

LICENCE CONDITIONS ON CASE REVIEWS BY CLINICAL ETHICS COMMITTEES

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

Overview and Application

1. These licence conditions (“**LCs**”) apply to all persons which have been licensed under the Healthcare Services Act 2020 (“**HCSA**”) (collectively, “**Licensees**”).
2. For avoidance of doubt,
 - (a) the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated; and
 - (b) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, and codes of practice made thereunder.
3. In these LCs, there are two sets of Licensees:
 - (a) Licensees which are authorised to provide an acute hospital service (“**AHS Licensees**”); and
 - (b) Licensees which are not AHS Licensees (“**Non-AHS Licensees**”).
4. Under Regulation 23C(1) of the Healthcare Services (General) Regulations 2021 (“**HCS (General) Regulations**”), every AHS Licensee must appoint one or more clinical ethics committees (“**CEC(s)**”) in accordance with Regulation 23C(2) of the HCS (General) Regulations.
 - (a) The functions and duties of CECs are prescribed in Regulation 23E of the HCS (General) Regulations. The duties of AHS Licensees as regards their CECs are prescribed in Regulation 23F of the HCS (General) Regulations.
 - (b) In addition to the prescribed functions and duties relating to CECs, AHS Licensees shall also comply with the LCs relating to CECs in **Section A** below.
5. Under section 26(2)(a) of the HCSA, an **AHS Licensee** that intends to provide a prescribed medical treatment (i.e. a medical treatment specified in Part 3 of the Third Schedule of the HCS (General) Regulations¹) must, before the prescribed medical treatment is provided to its patient, refer, or cause to be referred, the

¹ See section 26(1) of the HCSA and regulation 23D of the HCS (General) Regulations

patient's case to at least one of its CECs for an ethics review of the proposed prescribed medical treatment. The requirements for AHS Licensees as regards the referral of their cases for ethics reviews are set out in **Section B** below.

6. Under section 26(2)(b) of the HCSA, a **Non-AHS Licensee** that intends to provide a prescribed medical treatment must, before the prescribed medical treatment is provided to its patient, refer, or cause to be referred, the patient's case to any CEC appointed by an AHS Licensee for an ethics review of the proposed prescribed medical treatment. The requirements for **Non-AHS Licensees** as regards the referral of their cases for ethics reviews are set out in **Section C** below.
7. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:
 - (a) suspension or revocation of the Licensee's HCSA licence;
 - (b) shortening the term of the Licensee's HCSA licence;
 - (c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (d) a direction requiring the Licensee to pay a financial penalty.

Section A: CECs

Cases / medical treatments to be reviewed by CECs

8. The AHS Licensee shall ensure that its CEC(s) conduct an ethics review of —
- (a) every prescribed medical treatment relating to the care and treatment of a patient of the AHS Licensee²;
 - (b) every prescribed medical treatment relating to a patient of a referring Licensee^{3,4};
 - (c) any case other than a case mentioned in paragraph 8(a) referred to it by the AHS Licensee⁵;
 - (d) any case other than a case mentioned in paragraph 8(b) referred to it by any Licensee that is not the AHS Licensee⁶; and
 - (e) any proposed prescribed medical treatment or clinical case as may be directed by the Director-General of Health pursuant to Section 40(1) and/or Section 40(4) of the HCSA.

For avoidance of doubt, the AHS Licensee shall ensure that its CEC(s) do not reject the conduct of an ethics review of a case or prescribed medical treatment referred to it by the AHS Licensee or any referring Licensee.

9. Non-AHS Licensees shall not appoint their own CECs to conduct ethics reviews of cases or prescribed medical treatments referred to in paragraph 8 above.

10. For cases involving the conduct of multiple ethics reviews of the same patient with the same condition, the AHS Licensee shall ensure that its CEC(s) put in place a framework to determine whether or not multiple reviews are required.

Appointment of CEC members and chairperson

11. The AHS Licensee shall appoint a chairperson for each of its CECs amongst the members of each CEC, and in so doing, shall take into consideration the reputation, character, fitness, experience and past contribution to society of the proposed chairperson.

² As per regulation 23E(a)(i) of the HCS (General) Regulations

³ For the avoidance of doubt, “referring Licensee” in this LCs shall have the same meaning as the term “referring licensee” in regulation 19 of the HCS (General) Regulations, i.e. a Non-AHS Licensee who refers or causes to be referred any proposed prescribed medical treatment to the CEC for an ethics review under section 26(2)(b) of the HCSA.

⁴ As per regulation 23E(a)(ii) of the HCS (General) Regulations

⁵ As per regulation 23E(b) of the HCS (General) Regulations

⁶ As per regulation 23E(b) of the HCS (General) Regulations

12. In its appointment of members to its CECs in accordance with the requirements in Regulation 23C(2) of the HCS (General) Regulations, the AHS Licensee shall take into consideration the reputation, character, fitness, experience and past contribution to society of the proposed members.

Assessment of cases/medical treatments and decisions by a CEC

13. The AHS Licensee shall allow its CEC(s) to —

- (a) request the AHS Licensee (if the case/medical treatment was referred by the AHS Licensee) or the referring Licensee (if the case/medical treatment was referred by a referring Licensee) for such additional information or document to be provided by the AHS Licensee or the referring Licensee (as applicable) as it may consider necessary; or
- (b) interview any person in relation to the case or medical treatment,

when reviewing and advising on cases or medical treatments.

14. The AHS Licensee shall ensure that its CEC(s) will have regard to considerations of patient safety, public interest, community values and accepted standards of medical ethics, and such other considerations as the Director-General of Health may from time to time direct, in arriving at decisions on cases or medical treatments.

15. The AHS Licensee shall ensure that the quorum of any meeting of its CEC(s) shall be five members, comprising at least one member from each of the following three categories:

- (a) members who are healthcare professionals employed by the AHS Licensee which appointed the CEC;
- (b) members who are healthcare professionals and who are independent members⁷; and
- (c) members who are not healthcare professionals.

The AHS Licensee shall also ensure that 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 AHS Licensee shall then ensure that the members present for the meeting will appoint another member present as the acting chairperson.

16. The AHS Licensee shall ensure that a decision of its CEC(s) is not valid unless:

⁷ See the definition of “independent member” in regulation 23C(3) of the HCS (General) Regulations

- (a) such a quorum described in paragraph 15 is present; and
 - (b) more than half of the members who are present and voting agree. Members of the CEC who are involved in the direct care of the patient which the case or medical treatment relates to shall not participate or be involved in the decision.
17. The AHS Licensee shall ensure that its CEC(s) —
- (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 AHS Licensee (if the case/medical treatment was referred by the AHS Licensee) or the referring Licensee (if the case/medical treatment was referred by a referring Licensee) and the Director-General of Health within a reasonable time upon their request.
18. The AHS Licensee shall ensure that where its CEC(s) review cases or medical treatments under paragraphs 8(b), 8(d) or 8(e), the CEC(s) shall submit to the Director-General of Health the documentation and records referred to in paragraph 17(a), and any other document or information as deemed necessary by the Director-General of Health, within the following timelines:
- (a) with respect to any cases or medical treatments under paragraphs 8(b) or 8(d), within 10 calendar days of the date of its decision; and
 - (b) with respect to any cases or medical treatments under paragraph 8(e), in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 23(a) or 25(a) (as applicable), or where there is no such timeline, as soon as reasonably practicable.

Obligations of AHS Licensees in respect of their CECs

19. Each AHS Licensee which has established CEC(s) pursuant to Regulation 23C(1) of the HCS (General) Regulations shall take appropriate measures to ensure the proper functioning of its CEC(s), including—
- (a) deploying appropriate and adequate personnel to provide secretariat support to its CEC(s);
 - (b) providing adequate training and educational resources to members of its CEC(s) to enable the members to carry out their functions and duties

(including facilitating arrangements for any external consultation as may be required);

- (c) establishing a system to audit the procedures and decision-making of its CEC(s); and
- (d) periodically reviewing the system for referring Licensees to refer cases to, and the processes adopted by, each CEC that the AHS Licensee appoints, and taking appropriate measures to rectify any deficiencies detected (including the removal and replacement of any member of a CEC who, in the view of the AHS Licensee, is not discharging his duties satisfactorily).

20. The AHS Licensee shall ensure proper documentation of the measures taken under paragraph 19, including maintaining documents in respect of the credentialing of members of their CEC(s) (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 AHS Licensee shall provide these documents to the Director-General of Health in accordance with paragraph 22(c) and 23(d) (as applicable) or upon his request.

21. The AHS Licensee shall ensure that its CEC(s) comply with Regulation 23E of the HCS (General) Regulations.

Section B: Case Reviews for AHS Licensees

22. With respect to any of its cases or medical treatments under paragraph 8(a) or 8(c), the AHS Licensee shall —

- (a) ensure that the case or medical treatment is reviewed by a CEC established by it (in accordance with section 26(2)(a) of the HCSA) as soon as reasonably practicable;
- (b) take all reasonable steps to ascertain whether the case or medical treatment has been previously reviewed by any CECs, and whether the CEC(s) that conducted an ethics review of the case or medical treatment is/are satisfied that the medical treatment is ethically appropriate;
- (c) submit to the Director-General of Health the following documentation and records:
 - (i) the patient's informed consent to the medical treatment;
 - (ii) the documentation and records referred to in paragraphs 17(a) and 20;
 - (iii) documentation proving the steps taken in paragraph 22(b);
 - (iv) the decision(s) of all the CEC(s) which have reviewed the case or medical treatment; and
 - (v) and any other document or information as deemed necessary by the Director-General of Health,within 10 calendar days after the CEC completes the review of the case or medical treatment (see paragraph 22(a)); and
- (d) ensure that no steps are taken to commence or provide the medical treatment until every CEC(s) that the case or medical treatment was referred to has conducted an ethics review of the case or medical treatment, and is satisfied that the medical treatment is ethically appropriate.

23. With respect to any medical treatment or clinical case under paragraph 8(e), and where the medical treatment or clinical case relates to the patient of the AHS Licensee, the AHS Licensee shall —

- (a) comply with the requirements set out in all directives and circulars issued by the Director-General of Health in relation to that medical treatment/clinical case or that class of medical treatments/clinical cases;
- (b) ensure that the medical treatment or clinical case is reviewed by a CEC

pursuant to the direction given by the Director-General of Health under Section 40(1) and/or Section 40(4) of the HCSA as soon as reasonably practicable;

- (c) take all reasonable steps to ascertain whether the medical treatment or clinical case has been previously reviewed by any CECs, and whether the CEC(s) that conducted an ethics review of the medical treatment or clinical case is/are satisfied that the medical treatment is ethically appropriate;
- (d) submit to the Director-General of Health the following documentation and records:
 - (i) the patient's informed consent to the medical treatment;
 - (ii) the documentation and records referred to in paragraphs 17(a) and 20;
 - (iii) documentation proving the steps taken in paragraph 23(c);
 - (iv) the decision(s) of all the CEC(s) which have reviewed the medical treatment or clinical case; and
 - (v) and any other document or information as deemed necessary by the Director-General of Health,

in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 23(a), or where there is no such timeline, as soon as reasonably practicable; and

- (e) ensure that no steps are taken to commence or provide the medical treatment until:
 - (i) every CEC(s) that the medical treatment or clinical case was referred to has conducted an ethics review of the medical treatment or clinical case and is satisfied that the medical treatment is ethically appropriate; and
 - (ii) after the AHS Licensee has complied with paragraphs 23(a) to (d).

Section C: Case Reviews for Non-AHS Licensees

24. With respect to any of its cases or medical treatments in paragraph 8(b) or 8(d), the Non-AHS Licensee shall —

- (a) refer its case to a CEC of an AHS Licensee in accordance with section 26(2)(b) of the HCSA as soon as reasonably practicable;
- (b) take all reasonable steps to ascertain whether the case or medical treatment has been previously reviewed by any CECs, and whether the CEC(s) that conducted an ethics review of the case or medical treatment is/are satisfied that the medical treatment is ethically appropriate;
- (c) submit to the Director-General of Health the following documentation and records:
 - (i) the patient's informed consent to the medical treatment;
 - (ii) documentation proving the steps taken in paragraph 24(b);
 - (iii) the decision(s) of all the CEC(s) which have reviewed the case or medical treatment; and
 - (iv) any other document or information as deemed necessary by the Director-General of Health,

within 10 calendar days after the CEC completes the review of the case or medical treatment (see paragraph 24(a)); and

- (d) ensure that no steps are taken to commence or provide the medical treatment until every CEC(s) that the case or medical treatment was referred to has conducted an ethics review of the case or medical treatment, and is satisfied that the medical treatment is ethically appropriate.

25. With respect to any medical treatment or clinical case under paragraph 8(e), and where the medical treatment or clinical case relates to the patient of the Non-AHS Licensee, the Non-AHS Licensee shall —

- (a) comply with the requirements set out in all directives and circulars issued by the Director-General of Health in relation to that medical treatment/clinical case or that class of medical treatments/clinical cases;
- (b) ensure that the medical treatment or clinical case is reviewed by a CEC pursuant to the direction given by the Director-General of Health under Section 40(1) and/or Section 40(4) of the HCSA as soon as reasonably practicable;

- (c) take all reasonable steps to ascertain whether the medical treatment or clinical case has been previously reviewed by any CECs, and whether the CEC(s) that conducted an ethics review of the medical treatment or clinical case is/are satisfied that the medical treatment is ethically appropriate;
- (d) submit to the Director-General of Health the following documentation and records:
 - (i) the patient's informed consent to the medical treatment;
 - (ii) documentation proving the steps taken in paragraph 25(c);
 - (iii) the decision(s) of all the CEC(s) which have reviewed the medical treatment or clinical case; and
 - (iv) any other document or information as deemed necessary by the Director-General of Health,

in accordance with the timeline then applicable to such submission stipulated in any directive or circular referred to in paragraph 25(a), or where there is no such timeline, as soon as reasonably practicable; and
- (e) ensure that no steps are taken to commence or provide the medical treatment until:
 - (i) every CEC(s) that has conducted an ethics review of the case is satisfied that the medical treatment is ethically appropriate; and
 - (ii) after the Non-AHS Licensee has complied with paragraphs 25(a) to (d).