approval has been given by the Human Organ Transplant Board. 已請求延長呈交本表格的期限，而人體器官移植委員會已發出批准。

(Please state the File Reference and date of the approval for the extension 請註明批准延長的文件編號及批准日期):

VI. Submitted under section 6 of the Human Organ Transplant Ordinance by -

由以下人士根據《人體器官移植條例》第 6 條呈交 -

Dr. _____ HKIC/Passport* No _____
 醫生 (Full name in BLOCK letters, Surname first 請用正體書寫全名，元首姓氏) 香港身分證/護照號碼: _____

Telephone number 電話號碼: _____ Fax number 傳真號碼: _____

Address/Hospital name 地址/醫院名稱: _____

Date 日期: _____ Signature 簽署: _____

* Please delete whichever is inappropriate. 請將不適用者刪去。

Please tick if applicable and fill in the information as required. 適用時請加上“✓”號，並填寫所需資料。

In future, when the stored organ(s) is/are used for transplant, Form 2 must be submitted by the person who transplants it/them into the recipient. If the organ(s) is/are subsequently found unsuitable for transplant, the person who makes the decision to dispose of the organ(s) must submit Form 3 to the Board within 30 days of the disposal of the organ(s).
 當所貯存的器官日後用於移植時，將該/該等器官移植於器官受贈人體內的人須呈交表格 2。如該/該等器官後來被發現不適合移植，作出將該/該等器官處置的決定的人，須於處置該/該等器官的 30 天內向委員會呈交表格 3。

Notes 註:

- This form must be completed by the medical practitioner who removed the organ(s) or the medical practitioner authorized by the organ bank in the case where the technician appointed by the bank removed the organ(s) from the dead donor or, where no organ was removed but prior approval was given by the Board, it must be completed by the person who caused the matter to be referred to the Board for its approval or, where that person is no longer involved, by the person who made the decision not to remove the organ. Where more than one medical practitioner was involved in removing the organ, any of them can submit the information in Form 1. However, the medical practitioner who was in charge of the operation or the medical practitioner who is in charge of the organ bank is responsible for ensuring that Form 1 is submitted.
 本表格須由切除器官的醫生或器官貯存庫授權(就器官貯存庫委任的技術員從去世的器官捐贈人身上切除器官)的醫生填寫，如委員會已發出事先批准但器官並未切除，則本表格須由安排將有關事宜提交委員會以取得其批准的人填寫，如該人已不再牽涉於其中，則本表格須由作出不切除該器官的決定的人填寫。如該器官的切除涉及多於一名醫生，則其中任何一名醫生均可用表格 1 呈交資料。然而，主管該手術的醫生或主管該器官貯存庫的醫生有責任確保表格 1 已予呈交。
- One form should be used for each donor.
 應就每名器官捐贈人使用一份表格。
- Unless the Board has given approval for extension of the submission deadline, this form must be submitted within 30 days of the removal of the organ or the Board's approval if no removal subsequently took place.
 除非委員會已批准延長呈交表格的期限，否則須於器官切除的 30 天內呈交本表格，如後來器官切除沒有進行，則須於委員會發出批准的 30 天內呈交本表格。