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No. S 213

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

HUMAN ORGAN TRANSPLANT REGULATIONS 2004

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In exercise of the powers conferred by sections 15A (3) and 19 of the Human Organ Transplant Act, Mr Khaw Boon Wan, Senior Minister of State, Ministry of Finance, charged with the responsibility of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Human Organ Transplant Regulations 2004 and shall come into operation on 1st July 2004.

Definitions

2. In these Regulations, unless the context otherwise requires —

"donor", in relation to a living donor organ transplant, means the person from whom a specified organ is or will be removed for the purpose of its transplantation into the body of another living person;

"recipient", in relation to a living donor organ transplant, means the person into whose body a specified organ is or will be transplanted.

Forms for Parts II and III of Act

3.—(1) The form for authorising the removal of any organ from the body of a person under section 5(1) of the Act shall be in Form 1 in the First Schedule.

(2) The form for the objection to the removal of any organ under section 9(1) of the Act shall be in Form 2 in the First Schedule.

(3) The form for the acknowledgment of receipt of the objection to the removal of any organ under section 9(2) of the Act shall be in Form 3 in the First Schedule.

(4) The form for the withdrawal of the objection to the removal of any organ under section 11(1) of the Act shall be in Form 4 in the First Schedule.

(5) The form for the acknowledgment of the withdrawal of the objection to the removal of any organ under section 11(2) of the Act shall be in Form 5 in the First Schedule.

Approval and appointment of transplant ethics committees

4.—(1) For the purpose of enabling transplant ethics committees to be appointed under Part IVA of the Act —

- (a) the licensee of a hospital shall, with the approval of the Director, establish a panel of not less than 3 persons, who shall be medical practitioners employed or otherwise connected with the hospital; and
- (b) the Director shall establish
 - (i) a panel of medical practitioners; and
 - (ii) a panel of lay persons,

comprising such numbers of medical practitioners and lay persons, respectively, as the Director may determine.

[S 439/2009 wef 01/11/2009]

(1A) A member of any of the panels in paragraph (1) shall be appointed for a term of not more than 2 years and -

- (*a*) he may be re-appointed with the approval of the Director; and
- (b) his appointment may at any time be terminated by the Director.

[S 439/2009 wef 01/11/2009]

(2) The licensee of a hospital shall, when applying for the approval of the Director under sub-paragraph (*a*) of paragraph (1), submit to the Director the names and curriculum vitae of the persons nominated for the panel referred to in that sub-paragraph.

[S 439/2009 wef 01/11/2009]

(3) Subject to paragraphs (3A) and (4), the licensee of a hospital shall, from time to time as the circumstances may require, appoint a transplant ethics committee comprising —

- (a) one member from the panel referred to in paragraph (1)(a);
- (b) one member from the panel referred to in paragraph (1)(b)(i) who shall not be employed or otherwise connected with the hospital; and
- (c) one member from the panel referred to in paragraph (1)(b)(ii).

[S 439/2009 wef 01/11/2009]

(3A) Where it comes to the notice of the licensee of a hospital in which any living donor organ transplant is intended to be carried out, whether from the information provided in the application form for the written authorisation of the transplant ethics committee of the hospital or otherwise, that —

 (a) a prior application for written authorisation under section 15A(1) of the Act has been made to a transplant ethics committee in respect of the same prospective donor and prospective recipient; and (b) the transplant ethics committee referred to in sub-paragraph (a) has refused to grant written authorisation,

the licensee shall —

- (i) seek the approval of the Director if the licensee desires to proceed with the appointment of a transplant ethics committee under paragraph (3); and
- (ii) decline to appoint a transplant ethics committee if the Director does not grant his approval.

[S 439/2009 wef 01/11/2009]

(4) The licensee of a hospital may, with the approval of the Director, appoint one or more additional members to the transplant ethics committee.

(5) Subject to the provisions of the Act and these Regulations, a transplant ethics committee may make rules to regulate its own procedure.

(6) The licensee of a hospital may, with the approval of the Director, change the membership of the panel referred to in paragraph (1)(a).

[S 439/2009 wef 01/11/2009]

Procedures of transplant ethics committees

5.—(1) Every transplant ethics committee shall assess and give its written assessment, in a timely manner, of an application for its written authorisation of a living donor organ transplant under section 15A(1) of the Act.

(2) The quorum of any meeting of a transplant ethics committee shall be 3 members, of whom —

- (*a*) one shall be a medical practitioner employed or otherwise connected with the hospital;
- (b) one shall be a medical practitioner not employed or otherwise connected with the hospital; and
- (c) one shall be a lay person,

and no decision shall be made unless such a quorum is present.

(3) Subject to paragraph (6)(b), where an application for the written authorisation of a transplant ethics committee is assessed at a meeting of the transplant ethics committee, a person —

- (*a*) who is directly involved in the care of the donor or the recipient; or
- (b) who will be involved in the removal of any specified organ from the body of the donor or the transplantation of the specified organ to the body of the recipient,

shall not be present at the meeting.

(4) A decision at any meeting of a transplant ethics committee shall be adopted by a consensus of the members present.

- (5) Every transplant ethics committee shall
 - (a) submit a copy of the report of every decision made by it in authorising any living donor organ transplant or otherwise to the Director within 7 days of the date of the decision; and
 - (b) keep and maintain every report referred to in sub-paragraph (a).

(6) A transplant ethics committee may, when assessing any application for the written authorisation of a living donor organ transplant —

- (*a*) request for such additional information or document to be provided by the applicant as it may consider necessary; or
- (b) interview the donor, the recipient or any other person in relation to the application.

Additional considerations for giving of written authorisations

6. Every transplant ethics committee shall, in addition to the considerations specified in section 15A(2) of the Act, have regard to the considerations of public interest and community values when assessing an application for its written authorisation of a living donor organ transplant.

Review of decisions by transplant ethics committee

6A.—(1) An applicant for review who is aggrieved by the decision of a transplant ethics committee to refuse to grant written authorisation under section 15A(1) of the Act may make a written application to the Director to require the transplant ethics committee to review its decision.

(2) The applicant for review shall make the written application to the Director —

- (*a*) within a period of 21 days after the date on which the decision of the transplant ethics committee first comes to the notice of the applicant for review; or
- (b) within such further period as the Director allows, either before or after the end of that 21-day period.

(3) The applicant for review shall, in his written application to the Director, set out the grounds on which he is applying to the Director to require the transplant ethics committee to review its decision.

(4) Upon receipt of the written application, the Director may, as he sees fit —

- (a) dismiss the application; or
- (b) direct the transplant ethics committee to review its decision, and specify such considerations that the transplant ethics committee shall have regard to as the Director may direct under section 15A(3) of the Act.

(5) In this regulation, "applicant for review", in relation to a living donor organ transplant, means —

- (a) the person who made the application for the written authorisation of a transplant ethics committee under section 15A(1) of the Act;
- (b) the prospective donor; or
- (c) the prospective recipient.

[S 439/2009 wef 01/11/2009]

Period of validity of written authorisation

6B.—(1) For the purposes of section 15A(1) of the Act, every written authorisation of the transplant ethics committee of a hospital shall be valid for such period of time as the transplant ethics committee shall determine, not being a period longer than 60 days from the date the written authorisation is granted.

(2) Upon the expiry of the validity period of a written authorisation as determined by the transplant ethics committee of a hospital in accordance with paragraph (1), no living donor organ transplant shall be carried out in the hospital involving the same prospective donor and prospective recipient except within the validity period of a fresh written authorisation of the transplant ethics committee of the hospital.

[S 439/2009 wef 01/11/2009]

Forms for Part IVA of Act

7.—(1) The form for applying for the written authorisation of a transplant ethics committee under section 15A(1) of the Act —

- (a) shall be in Form 1 in the Second Schedule; and
- (b) shall be made by the medical practitioner who is principally responsible for the care of the donor.

(2) The form for authorising, or otherwise, the removal of a specified organ from the body of a living person by a transplant ethics committee under section 15A(1) of the Act shall be in Form 2 in the Second Schedule.

Offence

8. Any person who makes any declaration or statement in relation to an application for the written authorisation of a transplant ethics committee under section 15A(1) of the Act which is false or misleading in a material particular shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 12 months or to both.

Revocation

9. The Human Organ Transplant Regulations (Rg 1) are revoked.

FIRST SCHEDULE

Regulation 3

FORM 1
HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)
AUTHORISATION FOR REMOVAL OF ORGANS AFTER DEATH UNDER SECTION 5(1)
(To be completed in duplicate)
*(a) I hereby authorise the removal of the *kidneys/liver/heart/comeas of the deceased named
*NRIC No./Foreign Identification No. (FIN) for transplantation to the body of a living person.
*(b) I do not authorise the removal of the *kidneys/liver/heart/comeas of the deceased named, *NRIC No./Foreign Identification No. (FIN) for transplantation to the body of a living person for the following reason(s):
Name of Designated Officer Hospital Signature Date
<i>Note:</i> One copy of the Authorisation Form is to be kept in the patient's casenotes and the other is to be submitted to the Organ Transplant Unit.
*Delete whichever is inapplicable.

"FORM 2

Front

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	1							

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

OBJECTION TO ORGAN REMOVAL UNDER SECTION 9(1)

(Please complete all particulars in BLOCK LETTERS)

FULL NAME (as in NR	IC):		DATE OF BIRTH: _	
NRIC NO.:	SEX: Male Fe	emale RACE: 🗌 Chinese 🗌 Ma	alay 🗌 Indian 📄 Others:	(please specify)
CITIZENSHIP/RESIDE	NTIAL STATUS: 🗖 S'pore G	itizen 🗌 S'pore Permanent Resid	lent TEL. NO.:	,
HOME ADDRESS:			POSTAL CODE:	
Saya lidak Dezetuju memba (landakan *ノ*yang pertu) 人人村主なん、土人ら下お いめ、最にはたらび Spas. Selan	enarkan organ saya yang bunkut didu : 名文作方作其用注(計在注乡19地方	TO BEAG A GOOD A GREAT STATE WITH	iransplacialicn) seisiat saya me	
	Dat			
ADDRESS:			POSTAL CODE:	
Signature:	Dat	e:		

Reverse

Note:

- 1. This objection to organ removal only applies to --
 - (a) Singapore Citizens and Singapore Permanent Residents; and
 - (b) persons aged 21 years and above.
- 2. This form shall be invalid if it is not duly completed.
- Please forward the completed form together with a photocopy of your NRIC to the following address:

National Organ Transplant Unit c/o Singapore General Hospital Singapore 169608

 If you do not receive an acknowledgment to your objection to organ removal within 3 weeks, please contact the Officer-in-Charge at the above address or call Tel. No. 63214390.

FORM 3

Front

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

REGISTRATION OF OBJECTION TO ORGAN REMOVAL UNDER SECTION 9(2)

Name:

NRIC No.:

Reg. No.:

This is to certify that your name is in the Register of Objectors for:

Reverse

For further information, please contact the National Organ Transplant Unit at Tel. No. 63214390 or at the following address:

National Organ Transplant Unit c/o Singapore General Hospital Singapore 169608

FORM 4

Front

F	or	Off	icia	I U	se (Onl	y	
	-							

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

WITHDRAWAL OF OBJECTION TO ORGAN REMOVAL UNDER SECTION 11(1)

(Please complete all particulars in BLOCK LETTERS)

FULL NAME (as in NRI	C):		DATE OF BIRTH:
NRIC NO.:	□□ - □ SEX: □ Male □)	Female RACE: 🗌 Chinese 🗌 Malay 🗌] Indian Others:
CITIZENSHIP/RESIDEN	TIAL STATUS: 🗆 S'pore	Citizen 🗖 S'pore Permanent Resident	TEL. NO.:
HOME ADDRESS:			POSTAL CODE:
Saya bersetuju menarik baik aatekin saya maninggai dunia 素像信度计道性音,把或的 ate ggiciut-aci 3pm, 40kmoy bilgatian#30pir (Asitua-55 bilgatian#30pir (Asitua-55 Carjal 背は of gjioranua-	bentefran saya terhadap pende (landakan *** yang perlu): 下所品文作为谷社月治(資本 	சக்கை அகற்றப்படுவதற்கு மால் தெரிக்கத்துக்க ஆப த கட்டங்களில் இந்தத் சுறியை *** இடலு:. பெருதாப்பு குடி இசையம்	gunsan pemindahan (transplantation)
ADDRESS:			POSTAL CODE:
Signature:	D	ate:	

Reverse

Note:

- 1. This withdrawal of objection to organ removal only applies to --
 - (a) Singapore Citizens and Singapore Permanent Residents; and
 - (b) persons aged 21 years and above,
 - who have submitted their objections earlier to organ removal.
- 2. This form shall be invalid if it is not duly completed.
- Please forward the completed form together with a photocopy of your NRIC to the following address:

National Organ Transplant Unit c/o Singapore General Hospital Singapore 169608

 If you do not receive an acknowledgment to your withdrawal of objection to organ removal within 3 weeks, please contact the Officer-in-Charge at the above address or call Tel. No. 63214390.

FORM 5

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

ACKNOWLEDGMENT OF WITHDRAWAL OF OBJECTION TO ORGAN REMOVAL UNDER SECTION 11(2)

Reg No.:

NRIC No.:

[Name and address of objector]

Dear Sir/Madam,

Please be informed that your withdrawal of objection has been noted and your name has been removed from the Register of Objectors for the following organs:

*Your objection to ______ donation remains effective. Kindly contact the National Organ Transplant Unit if you require further clarification.

Yours faithfully,

Officer-in-Charge National Organ Transplant Unit for Director of Medical Services

*To be omitted where inapplicable.".

SECOND SCHEDULE

Regulation 7

"FORM 1

Front

HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

APPLICATION FOR WRITTEN AUTHORISATION OF LIVING DONOR ORGAN TRANSPLANT

All applications for written authorisation of living donor organ transplant shall be made using this form.

The application for the written authorisation of a living donor organ transplant shall be made by the medical practitioner who is principally responsible for the care of the prospective donor.

Particulars of prospective donor	Particulars of prospective recipient ¹
Name:	Name:
NRIC No/Passport No.:	NRIC No./Passport No.:
Nationality:	Nationality:
Date of birth:	Date of birth:

Medical practitioner for prospective donor	Medical practitioner for prospective recipient ¹
Medical practitioner who is principally responsible for the care of the donor:	Medical practitioner who is principally responsible for the care of the recipient:
Surgeon who will be principally involved in the removal of the organ (if different from above):	Surgeon who will be principally involved in the transplant of the organ (if different from above):

¹For cases of paired donation, this refers to the recipient of the prospective donor's choice. In this form, "paired donation" refers to the donation by a living donor (Donor A) of any organ from his body in consideration of —

⁽a) a donation of an organ from another living donor for the purpose of the transplantation of the organ to the body of a living recipient of Donor A's choice (Recipient A); or

⁽b) priority in the selection of Recipient A as a recipient of any organ, whether removed pursuant to section 5 of the Act or otherwise.

Section I — Declaration by medical practitioner principally responsible for the prospective donor

I DECLARE THAT:

 I am the medical practitioner principally responsible for the care of the prospective donor who has signed Section II of this form.

 I have explained to the prospective donor the nature of the medical procedure and the risks involved in the removal of *his/her *kidney/part of *his/her liver.

 So far as I am aware, the declarations that *he/she have made are true and I witnessed *his/her signature to Section II.

4. I have checked with the prospective donor and the prospective donor has confirmed that he/she

has not been previously reviewed by a transplant ethics committee OR

- has been previously reviewed by a transplant ethics committee, and the application was:
 - approved
 - rejected
 - others: ____

(please tick relevant boxes)

5. I have checked with the prospective recipient and the prospective recipient has confirmed that he/she

has not been previously reviewed by a transplant ethics committee OR

- has been previously reviewed by a transplant ethics committee, and the application was:
 - approved
 - rejected
 - □ others: ___

(please tick relevant boxes)

6. I am not aware of, nor do I have any knowledge of, any fact, circumstances or occurrence which may indicate or suggest that the prospective donor or any other person has been offered or given any valuable consideration, or has been offered or become involved in any contract or arrangement, for the prospective donor to consent to the removal of his organ.

1 A or a	1.00
 Agro	1

Disagree

(please tick relevant box)

 Based on my evaluation, the consent o (i) *is/is not given pursuant to any con (ii) *is/is not given or obtained by vir influence. 	ntract or arrangement; and
 I hereby apply for the written author *transplant/paired donation involving the above prospective recipient to be carried out. 	2 2
Signature	Date
Name and qualifications	MCR number
Hospital and clinic	
*Delete whichever is inapplicable.	
Any person who makes any declaration or state for the written authorisation of a transplant 15A(1) of the Human Organ Transplant Act misleading in a material particular shall be guilt on conviction to a fine not exceeding \$2.000 of	ethics committee under section (Chapter 131A) which is false or ty of an offence and shall be liable

exceeding 12 months or to both.

SECOND SCHEDULE — continued

Reverse
Section II - To be completed by prospective donor
Name: *NRIC No./Passport No. and country of issue: Permanent home address:
I wish to donate *my kidney/part of my liver for transplant to: (In case of paired donation ²) I wish to donate *my kidney/part of liver in consideration of a donation of *kidney/part of liver from another living donor for transplant to:
Name of recipient:
*NRIC No./Passport No. and country of issue:
I DECLARE THAT:
 I have been given an explanation of the nature of the medical procedure and the risks to me in the removal of *my kidney/part of my liver. That explanation was given by the medical practitioner principally responsible for my care named in Section I. The explanation was given *with/without a translator.
I understand the nature of the medical procedure and the risks to me as explained by that medical practitioner.
I consent to the removal of *my kidney/part of my liver.
 I have not been coerced in any way to give my consent for the removal of that organ.
5. I did not give my consent pursuant to any inducement, contract or arrangement and I am not aware that any other person has been offered any form of inducement, contract or arrangement for me to give my consent to the removal of that organ.
² In this form, "paired donation" refers to the donation by a living donor (Donor A) of any organ from his body in consideration of —
(a) a donation of an organ from another living donor for the purpose of the transplantation of the organ to the body of a living recipient of Donor A's choice (Recipient A); or
(b) priority in the selection of Recipient A as a recipient of any organ, whether removed pursuant to section 5 of the Act or otherwise.

6. I understand that I will be required by the transplant ethics committee to declare, to the best of my knowledge, the existence of any contract or arrangement or valuable consideration, including those providing only for the defraying or reimbursing, in money or money's worth, of such costs and expenses that may be reasonably incurred by me in relation to —
 (a) the removal, transportation, preparation, preservation, quality control or storage of the organ;
(b) the costs or expenses (including the costs of travel, accommodation, domestic help or childcare) or loss of earnings so far as are reasonably or directly attributable to the donation of the organ from my body; and
(c) any short-term or long-term medical care or insurance protection which is or may reasonably be necessary as a consequence of the donation of the organ from my body.
 I understand that I may withdraw my consent to the removal of that organ at any time before the operation to remove *my kidney/part of my liver is carried out.
8. I *have/do not have a well-established emotional relationship with the recipient.
 I have not been previously reviewed by a transplant ethics committee. OR
I have been previously reviewed by a transplant ethics committee, and the application was:
approved
rejected
others:
(please tick relevant boxes)
10. I understand that the information I have given on this form, any other information provided to the transplant ethics committee for the purpose of assessing this application, and the information on the cutome of the transplantation may be

10. I understand that the information I have given on this form, any other information provided to the transplant ethics committee for the purpose of assessing this application, and the information on the outcome of the transplantation, may be stored on a computer system maintained by the transplant ethics committee or provided to the Ministry of Health.

SECOND SCHEDULE — continued

Signature of prospective donor: Date:			
Signature of first witness:			
Signature of second witness:			
Name: *NRIC No./Passport No.:			
Relationship of translator to prospective donor:			
Any person who makes any declaration or statement in relation to an application for the written authorisation of a transplant ethics committee under section 15A(1) of the Human Organ Transplant Act (Chapter 131A) which is false or misleading in a material particular shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 12 months or to both.			
*Delete whichever is inapplicable.			

Section III - To be completed by prospective recipient

Name:
*NRIC No./Passport No. and country of issue:
Permanent home address:

I wish to receive a *kidney/part of a liver for transplant from:				
Name of donor (if identified):				
*NRIC No./Passport No. and country of issue:				

I DECLARE THAT:

 I have not offered any inducement, contract or arrangement nor am I aware that any other person has offered any form of inducement, contract or arrangement for the prospective donor to give his consent to the removal of his organ.

2. I understand that I will be required by the transplant ethics committee to declare, to the best of my knowledge, the existence of any contract or arrangement or valuable consideration, including those providing only for the defraying or reimbursing, in money or money's worth, of such costs and expenses that may be reasonably incurred by the donor in relation to —

- (a) the removal, transportation, preparation, preservation, quality control or storage of the organ;
- (b) the costs or expenses (including the costs of travel, accommodation, domestic help or childcare) or loss of earnings so far as are reasonably or directly attributable to the donation of the organ from the donor; and
- (c) any short-term or long-term medical care or insurance protection which is or may reasonably be necessary as a consequence of the donation of the organ from the donor.

 I *have/do not have a well-established emotional relationship with the donor.

- I have not been previously reviewed by a transplant ethics committee. OR
 - I have been previously reviewed by a transplant ethics committee, and the application was:
 - approved
 - rejected
 - □ others:

6	please	tick	relevant	boxes)
- 54	preuse	IIC N	10101010	DUACAJ

5. I understand that the information I have given on this form, any other information provided to the transplant ethics committee for the purpose of assessing this application, and the information on the outcome of the transplantation, may be stored on a computer system maintained by the transplant ethics committee or provided to the Ministry of Health.
Signature of prospective recipient: Date:
Signature of first witness:
Signature of second witness:
Name:
Relationship of translator to prospective recipient:
Any person who makes any declaration or statement in relation to an application for the written authorisation of a transplant ethics committee under section 15A(1) of the Human Organ Transplant Act (Chapter 131A) which is false or misleading in a material particular shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 12 months or to both.
*Delete whichever is inapplicable.

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HUMAN ORGAN TRANSPLANT ACT (CHAPTER 131A)

ASSESSMENT BY TRANSPLANT ETHICS COMMITTEE

Hospital:				
Organ to be transplanted:				
Name of medical practitioner who is principally responsible for the care of the prospective donor:				
Particulars of prospective donor Name:	Particulars of prospective recipient Name:			
*NRIC No/Passport No.:	*NRIC No./Passport No.:			
Date of birth:	Date of birth:			
Sex:	Sex:			
Race:	Race:			
Nationality:	Nationality:			

After taking all factors into consideration, the transplant ethics committee has decided to approve the application of organ *transplant/paired donation¹ to be carried out:

- between the abovenamed prospective donor and the abovenamed prospective recipient.
- between the abovenamed prospective donor and a recipient (to be identified).

The transplant shall be carried out within (maximum of 60) days from the date of grant of written authorisation.

*After taking all factors into consideration the transplant ethics committee has decided not to approve the application.

¹In this form, "paired donation" refers to the donation by a living donor (Donor A) of any organ from his body in consideration of —

⁽a) a donation of an organ from another living donor for the purpose of the transplantation of the organ to the body of a living recipient of Donor A's choice (Recipient A); or

⁽b) priority in the selection of Recipient A as a recipient of any organ, whether removed pursuant to section 5 of the Act or otherwise.

Name:				
Name: Independent medical practitioner	Signature:			
Name: Layperson	Signature:			
Date of authorisation:				
<i>Note:</i> If the living donor organ transplant is not carried out within the validity period, a fresh application for written authorisation shall be made to the transplant ethics committee.				
*Delete whichever is inapplicable."				

Made this 19th day of April 2004.

MOSES LEE Permanent Secretary, Ministry of Health, Singapore.

[MH 78:18/1 Vol. 6; AG/LEG/SL/131A/2003/1 Vol. 1]