**NUCLEIC ACID THERAPEUTICS INITIATIVE (NATi)**

**CFP T01 (OUTBREAK RESPONSE) PROPOSAL FORM**

**Instructions**

* Use the template below to prepare your application. All sections must be completed.
* Use Arial 10, single spacing throughout.
* Guiding instructions are provided in grey and italicised fonts. These can be removed to provide more room for the proposal.
* All documents must be in Word or PDF format. Do not submit scanned PDFs except for signatories.
* Relevant privileged or confidential information should be disclosed to help convey a better understanding of the project. Such information should be clearly marked in the proposal.
* The Director of Research (DOR) from the Lead Investigator's Host Institution must endorse the proposal submission. The email endorsement must be attached to the application.
* All budgets are to be calculated in Singapore dollars.
* Submit completed applications to enquiry@nati.sg by the deadline.

|  |  |
| --- | --- |
| **Section** | **Description** |
|  | Project Title |
|  | Project Duration (months) |
|  | Lay Abstract (non-confidential) |
|  | Project Team |
|  | Budget Request in Singapore dollars |
|  | Significance and Potential Impact to Singapore |
|  | Target Product Profile (TPP) |
|  | Project Implementation |
|  | Key Performance Indicators (KPIs) and Tracking Indicators (TIs) |
|  | Declaration of Ethics  |
|  | Undertaking |
| **ANNEX A** |
|  | Other Funding Support |
|  | Background Intellectual Property (BIP) |
|  | Foreground Intellectual Property (FIP) |
|  | Curriculum Vitae (CV) |

1. **PROJECT TITLE**

|  |
| --- |
|  |

1. **PROJECT DURATION (MONTHS)**

|  |
| --- |
| *Up to 12 months* |

1. **LAY ABSTRACT (NON-CONFIDENTIAL)**

*In no more than 300 words, outline how the deliverables in this proposal would address the outbreak in question. This should be non-confidential in nature and be easily understood by an audience of experts from other subject domains. Content may be released publicly for the purpose of announcing results of the Call for Proposals.*

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1. **PROJECT TEAM**
* *The Lead Investigator will coordinate research activities carried out by the project team. He/She will be responsible for all progress reporting on behalf of the project team.*
* *Team Leads will be the representative(s) leading the research at the Partner Institution.*
* *Co-Investigators(s) (Co-Is) will be the person(s) leading and managing a particular workstream in collaboration with the Lead Investigator or Team Lead within the same institution.*
* *Collaborator(s) refers to any company, institution or incorporated body who are engaged in the research in collaboration with the Lead Investigator or any Co-Is.*
* *Funding will be awarded to Singapore public sector research performers only. Collaborators do not receive funding.*
* *Leads and Co-I(s) should hold a primary appointment in a Singapore publicly funded institute or institute of higher learning (IHL). The lead investigator must hold a primary appointment of at least 0.7 FTE in Singapore.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Host Institution /Partner Institution/ Organisation** | **Email Address** |
| **Lead Investigator** |  |  |  |
| **Team Lead** |  |  |  |
| **Co-Investigator (Co-I)** |  |  |  |
| **Collaborator** |  |  |  |

*Add rows as required.*

*The percentage effort of work commitment of the individual team members must add up to 100%. Indicate how each team member will contribute to the project.*

|  |  |  |
| --- | --- | --- |
| **Name** | **Contribution** | **% Effort** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  | 100% |

*Add rows as required.*

1. **BUDGET REQUEST IN SINGAPORE DOLLARS**

*Ensure the budget numbers tally with the proposal budget template. The project team is strongly advised to budget prudently and according to the needs of the proposed work*.

1. *Provide a summary of the budget request for each institution.*
2. *A detailed breakdown of the budget requested using the “Proposal Budget Template” must accompany the proposal submission.*
3. *Researchers from overseas institutions and industry/companies can only participate as collaborators. No funding can be awarded to these collaborators. They may contribute technology or in-kind in terms of manpower, time or other resources.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | **Institution:**  | **Institution:**  | **Institution:**  | **TOTAL**  |
| **EOM** |    |   |   |  |
| **OOE** |    |   |   |  |
| **EQPT** |    |   |   |  |
| **OT** |  |  |  |  |
| **Direct Cost** |    |   |   |  |
| **Indirect cost**(30% of direct cost) |    |   |   |  |
| **Grand Total** |    |   |   |  |

1. **SIGNIFICANCE AND POTENTIAL IMPACT TO SINGAPORE**

*In no more than 500 words, explain the significance and potential impact of the proposed project and its relevance to Singapore in pandemic preparedness.*

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1. **TARGET PRODUCT PROFILE (TPP)**

*In* ***no more than 2 pages****, provide a preliminary TPP of the proposed therapeutic or vaccine. Please address the following points where possible.*

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| --- |
| 1. **Indication for use**

*Describe the disease/pathogen.*1. **Target population**

*Describe the population at risk of severe disease. Describe known symptoms that can be used to identify the target population. Provide an assessment of the risk to the Singapore demography.*1. **Epidemiology**

*Describe the outbreak pattern, known sources, transmission rate, and route of transmission. Provide figures relevant to Singapore where available. Provide an assessment of the risk to Singapore.*1. **Safety/reactogenicity**

*Define the required safety profile and efficacy outcomes that are measurable preclinically. Define any specific adverse effects that need to be addressed.*1. **Dose regimen**

*How many doses are expected to establish immunity against the pathogen? What is the expected durability of protection?*1. **Route of administration**

*How will your therapeutic or vaccine be introduced to the patient?*1. **Stability**

*Does your target product require any special storage or handling conditions?*1. **Manufacturing challenges**

*How would your target product be scaled up? Is the scale-up process currently available and ready for deployment?*1. **Competitive Landscape**

*Who else is working on this indication? How is your proposed product differentiated from competitors? Please also consider other modalities than RNA drugs.* |

1. **PROJECT IMPLEMENTATION**
2. **Methodology**

*In no more than 2 pages, please describe how your project will be implemented with reference to the TPP and the Gantt Chart below. Additional supporting figures and documents can be included in the annex.*

1. **Timeline & Deliverables**

*Using the template below as an example of a Gantt chart, provide details on how the project will achieve its stated outcomes in 1 year.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Deliverables** | **Party responsible** | **Q1** | **Q2** | **Q3** | **Q4** |
| **Workstream/Deliverable 1.1** e.g. Selection of 2-3 candidates for in vivo testing  |  |  |  |  |  |
| **Workstream/Deliverable 1.2** e.g. Production of vaccine candidates and validation of animal models |  |  |  |  |  |
| **Workstream/Deliverable 1.3** e.g. in vivo testing of RNA candidates and optimisation to achieve intended TPP |  |  |  |  |  |
| **Final Report** |  |  |  |  |  |

1. **Risk Mitigation Plan**

*Outline the potential risks and pitfalls, along with mitigation strategies to prevent them.*

1. **Plans for downstream development**

*Describe how successful outcomes of this project would be rapidly deployed to address the outbreak in question. Please consider sharing ongoing discussions with other funding entities, operating partners, and regulatory authorities.*

1. **KEY PERFORMANCE INDICATORS AND TRACKING INDICATORS**

*Include proposed key performance indicators and tracking indicators where applicable.*

|  |  |  |
| --- | --- | --- |
| **S/N** | **Key Performance Indicators** | **Proposed Target** |
| 1. | *e.g. pre-clinically validated influenza vaccine* | e.g. ≥2 |
| 2. | *e.g. Industry R&D Spending (IRS)* | e.g. S$200,000  |
| **S/N** | **Tracking Indicators** | **Proposed Target** (*Where applicable)* |
|  | e.g. Number of out-licensing deals |  |
|  | e.g. Number of spin-offs |  |
|  | e.g. Number of talents trained |  |
|  | e.g. Number of patents filed |  |
|  | e.g. Number of technical disclosures filed |  |

1. **DECLARATION OF ETHICS**

*Using the template below, indicate if the research involves ethical considerations. Note that the approval of the proposal is subject to the necessary ethics approvals.*

|  |  |
| --- | --- |
| Please check the box Yes or No if the project involves any of the following: | Please declare the participating institution(s) where the study requiring ethics approval is/are conducted: |
| a) | Human Subject | [ ]  Yes [ ]  No |  |
| b) | Use of human biological materials (HBM) | [ ]  Yes [ ]  No |  |
| c) | Conduct tissue banking activities regulated under the Human Biomedical Research Act (HBRA) | [ ]  Yes [ ]  No |  |
| d) | Use of health information or research data from primary donors | [ ]  Yes [ ]  No |  |
| e) | Use of commercially available HBM/animal tissues or cells | [ ]  Yes [ ]  No |  |
| f) | Animal experimentation not regulated under HBRA | [ ]  Yes [ ]  No |  |
| g) | Requirement for Class 2 containment and above | [ ]  Yes [ ]  No |  |
| h) | Multi-centre trials | [ ]  Yes [ ]  No |  |
| A copy of the ethics approval is attached. | [ ]  Yes [ ]  No |  |

1. **UNDERTAKING**

In signing this application form, the project team undertakes to:

1. Declare that all information provided is accurate and true to the best of their knowledge
2. Ensure that there is no financial conflict of interest
3. Be actively engaged in the execution of the research and ensure that the associated activities comply with all laws, rules and regulations pertaining to animal and human ethics
4. Ensure that all necessary licenses and approvals have been obtained or are being sought
5. Adhere to the prevailing Grant Terms and Conditions and Guidelines of the funding agency which may be amended from time to time
6. Agree to hold primary responsibility for the responsible conduct of research and shall abide and comply with the ethical, legal and professional standards relevant to research in accordance with the research integrity policy of the respective Institutions
7. Avoid sending similar versions or parts of this application/proposal to other agencies for funding
8. Ensure that the requested equipment/resources are not funded by another agency or proposal
9. Ensure that the funding agency is acknowledged in all publications
10. Ensure that the Director of Research (DOR) from the Lead Investigator's Host Institution has endorsed the proposal submission. The proof of endorsement (e.g. email) must be attached to the application.

**Submission Checklist:**

[ ]  Completed T01 proposal application form (including Annex A)

[ ]  Completed T01 proposal budget template

[ ]  Proof of DOR endorsement from Host Institution

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Institution** | **Signature** | **Date** |
| **Lead Investigator**  |  |  |  |  |
| **Co-Investigator** |  |  |  |  |

*Add rows as required.*

*Electronic signatures are acceptable.*

**ANNEX A – Other funding support, Intellectual Property, CVs**

1. **OTHER FUNDING SUPPORT**

*Using the template below, provide the details for all currently held or applied grants over the last 3 years preceding this application by the project team which are relevant to the proposed research. Highlight any potential overlap of funds with this application and mitigating measures. Note that double-dipping is not allowed.*

|  |
| --- |
| ***Currently held grants by (Name of Investigator)*** |
| 1. | Project Number/ID |  |
| Funding Agency |  |
| Project Title |  |
| Project Scope |  |
| Project Progress (%) |  |
| Total Amount Awarded |  |
| Project Start/End Date |  |
| Project Role |  |
| Potential overlap |  |

*Add table as required.*

|  |
| --- |
| ***Grant applications pending outcome by (Name of Investigator)*** |
| 1. | Funding Agency |  |
| Project Title |  |
| Project Scope |  |
| Total Amount Applied |  |
| Project Start/End Date |  |
| Project Role  |  |
| Potential overlap |  |

*Add table as required.*

1. **BACKGROUND INTELLECTUAL PROPERTY (BIP)**

*List the relevant patents, publications and technology disclosures which constitute BIP and Background Know-How which may potentially be required for the use, licensing or commercialisation of Foreground Intellectual Property or Foreground Know-How. Highlight any potential encumbrance or limitation in freedom to operate. Include any existing or planned licensing agreements with industry collaborators or others. A ‘NIL’ response is required.*

|  |  |  |
| --- | --- | --- |
| **S/N** | **BIP**  | **Details**  |
| 1. |  |  |
| **S/N** | **Background Know-How** | **Details** |
| 1. |  |  |

*Add rows as required.*

1. **FOREGROUND INTELLECTUAL PROPERTY (FIP)**

*List the potential FIP or commercialisation activities which will be generated through this project. Attach any licensing agreements/options for FIP. A ‘NIL’ response is required.*

|  |  |  |
| --- | --- | --- |
| **S/N** | **Potential FIP**  | **Details**  |
| 1. |  |  |
| **S/N** | **Potential Commercialisation Activities** | **Details** |
| 1. |  |  |

*Add rows as required.*

1. **CURRICULUM VITAE (CV)**

*Attach the CVs of all Investigators and Collaborators using the template below. Each CV should not exceed 1 page*.

|  |  |
| --- | --- |
| Name |  |
| Current position/appointment(s)/affiliation(s) |  |
| ORCID |  |
| Position(s) in a company/companies |  |
| Employment history in the last 15 years |
| Academic qualifications |
| Relevant publications (list up to 10 with corresponding journal impact factor) |
| Relevant project management experience |
| Key research achievements (licenses, awards, spin-off companies, external consultancy, etc) |
| Patents held |

*Add table as required.*