(Form 1)

**FY 2017 Advanced Research and Development Programs for Medical Innovation**

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

Paragraphs in blue are instructions or examples, so please delete them when preparing this form.

|  |  |
| --- | --- |
| R&D Area |  |
| Type | Please specify unit-type (AMED-CREST) or solo-type (PRIME) |
| Title of proposed R&D project |  |
| Name of R&D PI |  |
| Affiliated Institution, Section, Title |  |
| Researcher ID No. | Enter the 8-digit “e-Rad” login ID provided by registering researcher information onthe e-Rad system (http://www.e-rad.go.jp/.) |
| Academic Background | List the applicant’s undergraduate and graduate education as indicated below:Year: Undergraduate Institution, Major Degree, SupervisorYear: Graduate Institution, Major Degree, Supervisor |
| Professional Appointments | List, in chronological order, all academic/professional appointments of the applicant; finishing with the current appointment. Include the names of project leaders or supervisors who have occupied a mentoring position for the given appointment.Research PeriodEnter the starting and ending time periods (month and year) of the proposed research project. |
| R&D Period | Enter the starting and ending time periods (month and year) of the proposed R&D project.The starting period of the awarded projects is October 2017 or later.[mm. yy] – [mm. yy] |
| Total R&D Budget | Total Budget: \_\_\_\_\_\_\_\_\_\_ thousand yen (including indirect costs) |

・Please prepare this form within one A4-size sheet

・The ending time period of AMED-CREST can be set within five years and six months (prior to March 31, 2023 at the longest.) The ending time period of PRIME can be set within three years and six months (prior to March 31, 2021 at the longest.)

(Form 2)

**R&D Proposal Overview**

**1. Outline of the R&D Project**

・Provide an overall description of the R&D proposal within one A4-size sheet (no exceptions.) Use font size of 10.5 point or larger (If these instructions are not followed, the research proposal may not be accepted.)

*Do not exceed one A4-size sheet (no exceptions)*

(Form 3)

**R&D Project Plan**

・Do not exceed seven A4-size sheets (no exceptions.) Use font size of 10.5 point or larger (If these instructions are not followed, the research proposal may not be accepted.)

・In the Form 3, make effective references to the descriptions of achievements listed in Forms 8 and 9 to clarify the relationship between the achievement and the research being proposed by the applicant.

・Please specify clearly 1) the background of the R&D concept (necessity and importance of the research), 2) achievement of applicant and preliminary evidence and 3) R&D concept and plan.

**1. Target and Objectives**

・Objectives and goals of the proposed R&D project (expected achievements), and

・Significance in terms of outcome resulting directly from the abovementioned achievements.

**2. 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.

**3. R&D Plans and Approach**

Specify the plans of the proposed R&D project.

・Clarify the R&D approaches taken to achieve “1. Target and Objectives,” potential problems and solutions, alternative approach in cases of failing to obtain expecting results, and milestones during the R&D period with criteria for judging the achievement level.

・In AMED-CREST, clearly show the goal to be achieved within three years of commencing the R&D. This is one of the bases for interim evaluation.

・It is possible to specify them for every R&D subject.

・Strategy to acquire intellectual property rights. Specify relevant intellectual property rights owned by the applicants.

(Continued on the next page)

(Form 3 cont.)

(Continued from the previous page)

**4. R&D Fundamentals and Preparation**

Specify following fundamental things etc. to promote the proposed R&D project;

・Relevant projects conducted previously and personal research achievements (and those of other collaborating researchers, as required)

・Other preliminary knowledge, experimental evidence, etc. to support the R&D concept (if any)

・For proposals to AMED-CREST, please specify the content corresponding to “III. 3. (2) Selection Standards” in the Application Guidelines.

**5. Originality and Novelty of the Proposed R&D and Comparison to the Current State of Similar Studies**

Taking into account the research situation and trends, present the originality and novelty of the proposed R&D project and its advantages over others.

**6. Future R&D Prospects**

Specify the expected creation of scientific, technological, and medical innovation, acquiring and enforcement of intellectual property, and contributions to society, etc., likely to be realized in future, if successfully achieving the “1. Target and Objectives” in the Form 3.

**7. Timetable of R&D project**

*Do not exceed seven A4-size sheets (no exceptions)*

Please insert marks on each period when running subject.

|  |
| --- |
| Timetable of the R&D |
| Subject | Researcher in charge | 1st year(FY 2017) | 2nd year(FY 2018) | 3rd year(FY 2019) | 4th year(FY 2020) | 5th year(FY 2021) | 6th year(FY 2022) |
|  |  | First half | Latter half | First half | Latter half | First half | Latter half | First half | Latter half | First half | Latter half | First half | Latter half |
| (1) *Analysis of ○○**・MS of △△**・Synthesis of □□* | *○○ ○○* |  | *■* | *■* | *■* | *■**■* | *■**■* | *■* | *■* | *■* | *■* | *■* | *■* |
| （2）*Identification of ○○**・LC-MS of △△**・Prep of □□* | *△△ △△* |  |  |  | *■* | *■**■* | *■**■* | *■**■* | *■**■* | *■**■* | *■* | *■* | *■* |
| (3)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7) |  |  |  |  |  |  |  |  |  |  |  |  |  |

(Form 4)

**Organization Chart**

・In PRIME or if there is no R&D Co-Investigator in AMED-CREST, this form is not needed to be specified.

・Enter the R&D organization and the state of the conclusion of a contract. Example entries are shown below.

Rectangle: R&D PI group

Square with round corners : R&D Co-Investigator group (University etc.)

Ellipse : R&D Co-Investigator group (company)

Double arrow : Transfer of samples and information etc. and cooperation (specify the content)

・Please specify within one page.

|  |
| --- |
| 【Example】Supply of xx dataDevelopment of ○○ instrumentAnalysis of ○○Supply of ○○Supply of ○○Supply of data on ○○ProcessingProcessingR&D Co-InvestigatorAffiliation NameSubject「xxxxxxx」R&D Co-InvestigatorAffiliation NameSubject「xxxxxxx」R&D PIAffiliation NameSubject「xxxxxxx」  |

(Form 5)

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 Form 13 below. Please also refer to FAQ.

“Effort” indicates the percentage of time required by a researcher to engage in research when his/her total annual work hours is taken as 100%. “Total work hours” refers to overall substantial work time, including education, medical care and other activities and not only the time spent on research activities.

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

Please obtain the approval and mark the check box (□), according to “IV. 2. (3) Notes on preparing R&D 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 (□) 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.

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・In PRIME or if there is no joint researcher in AMED-CREST, this page is not needed to be specified.

* **R&D subjects and overview**

・**Title of R&D subjects in charge**

・**Objective and overview**

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

・**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.

・**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.

(Form 6)

**R&D Project Organization (R&D Co-Investigator’s Group)**

・In PRIME or if there is no joint researcher in AMED-CREST, this form is not needed to be specified.

・In AMED-CREST, please specify this Form 6, if Co-Investigator groups are necessary for the research plan. It is not mandatory to have Co-Investigator groups in the research unit.

・Although there is no maximum limit on the number of Co-Investigator groups, ensure a necessary and sufficient number of groups are present to execute the R&D PI’s research idea. If the R&D PI does not play a leading role, or if the assigned tasks of Co-Investigator groups are unclear, the unit framework is inappropriate.

・Add or delete rows to/from the table as required for the number of groups.

・Please specify the content corresponding to “III. 3. (2) Selection Standards” in the Application Guidelines.

**R&D Co-Investigator’s Group (1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **R&D Co-Investigator** | **Research Institution** | **Title** | **R&D charged in this proposal** | **Effort****(%)** |
| ○○ ○○(Researcher ID No.) | \*\*\* Team, \*\*\* Department, \*\*\* Laboratory(Institution ID: \*\*\*\*\*\*\*\*) | TeamLeader |  | 10 |
| **R&D****members** | **Affiliation** (Omit if the same as above) | **Title** | **R&D charged in this proposal** | **Effort****(%)** |
| ○○ ○○ |  | Principal Researcher |  | 5 |
| ○○ ○○ |  | Researcher |  | 15 |
| Will hire 2R&D members |  | Research Fellow |  | 100 |

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

Please obtain the approval and mark the check box (□), according to “IV. 2. (3) Notes on preparing R&D proposals” in the Application Guidelines.

(Continued on the next page)

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* **R&D subjects and overview**

・**Title of R&D Co-Investigator’s subjects in charge**

・**Objective and overview**

Provide a brief overview of the R&D subjects to be overseen by this R&D Co-Investigator’s group.

・**R&D subjects, milestones and R&D measures**

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

・**Role in the entire R&D project**

Specify the role which this R&D Co-Investigator’s group plays in realizing the proposed R&D project.

 (Form 7)

**Budget Plan**

・In PRIME, this form is not needed to be specified.

・Prepare the budget plan and sort it by items and groups for each year. Indirect costs are 30 % of total direct costs.

・A more detailed budget plan will be requested when the proposal proceeds to the interview.

・The budget plan, after adoption, may be revised during the R&D period according to the state of the project, R&D Area policy and project evaluation, etc.

* **R&D Budget plan by item (entire team)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1st year**(Oct. 2017 - Mar. 2018) | **2nd year**(Apr. 2018 - Mar. 2019) | **3rd year**(Apr. 2019 - Mar. 2020) | **4th year**(Apr. 2020 - Mar. 2021) | **5th year**(Apr. 2021 - Mar. 2022) | **Final year**(Apr. 2022 - Mar. 2023) | **Total (thousand yen)** |
| **Equipment** | 20,000 | 40,000 | 0 | 0 | 0 | 0 | 60,000 |
| **Supplies** | 20,000 | 40,000 | 30,000 | 30,000 | 20,000 | 20,000 | 160,000 |
| **Travel** | 1,000 | 2,000 | 2,000 | 2,000 | 2,000 | 1,000 | 10,000 |
| **Personnel and Services** | 6,000 | 12,000 | 12,000 | 12,000 | 12,000 | 6,000 | 60,000 |
| **Other** | 10,000 | 0 | 0 | 0 | 0 | 0 | 10,000 |
| **Indirect costs** | 17,100 | 28,200 | 13,200 | 13,200 | 10,200 | 8,100 | 90,000 |
| **Total (thousand yen)** | 74,100 | 122,200 | 57,200 | 57,200 | 44,200 | 35,100 | 390,000 |

○**Note**

・Be thoughtful in your budget allocation to optimize each item and ratios.

・When “Personnel and Services” exceeds 50% of the total budget, or when either “Supplies” or “Travel” exceeds 30%, justify it by providing detailed cost estimation and additional information herein.

 (Continued on the next page)

 (Form 7 cont.)

(Continued from the previous page)

* **R&D Budget plan by group**

・Organize an optimal R&D unit with necessary and sufficient number of groups. The appropriateness of budget allocations to R&D Co-Investigator’s groups and cost performance will be a key consideration during the selection process.

・Values of R&D costs should include indirect costs.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1st year**(Oct. 2016 - Mar. 2017) | **2nd year**(Apr. 2017 - Mar. 2018) | **3rd year**(Apr. 2018 - Mar. 2019) | **4th year**(Apr. 2019 - Mar. 2020) | **5th year**(Apr. 2020 - Mar. 2021) | **Final year**(Apr. 2021 - Mar. 2022) | **Total** **(thousand yen)** |
| **R&D PI****Group** | 26,000 | 52,000 | 32,500 | 32,500 | 26,000 | 19,500 | 188,500 |
| **R&D Co-****Investigator Group1** | 26,000 | 39,000 | 13,000 | 13,000 | 6,500 | 6,500 | 104,000 |
| **R&D Co-****Investigator Group2** | 22,100 | 31,200 | 11,700 | 11,700 | 11,700 | 9,100 | 97,500 |
| **Total** **(thousand yen)** | 74,100 | 122,200 | 57,200 | 57,200 | 44,200 | 35,100 | 390,000 |

* **List of major equipments costing 5 million yen or more (name of item, estimated cost**)

Expensive and versatile equipment/instrument to be purchased in this program should be considered to apply to the sharing system for research equipment/instrument defined in your research institution. If you are selected to the interview, you will be asked for the status of sharing in “Supplemental Information” form. For details, please refer to “Supplemental Information 2-(4)”.

(Example)

○○ group

|  |  |
| --- | --- |
| △△△△△△△△△△ | 15,000 T yen (thousand yen) |
| △△△△△△△△△△ | 5,000 T yen |
| △△△△△△△△△△ | 10,000 T yen |

○○ group

|  |  |
| --- | --- |
| △△△△△△△△△△ | 7,000 T yen |
| △△△△△△△△△△ | 10,000 T yen |

(Form 8)

**List of Achievements/Ex-Post Evaluation Results (R&D PI)**

**1. Principal Papers, Books and Other Publications Related to this R&D Proposal**

・List a maximum of 20 principal papers, books and other publications related to this R&D proposal, starting from the most recent to the past, in reverse sequence of the year of publication.

・Follow the format below when listing research papers (For books, adhere to this format.) The item sequence is not fixed.

・Place an asterisk (\*) at the start of the title of the papers referred to in Form 3.

Author(s) (all authors), title, title of journal/book, volume and page numbers and published year.

**2. Major Research Papers/Publications Other than the Above**

・In addition to No. 1 above, list a maximum of other 20 principal papers, books and other publications of the R&D PI, starting from the most recent to the past and in reverse sequence of the year of publication.

・Follow the format below when listing research papers (For books, adhere to this format.) The item sequence is not fixed.

Author(s) (all authors), title, title of journal/book, volume and page numbers and published year.

**3. Results of Ex-Post Evaluations of the Research Project served as Principal Investigator of Competitive Research Funding Programs and so on (only those open to the public after FY2013.)**

・Please specify the following:

Names of competitive research funding programs and so on, name of the research projects and URLs of ex-post evaluations (If opened)

(Form 9)

**List of Achievements (R&D Co-Investigator(s))**

・In PRIME or if there is no R&D Co-Investigator in AMED-CREST, this form is not needed to be specified.

・List selected publications of the R&D Co-Investigator, in reverse-chronological order, which are mainly considered relevant to the proposed R&D project and published in recent years. Do not exceed ten papers for each R&D Co-Investigator.

・Follow the format below when listing research papers (For books, adhere to this format.) The item sequence is not fixed.

Author(s) (all authors), title, title of journal/book, volume and page numbers and published year.

(Form 10)

**Patent List (R&D PI and R&D Co-Investigator(s))**

* **Major patents**

List important patent applications of recent years that are considered related to this proposal. Do not exceed one page.

Application number, inventor, title of invention, applicant and date of application

・**R&D PI**

・**R&D Co-Investigator(s)**

・In PRIME or if there is no R&D Co-Investigator in AMED-CREST, this section is not needed to be specified.

(Form 11)

**Information on Other Supports**

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” in the Application Guidelines.

**(Note)**

**・Your proposal may subsequently be canceled, even if selected, if your description is inaccurate.**

**・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:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Program** | **Status** | **Project title**(**Name of PI**) | **Research****Period** | **Role****(PI or Co-****Investigator)** | **((1) Allocated Budget****(For the entire period)****(2) FY 2018 (planned)****(3) FY 2017 (planned)****(4) FY 2016** | **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 (\*\* \*\*) | 2015.4 -2019.3 | 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 (\*\* \*\*) | 2017.4 -2023.3 | Co-Investigator | (1) 140,000 T yen(2) 35,000 T yen(3) 8,000 T yen(4) - | 25 |

・List grants that the proposer is currently receiving, or selected, in descending order of the allocated budget (for the entire period). Subsequently, list those for which the proposer 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 directorship or allocated work as “Role.”

・Enter the amount of allocated budget (direct cost.)”

・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.

(Continued on the next page)

(Form 11 cont.)

(Continued from the previous page)

・In PRIME or if there is no R&D Co-Investigator in AMED-CREST, this section is not needed to be specified.

**R&D Co-Investigator (1):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Program** | **Status** | **Project title**(**Name of PI**) | **Research****Period** | **Role****(PI or Co-****Investigator)** | **(1) Allocated Budget****(For the entire period)****(2) FY 2018 (planned)****(3) FY 2017 (planned)****(4) FY 2016** | **Effort****(%)** |
| AMED Advanced Research & Development Programs for Medical Innovation (AMED-CREST/PRIME) | Submitted |  | 10 |
| Health and Labour Sciences Research Grants | Awarded | Real world research for Z development(\*\* \*\*) | 2015.4 -2019.3 | PI | (1) 50,000 T yen(2) 20,000 T yen(3) 20,000 T yen(4) 5,000 T yen | 10 |
|  |  |  |  |  | (1)(2)(3)(4) |  |

**R&D Co-Investigator (2):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Program** | **Status** | **Project title**(**Name of PI**) | **Research****Period** | **Role****(PI or Co-****Investgator)** | **(1) Allocated Budget****(For the entire period)****(2) FY 2018 (planned)****(3) FY 2017 (planned)****(4) FY 2016** | **Effort****(%)** |
| AMED Advanced Research & Development Programs for Medical Innovation (AMED-CREST/PRIME) | Submitted |  | 5 |
| X Foundation/Y Research grant | Awarded | Aggressive research in the field of Y(\*\* \*\*) | 2016.4 –2018.3 | PI | (1) 2,000 T yen(2) 0 yen(3) 1,000 T yen(4) 1,000 T yen | 15 |
|  |  |  |  |  | (1)(2)(3)(4) |  |

(Form 12)

**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 (□) 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.

□ 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. Moreover, in the case of foreign R&D Co-Investigator group in R&D unit, make sure to describe the state how the regulation involved in the Security Export Control is arranged for the foreign R&D Co-Investigator group and domestic R&D Co-Investigator group.

Please indicate where this is not applicable.

(Form 13)

**References and Additional Statement**

**○ References**

Provide the names of two individuals with good knowledge of your R&D Project (non-Japanese person(s) are acceptable). Provide names of the reference persons, institutions and contact information (phone numbers and e-mail addresses). The evaluators (PS, PO, and R&D Area advisors) may contact them regarding the R&D proposal during the selecting process. Providing this reference information is not mandatory.

**○ 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 Research Institutions” 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. Do not exceed one A4-size sheet.