(Form E2)

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

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

|  |  |
| --- | --- |
| Title of proposed R&D project | *Study of ○○* |
| R&D area (Type) | *Enter R&D Area* (AMED-CREST) |
| R&D period | Oct. 1st 2019 ~ *Mar. 31th 2025*  (*5.5* years)  |
| R&D area |  |
| R&D discipline |  |
| R&D field |  |
| Key words in R&D field |  |
| Key words other than those in R&D field |  |
| Name of R&D PI | (Japanese) |  |
| (English) | *Mr. 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* | Accounting department name, contact information etc. | *XX Section, Administration Department, XXXX University* *Tel: Fax:**E-mail:* |
| Name of R&D Co-Investigator\*  | (Japanese) | *\*Record the details of all Co-Investigators* |
| (English) | *Ms. Zzzz Zzzzz* |
| Affiliated institution | *XX 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* | Accounting department name, contact information etc. | *XX Section, Administration Department, XXXX University* *Tel: 　　Fax:**E-mail address:* |

\* Please record the details of all the Co-Investigators, and add rows as needed in accordance with the number of R&D Co-Investigators, etc.

\* 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).

**Breakdown of Costs for Each Fiscal Year**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Main item | Sub items | FY2019 | FY2020 | FY2021 | FY2022 | FY2023 | FY2024 | 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 |  |  |  |  |  |  |  |

 (Unit: 1,000 yen)

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name (age)Researcher ID No. | Affiliated institutionDepartmentPosition(If the affiliated institution and the main place of research differ, please also indicate the main place of research.) | Current field of specializationDegree (final academic background)Responsibilities within each R&D project | FY 2019research costs\*(Unit: 1000 yen) | Effort (%) |
| R&D PI | *XXXX (XX)**12345678* | *XXXX University* | *XXX* | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* | *Ph. D (XXX)**(XX University)* |
| *XXX* | *XXX* |
| *Same as above* |  | *(Main place of research)**XX University* |  | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* |  |
| *XXX* |  |
| R&D Co-Investigator | *XXXX (XX)**98765432* | *XX University* | *XXX* | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* | *Ph. D (Field of specialization)* |
| *XXX* | *XXXXX* |
| *Same as above**同上* |  | *(Main place of research)**XX University* |  | *X,XXX* | *XX* |
| *XXX Department, Faculty of XXX* |  |
| *XXX* |  |
|  |  |  |  |  |  |
|  |  |
|  |  |
|  |  |  |  |  |  |
|  |  |
|  |  |
| Total: *2 people* | Total R&D costs | *X,XXX* |  |

\* Please detail the direct costs with regard to R&D 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]  |

**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: *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 FY2019[Amount for Entire Period](Unit: 1000 yen) | Effort (%)Total amount of the R&D project (direct costs)Example: (30,000 + 20,000 (Co-Investigator)) x 6 years | 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】**(2019～2024)* | *Study of XX**(XXXX)* | *Principal Investigator* | *30,000**[180,000]* | *40* | *(Total amount: 300,000)\** |
| *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*The amount to be used by applicant themselves over the entire R&D period (direct costs, projected sum) Example: 30,000 × 6 years*[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.*Enter the total amount of the R&D project in the case of R&D PI)*(Total amount: 9,000 )\** |
| *FY2019 XX Foundation research grant (2019, XX Foundation)* | *XX and YY research**(XXXX)* | *Co- Investigator* | *1,000**[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 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 FY2019[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) |
| *FY2018 XX Foundation research grant (2018, 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, 2017 - 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.

**R&D Co-Investigator (1): *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 FY2019[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】*(2019～2024) | *Study of XX**(XXXX)* | *Co-Investigator* | *15,000**[90,000]*  | *30* |  |
| *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)*The amount to be used by the Co-Investigator over the entire R&D period (direct costs, projected sum) Example: 15,000 × 6 years | *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 )\** |
| *FY2019 XX Foundation research grant (2019, XX Foundation)* | *XX and YY research**(XXXX)* | *Co-Investigator*Enter the total amount of the R&D project in the case of R&D PI | *1,000**[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 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 FY2019[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) |
| *FY2018 XX Foundation research grant (2018, XX Foundation)* | *XX and YY research**(XXXX)* | *Principal Investigator* | *1,000**[1,000]* | *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.**(Total amount: 5,000 )\** |
| *XX Project (AMED, 2017 - 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* %**

**R&D Co-Investigator (2): *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 FY2019[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】*(2019～2024) | *Study of XX**(Principal Investigator: XX XX)* | *Co-Investigator*The amount to be used by the Co-Investigator over the entire R&D period (direct costs, projected sum) Example: 5,000 × 6 years | *5,000**[30,000]* | *20* |  |
| *Grants-in-Aid for Scientific Research (KAKENHI)/ Challenging Exploratory Research (FY2019-FY2020, JSPS)* | *Investigative research on the dependence on XX of XX and XX (Principal Investigator: 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 )\** |
| *FY2019 XX Foundation research grant (2019, XX Foundation)* | *XX and YY research**(XXXX)* | *Co-Investigator* | *1,000**[1,000]* | Enter the total amount of the R&D project in the case of R&D PI) | *This proposed research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding.* |

 **(2) Research Funds/Grants Scheduled to be Received**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 FY2019[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) |
| *FY2018 XX Foundation research grant (2018, XX Foundation)* | *XX and YY research**(XXXX)* | *Principal Investigator* | *1,000**[1,000]* | *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.**(Total amount: 5,000 )\** |
| *XX Project (AMED, 2017 - 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: *40* %**

**5. 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 Principal Investigator and Co-Investigators 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 R&D funding system and other research funds, with consideration given to the following points.* For each research funding, note the research funding program name, period (fiscal year), research project title, whether for the Principal Investigator or the Co-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 funding).
* Be sure to distinguish the research funding for the AMED R&D funding system from other research funds.
 |

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

【The AMED R&D funding system】

*(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*

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

【The AMED R&D funding system】

*(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*

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

【The AMED R&D funding system】

*(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 E2)

**Implementation System Diagram**

|  |
| --- |
| 1. There is no need to enter and submit R&D Unit Organization, when there is no Co-Investigators in the R&D Project
2. Enter R&D Unit Organization with state of progress toward agreement conclusion process. The way of description is as follows:
	1. Rectangle: R&D Principal Investigator (PI) Group
	2. Rounded Rectangle: R&D Co-Investigator Group (Universities etc.)
	3. Oval: R&D Co-Investigator Group (private enterprises)
	4. Double Arrow: Exchange of samples and information, as well as assignment of responsibility for the R&D project
3. Enter information within one A4-size sheet.
 |

【*Example*】

*Sample provision of* ***○○***

*Sample provision of* ***○○***

*Data*

*Provision of* ***○○***

*Processing*

*R&D Co-Investigator*

*Affiliation, name*

*Project name: “XXXX”*

*R&D Co-Investigator*

*Affiliation, name*

*Project name: “XXXX”*

*Principal Investigator*

*Affiliation, name*

*Project Name: “\*\*\*\*\*”*

*Processing*

*Data*

*Provision of* ***○○***

*Development of* ***○○***

*Analysis of* ***○○***

(Annex E3)

**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** | **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* |
| **R&D****members** | **Affiliation** (Omit if the same as above) | **Position** | **The content that the R&D members will be in charge of under this proposal** | **Effort****(%)** |
| *XX XX* |  | *Associate Professor* |  | *5* |
| *XX XX* |  | *Lecturer* |  | *15* |
| *XX XX* | *\*\*\* 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 E5. 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.

*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.*

*If there are no Co-Investigators it is not necessary to submit any of the items from Annex E3 so please delete them.*

* **R&D Items and Overview**

**・****Title of R&D Items in Charge**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**・****R&D Objective and Overview**

Provide a brief overview of the R&D items to be overseen by this R&D PI’s group.

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.

**・****R&D Items, Milestones and R&D Measures**

Please specify the R&D items 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 this R&D PI’s group plays in realizing the proposed R&D project.

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○.

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

|  |
| --- |
| 1. There is no need to fill out and submit this form when there are no Co-Investigators in the R&D Project.
2. When the R&D project needs to include Co-Investigator’s groups in order to accomplish its plan of the R&D, enter the information in this form. It is not mandatory to include Co-Investigator’s groups to the R&D Unit Organization.
3. Although there is no upper limit to the number of members within a Co-Investigator’s group, a R&D Unit should be an organization which consist of the optimal members necessary to and sufficient for pursuing the R&D concept of the PI. When the PI would not take a leading part in the R&D project, as well as roles and positions of Co-Investigators would not be clearly defined, the unit organization would be inappropriate.
4. Add or delete lines of the table in accordance with the numbers of the groups of the R&D project.
5. 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 Co-Investigator’s Group (1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **R&D Co-Investigator** | **Research institution** | **Position** | **The content that the R&D Co-Investigator will be in charge of under this proposal** | **Effort****(%)** |
| *XX XX**(Researcher ID No.)* | *\*\*\* Team, \*\*\* Laboratory**(Institution ID: \*\*\*\*\*\*\*\*)* | *Team**Leader* |  | *30* |
| **R&D****members** | **Affiliation**(Omit if the same as above) | **Position** | **The content that the R&D members will be in charge of under this proposal** | **Effort****(%)** |
| *XX XX* |  | *Principal Researcher* |  | *5* |
| *XX XX* |  | *Researcher* |  | *15* |
| *Will hire 2**R&D members* |  | *Research Fellow* |  | *100* |

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

Verify the consent of any subsidiary institution which is subcontracted with the principal institution and mark the check box black (■).

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

* **R&D Items and Overview**

**・****Title of Co-Investigator’s R&D Items in Charge**

○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○○

**・****Objective and Overview**

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

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**・****R&D Items, 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.

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**・****Role and Necessity in the Entire R&D Project**

Please state the reasons why this R&D Co-Investigator’s group is essential in order to achieve the R&D PI’s R&D concept, and what its role will be.

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(Annex E4)

**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. Moreover, in the case of foreign R&D Co-Investigator’s 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’s group and domestic R&D Co-Investigator’s group.* *Please indicate where this is not applicable.*

(Annex E5)

**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
2. Hanako Iryo, Professor, Department of YYYYYY, ZZZZZZ University +1-XXX-YYY-ZZZZ, ZZZZZZ@YY.jp
* **Additional Statements**
* *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.*

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