(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	Study on XXX						
Name of Field/R&D Projects Being Solicited	Establish highly efficient Japanese cell lines (2-1) Develop platform technologies for continuous manufacturing of biologics (2-2) Validate platform technologies for continuous manufacturing of biologics (2-3) Research into quality control methods for the practical application of continuous manufacturing (2-4) Develop cutting-edge technologies for biomanufacturing (2-5)						
R&D period	YYYY/MM/DD - Y	YYY/M	M/DD				
R&D category	XXXX						
R&D area	XXX						
R&D field	XXX				with what you entered when discussion data.		
Key words in R&D field	XXX, XXX						
Key words other than those in R&D field							
Name of Principal Investigator	XXXX Mr.	Үууу Үууу	ууу				
Affiliated institution	XXXX University						
Address	<i>∓XXX-XXXX</i>						
Tel	XX-XXXX-XXXX		FAX	C .	XX-XXX-XXXX		
E-mail	YYY@YY.jp						
Department	XXX Department, Fac	culty of X	XX				
Position	XXX						
Person in charge of accounting work	XXXXAccounting department name, contact information etc.XXSection, Department, XXXUniversity TEL: E-mail:						
Name of Co-Investigator 💥	XXXX Mr.	Үууу Үууу	ууу				
Affiliated institution	XXXX University						
Address	$\overline{\top} XXX - XXXX$						
Tel	XX-XXXX-XXXX		FAX	2	XX-XXXX-XXXX		
E-mail	YYY@YY.jp						
Department	XXX Department, Fac	culty of X	XX				

Position	XXX		
Person in charge of accounting work	XX XX	Accounting department name, contact information etc.	XX Section, Administration Department, XXXXUniversity TEL: FAX: E-mail:

\* Add rows as needed in accordance with the number of Co-Investigators, etc.

# Breakdown of costs for each fiscal year (Unit: 1,000 yen)

Main	fain item Sub items		FY2018	FY2019	FY2020	Total
	1. Costs of goods	Equipment costs				
		Consumable item costs				
Di	2. Travel costs	Travel costs				
Direct costs	3. Personnel costs/ services costs	Personnel costs				
•	services costs	Services costs				
	4. Other	Subcontract costs				
	Other					
Indirect costs (In general, 30% of aforementioned direct costs)						
	Total					

(*Please do not include costs related to the engagement of young researchers in the breakdown.*) (1) Total (Enter the total contracted R&D costs for all participant institutions)

<sup>(2)</sup> 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	Main item Sub items		FY2018	FY2019	FY2020	Total
	1. Costs of goods	Equipment costs				
		Consumable item costs				
D:	2. Travel costs	Travel costs				
Direct costs	3. Personnel costs/ services costs	Personnel costs				
2	services costs	Services costs				
	4. Other	Subcontract costs				
		Other				
Indirect costs (In general, 30% of aforementioned direct costs)						
	Total					

]	Main item Sub items		FY2018	FY2019	FY2020	Total
	1. Costs of goods	Equipment costs				
		Consumable item costs				
Π	2. Travel costs	Travel costs				
Direct costs	3. Personnel costs/	Personnel costs				
sts	services costs	Services costs				
	4. Other	Subcontract costs				
		Other				
	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.* 

<b>D</b> ocoarch Organization	(Principal Investigator	and Co Investigator)
Research Organization	(I I incipal investigator	and Co-myesugator)

	News (	Affiliated institution	Current professional	FY 2018	Effort (%)
	Name (age) Researcher ID No.	Department	Degree (final academic background)	research costs (Unit: 1000 yen)	
		Position	Responsibilities within each R&D project	yen)	
Prir	XXXX (XX)	XX University	XXX	X,XXX	XX
Principal Investigator	98765432	Faculty of XXX XXX Department	Ph. D (XXX)		
stigator		XXX	XXXXX		
Co-Iı	XXXX (XX)	XX University	XXX	X,XXX	XX
Co-Investigator	98765432	Faculty of XXX XXX Department	Ph. D (XXX)		
r		XXX	XXXXX		
				-	
				-	
				-	
Total:	XXpeople		Total R&D costs	X,XXX	

### 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>

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

- 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) <u>In addition, attach as Annexes the main schedule for research and development (roadmap), a diagram showing the implementation system and so on.</u>

#### (Outline)

#### (Main text)

(Example) Annex 1Main schedule for R&D(Example) Annex 2Implementation system

XNot included in the 900 words in English.

#### 3. Research achievements

- 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: XX XX <Paper / Author > XM.Marusankaku, J.Aaaa, H.Bbbbb, A.Ccccc, Treatment of Hepatic....., Nature, 2015, 1,10-20 M.Marusankaku, T.Aaaa, A.Bbbbb, T.Ccccc, Risk factors for Fungal..., Nature, 2015, 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])

· Co-Investigator XX XX

<*Paper* • *Author* >

XM.Kakukaku, T.Dddd, A.Eeee, T.Ffff, Study on Hepatitis..., Nature, 2015,12,32-40 M.Kakukaku, T. Dddd, A. Eeee, T.Ffff, Study on Malaria..., Nature, 2015,10,45-54

(Example of copying & pasting of research map 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 2016

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 2016

Atomic spin resonance in a rubidium beam obliquel

### 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/g	rants currently bein	g applied for	1		1
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)
[ Application research project ] $(2017 \sim 2019)$	XX and XX (XXXX)	expected be allocated to applicant amount of the R&D project	<del>\$</del> ,000 [15,000]	30	Amount expected to be allocated to applicant Example) 6,000 x 3 years (Total amount: 18,000)*
Grants-in-Aid for Scientific Research (KAKENHI)/ Challenging Research (Exploratory) (FY2017-FY2018, JSPS)	Investigative research on the dependence on XX of XX and XX(XXXX)	Principal Investigator	Total amount for this research project 3,000 [10,000]	20	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 )*
FY 2017 XX Foundation research grant (2017 • XX Foundation)	×× and XX research (XXXX)	Co- Investigator	1,000 [10,000]	10	The research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding. (Total amount: 5,000)*

# (1) Research funds/grants currently being applied for

(2) Research funds/grants scheduled to be received

<u>, , , , , , , , , , , , , , , , , , , </u>					
Title of research funding program/ Research funds/grants (research period/ funding agency)	(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)

FY 2016 XX Foundation research grant (XX Foundation, 2016)	Research on XX and YY (XXXX)	Principal Investigator	1,000 [1,000]	10	The research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding. (Total amount: 5,000)*
XX Project (AMED, 2017 - 2019)	Research on XX and YY (XXXX)	Co- Investigator	780 [10,000]	10	The research is different in that it approaches the study from the perspective of XX, and conducting this research will promote comprehensive understanding. (Total amount: 3,900)*

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

(3) Other activities Effort: 20 %

#### 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.

(Example) Name of financing system: 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 facto evaluation:

.

[Funding system] (1)Basic research (A), 2009  $\sim$  2011, "Research on XX" Representative, 40,000 (1000 yen) Achievements: ××××

(2)Basic research (B), 2009  $\sim$  2011, "Research on XX" Representative, 40,000 (1000 yen) Achievements: ××××

[Other research costs] (3)Basic research (B), 2009 ~ 2011, "Research on XX" Representative, 40,000 (1000 yen Achievements: ××××

# (Example)

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 <u>one page or less</u>.

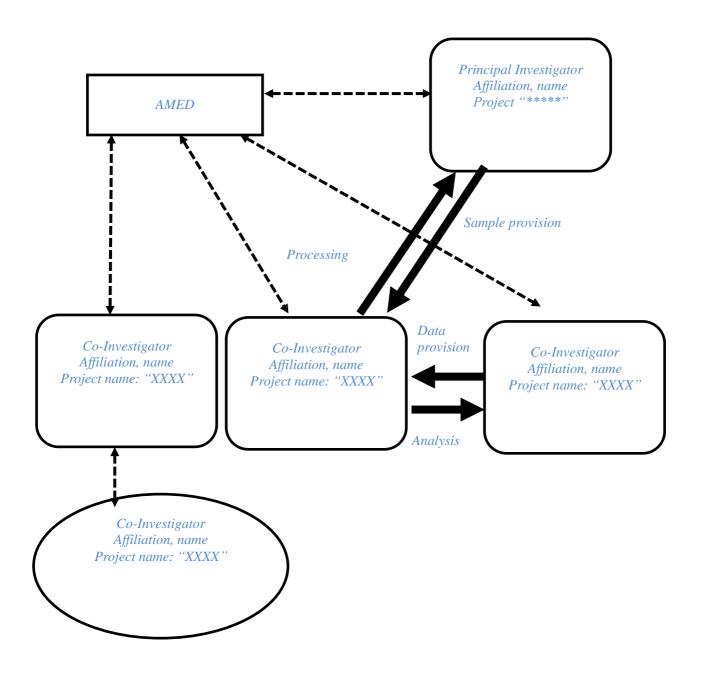
R&D item	Name of	1st year (FY2018)				2nd y	ear (FY	(2019)		3rd year (FY2020)			
Milestone	person in charge	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
<ul> <li>(1) Analysis of XX</li> <li>related gene</li> <li>manifestation</li> <li>Establishment of</li> <li>assay system</li> <li>Analysis of</li> <li>manifestation data</li> </ul>													
(2)													
(3)													
(4)													
(5)													
(6)													
(7)													

## (Example)

## **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.

[Example]



## **Summary of Proposal**

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

## 1. Project title

Nam eu lorem congue tortor volutpat scelerisque quis aliquet augue: Phasellus non dui id metus facilisis tincidunt

- 2. Principal investigator
- Name Hanako Iryou
- Sex Female
- Researcher ID (8 digits) XXXXXXX
- Date of birth 19XX / XX / XX (YYYY/MM/DD)
- Affiliation ZZZZZZ University
- Department
   Department of YYYYYY
- Position title Professor
- E-mail address ZZZZZ@YY.jp

## 3. Abstract (400 words maximum)

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

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Mauris vel tellus faucibus, iaculis elit quis, semper lectus. Nam ac odio at enim congue malesuada id nec dolor. Etiam dignissim varius orci, id sodales diam volutpat eget. Vestibulum scelerisque posuere dolor id scelerisque. Quisque euismod dignissim felis non blandit. Integer lobortis libero finibus eros interdum consequat. Cras non nunc ultrices, tempus odio eu, fermentum tellus. Quisque sem massa, venenatis a purus eget, bibendum sollicitudin ante. Duis consectetur lobortis augue, at venenatis arcu gravida nec. Nam eu lorem congue tortor volutpat scelerisque quis aliquet augue. Phasellus non dui id metus facilisis tincidunt. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Mauris vel tellus faucibus, iaculis elit quis, semper lectus. Nam ac odio at enim congue malesuada id nec dolor. Etiam dignissim varius orci, id sodales diam volutpat eget. Vestibulum scelerisque posuere dolor id scelerisque. Quisque euismod dignissim felis non blandit. Integer lobortis libero finibus eros interdum consequat. Cras non nunc ultrices, tempus odio eu, fermentum tellus. Quisque sem massa, venenatis a purus eget, bibendum sollicitudin ante. Duis consectetur lobortis augue, at venenatis arcu gravida nec. Nam eu lorem congue tortor volutpat scelerisque quis aliquet augue. Phasellus non dui id metus facilisis tincidunt. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Mauris vel tellus faucibus, iaculis elit quis, semper lectus. Nam ac odio at enim congue malesuada id nec dolor. Etiam dignissim varius orci, id sodales diam volutpat eget. Vestibulum scelerisque posuere dolor id scelerisque. Quisque euismod dignissim felis non blandit. Integer lobortis libero finibus eros interdum consequat. Cras non nunc ultrices, tempus odio eu, fermentum tellus. Ouisque sem massa, venenatis a purus eget, bibendum sollicitudin ante. Duis consectetur lobortis augue, at venenatis arcu gravida nec. Nam eu lorem congue tortor volutpat scelerisque quis aliquet augue. Phasellus non dui id metus facilisis tincidunt. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Mauris vel tellus faucibus, iaculis elit quis, semper lectus. Nam ac odio at enim congue malesuada id nec dolor. Etiam dignissim varius orci, id sodales diam volutpat eget. Vestibulum scelerisque posuere dolor id scelerisque. Quisque euismod dignissim felis non blandit. Integer lobortis libero finibus eros interdum consequat. Cras non nunc ultrices, tempus odio eu, fermentum tellus. Quisque sem massa, venenatis a purus eget, bibendum sollicitudin ante. Duis consectetur lobortis augue, at venenatis arcu gravida nec. Nam eu lorem congue tortor volutpat scelerisque quis aliquet augue. Phasellus non dui id metus facilisis tincidunt.

4. Keywords (10 items maximum)

List as many as 10 terms that most likely represent the essence of the proposed research. 1. XX Infectious disease 2. XXSynthetic inhibitor3. International development 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

XXXXの創出を目指した研究

2. 研究開発代表者

1.	氏名	医療 花子
2.	性別	女
3.	研究者番号(8桁)	XXXXXXXX
4.	生年月日(西暦)	19XX 年 XX 月 XX 日
5.	所属研究機関	XXXX 大学
6.	所属部局	XXX 学部
7.	職名	教授
8.	連絡先(E-mail)	ZZZZZZ@YY.jp

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. XX 感染症 2. XX 合成阻害剤 3. 国際展開 .....