

Rule for Establishing and Administering Ethical, Legal and Social Issues Committee for Cross-ministerial Strategic Innovation Promotion Program (SIP): Innovative AI Hospital System

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SIP: Innovative AI Hospital System

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(Purpose)

Sec. 1. This Rule intends to set forth, for the sake of operating the research and development project (the “PJ”) implemented by the Cross-ministerial Strategic Innovation Promotion Program (the “SIP”): Innovative AI Hospital System (the “AI Hospital”) (where Yusuke Nakamura serves as the program director (the “PD”)), the necessary matters for the administration of the ethical, legal, and social issues committee (the “ELSI Committee”) composed of third-party members in accordance with Section 6 of the Rule for Operating the Strategic Innovation Creation Program (SIP): “Advanced Diagnosis and Treatment System by AI (Artificial Intelligence) Hospital” (the “Operation Rule”).

(Scope of Authority)

Sec. 2. The Committee shall coordinate the matters provided under Sections 6 (1) to (4) of the Operation Rule.

(Organization and Members)

Sec. 3. The Committee shall comprise such third-party committee members as appointed by the PD and engaged by the Control Entity.

2. Each member of the Committee shall be a third party not involved in any issue of the AI Hospital and falling under any one of the following. The Committee must have at least one (1) member falling under each of subparagraphs (1) to (3):

- (1) Experts with the expertise in ethics (e.g., bioethics)
- (2) Experts with the expertise in law (e.g., criminal law, civil law)
- (3) Experts with the expertise in social studies (e.g., social studies)
- (4) Any other expert as deemed necessary by the PD

3. The term of office for any committee member shall be two (2) years, which may be renewed. However, the term of office for any substitute committee member shall expire upon the expiry of the term of office for the predecessor.

(Chairperson of Committee)

Sec. 4. The Committee shall maintain a chairperson, which shall preside over all matters of the Committee.

2. The chairperson shall be elected by the mutual vote of the committee members.

3. The term of office for the chairperson shall be two (2) years, which may be renewed.

4. In the event of any unavailability of the chairperson, the committee member as so designated by the chairperson in advance shall serve in place therefor.

(Committee)

Sec. 5. The chairperson shall convene the meetings of the Committee where necessary.

2. Any meeting of the Committee shall be validly constituted with the attendance of the majority of the committee members and by at least one (1) expert from each field of expertise as provided in Sections 3.2(1) to (3).

3. If the chairperson or any committee member has any interest in any matter to be deliberated or coordinated, the chairperson or such committee member shall be excluded from such deliberation and other activities.

4. All coordination concluded by the Committee shall be decided with the unanimous vote of all committee members. If such unanimous vote is not obtainable, such decision shall be made with the affirmative votes of the majority of the attending committee members, and in the event of a tie, the chairperson shall have the deciding vote.

5. No proxy may attend any meetings of the Committee in place of any absent committee member. Such committee member shall not assign any votes to any other committee member either.

6. Any absent committee member may submit an opinion or the like in connection with the matter to be deliberated by the Committee in writing through the chairperson.

7. If deemed necessary by the chairperson, a meeting of the Committee may be instituted in a round-robin manner. If any meeting of the Committee is instituted in a round-robin manner to decide any coordination, such decision shall be made *mutatis mutandis* in accordance with the provisions of paragraph 4 of this section, but such coordination shall be made by all committee members.

(Attendance by Outsider)

Sec. 6. If deemed necessary by the chairperson, the Committee may solicit any party other than the committee members for the submission of material, option, or explanation, the attendance to any meeting, or any other cooperation.

(Open Session of Committee)

Sec. 7. No session of the Committee may be publicly open unless otherwise excepted. Notwithstanding the foregoing, if the chairperson has determined it necessary to allow public access to any session of the Committee, such session of the Committee may be publicly open.

(Meeting Minutes of Committee)

Sec. 8. No meeting minutes of the Committee shall be made available to the public unless otherwise excepted, but the chairperson must make a summary of such minutes available to the public. Notwithstanding the foregoing, if the chairperson has determined it necessary, any meeting minutes in whole or in part may be made available to the public in an appropriate manner with the decision of the Committee.

(Committee Member's Duty of Confidentiality)

Sec. 9. No committee member may leak, exploit, use, divert, or otherwise utilize the contents of any deliberation or any other confidential information made accessible through the office. All committee members shall be bound by the same duties even after the termination of service for the office.

(General Administration)

Sec. 10. All general administration for the committee members, the Committee, and the like shall be processed through the Control Entity.

(Miscellaneous)

Sec. 11. Other than those provided herein, any matter necessary for the administration shall be determined by the chairperson through consultation with the PD.