(Form 1)

**R&D Proposal**

**Project Focused on Developing Key Technology for Discovering and Manufacturing Drugs for Next-Generation Treatment and Diagnosis(Development of advanced manufacturing technologies for biologics）（Standalone）**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Title of proposed R&D project |  | | | | | | | |
| Name of Field/R&D Projects Being Solicited |  | | | | | | | |
| R&D period |  | | | | | | | |
| R&D category |  | | | | | | | |
| R&D area |  | | | | | | | |
| R&D field |  | | | | | | | |
| Key words in R&D field |  | | | | | | | |
| Key words other than those in R&D field |  | | | | | | | |
| Name of Principal Investigator |  | | | | | | | |
| Affiliated institution |  | | | | | | | |
| Address | 〒 | | | | | | | |
| Tel |  | | | FAX | | | |  |
| E-mail |  | | | | | | | |
| Department |  | | | | | | | |
| Position |  | | | | | | | |
| Person in charge of accounting work |  | | Accounting department name, contact information etc. | | |  | | |
| Name of Co-Investigator※ |  | | | | | | | |
| Affiliated institution |  | | | | | | | |
| Address | 〒 | | | | | | | |
| Tel |  | | | FAX | | |  | |
| E-mail |  | | | | | | | |
| Department |  | | | | | | | |
| Position |  | | | | | | | |
| Person in charge of accounting work |  | Accounting department name, contact information etc. | | |  | | | |

※　Add rows as needed in accordance with the number of Co-Investigators, etc.Breakdown of costs for each fiscal year (Unit: 1,000 yen)

(1) Total (Enter the total contracted R&D costs for all participant institutions)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Main item | | Sub items | FY2018 | FY2019 | FY2020 | 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 |  |  |  |  |
| Indirect costs  (In general, 30% of aforementioned direct costs) | | |  |  |  |  |
| Total | | |  |  |  |  |

(2) Total [Enter the portion of (1) above that are related to contracted R&D costs of two-thirds contract research]

*Only enter the below when an institution receiving two-thirds contract research costs is involved.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Main item | | Sub items | FY2018 | FY2019 | FY2020 | 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 |  |  |  |  |
| Indirect costs  (In general, 30% of aforementioned direct costs) | | |  |  |  |  |
| Total | | |  |  |  |  |

(3) Total [Enter the costs borne by the institution (corporate partner) of two-thirds contract research］

*Only enter the below when an institution receiving two-thirds contract research costs is involved.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Main item | | Sub items | FY2018 | FY2019 | FY2020 | 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 |  |  |  |  |
| Total | | |  |  |  |  |

**Research Organization (Principal Investigator and Co-Investigator)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Name (age)  Researcher ID No. | Affiliated institution  Department  Position | Current professional  Degree (final academic background)  Responsibilities within each R&D project | FY 2018  research costs  (Unit: 1000 yen) | Effort (%) |
| Principal Investigator |  |  |  |  |  |
|  |  |
|  |  |
| Co-Investigator |  |  |  |  |  |
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|  |  |
| Total: 　people | | | Total R&D costs |  |  |

**1. Research objectives**

1. In 550 words or less, note specifically and clearly the objective of the research and why the research is needed, as well as its unique characteristics and original aspects, citing applicable references as needed.
2. Note any research, etc. that you have conducted up to now in relation to the current research plan, as well as other research plans needed to achieve the ultimate objectives of the research, and clarify the relationship of the research plan to publicly funded research and private sector research.
3. State clearly what needs to be clarified during the term of the research, and to what extent.
4. Describe the degree to which the unique characteristics and original aspects of the research have been clarified in other research (either domestic or international), and what aspects remain to be elucidated.

**2. Research plan and research methods**

**(1) Summary of Proposal (In Japanese and English)　<Attach to the end of this form as an Appendix>**

1. In 900 words in English or less, describe the specific research plan and method that will achieve the research objectives.
2. Clarify the specific roles of the Principal Investigator, Co-Investigator and collaborating researchers, etc. who will constitute the research for carrying out the research plan.
3. In the case of research that will span multiple years, describe the relationship between the overall research plan and the yearly plans.
4. For clinical research, specify the basic design, target number of cases and number of samples, evaluation method etc.
5. In addition, attach as Annexes the main schedule for research and development (roadmap), a diagram showing the implementation system and so on.

**(2) Research plan and research methods**

**3. Research achievements**

1. For each Principal Investigator and Co-Investigator, select major papers and authors that have been published in academic journals, etc. (within the past 5 years) and list them in order starting from the most recent year. Circle those that are directly related to the proposed topic.
2. Note the acquisition and application status of patent rights or other intellectual property rights, and any policy recommendations that have been made as a result of the implementation of the research project (guiding principles or guidelines to which you have contributed, etc.).

・Principal Investigator:

＜Paper / Author＞

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

＜Policy recommendations＞

・Co-Investigator

**4. Status of research application, acceptance and effort**

Note (1) the research costs currently being applied for (2) the research costs scheduled to be received and (3) other activities of the Principal Investigator for the application topic at the time of application, giving consideration to the points listed below. When noting this for multiple research costs, draw lines to demarcate the costs. For the specific notation methods and so on, check the Procedures for Preparing and Entering Research Proposal Document.

1. In the Effort column, note the percentage of researcher’s time exclusively spent for the R&D activities concerned against the researcher’s annual working hours.
2. At the beginning of the “Research costs currently being applied for”, enter the application research project.

Note: You may enter line breaks as needed, but make sure the resulting text length is one page or less.

**(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-Principal Investigator)  Amount expected to be allocated to applicant | Research costs for FY 2018  [amount for entire topic]  (Unit: 1000 yen) | Effort (%) | Differences in research content and reason for applying for this application research project in addition to other research costs  (Unit: 1000 yen) |
|  |  |  |  |  |  |
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**(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-Principal Investigator) | Research costs for FY 2018  [amount for entire topic]  (1000 yen) | Effort (%) | Differences in research content and reason for applying for this application research project in addition to other research costs  (Unit: 1000 yen) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

　\* In the parentheses ( ), enter the total direct expenses for the entire R&D period.

**(3) Other activities　　　Effort: %**

**5. Past research funds/grants received and resulting achievements**

1. In this box, select the portion of the research results, etc. achieved as a result of the research costs received by the Principal Investigator and Co-Investigator up to now (research costs provided by an affiliated research institution, and research costs from an office or ministry, local government organization, research grant corporation, private sector company etc., including research costs currently being received) that have been used in the drafting of the current research plan, dividing them into the research costs for this financing system and other research costs, with consideration given to the following points.

* For each research cost, note the research funding program name, period (fiscal year), research project title, whether for the Principal Investigator 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 costs).
* Be sure to distinguish the research costs for this funding system from other research costs.

Annex 1

**Main schedule for R&D**

* Note the R&D issues 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.

* Note the schedule for each item in a way that will be clearly understandable to the persons who will be in charge of conducting the research.

**Note: The schedule should be one page or less.**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Main schedule for R&D (roadmap)** | | | | | | | | | | | | | |
| R&D item  ※ Milestone | Name of person in charge | 1st year (FY2018) | | | | 2nd year (FY2019) | | | | 3rd year (FY2020) | | | |
| 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
| (1) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (2) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (3) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6) |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7) |  |  |  |  |  |  |  |  |  |  |  |  |  |

Annex 2

**Implementation System Diagram**

Attach an implementation system diagram showing the Principal Institution and Subsidiary Institution organizations, frameworks, collaboration and cooperation organizations, etc. The diagram should clearly show the roles of each institution. Also note the frameworks and methods for R&D project administration, promotion and progress management, etc.

Appendix: Summary of Proposal (in English and Japanese)

**Summary of Proposal**

\* Please limit this “Summary of Proposal” form to two (2) pages.

1. Project title

2. Principal investigator

* Name
* Sex
* Researcher ID (8 digits)
* Date of birth
* Affiliation
* Department
* Position title
* E-mail address

3. Abstract (400 words maximum)

*Outline your research proposal, mentioning the anticipated results, in 400 words or less.*

4. Keywords (10 items maximum)

*List as many as 10 terms that most likely represent the essence of the proposed research.*

1. 2. 3. 4.

5. 　　　　　　 6. 　　　　　　　7. 　　　　　　 8.

9. 　　　　　　 10.

5. Publication list (10 items maximum)

*List as many as 10 peer-reviewed articles published in English in reverse chronological order (most recent first), and specify the most relevant one(s) with an asterisk(s) (\*).*

1.

\*2.

3.

4.

5.

6.

7.

8.

9.

10.

**研究開発提案書要約**

※ 本「研究開発要約」は２頁以内に収めてください。

１．研究開発課題名

２．研究開発代表者

1. 氏名
2. 性別
3. 研究者番号(８桁)
4. 生年月日(西暦) 年 月 日
5. 所属研究機関
6. 所属部局
7. 職名
8. 連絡先(E-mail)

３．アブストラクト

*1000文字以内で簡潔に記載してください。(期待される成果も含む)。*

４．キーワード(10単語以内)

*提案内容を示す、適切かつ重要と思われる単語を記載してください。*

1． 2． 3．