(Form E2)

**Advanced Research and Development Programs**

**for Medical Innovation, AMED**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title of proposed R&D project | | Study of XXX | | |
| R&D area (Type) | | Click here to display the dropdown menu. Press ▼ on the right side and select your R&D area. | | |
| R&D period | | Oct. 1st 2022 ~ Mar. 31th 2028 (5.5 years) | | |
| Human WGS analysis | | □will be conducted □will not be conducted  \*Mark the check box black (■) either of the above. If analysis will be conducted, submit “(Appendix E3) Human Whole Genome Sequence Analysis Protocol” | | |
| e-Rad research field (main) keywords | |  | | |
| R&D Principal Investigator | Name | IRYO M. Hanako <LAST NAME Middle name First name> | | |
|  | Affiliated institution  (official name) | XX Corporation XX University | | |
|  | Address | XXXXX, XX Town, XX City, XX Prefecture XXX-XXXX (zip code) | | |
|  | Tel | XX-XXXX-XXXX | | |
|  | E-mail | YYY@YY.jp | | |
|  | Department/Division | Department of XXX, Faculty of XXX | | |
|  | Position | XXX | | |
|  | Person in charge of accounting work | XX XX | Accounting department/division name, contact information etc. | XX Section, Administration Department,  XXXX University  Tel: XX-XXXX-XXXX  E-mail: YYY@YY.jp |
| Co-Investigator\* | Name | XXXX | | |
|  | Affiliated institution  (official name) | XX Corporation XX University | | |
|  | Address | XXXXX, XX Town, XX City, XX Prefecture XXX-XXXX (zip code) | | |
|  | Tel | XX-XXXX-XXXX | | |
|  | E-mail | YYY@YY.jp | | |
|  | Department/Division | Department of XXX, Faculty of XXX | | |
|  | Position | XX XX | | |
|  | Person in charge of accounting work | XX XX | Accounting department/division name, contact information etc. | XX Section, Administration Department,  XXXX University  Tel: XX-XXXX-XXXX  E-mail: YYY@YY.jp |

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

Note: When submitting please **delete the examples in blue and the explanations in the green speech bubbles.**

But **do not delete the instructions in black.**

**Breakdown of Costs for Each Fiscal Year**

(Unit: 1,000 yen)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Main items | | Sub items | FY2022 | FY2023 | FY2024 | FY2025 | FY2026 | FY2027 | Total |
| Direct costs | 1. Costs of goods | Equipment costs |  |  |  |  |  |  |  |
| Consumable item costs |  |  |  |  |  |  |  |
| 1. Travel costs | Travel costs |  |  |  |  |  |  |  |
| 1. Personnel costs/ services costs | Personnel costs |  |  |  |  |  |  |  |
| Services costs |  |  |  |  |  |  |  |
| 1. Other | Subcontract costs |  |  |  |  |  |  |  |
| Other |  |  |  |  |  |  |  |
| Subtotal | |  |  |  |  |  |  |  |
| Indirect costs  (In general, 30% of aforementioned direct costs) | | |  |  |  |  |  |  |  |
| Total | | |  |  |  |  |  |  |  |

\* In the case of the projects for active resource of aging animals, add entry fields as needed in accordance with the project term.

**If you are allocating more than 10 million yen per item for equipment, explain the status of shared equipment and existing facilities in the affiliated institution and state the need for the equipment.**

Name of equipment to be purchased:

Status of shared equipment and existing facilities:

Necessity:

**R&D Principal Investigator and Co-Investigator(s)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name | Affiliated institution1 | Current professional field | FY 2022  research costs2  (Unit: 1000 yen) | Effort (%) |
| Month and year of birth (age as of April 1, 2022) | Department/Division1 | Degree (final academic background)  Year degree acquired |
| Researcher ID No. | Position1 | Responsibilities within each R&D project |
| R&D Principal Investigator | XX XX | XXXX University | XXX | X,XXX | XX |
| November 1974 (XX) | Department of XXX, Faculty of XXX | Ph. D (XXX) (XX University)  2002 |
| 12345678 | XXX | Research supervision |
|  | (Main place of research)1  XXXX University |  |  |  |
| Department of XXX, Faculty of XXX |
| XXX |
| Co-Investigator | XX XX | XXXX University | XXX | X,XXX | XX |
| November 1975 (XX） | Department of XXX, Faculty of XXX | Ph. D (XXX) (XX University)  2003 |
| 98765432 | XXX | Data analysis |
|  | (Main place of research)1  XXXX University |  |  |  |
| Department of XXX, Faculty of XXX |
| XXX |
| Co-Investigator\* |  |  |  |  |  |
|  |  |  |
|  |  |  |
| Total: 2 people | | | 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 the details of the main place of research (research institution, department/division, and position).

2 Enter direct costs with regard to research costs.

\* Add rows as needed in accordance with the number of Co-Investigators.**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 XXXX)  [*\*Necessary Information*] |

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

1. Enter (1) the research funds/grants (including and regardless of whether they are from Japan or overseas, and in addition to competitive research funds, grants from private sector foundations, contracted research funds from corporations and research funds such as joint research funds; the same applying hereinafter) currently being applied for, (2) the research funds/grants currently being received and scheduled to be received and (3) other activities, of the R&D Principal Investigator and Co-Investigator(s) at the time of application, giving consideration to the points listed below. At the beginning of “(1) Research funds/grants currently being applied for”, enter this proposed R&D project.
2. For each funding program, enter the research project title, research period, role (Principal Investigator or Co-Investigator), amount of research funds/grants received by the applicant, and effort, etc. State in descending order of the amount of research funds/grants received by the applicant (for the entire period) and add entry fields as needed.
3. In the Effort column, enter the percentage of researcher’s time exclusively spent for the R&D activities concerned against the researcher’s annual working hours (100%). Do not enter the efforts of the programs you are applying for or planning to apply for in “(1) Research funds/grants currently being applied 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, awarded funds/grants and other activities doesn’t exceed 100 %.
4. Also refer to “2.3. Limitations on Duplicate Applications within the Programs” in the Application Guidelines.
5. 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.
6. Your proposal may subsequently be canceled, even if selected, if your description is inaccurate.

**R&D Principal Investigator: XX XX**

**(1) Research funds/grants currently being applied for** (as of Month Day, Year) (e.g. as of May 1st, 2022)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of research funding program/  Research funds/grants (research period/ funding agency) | Title of R&D project  (name of R&D Principal Investigator) | Role  (Principal Investigator  or Co-Investigator) | Research costs for FY 2022  (direct costs)  [amount for entire period] (Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this R&D project being solicited in addition to other research funds/grants |
| This proposed R&D project  Total amount of the R&D project (direct costs)  Example: (30,000 + 20,000 (Co-Investigator)) x 6 years  Amount expected be allocated to applicant (direct costs)  (2022–2025)  The total amount expected to be used by the applicant over the R&D period (total scheduled sum of direct costs)  Example: 30,000 x 6 years = 180,000 | Study of XXX  (XXXX) | Principal Investigator | 30,000  [180,000] | 40 | (Total amount: 300,000)\* |
| Grants-in-Aid for Scientific Research (KAKENHI)/ Challenging Research (Exploratory) (JSPS, FY2022–FY2023)  Enter the total amount, if the applicant is a Principal Investigator. | Investigative research on the dependence on XX of XX and XX (XXXX) | Principal Investigator | 3,000  [9,000] |  | The 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 )\* |
| FY2022  XX Foundation research grant (XX Foundation, 2022) | Research on XX and YY  (XXXX) | Co- Investigator | 1,000  [1,000] |  | The 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 (direct costs), if the applicant is a Principal Investigator.

**(2) Research funds/****grants currently being received and scheduled to be received** (as of Month Day, Year)

(Note: Research funds/grants of which period ends before the fiscal year when this R&D project commences are not included.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of research funding program/  Research funds/grants (research period/ funding agency) | Title of R&D project  (name of R&D Principal Investigator) | Role  (Principal Investigator  or Co-Investigator) | Research costs for FY 2022  (direct costs)  [amount for entire period](Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this R&D project being solicited in addition to other research funds/grants |
| FY 2022  XX Foundation research grant (XX Foundation, 2022) | Research on XX and YY  (XXXX) | Principal Investigator | 1,000  [1,000] | 5 | The 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 Program (AMED, 2021–2023) | Research on XX and YY  (XXXX) | Co-Investigator | 1,000  [5,000] | 10 | The 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 (direct costs), if the applicant is a Principal Investigator.

Image of “other activities” other than (1) and (2) (organization of thinking)

Education Effort: 20%

Diagnosis & treatment Effort: 10%

Social services Effort: 5%

Others (university administration etc.) Effort: 10%

**(3) Other activities**

**Effort:** 45**%**

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

**(1) Research funds/grants currently being applied for** (as of Month Day, Year) (e.g. as of May 1st, 2022)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of research funding program/  Research funds/grants (research period/ funding agency) | Title of R&D project  (name of R&D Principal Investigator) | Role  (Principal Investigator  or Co-Investigator) | Research costs for FY 2022  (direct costs)  [amount for entire period] (Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this R&D project being solicited in addition to other research funds/grants |
| This proposed R&D project  (2022–2025)  The total amount expected to be used by the Co-Investigator over the R&D period (total scheduled sum of direct costs)  Amount expected be allocated to  Co-Investigator (direct costs) | Study of XXX  (XXXX) | Co- Investigator | 20,000  [120,000]  The total amount expected to be used by the Co-Investigator over the R&D period (total scheduled sum of direct costs) | 40 |  |
| Grants-in-Aid for Scientific Research (KAKENHI)/ Challenging Research (Exploratory) (JSPS, FY2022–FY2023)  Enter the total amount, if the applicant is a Principal Investigator. | Investigative research on the dependence on XX of XX and XX (XXXX) | Principal Investigator | 3,000  [9,000] |  | The 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 )\* |
| FY2022  XX Foundation research grant (XX Foundation, 2022) | Research on XX and YY  (XXXX) | Co- Investigator | 1,000  [1,000] |  | The 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 (direct costs), if the applicant is a Principal Investigator.

**(2) Research funds/grants currently being received and scheduled to be received** (as of Month Day, Year)

(Note: Research funds/grants of which period ends before the fiscal year when this R&D project commences are not included.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Title of research funding program/  Research funds/grants (research period/ funding agency) | Title of R&D project  (name of R&D Principal Investigator) | Role  (Principal Investigator  or Co-Investigator) | Research costs for FY 2022  (direct costs)  [amount for entire period](Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this R&D project being solicited in addition to other research funds/grants |
| FY 2022  XX Foundation research grant (XX Foundation, 2022) | Research on XX and YY  (XXXX) | Principal Investigator | 1,000  [1,000] | 5 | The 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 Program (AMED, 2021–2023) | Research on XX and YY  (XXXX) | Co-Investigator | 1,000  [5,000] | 10 | The 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 (direct costs), if the applicant is a Principal Investigator.

**(3) Other activities**

**Effort:** 45**%**

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

Add entry fields as needed in accordance with the number of Co-Investigators.

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

1. In this section, select and describe the portion of the research achievements, etc. made using the research funds/grants received by the R&D Principal Investigator and Co-Investigator(s) up to now that have been used in the drafting of this research proposal (namely, research funds/grants provided by an affiliated institution, and research funds/grants from an office or ministry, local government, research grant corporation, private sector company etc., including research funds/grants currently being received), dividing them into the research funds/grants for (1) the AMED program and (2) other research funds/grants, with consideration given to the following points.
2. Be sure to separately state the achievements between those of the AMED programs and other research funds/grants.
3. For each research fund/grant, state the research funding program name, period (fiscal year), R&D project title, whether it was received as a R&D Principal Investigator or 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 funding agency allocating those research funds/grants).

**R&D Principal Investigator:** XX XX

**(1) AMED program**

(Items to be recorded)

Name of financing program:

Period (FY): FY \_\_\_\_\_–FY\_\_\_\_\_\_

Name of R&D project:

Principal Investigator or Co-Investigator:

R&D costs (direct costs): \_\_\_\_\_\_\_\_\_\_ (Unit: 1000 yen)

Research achievements and results of interim / ex-post evaluation:

* + AMED XX Program (A), 2015–2017, “Research on XX” Principal Investigator, 40,000 (1000 yen)

Achievements: XXXX

* + AMED XX Program (B), 2017–2019, “Research on XX” Principal Investigator, 40,000 (1000 yen)

Achievements: XXXX

**(2) Other research funds/grants**

* + Basic research (B), 2014–2016, “Research on XX” Principal Investigator, 40,000 (1000 yen)

Achievements: XXXX

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

**(1) AMED program**

**(2) Other research funds/grants**

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

**(1) AMED program**

**(2) Other research funds/grants**

(Annex E2)

1. Draw an implementation system diagram showing the organizations (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) of Principal Institution and Subsidiary Institution(s), frameworks, collaboration and cooperation structures, etc.
2. The diagram should clearly show the roles of each institution. Also describe the frameworks and methods for R&D project administration, promotion and progress management, etc. The way of description is as follows:
3. Rounded rectangles: Universities etc. R&D Principal Investigator Group, R&D Co-Investigator Group
4. Oval: Companies. R&D Co-Investigator Group
5. Rectangle: AMED
6. Dotted arrows: Agreements/contracts
7. Double arrows: Exchange of samples and information etc./ role sharing
8. Enter information within 1 page (no exceptions).

**Implementation System Diagram**

【Example】

R&D Co-Investigator

Affiliation, Name

Title of R&D items: “XXXX”

AMED

Sample provision

Sample provision

Processing

Processing

R&D Principal Investigator

Affiliation, Name

Title of R&D items: “XXXX”

R&D Co-Investigator

Affiliation, Name

Title of R&D items: “XXXX”

Sample provision

Analysis

Data   
provision

Device   
Development

(Annex E3)

**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 |  | 30 |
| **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 |  | N/A |
| XX XX |  | Lecturer |  | N/A |
| XX XX | \*\*\* Laboratory, \*\*\* Co., Ltd. | Principal Researcher |  | N/A |

It is not necessary to enter efforts for the project participants.

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 (in Japanese).

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

Please obtain the approval and mark the check box black (■), according to “5.1.3 Proposal Document Forms and Notes for Preparation” in the Application Guidelines.

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

Please refer to Chapter 10 “Handling of R&D Accomplishments” of the Application Guidelines first and change “□” into “■” if you, as the contractor of this R&D, wish to own all of the IP rights produced as a result of this R&D on the following conditions: you shall comply with each of four items stipulated in Article 17 of the Industrial Technology Enhancement Act where “national government” shall be read as AMED; if you produce an invention related to the results of this R&D, you shall report, without delay, to AMED on the invention in writing using a form designated by AMED; you shall answer the survey on IP rights conducted by AMED. If you do not wish to do so, please state the reason.

Reason for not wishing to own the IP rights:

* **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*.*

Situation and reason:

* **R&D Items and Overview**

1. Use a font size of 10.5 points or larger, and do not exceed 3 pages (no exceptions). If these instructions are not followed, the research proposal may not be accepted.
2. When stating content, please ensure that there are no discrepancies or inconsistencies with “Form E1”.
3. Enter information in concert with the items described in the section (D) of “4.2.2 Review Criteria and Perspectives in Evaluating Projects” in the Application Guidelines.

**・Abstract**

Copy and paste “3. Abstract” in the (Appendix E1) Summary of Proposal (English).

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

**・Title of R&D Items in Charge**

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

**・R&D Objective and Overview**

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

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

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

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 approaches 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 entry fields as needed in accordance with the number of Co-Investigator groups of the R&D project.

**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 |
| **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 |  | Principal Researcher |  | N/A |
| XX XX |  | Researcher |  | N/A |
| XX XX |  | Research Fellow |  | N/A |

It is not necessary to enter efforts for the project participants.

* **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**

1. Use a font size of 10.5 points or larger, and do not exceed 2 pages (no exceptions). If these instructions are not followed, the research proposal may not be accepted.
2. When stating content, please ensure that there are no discrepancies or inconsistencies with “Form E1”.
3. Enter information in concert with the items described in the section (D) of “4. 2. 2 Review Criteria and Perspectives in Evaluating Projects” in the Application Guidelines.

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

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

**・R&D Objective and Overview**

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

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

Please specify the R&D items performed by the R&D Co-Investigator’s group, milestones (achievement steps to be completed during the R&D period) and approaches 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 Life Science and Medical/Health Research Involving Human Subjects\*

\*New guidelines that came into force after the Ethical Guidelines for Medical and Health Research Involving Human Subjects and the Ethical Guidelines for Human Genome/Gene Analysis Research were abolished on June 30, 2021.

(Please refer to <https://www.lifescience.mext.go.jp/bioethics/seimeikagaku_igaku.html>)

(in Japanese)

□ Guidelines for Gene Therapy Clinical Research

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

□ Clinical Trials Act

□ Ministerial Orders on Good Clinical Practice (GCP)

□ 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.

Research content, measures and actions:

(Annex E5)

**References and Additional Statements**

Use a font size of 10.5 points or larger and do not exceed 1 page (no exceptions).

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**

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**
* If the participation of overseas R&D Co-Investigator’s group(s) is planned, specify the reasons and necessities (please refer to “2.2. 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 other information freely and as required.
* When your current affiliation and the institution where you plan to conduct the R&D project are not the same (“Annex E3, R&D Project Organization”), specify the institution at which the research will be conducted.

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