Project Agreement

(Innovate in India for Inclusiveness Project)

between

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

and

BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL

Dated APRIL 24, 2018
PROJECT AGREEMENT

Agreement dated April 24, 2018, entered into between INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT ("Bank") and BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL ("BIRAC" or "Project Implementing Entity") in connection with the Loan Agreement ("Loan Agreement") of same date between INDIA ("Borrower") and the Bank. The Bank and BIRAC hereby agree as follows:

ARTICLE I — GENERAL CONDITIONS; DEFINITIONS

1.01. The General Conditions (as defined in the Appendix to the Loan Agreement) constitute an integral part of this Agreement.

1.02. Unless the context requires otherwise, the capitalized terms used in this Agreement have the meanings ascribed to them in the Loan Agreement or the General Conditions.

ARTICLE II — PROJECT

2.01. BIRAC declares its commitment to the objectives of the Project. To this end, BIRAC shall carry out the Project in accordance with the provisions of Article V of the General Conditions, and shall provide, promptly as needed, the funds, facilities, services and other resources required for the Project.

2.02. Without limitation upon the provisions of Section 2.01 of this Agreement, and except as the Bank and BIRAC shall otherwise agree, BIRAC shall carry out the Project in accordance with the provisions of the Schedule to this Agreement.

ARTICLE III — REPRESENTATIVE; ADDRESSES

3.01. BIRAC’s Representative is its Managing Director or any authorized representative.

3.02. The Bank’s Address is:

International Bank for Reconstruction and Development
1818 H Street, NW
Washington, DC 20433
United States of America

Cable: INTBAFRAD   Telex: 248423(MCI) or 64145(MCI)
Facsimile: 1-202-477-6391
3.03. BIRAC’s Address is:

1ST Floor, MTNL, Building 9, CGO Complex, Lodi Road
New Delhi, 110003

Telex: Facsimile:
+91 11 24389600 +91 11 24389611

AGREED at NEW DELHI, India, as of the day and year first above written.

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

By

Authorized Representative

Name: Hismam Abdo
Title: Acting Country Director, India

BIOTECHNOLOGY INDUSTRY RESEARCH ASSISTANCE COUNCIL

By

Authorized Representative

Name: Mohd. Aslam
Title: Managing Director
SCHEDULE

Execution of the Project

Section I. Implementation Arrangements

A. Institutional Arrangements

1. By no later than one (1) month after the Effective Date, BIRAC shall establish and thereafter maintain throughout the period of implementation of the Project:

(a) the Steering Committee ("SC") with a mandate and composition agreed with the Bank. Without limitation on the foregoing, the SC shall be: (i) chaired and made up of representatives from the Borrower's Department of Biotechnology; and (ii) responsible for, inter alia: (A) providing high-level policy advice; and (B) facilitating the coordination of Project activities;

(b) the Technical Advisory Group ("TAG") with a mandate and composition agreed with the Bank. Without limitation on the foregoing, the TAG shall be responsible for, inter alia, providing specific and technical advice on Project activities; and

(c) the Project Management Unit ("PMU"), with functions and resources satisfactory to the Bank and with staff in adequate numbers and with qualifications, experience and terms of reference satisfactory to the Bank. Without limitation on the foregoing, the PMU shall be: (i) chaired by a dedicated Project director; and (ii) responsible for, inter alia, carrying out the overall Project management, procurement, financial management, safeguards, monitoring and reporting.

B. Project Implementation Manual and Clinical Research Validation and Management Framework

1. BIRAC shall:

(a) implement the Project, and cause to be implemented, in accordance with the Project Implementation Manual and the Clinical Research Validation and Management Framework; provided however that in the event of conflict between the provisions of said manual and framework, on the one hand, and those of this Agreement and/or the Loan Agreement, on the other hand, the provisions of this Agreement and/or the Loan Agreement shall prevail; and

(b) refrain from amending, suspending, waiving, and/or voiding any provision of the Project Implementation Manual and/or the Clinical Research
Validation and Management Framework whether in whole or in part, without the prior written concurrence of the Bank.

2. Without limiting the generality of the foregoing and prior to the comment of any clinical trials under the Project, BIRAC shall ensure that: (a) full and informed written consent of all participants in clinical trials is obtained, recorded and retained by all Grantees; and (b) a grievance mechanism is set up, and implemented throughout Project implementation, in order to track complaints related to all Project activities (including clinical trials) and guide resolution of such complaints.

3. BIRAC represents and warrants that it has taken appropriate measures to protect itself and the Project from any adverse results relating to the carrying out of clinical trials financed and/or associated with the activities supported under the Project, including but not limited to, disputes over intellectual property; non-compliance in the conduct of clinical trials; and personal injuries.

C. Grant Agreements

1. For purposes of Part 1 and 2 of the Project, BIRAC shall provide Product Development Grants, Shared Facility Grants, Scientific Research Grants, Clinical Trial Network Grants, Training Grants and/or Technology Transfer Grants ("Project Grants") to Grantees who have fulfilled the requirements set forth in the Project Implementation Manual and/or the Clinical Research Validation and Management Framework ("CRVMF") on the terms and conditions set forth in this Section I.C.

2. Without limitation on the provision of paragraph 1 of this Section, BIRAC shall, prior to making any Project Grant, enter into an agreement with a Grantee, whereby BIRAC shall agree to provide such Grantee with any of the aforementioned Project Grants and the Grantee shall agree to carry out its respective Project activities, on terms and conditions satisfactory to the Bank ("Grant Agreement"), including the following additional terms and conditions:

(a) require the Grantee to: (i) carry out its respective Project activities with due diligence and efficiency in accordance with the technical, financial, managerial, and environmental requirements, standards and practices set forth in the Project Implementation Manual, EMF and CRVMF, as applicable; (ii) obtain, record and retain the informed consent of all participants in clinical trials prior to the commencement of any clinical trials when applicable; (iii) procure the goods, works and services to be financed out of any of the above-mentioned grants in accordance with the provisions of this Agreement; (iv) require the Grantee to maintain policies and procedures adequate to monitor and evaluate on an on-going basis the use of the Project Grant; (v) (1) maintain a financial management system and prepare financial reports in a format acceptable to BIRAC and the Bank; and (2) at BIRAC's or the Bank's request, have such financial reports audited by independent auditors acceptable to the Bank, in
accordance with consistently applied auditing standards acceptable to the Association, and promptly furnish the statements as so audited to BIRAC and the Bank; (vi) prepare and furnish to the Bank all such information as the Bank shall reasonably request relating to the foregoing; and (vii) require the Grantee to maintain policies and procedures adequate to monitor and evaluate on an on-going basis the use of the above-mentioned grants;

(b) enable the Borrower and the Bank to inspect any Project activity, its operation and any relevant records and documents and obtain and furnish all such information as the Borrower or the Bank shall reasonable request; and

(c) the right of BIRAC to suspend or terminate the right of the Grantee to use the proceeds of the Loan upon failure by such Grantee to perform its obligations under the respective Grant Agreement or obtain a refund of all or any part of the amount then withdrawn, upon the Grantee’s failure to perform any of its obligations under the Grant Agreement.

4. BIRAC shall: (a) exercise its rights under each Grant Agreement in such manner as to protect the interests of the Borrower and the Bank and to accomplish the purposes of the Loan; and (b) except as the Bank shall otherwise agree, not assign, amend, abrogate or waive any Grant Agreement or any provision thereof.

D. Anti-Corruption

BIRAC shall ensure that the Project is carried out in accordance with the provisions of the Anti-Corruption Guidelines.

E. Safeguards

1. BIRAC shall, and shall cause each Grantee to:

   (a) carry out the Project in accordance/compliance with the EMF and the relevant instruments (to be) prepared pursuant to paragraph 2 below, and pursuant to the objectives, policies, procedures and other provisions set forth therein, in a manner and substance satisfactory to the Bank; and

   (b) refrain from taking any action, or consenting to an action to be taken, which would prevent or interfere with the implementation of the EMF including any amendment, suspension, waiver, and/or voidance of any provision thereof, whether in whole or in part, without the prior written concurrence of the Bank.

2. Without limitation to the provisions of Section E.1. of this Schedule, and prior to the carrying out of any Project Grant activity, BIRAC shall: (a) carry out and/or cause to be carried out an environmental screening and/or an environmental
assessment (as the case may be) of the pertinent activities to be financed under a Grant Agreement; (b) approve, and/or cause the Grantee to approve an environmental/social management plan, acceptable to the Bank, for each said activity all in accordance with the provisions of the EMF; and (c) immediately after such approval, implement and/or cause to be implemented (as the case may be) the corresponding environmental/social management plan in accordance with its terms.

3. BIRAC shall, throughout the period of implementation of the Project maintain monitoring and evaluation protocols and record keeping procedures acceptable to the Bank and adequate to enable BIRAC and the Bank to supervise and assess, on an on-going basis, the implementation of/compliance with the EMF and each environmental management plan and/or social management plan prepared thereunder, as well as the achievement of the objectives thereof.

4. In the event of any conflict between the provisions of the EMF and any environmental management plan or social management plan prepared thereunder, on the one hand, and the provisions of this Agreement and/or the Loan Agreement, on the other hand, the provisions of this Agreement and/or the Loan Agreement shall prevail.

Section II. Project Monitoring, Reporting and Evaluation

A. Project Reports

BIRAC shall monitor and evaluate the progress of the Project and prepare Project Reports in accordance with the provisions of Section 5.08 (b) of the General Conditions and on the basis of indicators acceptable to the Bank. Each such Project Report shall cover the period of one (1) calendar semester, and shall be furnished to the Borrower and the Bank not later two (2) weeks after the end of the period covered by such report.

B. Financial Management, Financial Reports and Audits

1. BIRAC shall maintain a financial management system and prepare financial statements in accordance with consistently applied accounting standards acceptable to the Bank, both in a manner adequate to reflect the operations and financial condition of BIRAC, including the operations, resources and expenditures related to the Project.

2. Without limitation on the provision of Part A of this Section, BIRAC shall prepare and furnish to the Bank not later than forty-five (45) days after the end of each fiscal semester, interim unaudited financial reports for the Project covering the semester, in form and substance satisfactory to the Bank.
3. BIRAC shall have its financial statements referred to above audited by independent auditors acceptable to the Bank, in accordance with consistently applied auditing standards acceptable to the Bank. Each audit of these financial statements shall cover the period of one fiscal year of BIRAC. BIRAC shall ensure that the audited financial statements for each period shall be: (a) furnished to the Borrower and the Bank not later than nine (9) months after the end of the period; and (b) made publicly available in a timely fashion and in a manner acceptable to the Bank.

Section III. Procurement

All goods and services required for the Project and to be financed out of the proceeds of the Loan shall be procured in accordance with the provisions of Section III of Schedule 2 to the Loan Agreement.