Rule for Collaborative Organizations Participating in the Cross-ministerial Strategic Innovation Promotion Program (SIP): Innovative AI Hospital System

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SIP: Innovative AI Hospital System

Yusuke Nakamura, Program Director

## (Purpose)

Sec. 1. This Rule intends to set forth, for the sake of promoting 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 organizations provided under Section 2.4 of the SIP AI Hospital Operation Rule (the "Collaborative Organization") to participate in and provide cooperation, assistance, and whatsoever (to "Participate") to the matters of the AI Hospital with the aim to support the goal to be achieved by the AI Hospital and to accelerate and promote the social implementation and other practical application of the AI Hospital through the development, standardization, and whatsoever of the relevant technologies, services, and the like, as well as the funding contributing to the private finance initiative therefor.

# (Categories of Participation)

- Sec. 2. Participation in the AI Hospital shall be made in accordance with the following categories. Participation in two or more categories shall be allowed, in which case the distinction of the principal category and the subordinate category shall be clarified:
- (1) Participation through the research and development of machines, systems, services, and whatsoever
- (2) Participation through the testing on the practical application of machines, systems, services, and whatsoever
- (3) Participation through the funding or whatsoever to the research and development
- (4) Participation to the acceleration of the AI Hospital through any means other than the foregoing subparagraphs (1) to (3)

(Terms and Conditions for Participation by Collaborative Organization)

- Sec. 3. Any organization other than the adopted PJ desiring to Participate in the AI Hospital shall apply for Participation pursuant to Section 5.2 through the consultation with the PD.
- 2. Participation in the AI Hospital shall be granted only if the following requirements are satisfied:
- (1) If intending to Participate through category (1) under the preceding section, such organization must select the suitable sub-theme from AI Hospital Sub-Themes A to E.
- (2) If intending to Participate through category (2) under the preceding section, such organization must obtain a prior approval of the PJ that is already adopted in Sub-Theme D. Unless otherwise excepted, Participation shall be granted only to a hospital that maintains smooth coordination with the other medical institutions in the region where a collaborative organization is established.
- (3) If intending to Participate through category (3), Participation shall be granted only if such organization collaborates with the adopted PJ of Sub-Theme E.
- (4) If intending to Participate through category (4), Participation shall be granted only if such organization has determined the sub-theme for such Participation through the consultation with the PD prior to the application.

### (Deliberation of Participation)

- Sec. 4. The grant of Participation to any Collaborative Organization shall be decided by the panel comprising PD, sub-program directors (the "Sub PD"), and the Chairperson of the Assessment Committee.
- 2. In making a panel decision, none of the PD, Sub-PD, and the Chairperson of the Assessment Committee who has any interest in such Collaborative Organization may participate in such decision. If the Chairperson of the Assessment Committee has any interest in such Collaborative Organization, a deputy appointed by the PD in advance shall serve in place of the Chairperson of the Assessment Committee.

# (Administration)

- Sec. 5. All administration necessary for the Participation by the Collaborative Organizations shall be rendered by National Institutes of Biomedical Innovation, Health and Nutrition (the "Control Entity").
- 2. Any organization desiring to Participate must submit an application of Participation to the Control Entity in writing (including an electronic form) in a format separately provided.
- 3. Upon the grant of such Participation, the Control Entity shall provide a written notice (including an electronic notice) to the applicant without delay.

4. The Control Entity shall provide the notice of any Collaborative Organizations granted to Participate to the PJ and any other relevant parties without delay.

### (Execution of Contract)

Sec. 6. All Collaborative Organizations granted to Participate in the AI Hospital as the result of the panel decision under Section 4 shall enter into a nondisclosure agreement and a joint research and development agreement with the Control Entity or the research institute in charge of the adopted PJ (i.e., the organization for which the research manager as determined under the Operation Rule serves), depending on the form of such Participation. Such Collaborative Organization may participate in meetings of the AI Hospital and the like as an observer after the execution of such agreements.

# (Suspension of Participation)

- Sec. 7. Any Collaborative Organization intending to suspend its Participation must promptly make the application therefor to the Control Entity in writing (including an electronic form) in a format provided separately.
- 2. The Control Entity shall promptly provide a notice to the PD and the other relevant parties upon such application for suspension of Participation. Participation shall be suspended upon the date when such suspension is approved by the PD.
- 3. In the event of suspension of Participation, such Collaborative Organization shall take the appropriate action under the nondisclosure agreement or the joint research and development agreement as provided in the preceding section.

#### (Funding)

Sec. 8. No Collaborative Organization shall be entitled to reimbursement of any cost or any other arrangement from the expenses controlled by the Control Entity with respect to any project of the AI Hospital.

Sec. 9. Other than those provided herein, any matter necessary for Participation shall be determined by the PD.