

Guidelines on Biological Research Regulatory Approval (2022)



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1. Introduction

The present guidelines on Biological Research Regulatory Approval have been prepared with reference to the O.M. No. PID-99/22/2021-PPB-DBT-Part(2) dated 17.06.2022 by Department of Biotechnology and F. No. 13-26/2022-AR dated 30.06.2022 by Ministry of Education, Government of India.

With the rapid growth in research, innovation, and policy interest in recent years, importance of responsible research and innovation has become paramount. In the past few years, several reforms have taken place in India to facilitate biological research, its promotion, and adoption without compromising safety and security concerns. These reforms include implementation of user-friendly online transaction mechanisms of regulatory processes.

Biological Research activities involve handling and exchange of materials that include micro-organisms, plants, small and large animals, human samples as well as biodiversity resources of the country. The Government of India supports biological research through its Ministries/Departments providing statutory and administrative approvals through their regulatory agencies/committees. Health Ministry's Screening Committee (HMSC), Review Committee on Genetic Manipulation (RCGM), Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), National Biodiversity Authority (NBA), Directorate of Plant Protection, Quarantine & Storage (DPPQ) and Directorate General of Foreign Trade (DGFT) are amongst the regulatory agencies/committees facilitating biological research in India by providing requisite approvals.

2. Biological Research Regulatory Approval Portal (BioRRAP)

To streamline and strengthen biological research and innovation in the country, the Department of Biotechnology has developed Biological Research Regulatory Approval Portal (BioRRAP) (URL: <https://biorrap.gov.in/>). BioRRAP has been created to track the regulatory approvals for research projects that involve **international research** in life science including research studies on humans, animals, plants, and environment. The portal is one-of-a-kind digital gateway intended to make biological research more accessible and to provide more credibility and recognition.

BioRRAP provides a single route to direct the applicant to regulatory agencies providing requisite approval relevant to the biological research. Based on a succinct set of questions responded in affirmative by the applicant, the list of regulatory agencies from whom approvals may be required for biological research, is determined, and attached to the unique BioRRAP ID generated on the submission.

BioRRAP portal strengthens interdepartmental synergies and increases efficacy in functioning of agencies regulating various aspect of biological research. This further streamlines the regulatory process and affirms ease of doing biological science.

The information on **international research projects** that involve foreign collaborations, biosafety, biosecurity clearance including national sensitivity/security issues and transfer of biological material etc. as approved by the concerned line Ministries/Departments of Gol is expected to be integrated with BioRRAP (with Unique BioRRAP ID for each proposal). Further details in this regard can be accessed at <https://biorrap.gov.in/>.

3. Submission of application on BioRRAP Portal

Following steps are to be followed while submitting a request on BioRRAP portal:

1. Search Your Organization by clicking on "Organization Registration" from Menu or through the URL (<https://biorrap.gov.in/Home/SearchOrganization>)
2. In Search Organization Section, you can enter full Organization name or partial Organization name, then click 'Search' Button
3. Once the organization is found in the search list, then click on 'Request for New User'.
4. In New user request - Enter your Complete Name, Official Email ID and ten-digit Mobile Number then click on 'Save' Button.
5. Once the request for New User is approved by your Organization Admin, the login credentials will be sent to your registered Email ID. In case of rejection, the reason for rejection will be sent to your registered Email ID.
6. After getting login credentials, click on the "Submit new proposal" menu available after user login to submit research proposal for registration
7. Submit Research Proposal
8. After the submission of research proposal, BioRRAP ID would be generated.

9. BioRRAP ID is required for submission of research proposal on portals of relevant regulatory agencies.

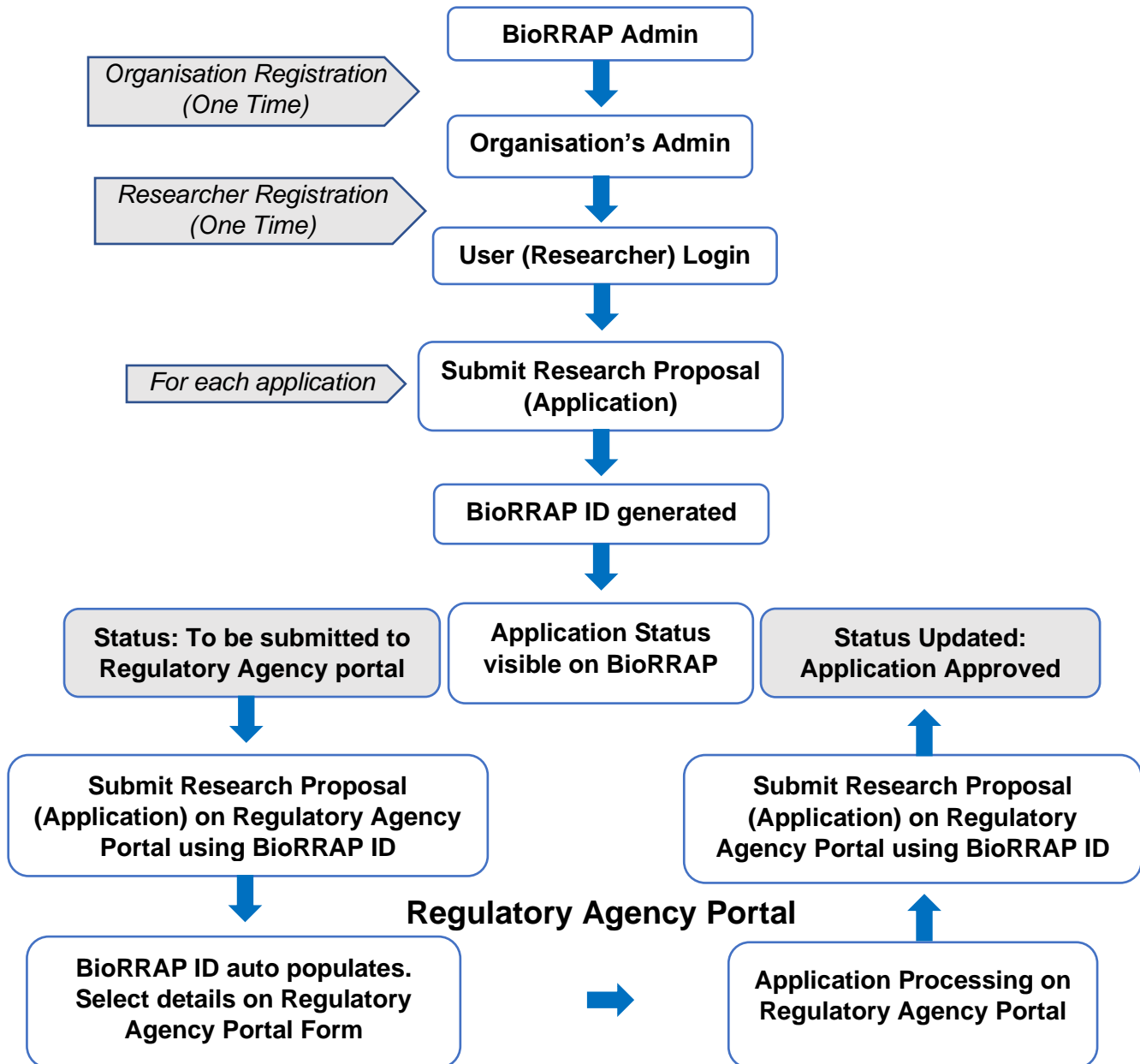


Figure 1. Flow diagram on the functioning of BioRRAP portal