SIP “Innovative AI Hospital System”

Application for Collaborative Organization

(Month) (Day), (Year)

Cross-ministerial Strategic Innovation Promotion Program (SIP)

“Innovative AI Hospital System”

Attn: Mr. Yusuke Nakamura, Program Director

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| --- | --- | --- | --- | --- | --- | --- |
| Applicant: | Name: | |  | | |  |
| Organization: | |  | | | |
| Department: | |  | | | |
| Title: | |  | | | |
| Address: | | (Postal Code) | | | |
|  | | | |
| Date of Birth: | |  | | | |
| Contact: | Telephone: |  | Extension: |  | |
| Direct: |  | Fax: |  | |
| E-Mail: |  | | | |

I hereby submit my (Request / Application) as follows to render my cooperation for the research and development to the Cross-ministerial Strategic Innovation Promotion Program (SIP): Innovative AI Hospital System.

1. Project Name of Research and Development

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2. Expected Term for Implementing Research and Development

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| --- | --- | --- | --- | --- | --- |
| Start | (Month) (Day), (Year)Note 1 | End | (Month) (Day), (Year) | Term | Total: \_\_\_ Years |

3. Category of Participation Note 2

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| □ | (1) ) Participation through the research and development of machines, systems, services, and whatsoever |
| □ | (2) Participation through testing of the practical application of machines, systems, services, and whatsoever (requires coordination with medical institutes and other sub-theme D affiliated organizations) |
| □ | (3) Participation through funding or whatsoever for research and development (requires coordination with sub-theme E) |
| □ | (4) Participation in the acceleration of the AI Hospital through any means other than (1) to (3). |

4. Category of Participating Sub-Theme

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| --- | --- | --- |
|  | CategoryNote 3 | Details of Participation,Note 4 Publicly-Solicited PJ to Be Coordinated withNote 5 |
| □ | Sub-Theme A |  |
| □ | Sub-Theme B |  |
| □ | Sub-Theme C |  |
| □ | Sub-Theme D |  |
| □ | Sub-Theme E |  |

Description for Spaces 2 to 4

Note 1) Please state the actual start date of the research as the start day of the expected term for the research.

Note 2) Please check the box of the applicable participation category.

Note 3) Please select the sub-theme (sub-themes A to E) of the AI hospital issues in which you wish to participate, and then check the applicable box.

Note 4) Please briefly describe the contents to be implemented in the participating sub-theme.

Note 5) If the coordination with the project adopted through the public solicitation (publicly solicited PJ) is already fixed, please reference the list of the adopted issues (14 issues) exhibited on http://www.nibiohn.go.jp/nibio/part/promote/sip/saitaku.html, and fill in the docket number for the applicable publicly-solicited PJ.

\*The participation in sub-theme D requires the Collaborative Organization to coordinate with the publicly solicited PJ.

\*There is no allocation of AI hospital project expenses to any Collaborative Organization.

5. Business Contact:

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| --- | --- | --- | --- | --- | --- | --- |
| Name: | |  | | | | |
| Organization/Department/Title | |  | | | | |
| Contact: | Telephone: |  | Extension: |  | Fax: |  |
| E-Mail: |  | | | | |

6. Organization of Research and Development Project (Research Manager (Representative), Contributors, etc.)

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| --- | --- | --- | --- | --- | --- |
|  | (1) Name | (2) Details of Research and DevelopmentNote1 | (3) Site for Implementation Note2 | (4) DepartmentNote3  (Official Title) | (5) ExpertiseNote4  (e-Rad ID) |
| Representative |  |  |  | （　　　　　　　　　　　　　　　　　） | （　　　　　　　　） |
| Contributors |  |  |  | （　　　　　　　　　　　　　　　　　） | （　　　　　　　　） |
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Note 1) Please describe the themes, fields, and the like for which you are in charge in the research and development plan in the space for (2) “Details of Research and Development.”

Note 2) Please describe the site for actually implementing the research and development in the space for (3) “Site for Implementation.”

Note 3) Please describe the organization for which you serve and the official title in the space for (4) “Organization (Official Title)” (please indicate the official title in the parenthesis).

Note 4) Please describe the field that you believe you have expertise in in the space for (5) “Expertise (e-Rad ID).” There is no problem even if the space is left blank. If you have any research ID issued by the Cross-ministerial R&D Management System (e-Rad), please specify such ID in the parenthesis.

\*If you need more spaces to describe the contributors, please add spaces to describe all contributors.

7. Summary of Research and Development Project

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\*Please describe the summary of 8. “Reason for Collaborative Participation in AI Hospital Issues” to 11. “Implementation Plan for Research and Development Project” with approximately 1,000 characters.

\*For any research and development project that requires a multiple of years, please also state the entire plan for such research and development project and the relationship with the plan for the relevant fiscal year.

\*Please attach the flow diagram, correlation diagram and the like as exhibits where necessary.

8. Reason for Collaborative Participation in AI Hospital Project

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\*Please specifically describe with approximately 1,000 characters the reasons for your collaborative participation in the AI hospital issues, and also the social issues to be solved by the acceleration of the research and development project as well as the background therefor with the citation of the references as needed.

9. Aim, Target, and Social Application Image of Research and Development Project

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\*Please describe in approximately 1,000 characters with reference citations as needed.

\*Please specifically describe the aim of the research and development project, the target for each fiscal year of the research and development term, and the application image upon the termination of the term.

\*Please also describe the relationship with any other research plan and research and development project necessary for achieving the final target of the research and development project (e.g., the research that you have been engaged in with respect to the research and development project).

10. Direct / Indirect Effect Expected from Implementation of Research and Development Project

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\*Please describe in approximately 1,000 characters with reference citations as needed.

\*Please specifically describe the detailed ideas and examples as to how your participation in the AI hospital issues as the Collaborative Organization contributes to the social problems.

11. Implementation Plan for Research and Development Project (If multiple years are required, please also describe the details of each fiscal year as much as possible.)

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\*Please describe the specific plan and means for achieving the targets of the research and development project in approximately 1,600 characters.

\*For any research and development project that requires multiple fiscal years, please specify the relationship between the entire plan and each annual plan.

\*Please make the description based on the status of the current research environment such as the procurement of the research facilities, materials, and fields for implementing the research and development project.

12. Guidelines to Be Complied with for Research

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| □ | Guidelines for Smooth Use of Research Tool Patent in Life Science Field (Council for Science and Technology Policy dated March 1, 2007) |
| □ | Promotion of Science and Technology with Citizens (Basic Program Policy) (Decision of State Minister in Charge of Science and Technology Policy and Expert Congressperson dated June 19, 2010) |
| □ | 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 (including Guidance) for Medical and Health Research Involving Human Subjects (Notification No. 1 of the Ministry of Education, Culture, Sports, Science and Technology / 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 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 / 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 Health Science Division Director, Minister Secretariat Department, the Ministry of Health, Labor and Welfare, as partially amended on February 20, 2015) |
| □ | Basic Guidelines for Implementing Animal Experiments at Institutes Supervised by the Ministry of Agriculture, Forestry and Fisheries (Notification dated June 1, 2006 by Secretary General of the Agriculture, Forestry and Fisheries Res. Council, the Ministry of Agriculture, Forestry and Fisheries) |
| □ | Others: |

\*Please check the box of the applicable items.

13. Compliance with Ethical Guidelines

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\*If at the time of the application, the research and development project is considered outside the scope of the ethical guidelines and the like indicated in 12 “Guidelines to Be Complied with for Research,” please describe such effect along with the reasons therefor. Please also describe the action plans if any ethical examination or the like is required under any ethical guideline in the future.

\*Please attach the notification of the examination result or other document (if any) from the Ethical Examination Committee or other organ as provided under the “Ethical Guidelines for Medical and Health Research Involving Human Subjects.”

14. Actions for Protection of Personal Information and Other Information Security

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\*Please describe the actions for the protection of personal information and the information security of medical information and the like.

15. Brief History of Applicant for Research and Development Project (including any research presentation, thesis, and publication)

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\*Please describe the career history, product development performance, reward and punishment, research history, research/presentation performance, and other relevant history of the applicant. In connection with the research history, research/presentation performance, and other relevant history, please make the description only if the same is relevant for the reference.

16. Expense Scale for Research and Development Project (Rough Estimation)

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| --- | --- | --- |
| Fiscal Year | Expense (Rough Estimation) (Unit: JPY) | Wherein: Self-Funding (Rough Estimation) (Unit: JPY) |
| FY: |  |  |
| FY: |  |  |
| FY: |  |  |
| FY: |  |  |
| FY: |  |  |
| Total: |  |  |

\*If the expense is not set per fiscal year, please indicate the total expense in the space for “Total.”

17. Status of Fund Acquisition from Government or Private Subsidy or Other Means

(Please make the description only when the fund for the research and development has been acquired from the source other than your organization)

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| --- | --- | --- | --- | --- |
| Name of Subsidy Organization:  (Name of Government Agency / Local Government / Corporation / Foundation) | Name of Subsidy Project | Term of Subsidy  (Number of Years for Term of Subsidy) | Amount of Subsidy (Unit: JPY)  (Acquired Fiscal Year) | Remarks |
|  |  | (Month)/(Day)/(Year) to (Month)/(Day)/(Year)  (\_\_ Years) | JPY (FY \_\_\_\_\_) | □ Representative  □ Contributor |
|  |  | (Month)/(Day)/(Year) to (Month)/(Day)/(Year)  (\_\_ Years) | JPY (FY \_\_\_\_\_) | □ Representative  □ Contributor |
|  |  | (Month)/(Day)/(Year) to (Month)/(Day)/(Year)  (\_\_ Years) | JPY (FY \_\_\_\_\_) | □ Representative  □ Contributor |
|  |  | (Month)/(Day)/(Year) to (Month)/(Day)/(Year)  (\_\_ Years) | JPY (FY \_\_\_\_\_) | □ Representative  □ Contributor |
|  |  | (Month)/(Day)/(Year) to (Month)/(Day)/(Year)  (\_\_ Years) | JPY (FY \_\_\_\_\_) | □ Representative  □ Contributor |

\*If any fund for the research and development has been acquired from any organization other than your organization (in particular, the public fund such as government subsidy), please describe the status of the fund acquisition for the fiscal year during which the research and development project is started in order for us to understand the relevancy with the purpose of such subsidy (expect for any fund for which the application is pending).

\*Please describe in the remark section under what position (e.g., whether as the representative or a contributor) such subsidy has been acquired.

\*If there is any subsidy having been acquired in the past and related to the research and development project, please describe the total amount of the acquisition and the fiscal years of such acquisition and of the expiry.

Reference Materials:

- Materials for the summary of the organization for which the applicant serves (i.e., applicant organization) and the business thereof.

- For the materials in connection with the coordination provided under Section 3.2(2) of the SIP AI Hospital Collaborative Organization Participation Rule, the recommendation letter from the local medical association or other entity, the examination result letter from the Ethical Examination Committee of the Japan Medical Association and other relevant materials.