Rule for Establishing and Administering Assessment Committee for Cross-ministerial Strategic Innovation Promotion Program (SIP): Innovative AI Hospital System

August 1, 2018

National Institutes of Biomedical Innovation, Health and Nutrition

As determined by Yusuke Nakamura, Program Director of Cross-ministerial Strategic Innovation Promotion Program: Innovative AI Hospital System

(Purpose)

Sec. 1. This Rule intends to set forth, in connection with the 2018 public solicitation guide for Cross-ministerial Strategic Innovation Promotion Program (the "SIP"): Innovative AI Hospital System (the "AI Hospital") (the "Public Solicitation Guide") implemented by the SIP: AI Hospital (where Yusuke Nakamura serves as the program director (the "PD")), the necessary matters as dictated by the PD for the administration of the assessment committee (the "Committee") composed of third-party assessors for assessing the adoption of any research and development project (the "PJ") submitted in response to the Public Solicitation Guide and assessing the same PJ on an annual basis or otherwise.

(Establishment)

Sec. 2. The Committee shall be established, as instructed by the PD, in the National Institutes of Biomedical Innovation, Health and Nutrition (the "Control Entity"), in other words, a control entity for the SIP AI Hospital as designated by the Cabinet Office.

(Scope of Authority)

Sec. 3. The Committee shall, in response to the inquiries made by the PD, report the assessment and other relevant matters for the selection of any PJ proposed in response to the Public Solicitation Guide for the SIP AIP Hospital and the assessment of such PJ upon the termination of the fiscal year, discontinuation of such PJ, or at any other time (including any matters related to whether or not to continue any PJ).

2. The Committee shall also conduct a peer review to ensure the effective, efficient, and proper administration of any PJ.

(Organization and Members)

Sec. 4. The Committees shall comprise such committee members as appointed by the PD and engaged by the Control Entity.

2. The Committee shall maintain a committee member missioned to conduct an assessment based on the PJ-related documents submitted by the applicant and Committee assessment (including any hearing with the applicant) (the "Para.2 Committee Member").

3. The Committee shall maintain a committee member missioned to conduct an assessment based on the PJ-related documents submitted by the applicant in a dedicated manner.

4. In appointing any committee member for the Committee, the PD shall make such appointment from the list specified in the following paragraph 5.

5. (1) Experts with expertise in medicine (e.g., cancer, circulatory system, pathological diagnosis, image diagnosis)

(2) Experts with expertise in AI (Artificial Intelligence) and IoT

(3) Experts with expertise in medical devices and sensors

(4) Experts with expertise in information security

(5) Experts with expertise in hospitals and medical systems

(6) Experts with expertise in industrialization, intellectual property, and bioethics

(7) Any other expert as deemed necessary by the PD

6. The Para.2 Committee Member shall be appointed by the PD from all committee members.

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

(Chairperson of Committee)

Sec. 5. The Committee shall maintain a chairperson, which shall represent the Committee.

2. The chairperson shall be appointed by the PD from the Para.2 Committee Members.

3. The chairperson shall preside over all matters of the Committee.

4. In the event of any unavailability of the chairperson, the Para.2 Committee Member as so designated by the PD shall serve in place therefor.

(Committee)

Sec. 6. The chairperson shall convene meetings of the Committee.

2. Any meeting of the Committee shall be validly constituted with the attendance of a majority of the Para.2 Committee Members.

3. If any committee member has any interest in the assessment of any matter, such committee member shall be excluded from the deliberation, assessment, and other activities.

4. All decisions shall be made with the affirmative votes of the majority of the attending Para.2 Committee Members, and in the event of a tie, the chairperson shall have the deciding vote.

5. No proxy may attend any meeting of the Committee in place of any absent Para.2 Committee Member. Such Para.2 Committee Member shall not assign any votes to any other Para.2 Committee Member either.

6. Any absent Para.2 Committee Member may submit an assessment, advice, or other opinion in connection with the PJ to be assessed 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.

8. If any meeting of the Committee is instituted in a round-robin manner for a decision, such decision shall be made with the affirmative vote of the majority of all Para.2 Committee Members, and in the event of a tie, the chairperson shall have the deciding vote.

(Means of Assessment)

Sec. 7. The standard and means for any specific assessment or the like of PJs shall be separately provided by the Control Entity in accordance with the instructions of PD, and the Committee shall conduct such assessment or the like in accordance therewith.

(Open Session of Committee)

Sec. 8. Given that the Committee deliberates non-public learning, knowledge, conception (idea), techniques, and other matters in connection with the research and development, 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. 9. No meeting minutes of the Committee shall be made available to the public unless otherwise excepted. 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.

2. Even if the meeting minutes of the Committee remain unavailable to the public, the chairperson shall endeavor to prepare a summary of such meeting minutes in whole or in part and to make such summary available to the public for the purpose of securing the transparency of the deliberations.

(Committee Member's Duty of Confidentiality)

Sec. 10. No committee member may leak, exploit, use, divert, or otherwise use any assessment 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.

(Submission of Material and Demand for Opinion)

Sec. 11. If deemed necessary by the chairperson, the Committee may require the applicant of any PJ to submit to the Committee any additional materials, statement of opinion or explanation, or to otherwise take any action necessary for the assessment and the like.

2. If deemed necessary by the chairperson, the Committee may require anybody other than the committee members serving for the Committee to submit to the Committee any additional materials, statement of opinion or explanation, or to otherwise render any cooperation necessary for the assessment and the like.

(General Administration)

Sec. 12. All general administration for the committee members, the Committee, and the like shall be processed through the Control Entity.

(Miscellaneous)

Sec. 13. Other than as provided herein, the procedures for deliberation and any other matter necessary for the administration of the committee members and the Committee shall be determined by the chairperson through consultation with the PD.

Supplemental Provisions

This Rule shall take effect on August 1, 2018, with the organizational decision of the Control Entity.

Exhibit

Standard and Means of Assessment for Cross-ministerial Strategic Innovation Promotion Program (SIP): Innovative AI Hospital System

Pursuant to Section 7 of the Rules for Establishing and Administering Assessment Committee for Cross-ministerial Strategic Innovation Promotion Program (the "SIP"): Innovative AI Hospital System (the "AI Hospital") (National Institutes of Biomedical Innovation, Health and Nutrition 30 Rule No. 16 dated August 1, 2018, as determined by Yusuke Nakamura, the program director (the "PD") in charge of the SIP AI Hospital, administered by the Cabinet Office Director General for Policies on Scientific Technologies and Innovations), the standard and the means for assessment for SIP AI Hospital shall be provided as follows:

1. Means of Assessment

(1) Timing for Assessment

A. Periodic Assessment

(a) When adopting a research and development project submitted in response to the 2018 public solicitation guide for AI Hospital (the "PJ")

(b) When conducting an annual assessment on the adopted PJ

(c) When the adopted PJ is terminated

B. Extraordinary Assessment

When the PD has determined that the assessment of the PJ is necessary (e.g., where the adoption of any PJ is terminated before the end of the fiscal year)

(2) Means of Assessment

A. Written Assessment by Committee Members [Note1]

Assessments shall be made based on the PJ plans, the self-assessment materials, and other materials (the "PJ Materials") submitted by the applicant, research manager, or joint researcher (the "Assessee").

[Note1] Prior to the written assessment by the committee members, the Control Entity will make some confirmation and coordination from the clerical standpoint (e.g., format, prerequisite for assessment) and may require resubmission, revision, exclusion from the written assessment, or any other necessary action in the event of a failure to satisfy the requirements.

B. Assessment through Interviews by the Committee

The Assessee shall be directly interviewed for the opinions during a meeting of the Committee (including any interview conducted by means of telephone, video, or other means), and assessments shall be made based on the results of such interviews.

C. Assessment Based on Site Inspection by Committee Members or the Committee (including the relevant government agency and the relevant parties of the Control Entity)

Visits shall be made to the site of the research and development by the Assessee, and assessments shall be made based on the progress of the PJ at the site and interviews from the relevant parties (including clerks).

(3) Procedures for Assessment (General Flow)

The Committee shall make the assessment in accordance with the following procedure:

[1] The Assessee submits the PJ Materials to the PD (Control Entity).

[2] The Control Entity confirms and coordinates the submission from the clerical perspective.

[3] The PD makes the inquiry to the Committee.

[4] The committee members conduct a written assessment, processing, and compilation.

[5] The Para.2 Committee Members conduct an assessment, processing, and compilation through the Committee (and require the additional materials and conduct an interview, site inspection, and whatsoever where necessary).

[6] The Committee determines its response (for the annual assessment and the termination assessment, the Committee makes a report as a third-party assessment result to the SIP Governing Board (the "GB") of the Council for Science, Technology and Innovation (the "CSTI") through the Control Entity).

[7] The Assessment Committee responds to the PD.

[8] The PD makes its determination and communicates the notice and the other matters to the Sub-PDs.

(4) Management of Conflicts of Interest (COI)

A. For the sake of securing the impartiality and reliability of the research and development, no committee member having any interest in any Assessee (including any organization Assessee) may participate in the assessment of the relevant PJ.

B. The same shall apply mutatis mutandis to any theme of research and development subcontracted to the organization for which any committee member currently serves.

C. With respect to each case, the Committee shall take appropriate action with reference to the Guidelines for Conflicts of Interest (dated July 12, 2018, by the Cabinet Office [in Charge of Scientific Technologies and Innovations]).

(5) Compliance with Ethical Guidelines

In the course of the research, it is necessary to ensure that the following laws, government ordinances, ethical guidelines, and the like with respect to the research ethic are complied with and that there is no problem with respect to any ethical aspect or safety measures. Assessment shall also be made on the status of the compliance with such laws, ordinances, guidelines, and the like.

For reference purposes, the following is indicative of the representative examples of the relevant laws, government ordinances, ethical guidelines, and the like:

- Act on Regulation of Human Cloning Techniques (2000 Act No. 146)

- Act on Prevention of Infections and Medical Care for Patients with Infections (2006 Act No. 106)

- Act on Conservation and Sustainable Use of Biological Diversity through Regulations on Use of Living Modified Organisms (2006 Act No. 97)

- Act on Securement of Safety in Regenerative Medicine (2013 Act No. 85)

- Clinical Trials Act (2017 Act No. 16)

- Ethical Guidelines and Guidance for Medical and Health Research Involving Human Subjects (Notification No. 1 of the Ministry of Education, Culture, Sports, Science and Technology / the Ministry of Health, Labor and Welfare dated February 28, 2017, and May 29, 2017)

- Guidelines for Handling Specified Embryo (2001 Notification No. 173 of the Ministry of Education, Culture, Sports, Science and Technology)

- Guidelines for Establishing Human ES Cells (2014 Notification No. 2 of the Ministry of Education, Culture, Sports, Science and Technology / the Ministry of Health, Labor and Welfare)

- Guidelines for Distributing and Exploiting Human ES Cells (2014 Notification No. 174 of the Ministry of Education, Culture, Sports, Science and Technology)

- Guidelines for Research on Producing Germ Cells from Human iPS Cells or Human Tissue Stem Cells (2010 Notification No. 88 of the Ministry of Education, Culture, Sports, Science and Technology)

- Ethical Guidelines for Research on the Human Genome / Gene Analysis (2013 Notification No. 1 of the Ministry of Education, Culture, Sports, Science and Technology / the Ministry of Health, Labor and Welfare / the Ministry of Economy, Trade and Industry)

- Ministerial Ordinance on Standards for Conducting Pharmaceutical Clinical Trials (1997 Ordinance No. 28 of the Ministry of Health, Labor and Welfare)

- Ministerial Ordinance on Standards for Implementation of Medical Device Clinical Trials (2005 Ordinance No. 36 of the Ministry of Health, Labor and Welfare)

- Ministerial Ordinance on Standards for Implementation of Regenerative Medical Product Clinical Trials (2014 Ordinance No. 89 of the Ministry of Health, Labor and Welfare)

- Ministerial Ordinance on Standards for Conducting Nonclinical Studies on Pharmaceutical Safety (1997 Ordinance No. 21 of the Ministry of Health, Labor and Welfare)

- Ministerial Ordinance on Standards for Conducting Nonclinical Studies on Medical Device Safety (2005 Ordinance No. 37 of the Ministry of Health, Labor and Welfare)

- Ministerial Ordinance on Standards for Conducting Nonclinical Studies on Regenerative Medical Product Safety (2014 Ordinance No. 88 of the Ministry of Health, Labor and Welfare)

- Guidance for Research and Development on Human Tissues Removed by Surgery (1998 Response by Health Sciences Council)

- Guidelines for Clinical Research of Gene Therapy, etc. (2015 Notification No. 344 of the Ministry of Health, Labor and Welfare)

- Ethical Guidelines for Research of Assisted Reproductive Technology for Creating Human Fertilized Embryo (2010 Notification No. 2 of the Ministry of Education, Culture, Sports, Science and Technology / the Ministry of Health, Labor and Welfare)

- Basic Guidelines for Implementing Animal Experiments at Research Institutes (2006 Notification No. 71 of the Ministry of Education, Culture, Sports, Science and Technology)

- Basic Guidelines for Implementing Animal Experiments at Institutes Supervised by Ministry of Health, Labor and Welfare (Notification dated June 1, 2006, by the Health Science Division Director, Minister Secretariat Department, Ministry of Health, Labor and Welfare, as partially amended on February 20, 2015), or Basic Guidelines for Implementing Animal Experiments at Institutes Supervised by the Ministry of Agriculture, Forestry and Fisheries (Notification dated June 1, 2006, by the Secretary General of the Agriculture, Forestry and Fisheries Res. Council, Ministry of Agriculture, Forestry and Fisheries)

(6) Assessment Items

Assessments shall be made on the following items, including such items as guided in the Assessment on SIP System and Project (as determined by the CSTI SIP GB on August 2,

2018), the Guidelines for Advancing Peer Reviews (as determined by the SIP Supervisor of Cabinet Office on August 8, 2018), and any other relevant guidelines.

In assessing each individual theme, the assessment shall be made in accordance with the spirit embodied in the research and development plan for the SIP AI Hospital.

The following shall describe the representative items of and weighted rating for the general perspective, expert and technical perspectives, and other perspectives.

A. Adoption Assessment

(A) General Perspective

◊ Understanding of Project Outline

- Whether or not understanding the outline of the SIP

- Whether or not understanding the outline of the AI Hospital

(B) Expert and Technical Perspective

◊ Target of Research and Development and Appropriateness of Research and Development Plan (10 scores)

- Whether or not the target is clearly indicated as an achievable target

- Whether or not the research and development plan is reasonable in light of the thus-far technical accumulation made by the proper entities

- Whether or not the issues at each step in the research and development and the solutions therefor are clearly and properly planned

◊ Strategies for Practical Application and Commercialization (25 scores)

- Whether or not the images of the products or services for practical application or commercialization are specifically proposed

- Whether or not the needs at the medical sites are fully analyzed, and the products or services satisfy such needs and clearly possess the superiority to those provided by the competitors

- Whether or not the applicant already possesses any technique or patent

- Whether or not there is any third-party patent that may be an impediment to practical application

◊ System, Budget, and Scale for Implementing Research and Development (10 scores)

- Whether or not the system capable of implementing the Project is prepared from the perspective of the composition of the personnel in charge of the research and development and the machinery at the facilities and from other perspectives

- Whether or not the applicant has the experience and achievement in the research and development of the relevant theme

- Whether or not the applicant is excellent in the capability of managing the progress of the research and development and the administration of the budget

- Whether or not the allocation of the budget is appropriate in the plan for research and development

- Whether or not the management foundation is firmly set

B. Annual Assessment

(A) General Perspective

◊ Operation Compatible with Outline of Project

- Whether or not the operation and the results are achieved properly in conformance with the outline of the SIP

- Whether or not the operation and the results are achieved properly in conformance with the outline of the AI Hospital

(B) Expert and Technical Perspective

◊ Achievement of Plan for Research and Development (5 scores)

- Whether or not research and development have progressed and the results are achieved as initially planned

◊ Appropriateness of Future Plan for Research and Development (5 scores)

- Whether or not there is any problem in the plan for further progressing the research and development and what change is required to the plan if any

- Whether or not the results as planned are expected to be achieved in the future

◊ Capability of Continuing Research and Development (5 scores)

- Whether or not the system for research and development (e.g., composition of the personnel in charge thereof) is appropriate in terms of continuing the development and achieving the target as planned therefor, and what change is required to the system of the research and development if any

◊ Appropriateness of Administration of Project Budget (5 scores)

- Whether or not the expense performance is appropriate in light of the expense plan or the like

- Whether or not the future expense plan is appropriate

◊ Appropriateness of Commercialization Strategies (10 scores)

- Whether or not the images of the products or services for practical application or commercialization are specifically proposed

- Whether or not the needs at the medical sites are fully analyzed and the products or services satisfy such needs and clearly possess superiority to those provided by competitors

◊ IP or Commercialization (10 scores)

- Whether or not the system for filing, maintaining, and managing patents is ready

- Whether or not the patent and other intellectual property rights necessary for the practical application are secured

- Whether or not there is any third-party patent that may be an impediment to the practical application

- Whether or not the organization system for the commercialization is ready

- Whether or not the funding plan for the commercialization is ready

C. Annual Assessment (Final Fiscal Year)

(A) General Perspective

◊ Comprehensive Assessment

- Whether or not the results and social ripple effects are achieved properly in conformance with the outline of the SIP

- Whether or not the results and social ripple effects are achieved properly in conformance with the outline of the AI Hospital

(B) Expert and Technical Perspective

◊ Achievement of Plan for Research and Development (5 scores)

- Whether or not the research and development are achieved as planned, and if not achieved, what the problem is

◊ Appropriateness of Future Plan for Research and Development (5 scores)

- Whether or not the future development plan for the commercialization is proper

- Whether or not the activity plan for the commercialization is properly formulated

- Whether or not the results as planned are expected to be achieved in the future

◊ Capability of Continuing Research and Development (5 scores)

- Whether or not the system for research and development (e.g., composition of the personnel in charge thereof) is appropriate in terms of continuing the development and achieving the target, and what change is required to the system of the research and development if any

◊ Appropriateness of Administration of Project Budget (5 scores)

- Whether or not the expense performance has been appropriate in light of the expense plan or the like

◊ Appropriateness of Commercialization Plan (10 scores)

- Whether or not the plan for growth and profitability after commercialization has been appropriate

◊ IP or Commercialization (10 scores)

- Whether or not the system for filing, maintaining, and managing patents is ready

- Whether or not the patent and other intellectual property rights necessary for the candidate development products are secured

- Whether or not there is any third-party patent that may be an impediment to the practical application

- Whether or not the organization system for the commercialization is ready

- Whether or not the funding plan for the commercialization is formulated