(Form E1)

**FY2019 Advanced Research and Development Programs for Medical Innovation**

**Research and Development (R&D) Proposal**

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| Title of proposed R&D project | *Study of XXXX* |
| R&D area (Type) | *Enter R&D Area* (AMED-CREST) |
| R&D period | Oct. 1st 2019 ~ *Mar. 31th 2025*  (*5.5* years) |
| Name of R&D PI | Hanako M. Iryo <First name Middle name Last name> |
| Affiliated institution, department, position |  |
| Academic background  (since University) | ----Example----  <Undergraduate Institution>  yyyy (year of completion): Department of WWWW, Faculty of XXXX, YYYY University  <Graduate Institutions>  Master’s Course: yyyy (year of completion): Department of WWWW, Faculty of XXXX, YYYY University  (Supervisor: Prof. Wwww Y. XXXX) [Necessary Information]  Doctoral Course: yyyy (year of completion): Department of WWWW, Faculty of XXXX, YYYY University  (Supervisor: Prof. Wwww Y. XXXX) [Necessary Information]  Academic Degree: yyyy (year of acquisition): Ph.D. (Field of Specialty) at ZZZZ University  *(Supervisor\*: Professor Wwww Y. XXXX; Head of Laboratory\*: Professor Aaaa B. CCCC) [\*Necessary Information]* |
| Professional Appointments  (Major careers and Fields of R&D) | ----Example----  From yyyy to xxxx: Assistant Professor, Department of Medicine, WWWW University  (Researched XXXX at the laboratory of Professor Aaaa B. CCCC\*)  From yyyy to xxxx: Associate Professor, Department of Medicine, WWWW University  (Researched XXXX at the laboratory of Professor Aaaa B. CCCC\*)  From yyyy to xxxx: Associate Professor, Department of Medicine, WWWW University  (Researched XXXX at the laboratory of Professor Aaaa B. CCCC\*)  *[\*Necessary Information]* |

\* Please submit after deleting the entry examples and explanations (the characters in blue, all sections in italics and the out of text parts in green characters).

1. **Research Objectives**  (Do not exceed four A4-size sheets (no exceptions))

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| 1. Use a font size of 10.5 points or larger. If these instructions are not followed, the research proposal may not be accepted. 2. On this Form, make effective references to the descriptions of achievements listed in the “3. Research Achievements” to clarify the relationship between the achievements of the applicant and the research being proposed. 3. Please specify clearly 1) the background of the R&D concept (necessity and importance of the research), 2) the achievements of the applicant (and preliminary evidence) and 3) R&D concepts and plans. 4. Where necessary insert diagrams etc. to ensure the details you enter are clearly comprehensible. |

1. **Targets and Objectives**

Specify the research objectives of the proposed R&D project (expected achievements at the end of the research period), and the targets of the proposed R&D (in terms of outcome resulting directly from the above mentioned achievements).

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1. **Background**

Specify scientific and technological needs, social demands and requests from economic and industrial interests, including trends in related fields, in order to illustrate the importance and necessity of the proposed R&D project.

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1. **R&D Fundamentals and Preparations**

Specify the relevant projects conducted previously and the personal research achievements of the R&D PI (and those of the R&D Co-Investigators, and other collaborating researchers, as required), and other preliminary knowledge, experimental evidence, etc. to support the R&D concept. Specify the contents corresponding to “III. 3. (2) (d)” in the Application Guidelines.

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1. **Originality and Novelty of the Proposed R&D and Comparison to the Current Status of Similar Studies Worldwide**

Explain the originality and novelty of the proposed R&D project, and the advantages of this R&D project over others in the world, taking into account the research situation and trends worldwide.

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1. **Future R&D Prospects**

Explain the creation of scientific and technological innovation, creation of seeds for medical applications, contributions to society, and acquisition and enforcement of intellectual property that are expected to be realized in future if the “I. 1. Targets and Objectives” stated on this Form E1 are successfully achieved.

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1. **R&D Plan and Approaches** (Do not exceed four A4-size sheets (no exceptions.))

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| 1. Explain the R&D approaches taken to achieve “1. I. Targets and Objectives” and potential problems and solutions, as well as alternative approaches for in the case that the project fails to obtain the expected results during the R&D period with certain milestones, including criteria for evaluating achievement levels and time periods for conducting the R&D. 2. Clearly stipulate the goals to be achieved within three years of commencing the R&D (This is a basic item for Mid-term Review). 3. R&D plan and approaches may be specified for each R&D item.   With regard to intellectual property and other matters anticipated in this R&D concept (such as applications, licensing, and management), specify the following: 1) relevant intellectual property rights owned by the applicants, and 2) strategy for acquiring intellectual property rights during the course of the R&D.  Refer to notes in “1. Research Objectives.” |

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1. **Research Achievements**

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| 1. For each R&D Principal Investigator and Co-Investigators, select major papers and authors that have been published in academic journals, etc. (within the past 5 years) and list these in order starting from the most recent year. Circle those that are directly related to the proposed topic. 2. Note the acquisition and application status of patent rights or other intellectual property rights, as well as any policy recommendations that have been made as a result of implementation of the research project (guiding principles or guidelines to which you have contributed, etc.). |

・R&D Principal Investigator: *Hanako M. Iryo*

＜Paper / Author＞

*○M.Marusankaku, J.Aaaa, H.Bbbbb, A.Ccccc, Treatment of Hepatic……, Nature, 2015, 1, 10-20*

*M.Marusankaku, T.Aaaa, A.Bbbbb, T.Ccccc, Risk factors for Fungal…, Nature, 2015, 2, 17-26*

＜Acquisition and application status of patent rights or other intellectual property rights＞

*Application number, inventor, title of invention, applicant, filing date*

＜Policy recommendations＞

*XXXXXX Guideline (issued by XX Academic Association XXXX [year])*

・R&D Co-Investigators: *Taro M. Iryo*

＜Paper / Author＞

*○M.Marusankaku, J.Aaaa, H.Bbbbb, A.Ccccc, Treatment of Hepatic……, Nature, 2015, 1, 10-20*

*M.Marusankaku, T.Aaaa, A.Bbbbb, T.Ccccc, Risk factors for Fungal…, Nature, 2015, 2, 17-26*

＜Acquisition and application status of patent rights or other intellectual property rights＞

*Application number, inventor, title of invention, applicant, filing date*

＜Policy recommendations＞

*XXXXXX Guideline (issued by XX Academic Association XXXX [year])*

・R&D Co-Investigators: *Taro M. Iryo*

＜Paper / Author＞

*○M.Kakukaku, T.Dddd, A.Eeee, T.Ffff, Study on Hepatitis…………, Nature, 2015, 12, 32-40*

*M.Kakukaku, T. Dddd, A. Eeee, T.Ffff, Study on Malaria………, Nature, 2015, 10, 45-54*

＜Acquisition and application status of patent rights or other intellectual property rights＞

*Application number, inventor, title of invention, applicant, filing date*

＜Policy recommendations＞

*XXXXXX Guideline (issued by XX Academic Association XXXX [year])*

(Annex E1)

**Main Schedule for R&D**

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| 1. Enter the R&D items to address in order for accomplishing the R&D goals, with the R&D periods.   Milestones: Attainments/ accomplishments as important events to achieve   1. Enter the schedule and R&D researchers in charge (R&D PI or Co-Investigator(s)) by R&D item. 2. Please detail the approximate allocated amount (direct costs) of the contracted R&D funds for the entire R&D period. Detail the total sum of the planned allotted amount for each R&D item so they equal the direct costs of the sum applied for.   Enter information within one A4-size sheet. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| R&D item  Milestone  Allotted R&D funds (planned) | Name of person in charge | 1st Year  (FY2019) | | 2nd Year  (FY2020) | | 3rd Year  (FY2021) | | 4th Year  (FY2022) | | 5th Year  (FY2023) | | 6th Year  (FY2024) | |
|  |  | H1 | H2 | H1 | H2 | H1 | H2 | H1 | H2 | H1 | H2 | H1 | H2 |
| (1) *Analysis of XX related gene manifestation*  *- Establishment of assay system*  *- Analysis of manifestation data*  **Research Costs:**  XX million yen | *PI* |  | *■* | *■* | *■* | *■*  *■* | *■*  *■* | *■* | *■* | *■* | *■* | *■* | *■* |
| (2)   * *a* * *a*   **Research Costs:**  XX million yen | *Co-Investigator* |  |  |  | *■* | *■*  *■* | *■*  *■* | *■*  *■* | *■*  *■* | *■*  *■* | *■* | *■* | *■* |
| (3)   * *b* * *b*   **Research Costs:**  XX million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4)   * *c* * *c*   **Research Costs:**  XX million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5)   * *d* * *d*   **Research Costs:**  XX million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |