(Form P1)

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

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Title of proposed R&D project | *Study of XXXX* | | | | | | |
| R&D area (Type) | *Enter R&D Area* (PRIME) | | | | | | |
| R&D period | Oct. 1st 2020 ~ *Mar. 31th 2024*  (*3.5* years) | | | | | | |
| R&D area |  | | | | | | |
| R&D discipline |  | | | | | | |
| e-Rad research field (main) keywords |  | | | | | | |
| Name of R&D PI | (Japanese) |  | | | | | |
| (English) | *Yyyy Yyyyyy* | | | | | |
| Affiliated institution | *XXXX University* | | | | | | |
| Address | 〒*XXX-XXXX* | | | | | | |
| Tel | *XX-XXXX-XXXX* | | | Fax | | | *XX-XXXX-XXXX* |
| E-mail | *YYY@YY.jp* | | | | | | |
| Department | *XXX Department, Faculty of XXX* | | | | | | |
| Position | *XXX* | | | | | | |
| Person in charge of accounting work | *XX XX* | | Accounting department name, contact information etc. | | *XX Section, Administration Department, XXXX University*  *Tel: 　　Fax:*  *E-mail:* | | |
| Name of R&D  Co-Investigator\* | (Japanese) |  | | | | | |
| (English) |  | | | | | |
| Affiliated institution |  | | | | | | |
| Address |  | | | | | | |
| Tel |  | | | Fax | |  | |
| E-mail |  | | | | | | |
| Department |  | | | | | | |
| Position |  | | | | | | |
| Person in charge of accounting work |  | | Accounting department name, contact information etc. | |  | | |

\* You are requested to detail all of the R&D Co-Investigators. In addition, add rows as needed in accordance with the number of R&D Co-Investigators, etc.

\* Please delete the examples and explanation (the parts in blue italics and the out of text parts in green characters) before submission.

**Breakdown of Costs for Each Fiscal Year**

(Unit: 1,000 yen)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Main item | | Sub items | FY2020 | FY2021 | FY2022 | FY2023 | Total |
| Direct costs | 1. Costs of goods | Equipment costs |  |  |  |  |  |
| Consumable item costs |  |  |  |  |  |
| 2. Travel costs | Travel costs |  |  |  |  |  |
| 3. Personnel costs/ services costs | Personnel costs |  |  |  |  |  |
| Services costs |  |  |  |  |  |
| 4. Other | Subcontract costs |  |  |  |  |  |
| Other |  |  |  |  |  |
| Subtotal | |  |  |  |  |  |
| Indirect costs  (In general, 30% of aforementioned direct costs) | | |  |  |  |  |  |
| Total | | |  |  |  |  |  |

**Research Organization (R&D Principal Investigator and Co-Investigator)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name  (age as of April 1, 2020)  Researcher ID No. | Affiliated institution\*1  Department\*1  Position\*1 | Current field of specialization  Degree (final academic background)  Year degree acquired  Responsibilities within each R&D project | FY2020  research costs\*2  (Unit: 1000 yen) | Effort (%) |
| R&D Principal Investigator | *XXXX (XX)*  *12345678* | *XX University* | *XXX* | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* | *Ph. D (XXX)*  *(XX University)*  *2002* |
| *XXX* | *XXX* |
| *Same as above* |  | *(Main place of research)*  *XX University* |  | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* |  |
| *XXX* |  |
| R&D Co-Investigator |  |  |  |  |  |
|  |  |
|  |  |
| *Same as above* |  |  |  |  |  |
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|  |  |
|  |  |
| Total: 1 person | | | Total R&D costs | *X,XXX* |  |

\*1 In the event that the affiliated institution and the main place of research are different bodies also provide details of the main place of research

\*2 Please detail direct costs with regard to research costs. **Academic Background and Professional Appointments of R&D PI**

|  |  |
| --- | --- |
| 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 positions and fields of R&D) | ----Example----  From yyyy to xxxx: Assistant Professor, Department of XXXX, WWWW University  (Researched XXXX at the laboratory of Professor Aaaa B. CCCC\*)  From yyyy to xxxx: Researcher, WWWW Laboratory  (Researched XXXX at the laboratory of Dr. Aaaa B. CCCC\*)  From yyyy to xxxx: Professor, Department of XXXX, WWWW University  (Researched WWWW)  [\*Necessary Information] |

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

|  |
| --- |
| 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-Investigator, and other project participants, 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.))

|  |
| --- |
| 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**

|  |
| --- |
| 1. For R&D Principal Investigator, 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])*

1. **Status of Research Application, Acceptance and Effort**

|  |
| --- |
| 1. Your proposal may subsequently be canceled, even if selected, if your description is inaccurate. 2. List grants from government competitive research funds and any other research subsidies (including private foundations and overseas institutions) that the R&D PI is currently receiving, applying for, or planning to apply for by program name, indicating the project title, research period, roles, annual budget and effort. Also refer to “II. 3. “Limitations on Duplicate Applications within the Program” in the Application Guidelines. 3. When you will be selected to the interview portion of the selection process, you may be asked to provide information on applications, plans, etc. submitted to other programs. |

**R&D PI: *XX XX***

**(1) Research Funds/Grants Currently Being Applied for**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of Research Funding Program/  Research Funds/Grants (Research Period/ Funding Agency) | Title of Research Project  (Name of Principal Investigator) | Role (Principal Investigator or Co-Investigator) | Research Costs (Direct Cost) for FY2020  [Amount for Entire Period]  (Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this AMED program in addition to other research funds  (Unit: 1000 yen) |
| *【R&D proposal on this form】*  *(2020～2023)* | *Study of XX*  *(XXXX)* | *Principal Investigator* | *10,000*  *[40,000]* | *40* |  |
| *Grants-in-Aid for Scientific Research (KAKENHI)/ Challenging Exploratory Research (FY2019-FY2020, JSPS)* | *Investigative research on the dependence on XX of XX and XX (XXXX)* | *Principal Investigator* | *3,000*  *[9,000]* |  | *This proposed research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding.*  *(Total amount: 9,000 )\** |
| *FY2020 XX Foundation research grant (2020, XX Foundation)* | *XX and YY research*  *(XXXX)* | *Co-Investigator* | *1,000*  Enter the total amount of the R&D project in the case of R&D PI)  *[1,000]* |  | *This proposed research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding.* |

Including receipt of already approved research costs; may be reinterpreted as necessary

**(2) Research Funds/Grants Currently Being Received (Including Funds/Grants Scheduled to Be Received)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of Research Funding Program/  Research Funds/Grants (Research Period/ Funding Agency) | Title of Research Project  (Name of Principal Investigator) | Role (Principal Investigator or Co-Investigator) | Research Costs (Direct Cost) for FY2020  [Amount for Entire Period]  (Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this AMED program in addition to other research funds  (Unit: 1000 yen) |
| *FY2019 XX Foundation research grant (2019, XX Foundation)* | *XX and YY research*  *(XXXX)* | *Principal Investigator* | *1,000*  *[1,000]* | *10* | *This proposed research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding.*  *(Total amount: 5,000 )\** |
| *XX Project (AMED, 2019 - 2021)* | *XX and YY research*  *(XXXX)* | *Co-Investigator* | *1,000*  *[5,000]* | *20* | *This proposed research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding.* |

\* In the parentheses ( ), enter the total direct expenses for the entire R&D period.

**(3) Other activities Effort: *30* %**

*・* List grants that the applicant is currently receiving, or selected, in descending order of the allocated budget (for the entire period). Subsequently, list those for which the applicant is currently applying or planning to apply (specify “submitted” or “preparing” in the “Program” column.)

・ Specify “PI” or “Co-Investigator” as “Role.”

・ Do not enter the efforts of the programs you are applying for, or planning to apply for. Enter only the efforts received or planned to receive assuming only this program is selected. Make sure that the sum of efforts for this program and awarded funds doesn’t exceed 100 %.

・ Add rows if needed.

1. **Past Research Funds/Grants Received and Resulting Achievements**

|  |
| --- |
| In this section, select the portion of the research results, etc. achieved as a result of the research funding received by the R&D Principal Investigator up to now (research funding provided by an affiliated research institution, and research costs from a ministry or agency, local governments, research grant corporation, private sector company etc., including research funding currently being received) that have been used in the drafting of the current research plan, dividing them into the research funding for the AMED program and other research funds, with consideration given to the following points.   * Be sure to separately state the results between those of the AMED programs and other research funds/grants * For each research funding, note the research funding program name, period (fiscal year), R&D project title, whether it is for the R&D Principal Investigator or the R&D Co-Investigator, and the research costs (direct costs). In addition, briefly describe also the research achievements and the results of interim and ex post evaluations (only if conducted by the institution allocating those research funding). |

**R&D PI: *XX XX***

【The AMED program】

*(1) AMED XX program, FY2009-FY2011, Research on XX, Principal Investigator, 40,000 (Thousand Yen)*

*Achievements: XXXX*

*(2) AMED XX program, FY2009-FY2011, Research on XX, Principal Investigator, 40,000 (Thousand Yen)*

*Achievements: XXXX*

【Research funds other than the above】

*(3) Grant-in-Aid for Scientific Research (B), FY2009-FY2011, Research on XX, Principal Investigator, 40,000(Thousand Yen)*

*Achievements: XXXX*

(Annex P1)

**Main Schedule for R&D**

|  |
| --- |
| 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) 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. |

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

(Annex P2)

**R&D Project Organization (R&D PI’s Group)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **R&D PI** | **Research institution** | **Position** | **The content that the R&D PI will be in charge of under this proposal** | **Effort**  **(%)** |
| *XX XX* | *Department of \*\*\*, Graduate School of \*\*\*, \*\*\* University* | *Professor* |  | *40* |
| **Project participants** | **Affiliation (Omit if the same as above)** | **Position** | **The content that the project participants will be in charge of under this proposal** | **Effort**  **(%)** |
| *XX XX* |  | *Associate Professor* |  |  |
| *XX XX* |  | *Lecturer* |  |  |
| *XX XX* | *\*\*\* Laboratory, \*\*\* Co., Ltd.* | *Principal Researcher* |  |  |

*If your R&D project is selected, but you will be performing the research at a facility other than your current affiliated institution, specify the name of the institution at which the research will be conducted. Also please inform us of the situation on Annex P4. Please also refer to FAQ.*

* **Approval of the affiliated institution for proposing R&D project:** □ Obtained

Please obtain the approval and mark the check box black (■), according to “IV. 2. (3) Notes on Preparing Proposals” in the Application Guidelines.

* **Ownership of intellectual property right:** □ I hope

After referring to “VII. Handling of R&D Accomplishments” in the Application Guidelines, please mark the check box black (■) if you hope to own intellectual property rights created in this R&D project to the affiliated institution, under committing the conditions that you shall comply the four items stipulated in Paragraph 1 of Article 19 of Industrial Technology Enhancement Act, with replacing “the national government” with AMED, that you shall report inventions, etc. created in this R&D project without delay, by using the form designated by AMED, and that you shall reply any surveys about intellectual property right executed by AMED.

If you won’t hope to own the rights, please describe the reasons.

* **Note**

*When special duties (managerial positions, such as the dean, chairperson of an academic society, etc.) involve working hours (effort), explain the situation and reason.*

(Annex P3)

**Ethical Considerations**

**1．****Laws and Guidelines Applicable to the Research**

Select all required laws and guidelines to be observed for implementing the R&D project and mark the check box black (■).

□ Act to Ensure Safety in Regenerative Medicine

□ Ethical Guidelines for Medical and Health Research Involving Human Subjects

□ Ethical Guidelines for Human Genome/Gene Analysis Research

□ Guidelines for Gene Therapy Clinical Research

□ Fundamental Guidelines for the Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions

□ Other guidelines, etc. (Guideline name: )

**2．Clinical Research Planned During this R&D Project**

Select “Yes” or “No” for the planned clinical research and mark the associated checkbox black (■).

□ Yes

□ No

\* If “Yes,” enter the prospective details of the plans and dates in the following table

|  |  |
| --- | --- |
| Target illness | Details and period |
|  |  |
|  |  |
|  |  |

**3．Protection of Human Rights and Compliance with Laws and Regulations**

*Specify the measures and actions you will take if your research involves compliance with related laws and regulations (e.g. research requiring the consent and cooperation of the other party when implementing the research plan, research requiring consideration of the handling of personal information, and research requiring efforts regarding Security Export Control, bioethics and safety measures.)*

*This applies to surveys, research, experiments requiring an approval procedure in an ethics committee within and outside the research institution, e.g. questionnaire surveys in which personal information is involved, interview surveys, the use of provided samples, analytical study of the human genome, recombinant DNA experiments, experiments on animals, etc. Please indicate where this is not applicable.*

(Annex P4)

**References and Additional Statements**

Use a font size of 10.5 points or larger and do not exceed one A4-size sheet.

* **References**

|  |
| --- |
| 1. Reference information is not required. 2. Specify two researchers who well recognize the R&D project (You may choose foreign researchers). Enter name, affiliation, contact information (telephone number/ e-mail address), respectively. During the period of review (ex-ante evaluations), members of the Project Evaluation Panel may make inquiries about the R&D projects. |

References for the R&D project

1. Hanaki Iryo, Professor, Department of YYYY, ZZZZ University, 03-XXXX-YYYY, [ZZZZZ@YY.jp](mailto:ZZZZZ@YY.jp)
2. Hanako Iryo, ZZZZZZ University, Department of YYYYYY, Professor, +1-XXX-YYY-ZZZZ, ZZZZZZ@YY.jp

* **Additional Statements**

*・Write why you are applying to the Advanced Research and Development Programs for Medical Innovation, your R&D ambitions, special awards that should be noted, explanation for specific terms used in the proposal, plans to transfer and reasons and other information freely and as required.*

*・When your current affiliation and the organization where you plan to conduct the R&D project are not the same, specify the latter organization.*

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