**Project Risk Management Plan**

To comply with DBT, World Bank & BIRAC’s mission to promote innovation and self-sufficiency in the biotechnology sector while striving to reduce any social and environmental risks in its activities, M/s\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, Fund Recipients for the proposal entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

has identified the following risks related to Project, Environment (including occupational health and community) and during conduct of clinical trials (if applicable). Risk mitigation measures are being taken by M/s\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ as defined in the following annexures:

1. Project Implementation Risk Management plan: identifies project monitoring mechanisms, complaint redressal mechanism and describes the mitigation measures being implemented for the programme components based on the identified risks. Institutional arrangements in order to implement safeguard parameters, methods for periodical review, monitoring strategy and grievance redressal mechanism are described in this annexure.
2. Environmental and Health Risk Management Plan: Compliance to corresponding legislations, Good practices in research and development methods, including while use of animals will be followed. We have referred to the Environment, Occupational Health and Safety Management Framework (EMF) document while preparing this annexure. Facility-specific occupational health and safety hazards have been identified based on risk assessment using established methodologies. The Community health and safety impacts related to handling and storage of solid, liquid and gaseous substances have been evaluated and accordingly mitigation measures will be implemented during project implementation. Impacts due to significant exposures to workers and potentially to surrounding communities, depending on quantities and types of accidentally released chemicals and biologicals have been thoroughly evaluated and addressed.
3. Clinical Trial Risk Management Plan: Ensures adherence to bioethics principles in conduct of clinical trial. The plan abides by the legal, regulatory and ethics requirements as per the national and global guidelines and the social safeguard policies.

**Project Implementation Risk Management Plan**

1. **Project Risk Management:**

|  |  |  |
| --- | --- | --- |
| **Risk** | **Mitigation Measures** | **Monitoring parameters** |
| **Technical** | | |
| Breach of any license terms and termination of license agreement (if applicable) |  |  |
| Scientific failure that product will not reach the market. |  |  |
| Project Non-Progress |  |  |
| Manpower risk and backup plan and turnaround time to recruit an alternate person |  |  |
| Others (if any) |  |  |
| **Social** | | |
| Failure to meet affordability |  |  |
| Gender non-representation |  |  |
| Employment generation |  |  |
| Others (if any) |  |  |
| **Financial** | | |
| Misutilization of funds |  |  |
| Non-repayment of existing loans. Risk of being listed as NPA. |  |  |
| Adverse audit findings |  |  |
| Late disbursal of funds from NBM |  |  |
| Others (if any) |  |  |
| **Data Management** | | |
| Loss of Data |  |  |
| Misutilization of Data |  |  |
| **Procurement** | | |
| Irregularity in procurement |  |  |
| Failures during vendor validations processes. |  |  |
| Lack of vendor databases |  |  |
| Others (if any) |  |  |
| **Legal** | | |
| IP conflict regarding use of technology |  |  |
| Non-compliance to regulatory framework for conduct of study |  |  |
| Termination of license |  |  |
| Dispute with outsourcing agency |  |  |
| Change of entity status due to statutory non-compliance |  |  |
| Others (if any) |  |  |
| **Preclinical and Regulatory** | | |
| Delay in approval by the competent authority (eg. IAEC, CPSCEA) |  |  |
| Unavailability of animals to conduct study. |  |  |
| GLP Compliance |  |  |
| Animal welfare/Loss of animal during the study period |  |  |
| Inconclusive study |  |  |
| Others (if any) |  |  |

1. **Complaint Redressal:**

|  |  |
| --- | --- |
| **Internal Grievance/ Complaint Redressal** | **Mechanism/ Mitigation** |
| Employees | Insurance?  Whistle blower policy? |
| Women Employees | Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act? |
| Vendors/ Partners |  |
| Customers |  |

1. **Project Monitoring Mechanism:**

|  |  |  |
| --- | --- | --- |
|  | **Monitoring Mechanism** | **Strategy** |
| 1 | Financial Audit Reports on monitoring Fund utilization, Fund re-appropriation | Company audits? |
| 2 | Internal Technical Reviews |  |

1. **Impact of the project:**

* **Affordability:**

How funding from NBM will impact: affordability of the product(s) – cost of product with/without NBM funding, product availability/ affordability under National missions, technology licensing to MSMEs/ start-ups. Please share the cost sharing ratio,

* **Social:**

Use of product/ technology, target population, public health programs, availability of product/ technology to MSMEs for further usage, generation of employment among local population.

**Environmental and Health Risk Management Plan**

1. **Institutional Arrangements**

|  |  |  |
| --- | --- | --- |
| **Requirements** | **Current Status** | **Mitigation Steps** |
| Institutional Bio-Safety Committee (IBSC) |  |  |
| EHS Team |  |  |
| Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures. |  |  |
| SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc. |  |  |
| General Safety and Storage |  |  |

1. **Environmental Impact and risk mitigation**

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| --- | --- | --- | --- |
| **Risks** | **Project Specific Risk** | **Potential Impact** | **Mitigation Steps** |
| Air Pollution |  |  |  |
| Water Pollution and Waste water treatment |  |  |  |
| Chemical waste |  |  |  |
| Biological Waste |  |  |  |
| Heavy metals |  |  |  |
| Radiation Waste |  |  |  |
| Electronic Waste |  |  |  |
| Hazardous and C&D Waste |  |  |  |
| Destruction/alteration of surrounding ecosystem |  |  |  |
| Others |  |  |  |

1. **Occupational Health and Safety** and **risk mitigation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risks** | **Project Specific Risk** | **Potential Impact** | **Mitigation Steps** |
| Heat Hazards |  |  |  |
| Chemical hazards, including fire and explosions |  |  |  |
| Pathogenic and biological hazards |  |  |  |
| Radiological hazards |  |  |  |
| Electronic Waste |  |  |  |
| Hazardous and C&D Waste |  |  |  |
| Noise |  |  |  |
| Process safety |  |  |  |
| others |  |  |  |

1. **Community Health and Safety and risk mitigation**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risks** | **Project Specific Risk** | **Potential Impact** | **Mitigation Steps** |
| Safety Transportation Management System (for transport of hazardous material) |  |  |  |
| Emergency preparedness and participation of local authorities and potentially affected communities |  |  |  |
| In case your organization already has **EHS guideline**, please summarise the same. Also, share details of the **EHS Officer/ Contact Person** of the organization. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.** | | | |

**Clinical Trial Risk Management Plan (if applicable)**

|  |  |  |
| --- | --- | --- |
| **Clinical and Regulatory** | | |
| **Area of Risk** | **Monitoring Parameters** | **Mitigation Measures** |
| Production of CT material |  |  |
| Protocol design and scientific validity ensuring Favourable risk-benefit ratio |  |  |
| Regulatory approvals |  |  |
| Ethics approvals |  |  |
| Ensuring appropriate informed consent process and respect for human subjects |  |  |
| Capacity of the sponsor |  |  |
| Staff at the trial site and Investigator responsibilities |  |  |
| Recruitment of study subjects and fair subject selection |  |  |
| Safety Management (AE and SAE) |  |  |
| Costs and reimbursements to subjects |  |  |
| Compensation and Insurance |  |  |
| Breach of confidentiality and protocol violations |  |  |
| Audit and independent reviews |  |  |
| Logistics and Data quality |  |  |
| Serology / efficacy |  |  |
| Post- trial access issues (if applicable) |  |  |