(Form P1)

**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 2026 (3.5 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 P2) 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 UniversityTel: XX-XXXX-XXXXE-mail: YYY@YY.jp |

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 | 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 |  |  |  |  |  |

**If you are allocating more than 5 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name | Affiliated institution1 | Current professional field | FY 2022research 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)1XXXX University |  |  |  |
| Department of XXX, Faculty of XXX |
| XXX |
| Total: 1 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.**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: Associate Professor, Department of XXXX, WWWW University (Researched XXXX)[*\*Necessary Information*] |

**1. Research Objectives**

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. Make effective references to the descriptions of achievements listed in the “3. Research Achievements” to clarify the relationship between the achievements of the applicant and the research being proposed.
3. Please specify clearly the background of the R&D concept (necessity and importance of the research), the achievements of the applicant (and preliminary evidence) and the R&D concepts and plans.
4. State the information in an easy-to-understand manner, inserting diagrams and charts as necessary.
5. **Targets and Objectives**

Specify the research objectives of the proposed R&D project (expected achievements at the end of the research period), and the targets of the proposed R&D (in terms of outcome resulting directly from the above-mentioned achievements).

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1. **Background**

Specify scientific and technological needs, social demands and requests from economic and industrial interests, including trends in related fields, in order to illustrate the importance and necessity of the proposed R&D project.

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1. **R&D Fundamentals and Preparations**

Specify the relevant projects conducted previously and the personal research achievements of the R&D PI (and those of other collaborating researchers, as required), and other preliminary knowledge, experimental evidence, etc. to support the R&D concept.

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1. **Originality and Novelty of the Proposed R&D and Comparison to the Current Status of Similar Studies Worldwide**

Explain the originality and novelty of the proposed R&D project, and the advantages of this R&D project over others in the world, taking into account the research situation and trends worldwide.

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1. **Future R&D Prospects**

Explain the creation of scientific and technological innovation, creation of seeds for medical applications, contributions to society, and acquisition and enforcement of intellectual property that are expected to be realized in future if the “1.I. Targets and Objectives” stated on this Form P1 are successfully achieved.

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**2. R&D Plan and Approaches**

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. Also refer to notes in “1. Research Objectives.”
2. Explain the R&D approaches taken to achieve “1. I. Targets and Objectives” and potential problems and solutions, as well as alternative approaches for in the case that the project fails to obtain the expected results during the R&D period with certain milestones. The milestones are including criteria for evaluating achievement levels and time periods for conducting the R&D.
3. The R&D plan and approaches should be consistent with the schedule described in “(Annex P1) Main Schedule for R&D”, and also should be specified for each R&D item.
4. With regard to intellectual property and other matters anticipated in this R&D concept (such as applications, licensing, and management), specify the relevant intellectual property rights owned by the applicants, and the strategy for acquiring intellectual property rights during the course of the R&D.
5. **Abstract**

Copy and paste “3. Abstract” in the (Appendix P1) Summary of Proposal (English).

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1. **R&D Plan and Approaches**

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

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

**3. Research Achievements**

1. Select major papers that have been published in academic journals, etc. and books (within the past 5 years) and list them in order starting from the most recent year. Put circle (●) at the start of lines for those that are directly related to the proposed project.
2. State 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 R&D project (guiding principles or guidelines to which you have contributed, etc.)

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

Papers /Books

●M.Marusankaku, J.Aaaa, H.Bbbbb, A.Ccccc, Treatment of Hepatic……, Nature, 2020 , 1,10-20

M.Marusankaku, T.Aaaa, A.Bbbbb, T.Ccccc, Risk factors for Fungal…, Nature, 2019, 2,17-26

Acquisition and application status of patent rights or other intellectual property rights

Policy recommendations

XXXXXX Guideline (issued by XX Academic Association, XXXX [year])

(Example of pasting researchmap text output)

Non-negligible collisions of alkali atoms with background gas in buffer-gas-free cells coated with paraffin

Applied Physics B-Lasers and Optics 122(4) 81-1-81-6, March 2020

Laser frequency locking with 46 GHz offset using an electro-optic modulator for magneto-optical trapping of francium atoms

Applied Optics 55(5) 1164-1169, February 2020

Atomic spin resonance in a rubidium beam obliquel

**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 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.

**(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 Investigatoror 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 projectAmount 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) | Study of XXX(XXXX) | Principal Investigator | 10,000[40,000] | 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 )\* |
| FY2022XX 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 Investigatoror 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 2022XX 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**%**

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%

**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 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.
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).

**(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

(Annex P1)

**Main Schedule for R&D**

1. Enter the R&D items that must be dealt with in order to achieve the objectives, as well as the period of execution.
Milestones: Points of arrival or matters to be achieved that constitute turning points in the achievement in the R&D.
2. For each R&D item, enter the schedule and the persons in charge
3. Please detail the approximate allocated amount (direct costs) of the contracted R&D funds for the entire R&D period. Detail the total sum of the planned allotted amount for each R&D item so they equal the direct costs of the sum applied for.
4. Enter information within 1 page (no exceptions).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| R&D itemResearch Costs | Person in charge | 1st Year(FY2022) | 2nd Year(FY2023) | 3rd Year(FY2024) | 4th Year(FY2025) |
| H1 | H2 | H1 | H2 | H1 | H2 | H1 | H2 |
| *(1) Analysis of XX related gene manifestation**- Establishment of assay system**- Analysis of manifestation data***R&D Costs:***XX thousand yen* | *PI**IRYO M. Hanako* |  | *■* | *■* | *■* | *■**■*▲Milestone: ○○○○○○○○○○○○○○○○○○○○○○○ | *■**■* | *■* | *■* |
| (*2) AAA AAA* *- a* *- a***Research Costs:***XX thousand yen* | *PI**IRYO M. Hanako* |  |  |  | *■* | *■**■* | *■**■*▲Milestone: ○○○○○○○○○○○○○○○○○○○○○○○ | *■**■* | *■**■* |
| (3) BBB BBB*- b**- b***Research Costs:***XX thousand yen*  | *PI**IRYO M. Hanako* |  |  |  |  |  |  |  |  |
| (4) CCC CCC*- c**- c***Research Costs:***XX thousand yen* | *PI**IRYO M. Hanako* |  |  |  |  |  |  |  |  |

(Annex P2)

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **R&D PI** | **Research institution** | **Position** | **The content that the R&D PI will be in charge of under this proposal** | **Effort****(%)** |
| XX XX | Department of \*\*\*, Graduate School of \*\*\*, \*\*\* University  | Associate 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 P4” 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:

(Annex P3)

**Ethical Considerations**

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

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

□ Act to Ensure Safety in Regenerative Medicine

□ Ethical Guidelines for 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 P4)

**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
2. Hanako Iryo, ZZZZZZ University, Department of YYYYYY, Professor, +1-XXX-YYY-ZZZZ, ZZZZZZ@YY.jp
* **Additional Statements**
* Write why you are applying to the Advanced Research and Development Programs for Medical Innovation, your R&D ambitions, special awards that should be noted, explanation for specific terms used in the proposal, plans to transfer and 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 P2, R&D Project Organization”), specify the institution at which the research will be conducted.

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