(Form P)

**FY2018 Advanced Research and Development Programs for Medical Innovation**

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

|  |  |
| --- | --- |
| Title of proposed R&D project | *Study of ○○* |
| R&D Area (Type) | *Enter R&D Area* (PRIME) |
| R&D Period | Oct. 1st 2018 ~ *Mar. 31th 2022*  (*3.5* years) |
| Area |  |
| Discipline |  |
| Research Field |  |
| Research fieldKeyword |  |
| Keyword |  |
| Name of R&D PI | (Japanese) |  |
| (English) | *Mr./Ms. Yyyy Yyyyyy* |
| Affiliated Institution | *○○○○University* |
| Address | 〒*XXX-XXXX* |
| Phone Number | *XX-XXXX-XXXX* | FAX Number | *XX-XXXX-XXXX* |
| E-mail | *YYY@YY.jp* |
| Section | *○○○○* |
| Title | *○○○○* |
| Person in charge of accounting work | *○○ ○○* | Accounting department name, contact information etc. |  |
| R&D Co-Investigator\* | （Japanese） |  |
| （English） |  |
| Affiliated Institution |  |
| Address | 〒 |
| Phone Number |  | FAX Number |  |
| E-mail |  |
| Section |  |
| Title |  |
| Person in charge of accounting work |  | Accounting department name, contact information etc. |  |

Academic Background and Professional Appointments of R&D PI

|  |  |
| --- | --- |
| Academic Background(since University) | ----Example----<Undergraduate Institution>yyyy (year of completion): Department of XXXX, YYYY University<Graduate Institutions>Master’s Course: yyyy (year of completion): Faculty of WWWW, Department of XXXX, YYYY University (Supervisor: Prof. Wwww Y. XXXX)[Necessary Information]Doctor’s Course: yyyy (year of completion): Faculty of WWWW, Department 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 (working on XXXX at the Laboratory of Professor Aaaa B. CCCC\*)From yyyy to xxxx: Associate Professor, Department of Medicine, WWWW University (working on WWWW at the Laboratory of Professor Aaaa B. CCCC\*)From yyyy to xxxx: Associate Professor, Department of Medicine, WWWW University (working on WWWW at the Laboratory of Professor Aaaa B. CCCC\*)*[\*Necessary Information]* |

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

|  |
| --- |
| 1. Use font size of 10.5 point or larger. If these instructions are not followed, the research proposal may not be accepted.
2. In this section, make effective references to the descriptions of achievements listed in “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) achievements of applicant (and preliminary evidence) and 3) R&D concepts and plans.
 |

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. **Backgrounds**

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 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 State of Similar Studies Worldwide**

Specify 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**

Specify the expected creation of scientific and technological innovation, creation of seeds for medical applications, contributions to the society, and acquiring and enforcement of intellectual property, which are likely to be realized in future, if successfully achieving the “1. I. Targets and Objectives”.

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**2. R&D Plans and Approach** (Do not exceed two A4-size sheets (no exceptions.))

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| 1. Clarify the R&D approaches taken to achieve “1. I. Target and Objectives,” potential problems and solutions, as well as alternative approach in cases of failing to obtain expecting results during the R&D period with certain milestones including criteria for judging the achievement level and time periods on the way of the R&D.
2. Clearly show the goals to be achieved within three years of commencing the R&D (This is one of the bases for interim evaluation etc.).
3. It is possible to specify them for every R&D subject.

Relating to intellectual property and others including applications, licensing and management, assumed during making the plans of the R&D, specify the followings: 1) Relevant intellectual property rights owned by the applicants, and 2) Strategy to acquire intellectual property rights during the course of the R&D.Refer to notes in “1. Research Objectives.” |

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**3. Research Achievements**

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| 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 them 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, and any policy recommendations that have been made as a result of the 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＞

＜Policy recommendations＞

**4. 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 and/or R&D Co-Investigators are 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：*○○ ○○***

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| **Program** | **Status** | **Project title**(**Name of PI**) | **Research****Period** | **Role****(PI or Co-****Investigator)** | **(1) Allocated Budget****(For the entire period)****(2) FY 2019 (planned)****(3) FY 2018 (planned)****(4) FY 2017****(Unit: Thousand Yen)** | **Effort****(%)** |
| AMED Advanced Research & Development Programs for Medical Innovation(AMED-CREST/ PRIME) | Submitted |  | *40* |
| *Grants-in-Aid for Scientific Research, Fundamental research (S)* | *Awarded* | *Creating W by V (\*\* \*\*)* | *2016.4 -**2020.3* | *PI* | (1) *100,000 T Yen*(2) *25,000 T Yen*(3) *25,000 T Yen*(4) *5,000 T Yen* | *20* |
| *ALCA, JST Strategic Basic Research Programs* | *Submitted* | *Achieving high performance in X by Y (\*\* \*\*)* | *2018.4 -**2024.3* | *Co-**Investigator* | (1) *140,000 T Yen*(2) *35,000 T Yen*(3) *8,000 T Yen*(4) - | *25* |

* 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.)
* Type “Awarded” if currently awarded or a decision has been made to award, and type “Submitted” for any other status.
* Specify “PI” or “Co-Investigator” as “Role.”
* Enter the amount of allocated budget to the applicant.
* 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.

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

|  |
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| In this section, select the portion of the research results, etc. achieved as a result of the research costs received by the Principal Investigator up to now (research costs provided by an affiliated research institution, and research costs from an office or ministry, local government organization, research grant corporation, private sector company etc., including research costs currently being received) that have been used in the drafting of the current research plan, dividing them into the research costs for this financing system and other research costs, with consideration given to the following points.* + For each research cost, note the research funding program name, period (fiscal year), research project title, whether for the Principal Investigator and the research costs (direct costs), and then briefly describe the research achievements and the results of interim and ex post evaluations (only if conducted by the institution allocating those research costs).
	+ Be sure to distinguish the research costs for this funding system from other research costs.
 |

*(Example)*

*Name of financing system:*

*Period (FY): FY \_\_\_\_\_ ～ FY\_\_\_\_\_\_*

*Name of R&D project :*

*Principal Investigator or Co-Investigator:*

*R&D costs (direct costs): \_\_\_\_\_\_\_\_\_\_ (Unit: Thousand Yen)*

*Research achievements and results of interim / ex post facto evaluation:*

*【Funding system】*

1. *Basic research (A), 2009 ～ 2011, “Research on XX” Representative, 40,000 (Thousand Yen)*

*Achievements: ××××*

1. *Basic research (B), 2009 ～ 2011, “Research on XX” Representative, 40,000 (Thousand Yen)*

*Achievements: ××××*

*【Other research costs】*

1. *Basic research (B), 2009 ～ 2011, “Research on XX” Representative, 40,000 (Thousand Yen)*

*Achievements: ××××*

(Annex P1)

**Breakdown of Costs for Each Fiscal Year** (Unit: Thousand Yen)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Main item | Sub items | FY2018 | FY2019 | FY2020 | FY2021 | Total |
| Direct Cost | 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 |  |  |  |  |  |
| Direct Cost Total |  |  |  |  |  |
| Indirect costs(In general, 30% of direct costs) |  |  |  |  |  |
| Subcontract Cost | 0 | 0 | 0 | 0 | 0 |
| Total |  |  |  |  |  |

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| 1. Enter the “R&D Funding Amount by Items of Expenditure” by fiscal year. Appropriate the total amount of the expenditures (including indirect cost) of subsidiary institutions to which a subcontract will be concluded. Indirect cost is 30% of R&D cost (direct cost).
2. After selected, the R&D Funding Amount of a project may be reviewed during the R&D Period, in accordance with status of the total budget for this program, management made by PS and PO of the R&D Area, and results of the R&D project evaluations, and others.
 |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name (age)Researcher ID No. | Affiliated institutionDepartmentPosition | Current professionalDegree (final academic background)Responsibilities within each R&D project | FY2018research costs(Unit: Thousand Yen) | Effort (%) |
| R&D Principal Investigator | *XXXX (XX)**12345678* | *XXXX University* | *XXX* | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* | *Ph. D (XXX)*(*XX University)* |
| *XXX Director* | *XXX* |
| R&D Co-Investigator |  |  |  |  |  |
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| Total *XX* People | Total R&D Cost  | *X,XXX* |  |

(Annex P2)

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

Enter information in concert with the items described in the section (d) of “III. 3. (2) Review Criteria and Perspectives in Evaluating Projects,” illustrated in Application Guidelines.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **R&D PI** | **Research Institution** | **Title** | **R&D charged in this proposal** | **Effort****(%)** |
| *○○ ○○* | *Department of \*\*\*, Graduate School of \*\*\*, \*\*\* University*  | *Professor* |  | *40* |
| **R&D****members** | **Affiliation (Omit if the same as above)** | **Title** | **R&D charged in this proposal** | **Effort****(%)** |
| *○○ ○○* |  | *Associate Professor* |  | *5* |
| *○○ ○○* |  | *Lecturer* |  | *15* |
| *×× ××* | *\*\*\* Laboratory, \*\*\* Co., Ltd.* | *Principal Researcher* |  | *20* |

*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 J6. 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 as (■), 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 as (■) 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.

*Please regulate ownership of intellectual property right created in subsidiary institution which is subcontracted with principal institution, when concluding subcontracted R&D agreement.*

**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.*

**R&D subjects and overview**

* **Title of R&D subjects in charge**

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* **Objective and overview**

Provide a brief overview of the R&D subjects to be overseen by the R&D PI’s Group.

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* **R&D subjects, milestone and R&D measures**

 Please specify briefly the R&D subjects performed by the R&D PI’s group, milestones (achievement steps to be completed during the R&D period) and measures for achievement.

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* **Role in the entire R&D project**

Specify the role which the R&D PI’s group plays in realizing the proposed R&D project.

*○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.*

*○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.*

 (Annex P3)

**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 achieve1. Enter the schedule and R&D researchers in charge by R&D item.

Enter information within one A4-size sheet. |

|  |
| --- |
| **Main schedule for R&D (roadmap)** |
| R&D item Milestone | Name of person in charge | 1st Year(FY2018) | 2nd Year(FY2019) | 3rd Year(FY2020) | 4th Year(FY2021) |  |  |
|  |  | H1 | H2 | H1 | H2 | H1 | H2 | H1 | H2 |  |  |  |  |
| (1) *Analysis of XX related gene manifestation**・Establishment of assay system**・Analysis of manifestation data* | *PI* |  | *■* | *■* | *■* | *■**■* | *■**■* | *■* | *■* |  |  |  |  |
| (2) | *Co-Investigator* |  |  |  | *■* | *■**■* | *■**■* | *■**■* | *■**■* |  |  |  |  |
| (3)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7) |  |  |  |  |  |  |  |  |  |  |  |  |  |

(Annex P4)

**Ethnic Considerations**

**1. Laws and guidelines applicable to the research**

Select all required laws and guidelines for implementing the R&D project and mark the check box as (■) appended for the guideline.

□ 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 as (■).

□ 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 P5）

**References and Additional Statement**

Use font size of 10.5 point 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.
3. When there are some researchers who are in a direct competitive relationship as for the R&D project and you would like to avoid being reviewed by them, enter the information of up to three of such researchers. Still when it is deemed to be necessary, those researchers may be involved in the review process.
 |

References for R&D project

1. *Hanaki Iryo, Professor, Department of YYYY, ZZZZ University, 03-XXXX-YYYY,* *ZZZZZ@YY.jp*
2. *Haruko Iryo, Professor, Department of XXXX, University of WWWW, +1-xxx-yyy-wwww, RRRR@JJ.us*

Researchers in a competitive relationship

1. *Taro Iryo, Professor, Department of UUUU, University of EEEE, 03-xxxx-yyyy, zzzz@YY.jp*
2. *Jiro Iryo, Professor, Department of yyyy, University of KKKK, +33-xxxx-yyyy-zzzz, tttt@KK.uk*
3. *Saburo Iryo, Associate Professor, Department of SSSSS, University of YYYY, +1-eeee-ffff-ssss, UUUU@FF.fr*

**Additional Statement**

* *If the participation of overseas R&D Co-Investigator’s group(s) is planned, specify the reasons and necessities (please refer to “II. 2. Requirements for Organizing a R&D Project” in the Application Guidelines).*
* *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.*

*○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.*