MINISTRY OF HEALTH
SINGAPORE

MH 78:04

MOH Circular No. 12/2021

27 January 2021

Licensees / Managers of PHMCA-licensed Institutions

LICENSING TERMS AND CONDITIONS ON CLINICAL ETHICS COMMITTEES

These licensing terms and conditions (LTCs) will apply to all licensees under the Private Hospitals and Medical Clinics Act (PHMCA), and will refer to two separate groups of licensees, being:

(a) Hospital Licensees, which refer to private hospitals (other than a convalescent hospital, nursing or maternity home) and to any other institution the Director specifies; and

(b) Non-Hospital Licensees, which refer to all other licensees under the PHMCA which are not Hospital Licensees.

2. Under these LTCs:

(a) Every hospital ethics committee (HEC) established by Hospital Licensees under the licensing terms and conditions on Hospital Ethics Committee dated 7 December 2012 (HEC LTCs) shall be referred to as "clinical ethics committee" (CEC). Hospital Licensees are each required to set up a CEC, and have cases involving any of the prescribed medical treatments reviewed by its own CEC.

(b) Non-Hospital Licensees are allowed, but are not required, to establish a CEC. Non-Hospital Licensees are also required to refer cases involving any of the prescribed medical treatments to a CEC for ethics review.

3. These LTCs also set out the list of prescribed medical treatments to be reviewed by the CEC, as well as the obligations of all licensees in respect of these cases. **All licensees are not to proceed with the prescribed medical treatment**

Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg

unless the CEC that has conducted an ethics review of the case is satisfied that the prescribed medical treatment is ethically appropriate.

4. These LTCs, entitled "Licensing Terms and Conditions on Case Reviews by Clinical Ethics Committees", are enclosed with this circular and shall take effect on **1 April 2021**. Upon these LTCs coming into effect, the HEC LTCs (which only apply to Hospital Licensees) will no longer be applicable.

5. All licensees are to comply with these LTCs before transiting to the Healthcare Services Act (HCSA), which will be implemented in various phases from Q3 2021. These LTCs will align the obligations of all licensees with those under the HCSA. Under the HCSA, a licensee intending to provide medical treatment of a prescribed category or description involving complex ethical dilemmas must refer the case to a CEC (to be established pursuant to the HCSA) for an ethics review. The licensee cannot proceed with the prescribed medical treatment unless each CEC that has conducted an ethics review of the case is satisfied that the prescribed medical treatment is ethically appropriate.

6. Please contact MOH by email at eLIS@moh.gov.sg if you require any further information or clarification.

A/PROF KENNETH MAK
DIRECTOR OF MEDICAL SERVICES
MINISTRY OF HEALTH

Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg

LICENSING TERMS AND CONDITIONS ON

CASE REVIEWS BY CLINICAL ETHICS COMMITTEES

IMPOSED UNDER SECTION 6(5) OF
THE PRIVATE HOSPITALS AND MEDICAL CLINICS ACT (CAP 248)

Overview and Application

1. These licensing terms and conditions ("LTCs") apply to all licensees under the Private Hospitals and Medical Clinics Act ("PHMCA") (collectively, "Licensees"), and shall come into effect on **1 April 2021**.

2. These LTCs will refer to two separate groups of Licensees:

(a) "**Hospital Licensees**", which refer to private hospitals (other than a convalescent hospital, nursing or maternity home), as well as to any other institution the Director specifies; and

(b) "**Non-Hospital Licensees**", which refer to all other licensees under the PHMCA which are not Hospital Licensees.

3. Upon these LTCs coming into effect:

(a) The licensing terms and conditions on Hospital Ethics Committee dated 7 December 2012 ("HEC LTCs") shall no longer be effective. Nonetheless, under these LTCs, Hospital Licensees are each required to set up a clinical ethics committee (instead of "hospital ethics committee" as referred to under the HEC LTCs) in accordance with **Section B (Part 1)** below, and to have cases involving any of the prescribed medical treatments reviewed by its own clinical ethics committee in accordance with **Section B (Part 2)** below.

(b) Non-Hospital Licensees are allowed, but are not required, to establish one or more clinical ethics committees to conduct ethics review of cases, and shall do so in accordance with **Section C (Part 1)** below. Non-Hospital Licensees are required to refer cases involving any of the prescribed medical treatments to a clinical ethics committee for ethics review, in accordance with **Section C (Part 2)** below.

4. The functions and requirements of clinical ethics committees are set out in **Section A** of these LTCs.

5. A breach of these LTCs may attract potential consequences under the PHMCA, including but not limited to —

(a) suspension or revocation of PHMCA licence; and

(b) prosecution.

Section A: Clinical ethics committees

Functions of a clinical ethics committee

6. The functions of a clinical ethics committee shall be to encourage and promote the ethical care and treatment of patients and to assist in resolving ethical problems involving their care and treatment.

7. A clinical ethics committee may carry out its functions in several ways, including—

(a) making recommendations to the Licensee that established it on the formulation of policies;

(b) fostering appropriate education and training; and

(c) reviewing and providing advice and recommendations on specific cases,

in connection with the ethical provision of healthcare services.

8. Clinical ethics committees shall review and advise on ethical problems—

(a) in such cases as may be referred to it by the Licensee that established it or any person designated for this purpose by that Licensee;

(b) in any cases involving any of the procedures set out in the First Schedule to be carried out by the Licensee that established it;

(c) in any cases involving any of the procedures set out in the Second Schedule to be carried out by the Licensee that established it; and

(d) in such other cases or classes of cases as the Director may, from time to time, in his discretion direct.

9. Clinical ethics committees may review and advise on ethical problems in such cases as may be referred to it by any other Licensees or any person designated for this purpose by such other Licensees, in relation to:

(a) any cases involving any of the procedures set out in the First Schedule; and

(b) any cases involving any of the procedures set out in the Second Schedule.

Appointment and Constitution of clinical ethics committees

10. The Licensee shall appoint a chairperson and members of a clinical ethics committee in accordance with the requirements in paragraph 11, and in so doing, shall take into consideration the reputation, character, fitness, experience and past contribution to society of the proposed chairperson and members.

11. A clinical ethics committee shall comprise no less than 9 members (including the chairperson, who shall be appointed by the Licensee from among the members), of whom—

(a) at least 3 members shall be healthcare professionals (including but not limited to medical practitioners, nurses, pharmacists, allied health professionals, medical social workers, psychologists but excluding administrative personnel) with no less than 10 years of practice experience, and who are in active practice (including part-time and locum practice);

(b) at least 3 members shall be lay persons; and

(c) at least 3 members shall be healthcare professionals (including but not limited to medical practitioners, nurses, pharmacists, allied health professionals, medical social workers, psychologists but excluding administrative personnel) with no less than 10 years of practice experience, are in active practice (including part-time and locum practice), and are not employed or otherwise connected with the Licensee.

Assessment of cases and decisions by a clinical ethics committee

12. In reviewing and advising on specific cases, a clinical ethics committee may—

(a) request the Licensee that requested the review for such additional information or document to be provided by the Licensee as it may consider necessary; or

(b) interview any person in relation to the case.

13. In arriving at decisions on specific cases, a clinical ethics committee shall have regard to considerations of patient safety, public interest, community values and accepted standards of medical ethics, and such other considerations as the Director may from time to time prescribe.

14. The quorum of any meeting of a clinical ethics committee shall be 4 members, comprising at least one member from each of the categories at paragraph 11. If the chairperson will not be present for the meeting, the chairperson shall appoint another member as the acting chairperson prior to the meeting. If the acting chairperson is not present during the meeting, the meeting shall then appoint another member present as the acting chairperson.

15. A decision of a clinical ethics committee shall not be valid unless such a quorum is present.

16. A decision of a clinical ethics committee shall not be valid unless more than half of the members who are present and voting agree.

17. A clinical ethics committee shall—

(a) keep and maintain proper records, including minutes of all meetings and interviews conducted by the committee, the committees' written grounds of decision and all relevant documents and literature reviewed by the committee in arriving at its decision; and

(b) provide these records to the Licensee that requested its review and the Director upon their request.

18. Where a clinical ethics committee reviews cases as directed by the Director or cases other than those of the Licensee that established it, the clinical ethics committee shall submit to the Director the documentation and records referred to in paragraph 17(a), and any other document or information as deemed necessary by the Director, within the following timelines:

(a) with respect to any cases under paragraph 9(a), within 10 calendar days of the date of its decision; and

(b) with respect to any cases under paragraph 8(d) or 9(b), in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 24(a) or 29(a) (as applicable), or where there is no such timeline, as soon as reasonably practicable.

Obligations of Licensees in respect of their clinical ethics committees

19. Each Licensee which has established a clinical ethics committee(s) pursuant to paragraph 21 or 25 below (as applicable) shall take appropriate measures to ensure the proper functioning of its clinical ethics committee(s), including—

(a) appointing appropriate and adequate staff to provide secretariat support to its clinical ethics committee(s);

(b) providing adequate training and educational resources to members of its clinical ethics committee(s) (including facilitating arrangements for such external consultation as may be required); and

(c) establishing a system of auditing the procedures and decision-making of its clinical ethics committee(s) and the taking of necessary measures to rectify any deficiencies identified (including the removal and replacement of any member of a clinical ethics committee who, in the view of the Licensee, is not discharging his duties satisfactorily).

20. The Licensee shall ensure proper documentation of measures taken under paragraph 19, including maintaining documents in respect of the credentialing of members of a clinical ethics committee (including but not limited to the most updated terms of reference and appointment letters), training records, and documentation in respect of audits and measures taken to rectify deficiencies identified. The Licensee shall provide these documents to the Director in accordance with paragraph 23*(c)*, 24*(d)*, 28*(d)* or 29*(e)* (as applicable) or upon his request.

Section B: Case Reviews for Hospital Licensees

Part 1: Obligation to establish clinical ethics committee(s)

21. Each Hospital Licensee shall establish, in accordance with these terms and conditions, one or more clinical ethics committees with the constitution and functions specified in **Section A**.

22. Each Hospital Licensee shall ensure that the clinical ethics committee(s) established by it under paragraph 21 comply with paragraphs 6 to 9 and 11 to 18 of **Section A**.

Part 2: Obligation to have cases reviewed by its own clinical ethics committee

23. With respect to any cases under paragraph 8*(b)*, the Hospital Licensee shall—

(a) ensure that the case is reviewed by a clinical ethics committee established by the Hospital Licensee as soon as reasonably practicable;

(b) take all reasonable steps to ascertain whether the case has been previously reviewed by any ethics committees (including any hospital ethics committees previously established under the HEC LTCs), and whether the ethics committee(s) that conducted an ethics review of the case is/are satisfied that the case is ethically appropriate;

(c) submit to the Director the following documentation and records:

(i) the patient's informed consent to the proposed procedure or treatment;

(ii) the documentation and records referred to in paragraphs 17*(a)* and 20;

(iii) documentation proving the steps taken in paragraph 23*(b)*;

(iv) the decision(s) of all the ethics committee(s) which have reviewed the case; and

(v) and any other document or information as deemed necessary by the Director,

within 10 calendar days of the date of the clinical ethics committee's decision in paragraph 23*(a)*; and

(d) ensure that no steps are taken to commence the proposed procedure or treatment or implement the proposed management of the case until:

(i) every ethics committee(s) that has conducted an ethics review of the case is satisfied that the case is ethically appropriate;

(ii) in the event that the Director notifies the Hospital Licensee that he has any concern with the case or the Director requires more information from the Hospital Licensee, the date notified by the Director to the Hospital Licensee; and

(iii) in all other events, after the date which is 14 calendar days after the Hospital Licensee has complied with paragraphs 23*(a)* to *(c)*.

24. With respect to any cases under paragraph 8*(c)* or 8*(d)*, the Hospital Licensee shall —

(a) comply with the requirements set out in all directives and circulars issued in relation to that case or that class of cases;

(b) ensure that the case is reviewed by a clinical ethics committee established by the Hospital Licensee as soon as reasonably practicable;

(c) take all reasonable steps to ascertain whether the case has been previously reviewed by any ethics committees (including any hospital ethics committees previously established under the HEC LTCs), and whether the ethics committee(s) that conducted an ethics review of the case is/are satisfied that the case is ethically appropriate;

(d) submit to the Director the following documentation and records:

(i) the patient's informed consent to the proposed procedure or treatment;

(ii) the documentation and records referred to in paragraphs 17*(a)* and 20;

(iii) documentation proving the steps taken in paragraph 24*(c)*;

(iv) the decision(s) of all the ethics committee(s) which have reviewed the case; and

(v) and any other document or information as deemed necessary by the Director,

in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 24*(a)*, or where there is no such timeline, as soon as reasonably practicable; and

(e) ensure that no steps are taken to commence the proposed procedure or treatment or implement the proposed management of the case until:

(i) every ethics committee(s) that has conducted an ethics review of the case is satisfied that the case is ethically appropriate; and

(ii) after the Hospital Licensee has complied with paragraphs 24*(a)* to *(d)*.

Section C: Case Reviews for Non-Hospital Licensees

Part 1: Option to establish clinical ethics committee(s)

25. Non-Hospital Licensees shall be allowed, but are not required, to establish one or more clinical ethics committees, with the constitution and functions specified herein, to conduct ethics review of cases.

26. The Non-Hospital Licensee shall inform the Director in writing, as soon as reasonably practicable, of:-

(a) the date in which its clinical ethics committee(s) will be established;

(b) the list of persons who are appointed as members of its clinical ethics committee(s), and documents proving that these members fulfil the criteria set out in paragraph 11;

(c) the dissolution of its clinical ethics committee(s) and the date in which the clinical ethics committee(s) will cease all functions, in the event that the Non-Hospital Licensee intends to dissolve its clinical ethics committee(s); and

(d) such other documents or information as the Director may, from time to time, require.

27. The Non-Hospital Licensee shall ensure that the clinical ethics committee(s) it establishes under paragraph 25 comply with paragraphs 6 to 9 and 11 to 18 of **Section A**.

Part 2: Obligation to refer cases to a clinical ethics committee for ethics review

28. With respect to any of its cases involving any of the procedures set out in the First Schedule, the Non-Hospital Licensee shall —

(a) if a clinical ethics committee has been established by the Non-Hospital Licensee pursuant to **Section C (Part 1)** above, ensure that the case is referred to and reviewed by the said clinical ethics committee as soon as reasonably practicable;

(b) if a clinical ethics committee has not been established by the Non-Hospital Licensee, ensure that the case is referred to a clinical ethics committee established by other Licensees for ethics review as soon as reasonably practicable;

(c) take all reasonable steps to ascertain whether the case has been previously reviewed by any ethics committees (including any hospital ethics committees previously established under the HEC LTCs), and whether the ethics committee(s) that conducted an ethics review of the case is/are satisfied that the case is ethically appropriate;

(d) submit to the Director the following documentation and records:

(i) the patient's informed consent to the proposed procedure or treatment;

(ii) if the case is reviewed in accordance with paragraph 28*(a)*, the documentation and records referred to in paragraphs 17*(a)* and 20*;*

(iii) documentation proving the steps taken in paragraph 28*(c)*;

(iv) the decision(s) of all the ethics committee(s) which have reviewed the case; and

(v) any other document or information as deemed necessary by the Director,

within 10 calendar days of the date of the decision by the clinical ethics committee in paragraphs 28*(a)* or 28*(b)*; and

(e) ensure that no steps are taken to commence the proposed procedure or treatment or implement the proposed management of the case until:

(i) every ethics committee(s) that has conducted an ethics review of the case is satisfied that the case is ethically appropriate;

(ii) in the event that the Director notifies the Non-Hospital Licensee that he has any concern with the case or the Director requires more information from the Non-Hospital Licensee, the date notified by the Director to the Non-Hospital Licensee; and

(iii) in all other events, after the date which is 14 calendar days after the Non-Hospital Licensee has complied with paragraphs 28*(a)* to 28*(d)*.

29. With respect to any of its cases involving any of the procedures set out in the Second Schedule, or such other cases or classes of cases as the Director may from time to time in his discretion direct, the Non-Hospital Licensee shall —

(a) comply with the requirements set out in all directives and circulars issued in relation to that case or that class of cases;

(b) if a clinical ethics committee has been established by the Non-Hospital Licensee pursuant to **Section C (Part 1)** above, ensure that the case is referred to and reviewed by the said clinical ethics committee as soon as reasonably practicable;

(c) if a clinical ethics committee has not been established by the Non-Hospital Licensee, ensure that the case is referred to a clinical ethics committee established by other Licensees for ethics review as soon as reasonably practicable;

(d) take all reasonable steps to ascertain whether the case has been previously reviewed by any ethics committees (including any hospital ethics committees previously established under the HEC LTCs), and whether the ethics committee(s) that conducted an ethics review of the case is/are satisfied that the case is ethically appropriate;

(e) submit to the Director the following documentation and records:

(i) the patient's informed consent to the proposed procedure or treatment;

(ii) if the case is reviewed in accordance with paragraph 29*(b)*, the documentation and records referred to in paragraphs 17*(a)* and 20*;*

(iii) documentation proving the steps taken in paragraph 29*(d)*;

(iv) the decision(s) of all the ethics committee(s) which have reviewed the case; and

(v) any other document or information as deemed necessary by the Director,

in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 29*(a)*, or where there is no such timeline, as soon as reasonably practicable; and

(f) ensure that no steps are taken to commence the proposed procedure or treatment or implement the proposed management of the case until:

(i) every ethics committee(s) that has conducted an ethics review of the case is satisfied that the case is ethically appropriate; and

(ii) after the Non-Hospital Licensee has complied with paragraphs 29*(a)* to *(e)*.

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FIRST SCHEDULE

[*Paragraphs 8(b), 9(a) and 28*]

1. Surgical separation of conjoint twins

2. Psychosurgery[1]

3. Treatment for sexual sterilization (as defined in the Voluntary Sterilization Act) on an unmarried person who is (a) below 21 years of age; and (b) not a person who lacks capacity within the meaning of section 4 of the Mental Capacity Act to consent to such treatment.

4. Reproductive organ transplants and gender reassignment surgery

5. Deep brain stimulation for unapproved / non-established / novel indications[2]

6. Transcranial direct current stimulation for unapproved / non-established / novel indications

7. Preimplantation genetic diagnosis (PGD) with Human Leukocyte Antigen typing for the creation of saviour siblings

8. Testicular biopsy and testicular tissue freezing for fertility preservation in prepubertal age group going for gonadotoxic therapy and Klinefelter syndrome

9. Inter-generational gamete or embryo donation within families for assisted reproduction procedures

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[1] Any surgical procedure or technique designed to irreversibly lesion brain tissue or modulate brain function with implantable devices for the primary purpose of altering the thought, emotions or behaviour of a human being.

[2] Parkinson's disease, dystonia, essential tremor and epilepsy are currently the only approved indication for deep brain stimulation.

SECOND SCHEDULE

[*Paragraphs 8(c), 9(b) and 29*]

1. In-house manufactured Cell, Tissue, Gene Therapy Products (CTGTPs) used for innovative salvage therapy[3]

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Dated this 27th day of January 2021.

A/PROF KENNETH MAK
DIRECTOR OF MEDICAL SERVICES
MINISTRY OF HEALTH

[3] Innovative therapy may be offered when conventional therapy is unhelpful and it is a desperate or dire situation. There must be professional consensus on the use of innovative therapy in the particular clinical situation, and consent must be obtained from patients. Please see MOH Directive No. 6/2020 for the Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions on https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars/details/directive-on-the-use-of-cell-tissue-and-gene-therapy-products-manufactured-in-house-by-healthcare-institutions.