(Form-2)

**R&D Proposal**

**(Rare/Intractable Disease Project, AMED FY2019)**

**1. Research outline and objectives**

**1.1 Outline of R&D project**

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| 0. Grant type at time of submission | □Elucidation of the pathogenesis of neurological or muscular diseases (young researchers) | |
| 1. Title of proposed R&D project |  | |
| 2. R&D period | Date contract concluded in 　　　 to March 　　　, 　　　 (scheduled) | |
| 3. R&D funds | 1st year (　　　)  2nd year (　　　)  3rd year (　　　) | yen  　 yen  　 yen |
| 4. Name of R&D Principal Investigator |  | |
| 5. Affiliation, department and position of R&D Principal Investigator |  | |
| 6. Target disease(s) |  | |
| 7. Number of patients suffering from target disease |  | |
| 8. Research stage  (select as many as appropriate） | □Research contributing to reflection in guidelines □ Research on actual condition of patients  □ Construction of research infrastructure ■Basic research □ Clinical study not subject to the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices  □ Step 0 (selection of seeds) □ Step 1（pre-clinical phase）□ Step 2 (investigator-initiated clinical trials) | |
| 9. Highlights: 1) Objective 2 ) Uniqueness/Originality 3) Feasibility of accomplishment 4) Anticipated accomplishments  1)  2)  3)  4) | | |
| 10. Anticipated accomplishments  (select as many as appropriate) | □Drug development □Medical device development  □Regenerative medicine product development □Diagnostic method development  □Evidence creation □Causative gene identification □Biomarker development  □Elucidation of pathogenesis □Registry building □Animal model development  □Others (\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | |
| 11.Research keywords  (10 or less) | 1(　　　 ) 2(　　　) 3(　　　)  4( 　　　　) 5( 　　　　　 ) 6( )  7( 　　　　) 8( 　　　　　 ) 9( )  10( 　　　 ) | |

**1.2 Overall details of the R&D**

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| 1. Outline etc. |
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| If you have an outline diagram please insert it here.) |

**2. Research plan and research methods**

**2.1 Overall view of R&D and progress**

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| 2. Main schedule for R&D (roadmap) | | | | | | | | | | | | | | |
| R&D item  Milestone | Name of person in charge | 1st year (FY2019) | | | | 2nd year (FY2020) | | | | 3rd year (FY2021) | | | | Attainment  rate |
| 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
| (1)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (2)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (3)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (4)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (5)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (6)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| (7)  ・Research budget:  million yen |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**2.2 R&D outline by R&D item**

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| --- | --- |
| R&D item (1) |  |
| Name of person in charge of R&D |  |
| Affiliation/department/position |  |
| R&D item outline  **Milestone 1**  Person in charge:  Objectives, details and accomplishments to be achieved    **Milestone 2**  Person in charge:  Objectives, details and accomplishments to be achieved | |

|  |  |
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| R&D item (2) |  |
| Name of person in charge of R&D |  |
| Affiliation/department/position |  |
| R&D item outline    **Milestone 1**  Person in charge:  Objectives, details and accomplishments to be achieved    **Milestone 2**  Person in charge:  Objectives, details and accomplishments to be achieved | |

|  |  |
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| R&D item (3) |  |
| Name of person in charge of R&D |  |
| Affiliation/department/position |  |
| R&D item outline    **Milestone 1**  Person in charge:  Objectives, details and accomplishments to be achieved    **Milestone 2**  Person in charge:  Objectives, details and accomplishments to be achieved | |