

LEGISLATIVE COUNCIL BRIEF

Human Organ Transplant Ordinance
(Cap. 465)

Human Organ Transplant (Appeal Board) Regulation Human Organ Transplant (Amendment) Regulation 2010

INTRODUCTION

In accordance with the Human Organ Transplant Ordinance (Cap. 465), the Secretary for Food and Health (“SFH”) has made the Human Organ Transplant (Appeal Board) Regulation (“HOT(AB)R”) at **Annex A** to put into operation the mechanism for exemption of regulated products; and the Human Organ Transplant Board (“HOTB”) has made the Human Organ Transplant (Amendment) Regulation 2010 (“HOT(A)R”) at **Annex B** to update the specified form for reporting activities relating to organ transplant.

JUSTIFICATIONS

Human Organ Transplant (Appeal Board) Regulation (HOT(AB)R)

2. Under the Human Organ Transplant Ordinance (Cap. 465) (“HOTO”), commercial dealings of human organs for transplant are prohibited. The Human Organ Transplant (Amendment) Ordinance 2004 (Ord. No. 29 of 2004) (“Amendment Ordinance”) provides that exemption may be allowed for commercial products made from human tissues such as skin tissues and derived bone products¹, so that patients with genuine medical need for

¹ Section 7A(3) added by the Amendment Ordinance limits the exemption to a commercial product that is

transplant could benefit from the use of these products.

3. Anyone who intends to make available these commercial products for transplant must apply for and obtain exemption from the Director of Health (“DoH”). The exemption mechanism provides for appeals to be made by those aggrieved by DoH’s decisions on their applications for exemption. The HOT(AB)R is made to provide for rules and procedures for those appeals. The relevant provisions of the Amendment Ordinance has yet to be put into operation pending the setting up of the exemption and appeal mechanism.

Human Organ Transplant (Amendment) Regulation 2010 (HOT(A)R)

4. There are three forms under the Schedule to the HOTO for providing the HOTB with the information about removal, transplant and disposal of organs from living and dead donors, with one for organ(s) removed from a donor for transplant, another for organ(s) received by a recipient in a transplant and the third one for disposal of organs removed or imported for transplant. The forms correspond to the requirements under the HOTO for provision of such information by practitioners. The purpose of the HOT(A)R is to make technical amendments to these forms so as to align with the provisions of the HOTO as amended by the Amendment Ordinance.

THE REGULATIONS

HOT(AB)R

5. The major provisions of HOT(AB)R are outlined below -

- (a) Sections 4 to 7 provide for the procedures before the fixing of a date for the hearing of an appeal, including—

safe and is made from human tissues that were obtained without coercion or the offer of inducement and without payment.

- i. the time within which and the manner in which an appellant must give a notice of appeal and DoH must give his response; and
 - ii. the Appeal Board's power to give directions and the consequences of failing to comply with them.
- (b) Section 8 provides for the fixing of a date for the hearing of an appeal and provides that the parties must be notified at least 21 days before the hearing.
- (c) Section 9(1) provides that, if DoH does not respond to or does not oppose an appeal, the Appeal Board must remit the decision under appeal to him for re-consideration. Section 9(2) also provides that an appeal raising issues that have been previously determined may be dismissed without an oral hearing. Section 9(3) provides that an appeal may be determined on the basis of written submissions only, without an oral hearing, if the parties agree or indicate that they do not wish to attend the hearing.
- (d) Section 10 provides that a hearing of an appeal must be held in public, subject to the Appeal Board's directions for a private hearing or for prohibiting or restricting the publication, disclosure or use of evidence.
- (e) Section 11 provides that an appeal may be determined in the absence of a party who, having been notified of the hearing, fails to attend the hearing of the appeal without giving sufficient reason in advance. If the absentee is the appellant, the appeal may be dismissed.
- (f) Section 12 provides for the conduct of the hearing to receive evidence, examine witnesses, etc.
- (g) Sections 13 to 15 provide for other procedural matters including the Appeal Board's power to regulate its own procedures.

- (h) Section 16 provides that the proceedings of the Appeal Board must be recorded in the form of a summary in writing. Section 17 provides that a decision by the Appeal Board, if not unanimous, is to be that of the majority of its members; the secretary to the Appeal Board must notify the parties of the Appeal Board's decision and the reasons for the decision.
- (i) Sections 18 to 21 provide for miscellaneous matters. In particular, section 20 requires witness statements to be made on oath or affirmation. Section 21 makes it an offence to knowingly or recklessly furnish false or misleading information to the Appeal Board.

HOT(A)R

6. The major provisions of the three amended forms are summarised as follows –

- (a) Form 1 is intended for the supply of information on removal of organs for transplant into another person. Items to be supplied by the Form are (i) the personal particulars of the donor, (ii) whether the donor is living or dead at the time of the removal of organs, (iii) the relationship between the living donor and recipient, (iv) the description of the organ removed, (v) the description of the organ not removed subsequent to approval by HOTB for its removal, (vi) if the removed organ was not transplanted within 30 days after removal, why the transplant did not take place and the place of storage of the organ, (vii) the application for extension of deadline and (viii) the personal particulars of the person submitting the Form. The Notes to the form provide general guidance for filling in the Form.
- (b) Form 2 is intended for the supply of information on transplant of organs. Items to be supplied by the Form are (i) the personal particulars of the recipient, (ii) the particulars of the organ or, if the organ is imported, the date on which the relevant certificate

was submitted, (iii) the relationship between the living donor and the recipient and particulars of compliance with the HOTO if the organ is removed in Hong Kong, (iv) the application for extension of deadline and (v) the personal particulars of the person submitting the Form. Similar to that of Form 1, the Notes to Form 2 provide general guidance for filling in the Form.

- (c) Form 3 is intended for the supply of information on final disposal of organs removed or imported. Items to be supplied by the Form are (i) the particulars of the donor, (ii) the description of the disposed organ and the reason and manner of disposal and (iii) the personal particulars of the person submitting the Form. Similar to that of Form 1 and 2, the Notes to Form 3 provide general guidance for filling in the Form.

LEGISLATIVE TIMETABLE

7. The legislative timetable for both regulations is as follows –

Publication in the Gazette	29 October 2010
Tabling at the Legislative Council	3 November 2010

8. As provided for in their respective commencement provisions, the HOT(AB)R and HOT(A)R will commence on the respective days appointed for the commencement of sections 11 and 21 of the Amendment Ordinance. All provisions of the Amendment Ordinance that have not yet come into operation will commence on a day through a commencement notice to be made by SFH after the expiry of the negative vetting period. We are currently planning to commence operation of the relevant provisions of the Amendment Ordinance and in turn the HOT(AB)R and HOT(A)R in 4th quarter, 2011.

IMPLICATIONS OF THE PROPOSALS

9. Both HOT(AB)R and HOT(A)R have no sustainability and financial and civil service implications. They do not affect the binding effect of the HOTO. They are also in conformity with the Basic Law, including the provisions concerning human rights.

PUBLIC CONSULTATION

10. We consulted the Panel on Health Services of the Legislative Council on 8 March 2010. Members present had no objection to the proposals.

PUBLICITY

11. A spokesman will be made available to answer enquiries.

ENQUIRY

12. Any enquiries on this Brief may be addressed to Mr Chris SUN, Principal Assistant Secretary for Food and Health (Health)³ on 2973 8225.

Food and Health Bureau
November 2010

Human Organ Transplant (Appeal Board) Regulation

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Human Organ Transplant (Appeal Board) Regulation

(Made by the Secretary for Food and Health under section 7J of the Human Organ Transplant Ordinance (Cap. 465) and section 28(1)(e) of the Interpretation and General Clauses Ordinance (Cap. 1))

Part 1**Preliminary****1. Commencement**

This Regulation comes into operation on the day appointed for the commencement of section 11 of the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004).

2. Interpretation

(1) In this Regulation—

appeal (上訴) means an appeal made to the Appeal Board under section 7F of the Ordinance;

appellant (上訴人) means a person who makes an appeal;

Chairman (主席) means the Chairman of the Appeal Board appointed under section 7G(4) of the Ordinance;

notice of appeal (上訴通知) means a notice of appeal referred to in section 4(1);

Panel (備選團) means the Appeal Board Panel appointed under section 7I of the Ordinance;

party (方、一方), in relation to an appeal, means the appellant or the Director;

secretary (秘書), except in section 3, means the person who serves as secretary to the Appeal Board under section 3;

specified form (指明表格) means a form specified under section 18;

witness statement (證人陳述書) includes a statement of expert evidence (whether of fact or opinion) and an expert report.

(2) All words and expressions used in this Regulation and defined in section 7A(1) of the Ordinance for the purposes of Part 7 of the Ordinance have the same meaning as in that Part.

3. Secretary to Appeal Board

The secretary appointed to the Panel under section 7I(8) of the Ordinance is the secretary to the Appeal Board.

Part 2

Appeal Procedure

4. Notice of appeal

- (1) A person aggrieved by a decision of the Director under section 7C or 7D of the Ordinance who wishes to appeal to the Appeal Board must give the secretary a notice of appeal within 30 days after the date of the notice of the decision given by the Director under that section.
- (2) The notice of appeal must be in writing and in the specified form, and must set out—
 - (a) the name, address and contact details of the appellant;
 - (b) the name, address and contact details of the appellant's authorized representative (if any);
 - (c) the address at which documents relating to the appeal are to be delivered or sent to the appellant;
 - (d) the particulars of the regulated product that is the subject matter of the decision under appeal; and
 - (e) the particulars of the decision under appeal.
- (3) The notice of appeal must be accompanied by—
 - (a) a copy of the notice of the decision given by the Director under section 7C or 7D of the Ordinance;
 - (b) a statement setting out the grounds of appeal; and
 - (c) all documents on which the appellant intends to rely in support of the appeal, including witness statements.
- (4) The secretary must give a copy of the notice of appeal and any accompanying documents to the Director within 7 days after they are received by the secretary.

5. Director's response to notice of appeal

- (1) The Director must, within 28 days after receipt of the copy of the notice of appeal and any accompanying documents under section 4, give a written response to the secretary.
- (2) The Director's response—
 - (a) must state whether or not the Director intends to oppose the appeal;
 - (b) if the Director intends to oppose the appeal, must set out the grounds of opposition; and
 - (c) must be accompanied by all documents on which the Director intends to rely in opposing the appeal, including witness statements.
- (3) The Director must, within the period mentioned in subsection (1), give a copy of the Director's response and any accompanying documents to the appellant.

6. Appeal Board may give directions

- (1) The Appeal Board may at any time give directions that it considers necessary or desirable for clarifying the issues arising on the appeal and generally as it considers necessary or desirable for the just disposal of the proceedings.
- (2) Without limiting subsection (1), the Appeal Board may give directions—
 - (a) requiring a party to provide to the Appeal Board any particulars or supplementary statements (including witness statements), or any documents or other material in the party's custody or control, as it may reasonably require for the determination of the appeal, and to give a copy to the other party;
 - (b) specifying the time within which and manner in which any particulars, statements, documents or material or copies are to be provided or given as the Appeal Board may consider reasonable;

- (c) requiring any person to attend as a witness at a hearing of the appeal and to answer any questions, or produce any documents or other material in the person's custody or control, which relate to any matter in question in the appeal; and
 - (d) prohibiting or restricting the publication, disclosure or use of any particulars, statements, documents or material or copies provided or given in response to the Appeal Board's directions or any answers, documents or other material given or produced at a hearing.
- (3) In exercising its powers under subsection (2)(d), the Appeal Board must take into account the need to protect—
- (a) intimate personal and financial information;
 - (b) commercially sensitive information; and
 - (c) information communicated or obtained in confidence.
- (4) Despite subsections (1) and (2), no person may be compelled to give any evidence or provide or produce any document or other material that the person could not be compelled to give, provide or produce at a trial of an action in a court of law.

7. Failure to comply with directions

- (1) If the appellant does not comply with any directions given to the appellant under section 6, the Appeal Board may, at any stage of the proceedings, dismiss the whole or any part of the appeal.
- (2) If the Director does not comply with any directions given to the Director under section 6, the Appeal Board may, at any stage of the proceedings—
 - (a) strike out the whole or any part of the Director's response; and
 - (b) where appropriate, remit the decision under appeal to the Director for reconsideration.

- (3) The Appeal Board may exercise its powers under subsection (1) or (2) against a party to the appeal only if the Appeal Board has given that party notice of its intention to exercise those powers and has given that party not less than 21 days to make representations to the Appeal Board as to why it should not exercise those powers.

8. Date, time and place of hearing

- (1) Unless an appeal is wholly disposed of under section 7 or 9, the secretary must—
 - (a) appoint a date, time and place for the hearing of the appeal; and
 - (b) at least 21 days before the date appointed, give to each party to the appeal a notice in writing of the date, time and place.
- (2) At least 7 days before the date appointed for the hearing of the appeal, each party must inform the Appeal Board and the other party in writing whether the party wishes to attend the hearing, either in person or by an authorized representative.
- (3) A party who wishes to attend the hearing of the appeal must, at least 7 days before the date appointed for the hearing, provide the Appeal Board and the other party with—
 - (a) particulars of the evidence the party intends to adduce at the hearing;
 - (b) particulars of the documents the party intends to produce at the hearing; and
 - (c) the names of the persons the party intends to call as witnesses.
- (4) A party who does not wish to attend the hearing of the appeal may, at least 7 days before the date appointed for the hearing, give to the Appeal Board additional written representations (including witness statements).

- (5) A party who gives additional written representations to the Appeal Board under subsection (4) must, at least 7 days before the date appointed for the hearing of the appeal, give a copy of those representations to the other party.

9. Determining appeal without oral hearing

- (1) If—
- (a) the Director's response is not received by the Appeal Board within the period mentioned in section 5(1); or
 - (b) the Director informs the Appeal Board in writing that the Director—
 - (i) does not oppose the appeal; or
 - (ii) withdraws opposition to the appeal,
 the Appeal Board must determine the appeal by remitting the decision under appeal to the Director for reconsideration.
- (2) The Appeal Board may dismiss an appeal without an oral hearing if, after having given the appellant an opportunity to make representations, the Appeal Board is of the opinion that—
- (a) the issues raised on the appeal have been determined on a previous appeal brought by the appellant; and
 - (b) the previous appeal was brought on the basis of facts which do not materially differ from those to which the appeal in question relates.
- (3) The Appeal Board may determine an appeal without an oral hearing if—
- (a) both parties to the appeal agree in writing that the appeal is to be determined without an oral hearing; or
 - (b) both parties inform the Appeal Board in writing that they do not wish to attend the hearing.

- (4) Before the Appeal Board meets to determine an appeal without an oral hearing under subsection (3), the secretary must inform the parties in writing of—
- (a) the Appeal Board's intention to meet to determine the appeal without an oral hearing; and
 - (b) the date, time and place at which the Appeal Board is to meet to determine the appeal.
- (5) In determining an appeal without an oral hearing under subsection (3), the Appeal Board must consider the parties' written submissions.
- (6) In subsection (5)—
- written submissions** (書面陳述), in relation to a party to an appeal, includes—
- (a) in the case of the appellant, the notice of appeal and any accompanying documents mentioned in section 4(3);
 - (b) in the case of the Director, the Director's response and any accompanying documents mentioned in section 5(2)(c);
 - (c) any particulars, statements, documents or material provided by that party in response to the Appeal Board's directions under section 6; and
 - (d) any additional written representations given by that party under section 8(4).
- (7) This section applies whether or not a notice of hearing has been given under section 8.

10. Hearings to be in public except in special circumstances

- (1) Subject to subsections (2), (3) and (4), a hearing before the Appeal Board must be held in public.
- (2) If the Appeal Board is satisfied that it is appropriate to do so, it may—

- (a) direct that a hearing or part of a hearing is to take place in private and give directions as to the persons who may be present at the hearing; and
- (b) give directions prohibiting or restricting—
 - (i) the publication or disclosure to either or both of the parties to the appeal, or to some or all of the persons who may be present at the hearing, of any evidence given before the Appeal Board or of any matter contained in any document given to the Appeal Board or received in evidence by it; or
 - (ii) the publication, disclosure or use by either or both of the parties, or by some or all of the persons who may be present at the hearing, of any evidence, matter or document referred to in subparagraph (i).
- (3) The Appeal Board may exercise its powers under subsection (2)(b) in relation to any evidence, matter or document, whether or not it has given directions under section 6(2)(d) in respect of that evidence, matter or document.
- (4) In exercising its powers under subsection (2), the Appeal Board must take into account the need to protect—
 - (a) intimate personal and financial information;
 - (b) commercially sensitive information; and
 - (c) information communicated or obtained in confidence.

11. Failure of party to attend hearing

- (1) If a party to an appeal, having been given a notice of hearing under section 8, fails to attend the hearing, either in person or by an authorized representative, the Appeal Board may—
 - (a) proceed to hear and determine the appeal in the party's absence; or
 - (b) if the appellant fails to attend the hearing, dismiss the appeal.

- (2) The Appeal Board must not exercise its powers under subsection (1) against a party if, before the time appointed for the hearing, that party—
 - (a) informs the Appeal Board in writing that the party will not be able to attend the hearing; and
 - (b) satisfies the Appeal Board that the party has sufficient reason for not doing so.

12. Procedure at hearing

- (1) The Appeal Board may conduct the hearing in any manner it considers most suitable for the just disposal of the proceedings.
- (2) Either party to the appeal may attend the hearing, either in person or by an authorized representative (including a legal representative).
- (3) The parties are entitled to give evidence, to call witnesses, to question any witnesses and to address the Appeal Board both on the evidence and generally on the subject matter of the appeal.
- (4) The Appeal Board may—
 - (a) receive and consider any material that the Appeal Board considers relevant, whether by way of oral evidence, witness statements, documents or otherwise, and whether or not the material would be admissible in proceedings before a court of law;
 - (b) by notice in writing signed by the Chairman, require any person to attend before it at any hearing and to give evidence and produce documents or other material;
 - (c) require any witness to give evidence on oath or affirmation;
 - (d) examine on oath, affirmation or otherwise any person attending before it and require the person to answer all

questions put by or with the consent of the Appeal Board; and

- (e) determine the manner in which the material referred to in paragraph (a) is to be received.
- (5) Any member of the Appeal Board may administer oaths or affirmations for the purposes of this section.
- (6) Despite subsection (4), no person may be compelled to give any evidence or produce any document or other material that the person could not be compelled to give or produce at a trial of an action in a court of law.
- (7) The Chairman may at any stage of the proceedings adjourn a hearing to a later time or date.

13. Abandonment of appeal

- (1) An appellant may, at any time, abandon the appeal or any part of the appeal by notice in writing given to the secretary.
- (2) An appellant who gives a notice under subsection (1) must give a copy of the notice to the Director.

14. Extension of time limits

- (1) The Chairman may, on an application made in writing by a party to an appeal, extend any period of time prescribed by this Regulation or specified by the Appeal Board for doing any act and may impose conditions with respect to the extension.
- (2) If the Chairman grants an extension of time, the Chairman may, if the Chairman thinks fit, without hearing the party in whose favour the extension is granted, grant a reasonable extension of the period of time in which the other party is required to take any subsequent step.
- (3) A period of time may be extended either before or after the period in question has expired.

- (4) If any period of time prescribed by this Regulation, or specified by the Appeal Board, for doing any act is extended in relation to an appeal, this Regulation has effect in relation to the appeal as if references in this Regulation to that period were references to that period as extended.

15. Appeal Board to regulate own procedure

Subject to this Regulation, the Appeal Board may regulate its own procedure.

16. Record of proceedings

- (1) The secretary must make or cause to be made in writing a summary of the following matters in respect of every appeal determined by the Appeal Board—
 - (a) the name of the appellant;
 - (b) the name of any person who gives evidence;
 - (c) the grounds of the appeal;
 - (d) the major findings of facts;
 - (e) the decision of the Appeal Board and the reasons for the decision;
 - (f) any other matters directed by the Appeal Board to be recorded in the summary.
- (2) The summary taken under subsection (1) must be signed by the Chairman.

17. Decision of Appeal Board

- (1) A decision by the Appeal Board, if not unanimous, is to be that of the majority of the members of the Appeal Board.

- (2) As soon as practicable after the Appeal Board has determined an appeal, the secretary must send to each party to the appeal a notice in writing of the Appeal Board's decision and a statement of the reasons for the decision.
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Part 3

Miscellaneous

18. Specified forms

- (1) The Secretary for Food and Health (referred to in this section as *the Secretary*) may specify the forms to be used for the purposes of this Regulation.
- (2) The Secretary is to make available, on request, copies of the specified forms during office hours at the office of the Secretary.
- (3) The Secretary is to make available copies of the specified forms through any other means that the Secretary considers appropriate.

19. Method of sending documents, etc.

- (1) Any document (however described) that is required or authorized by this Regulation to be given, provided or sent to the Appeal Board, the Chairman, an appellant, the Director or any other person must be delivered in person or sent by post.
- (2) Any document (however described) delivered in person or sent by post to the Appeal Board or the Chairman under this Regulation must be addressed to the secretary.
- (3) Any application made to the Appeal Board or the Chairman under this Regulation must be addressed to the secretary.

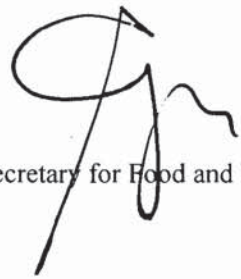
20. Witness statements to be made on oath or affirmation

- (1) A witness statement must be made on oath or affirmation.
- (2) The Appeal Board may waive the requirement in subsection (1) in respect of certain witness statements or classes of witness statements, whether before or after the witness statements are made.

- (3) The Appeal Board may refuse to consider, for the purposes of determining an appeal, any witness statement if the requirement in subsection (1) is not complied with in respect of the witness statement and is not waived in respect of it.
- (4) This section does not affect the Appeal Board's power to receive and consider any material under section 12(4).

21. Offence for false or misleading information

- (1) A person commits an offence if the person—
 - (a) makes any statement or representation or furnishes any information, to the Appeal Board or the Chairman for the purposes of an appeal, that the person knows to be false or misleading in a material respect; or
 - (b) recklessly makes any statement or representation or furnishes any information, to the Appeal Board or the Chairman for the purposes of an appeal, that is false or misleading in a material respect.
- (2) A person who commits an offence under subsection (1) is liable on conviction to a fine of \$5,000 and to imprisonment for 6 months.



Secretary for Food and Health

26 - 10 - 2010

Explanatory Note

This Regulation provides for the procedures of lodging, opposing, hearing and determination of an appeal against a decision of the Director of Health (**Director**) with respect to an application for an exemption in respect of a regulated product for transplant purpose. (See new Part 8 of the Human Organ Transplant Ordinance (Cap. 465) (added by the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004)).

2. Sections 4, 5, 6 and 7 provide for the procedures before the fixing of a date for the hearing of an appeal, including—
 - (a) the time within which and the manner in which an appellant must give a notice of appeal and the Director must give the Director's response; and
 - (b) the Appeal Board's power to give directions and the consequences of failing to comply with the directions.
3. Section 8 provides for the fixing of a date for the hearing of an appeal and provides that the parties must be notified at least 21 days before the hearing.
4. Section 9(1) provides that, if the Director does not respond to or does not oppose an appeal, the Appeal Board must remit the decision under appeal to the Director for reconsideration. Section 9(2) also provides that an appeal raising issues that have been previously determined may be dismissed without an oral hearing. Section 9(3) provides that an appeal may be determined on the basis of written submissions only, without an oral hearing, if the parties agree or indicate that they do not wish to attend the hearing.
5. A hearing of an appeal must be held in public, subject to the Appeal Board's directions for a private hearing or for prohibiting or restricting the publication, disclosure or use of evidence (section 10).

6. An appeal may be disposed of in the absence of a party who, having been notified of the hearing, fails to attend the hearing of the appeal without giving sufficient reason in advance (section 11).
7. Section 12 provides for the conduct of the hearing to receive evidence, examine witnesses, etc.
8. Sections 13 to 15 provide for other procedural matters including the Appeal Board's power, subject to this Regulation, to regulate its own procedure.
9. The proceedings of the Appeal Board must be recorded in the form of a summary in writing (section 16). A decision by the Appeal Board, if not unanimous, is to be that of the majority of its members; the secretary to the Appeal Board must notify the parties of the Appeal Board's decision and the reasons for the decision (section 17).
10. Sections 18 to 21 provide for miscellaneous matters. In particular, section 20 requires witness statements to be made on oath or affirmation. Section 21 makes it an offence to knowingly or recklessly furnish false or misleading information to the Appeal Board.

Human Organ Transplant (Amendment) Regulation 2010

(Made by the Human Organ Transplant Board under section 6 of the Human Organ Transplant Ordinance (Cap. 465))

1. Commencement

This Regulation comes into operation on the day appointed for the commencement of section 21 of the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004).

2. Human Organ Transplant Regulation amended

The Human Organ Transplant Regulation (Cap. 465 sub. leg. A), as amended by section 21 of the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004), is amended as set out in section 3.

3. Schedule substituted

The Schedule—

Repeal the Schedule

Substitute

“Schedule

[s. 3]

Forms

Form 1

[s. 3(1) & (5)]

HUMAN ORGAN TRANSPLANT ORDINANCE (CHAPTER 465)

HUMAN ORGAN TRANSPLANT REGULATION

INFORMATION ON REMOVAL OF ORGAN(S) FOR TRANSPLANT INTO ANOTHER PERSON

Serial Number:

(for internal use)

I. Particulars of the Donor

Full name:

(in BLOCK letters, Surname first)

*HK Identity Card No.^(Note 5)/HK Birth Certificate No./Passport No.
*(please specify the place of issue)/Other identity document No. (please
specify the type of document and place of issue)^(Note 6).*

Age:

Sex: *M/F

(a) ☐ The donor was **LIVING** at the time of the removal of the organ(s)—

(i) ☐ The donor and the recipient are genetically related. They

Section 3

3

are (please state the genetic relationship) and a copy of proof is enclosed. I am satisfied that—

- * all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with.

[OR]

- * all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with except that the requirement in section 5D(1)(d) has been waived in accordance with section 5E of that Ordinance.

- (ii) ☐ 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—

- * all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with.

[OR]

- * all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with except that the requirement in section 5D(1)(d) has been waived in accordance with section 5E of that Ordinance.

- (iii) ☐ The donor and the recipient are neither genetically related nor a married couple whose marriage has subsisted for not less than 3 years. Approval has been given by the Human Organ Transplant Board for the removal and/or transplant through File Reference dated

- (b) ☐ The donor was **DEAD** at the time of the removal of the organ(s)—

Section 3

4

Date and time of death: / /; *am/pm
Day Month Year

Cause of death (please state "pending coroner's inquest" for such cases and supply the cause of death to the Human Organ Transplant Board as soon as it is available):
.....

II. ☐ **Organ(s) removed**

Description of the organ(s) removed:

Date of the removal: / /
Day Month Year

Name of the hospital/clinic/institution where the removal of the organ(s) took place: (Also state the address if the removal of the organ(s) took place in a clinic or institution)
.....
.....

III. ☐ **Organ(s) not removed within 30 days after approval given by the Human Organ Transplant Board**

Description of the organ(s) not removed:

Approval was given by the Human Organ Transplant Board through File Reference dated but **no removal** subsequently took place because (please state reasons):
.....

IV. ☐ **Organ(s) removed but not transplanted**

The organ(s) was/were removed but **no transplant** subsequently took place within 30 days after the removal because:

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(please tick as appropriate)

- (a) ☐ The organ(s), after removal, was/were considered to be unusable—

Description of unusable organ(s): *(Complete ONLY if more than one organ has been removed as stated in Part II)*

.....

Reason(s) why the organ(s) was/were unusable:

.....

Manner of disposal of the organ(s):

.....

Date of disposal: / /
Day Month Year

- (b) ☐ # The organ(s) removed is/are being kept in:
- (i) ☐ The hospital/clinic/institution stated in Part II above
- (ii) ☐ Other institution *(please specify name and address)*:

.....

V. Extension of Deadline

- ☐ 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. *(Please state the File Reference and date of the approval for the extension)*:

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

Dr.
(Full name in BLOCK letters, Surname first)

*HK Identity Card No. ^(Note 5)/Passport No. *(please specify the place of issue)*/Other identity document No. *(please specify the type of document and place of issue)* ^(Note 6):

.....

Telephone No.: Fax No.:

Name of hospital/clinic/institution: *(Also state the address in the case of a clinic or institution)*

.....

Date: Signature:

* Please delete whichever is inappropriate.

☐ Please tick if applicable and fill in the information as required.

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 Human Organ Transplant Board within 30 days after the disposal of the organ(s).

Notes:

- This form must be completed for organ(s) removed in Hong Kong for transplant into another person—
 - by the medical practitioner who removed the organ(s);
 - if a technician appointed by an organ bank removed the organ(s) from a dead donor, by a medical practitioner authorized by the organ bank; or
 - if the Human Organ Transplant Board (referred to in these Notes as *the Board*) gave approval under section 5C of the Human Organ Transplant Ordinance (Cap. 465) for the organ(s) to be removed and the organ(s)

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is/are subsequently not removed, by the person who referred the proposed operation to the Board for its approval or, if that person is no longer involved, by the person who made the decision not to remove the organ(s).

If more than one medical practitioner was involved in removing the organ(s), any one of them can complete this form. 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 this form is submitted.

2. One form may only contain information relating to one donor.
3. (a) If an organ and its associated appendage tissues are removed together as a functional unit (for example, liver and its blood vessels and connective tissues)—
 - (i) if the appendage tissues are, at the time of removal, intended to be used for transplant separately from the organ, information on both the organ and the appendage tissues is required for the purpose of this form;
 - (ii) in any other case, it is sufficient for the purpose of this form to provide information on the organ, even without providing information on the appendage tissues.
- (b) However, if appendage tissues associated with an organ are removed without the organ itself being removed, this form must be completed for the appendage tissues.
4. Unless the Board has given approval for extension of the submission deadline, this form must be submitted—
 - (a) within 30 days after the removal; or
 - (b) (if the Board gave approval for the organ(s) to be removed and the organ(s) is/are subsequently not removed) within 30 days after the date on which the Board gave the approval for the removal.
5. If the person concerned is the holder of a Hong Kong Identity Card, his or her Hong Kong Identity Card number must be provided in this form.
6. If the person concerned is not the holder of any of the identity documents listed in this form, please specify the identity document that has enabled the person to be granted permission to enter Hong Kong.

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Form 2

[s. 3(1)]

HUMAN ORGAN TRANSPLANT ORDINANCE (CHAPTER 465)

HUMAN ORGAN TRANSPLANT REGULATION

INFORMATION ON TRANSPLANT OF ORGAN(S)**Serial Number:***(for internal use)***I. Particulars of the Recipient**

Full name:

(in BLOCK letters, Surname first)

*HK Identity Card No.^(Note 5)/HK Birth Certificate No./Passport No.
(please specify the place of issue)/Other identity document No. (please specify the type of document and place of issue)^(Note 6).

.....

Age:

Sex: *M/F

II. Particulars of the Organ(s)

- ☐ The organ(s) is/are removed in Hong Kong from a donor—

Full name of the Donor:
(in BLOCK letters, Surname first)

*HK Identity Card No. ^(Note 5)/HK Birth Certificate No./Passport No. (please specify the place of issue)/Other identity document No. (please specify the type of document and place of issue) ^(Note 6);

- ☐ The organ(s) is/are imported—

Before the transplant took place, *the original/a copy of the certificate accompanying the organ(s) was supplied to the Human Organ Transplant Board under section 7 of the Ordinance on: / /
Day Month Year

Description of the organ(s) transplanted:

Date of the transplant: / /
Day Month Year

Name of the hospital/clinic/institution where the transplant took place: *(Also state the address if the transplant took place in a clinic or institution)*

III. Further Particulars — required in the case of Organ(s) removed in Hong Kong only

- (a) ☐ The donor was **LIVING** at the time of the removal of the organ(s)—

- (i) ☐ The donor and the recipient are genetically related. They are (please state the genetic relationship) and—

* a copy of proof has been enclosed with Form 1 submitted to the Human Organ Transplant Board on / / in respect of the
Day Month Year
 removal of the organ(s).

[OR]

* a copy of the proof is enclosed.

AND I am satisfied that—

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with.

[OR]

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with except that the requirement in section 5D(1)(d) has been waived in accordance with section 5E of that Ordinance (copies of the certificates and medical report referred to in section 5E(1)(a), (b) and (c) are enclosed).

- (ii) ☐ The donor and the recipient are a married couple. Their marriage has subsisted for not less than 3 years and—

* a copy of the proof has been enclosed with Form 1 submitted to the Human Organ Transplant Board on / / in respect of the
Day Month Year
removal of the organ(s).

[OR]

* a copy of the proof is enclosed.

AND I am satisfied that—

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with.

[OR]

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with except that the requirement in section 5D(1)(d) has been waived in accordance with section 5E of that Ordinance (copies of the certificates and medical report referred to in section 5E(1)(a), (b) and (c) are enclosed).

- (iii) ☐ The donor and the recipient are neither genetically related nor a married couple whose marriage has subsisted for not less than 3 years. Approval has been given by the Human Organ Transplant Board for the removal and/or transplant through File Reference dated

- (iv) ☐ The organ(s) was/were removed for the therapy of the donor at the time of the removal.

- (b) ☐ The donor was **DEAD** at the time of the removal of the organ(s).

IV. Extension of Deadline

- ☐ 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. *(Please state the File Reference and date of the approval for the extension):*

V. Submitted under section 6 of the Human Organ Transplant Ordinance by—

Dr.
(Full name in BLOCK letters, Surname first)

*HK Identity Card No. ^(Note 5)/Passport No. *(please specify the place of issue)*/Other identity document No. *(please specify the type of document and place of issue)* ^(Note 6):

.....

Telephone No.: Fax No.:

Name of hospital/clinic/institution: *(Also state the address in the case of a clinic or institution)*

Date: Signature:

* Please delete whichever is inapplicable.

- ☐ Please tick if applicable and fill in the information as required.

Notes:

1. This form must be completed by the medical practitioner who transplanted the organ(s) into the recipient in Hong Kong. If more than one medical practitioner was involved in transplanting the organ(s), any one of them can complete this form. However, the medical practitioner who was in charge of the operation is responsible for ensuring that this form is submitted.
2. One form may only contain information relating to organ(s) received by one recipient from one donor in one operation.
3. (a) If an organ and its associated appendage tissues are transplanted together as a functional unit (for example, liver and its blood vessels and connective tissues).

it is sufficient for the purpose of this form to provide information on the organ, even without providing information on the appendage tissues.

- (b) However, if appendage tissues associated with an organ of a donor are used for transplant into the recipient without the organ of the same donor being transplanted into the recipient as well, this form must be completed and submitted in respect of the appendage tissues, regardless of whether Form 1 is completed and submitted in respect of the appendage tissues.
4. Unless the Human Organ Transplant Board has given approval for extension of the submission deadline, this form must be submitted within 30 days after the transplant.
5. If the person concerned is the holder of a Hong Kong Identity Card, his or her Hong Kong Identity Card number must be provided in this form.
6. If the person concerned is not the holder of any of the identity documents listed in this form, please specify the identity document that has enabled the person to be granted permission to enter Hong Kong.

Form 3

[s. 3(1)]

HUMAN ORGAN TRANSPLANT ORDINANCE (CHAPTER 465)

HUMAN ORGAN TRANSPLANT REGULATION

INFORMATION ON FINAL DISPOSAL OF ORGAN(S)
REMOVED/IMPORTED

Serial Number:

(for internal use)

I. Particulars of the Donor

For organ(s) removed in Hong Kong only

- (i) Full name:
(in BLOCK letters, Surname first)
- (ii) *HK Identity Card No.^(Note 5)/HK Birth Certificate No./Passport No. (please specify the place of issue)/Other identity document No. (please specify the type of document and place of issue)^(Note 6).

For imported organ(s) only

- (i) Name of donor in full:
(in BLOCK letters, Surname first)
- (ii) Name of airline or carrier:
- (iii) Date of shipment: / /
Day Month Year

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II. Disposal of Organ(s)

- (i) Description of the organ(s):
- (ii) Reason(s) why the organ(s) was/were considered unusable:
.....
- (iii) Manner of disposal of the organ(s):
.....
- (iv) Date of disposal: / /
Day Month Year

III. Submitted under section 6 of the Human Organ Transplant Ordinance by—

*Dr./Mr/Ms
(Full name in BLOCK letters, Surname first)

*HK Identity Card No.^(Note 5)/Passport No. (please specify the place of issue)/Other identity document No. (please specify the type of document and place of issue)^(Note 6):

Telephone No.: Fax No.:

Name of hospital/clinic/institution: (Also state the address in the case of a clinic or institution)

Date: Signature:

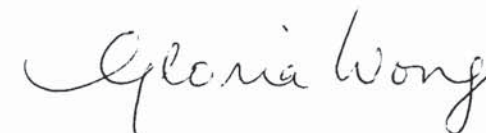
* Please delete whichever is inappropriate.

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Notes:

1. This form must be completed if organ(s) removed/imported for transplant into a person is/are disposed of. This form must be completed by the person who made the decision to dispose of the organ(s).
2. One form may only contain information relating to one occasion of disposal of the organ(s) removed from one donor.
3. (a) If an organ and its associated appendage tissues are removed together as a functional unit (for example, liver and its blood vessels and connective tissues), information on the disposal of the appendage tissues is required for the purpose of this form only if information on them was included in a Form 1 submitted to the Human Organ Transplant Board (referred to in these Notes as *the Board*).
(b) However, if appendage tissues associated with an organ are removed without the organ itself being removed, this form must be completed for the appendage tissues.
4. Unless the Board has given approval for extension of the submission deadline, this form must be submitted within 30 days after the disposal.
5. If the person concerned is the holder of a Hong Kong Identity Card, his or her Hong Kong Identity Card number must be provided in this form.
6. If the person concerned is not the holder of any of the identity documents listed in this form, please specify the identity document that has enabled the person to be granted permission to enter Hong Kong.”



Chairman,
Human Organ Transplant Board

30th Sept 2010

Explanatory Note

The object of this Regulation is to make amendments to the Human Organ Transplant Regulation (Cap. 465 sub. leg. A) (*principal Regulation*) consequent upon the enactment of the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004) (*2004 Amendment Ordinance*). This Regulation incorporates technical revisions to the statutory forms in the Schedule to the principal Regulation, as amended by the 2004 Amendment Ordinance, to facilitate compliance with the requirements for supplying information to the Human Organ Transplant Board as provided in the Human Organ Transplant Ordinance (Cap. 465), as amended by the 2004 Amendment Ordinance.