**Check list for the BioRRAP application.**

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| --- | --- |
| **Research involves rDNA technology.**  **If Yes**   1. Category I GE experiments 2. Category II GE experiments 3. Category III GE experiments | [(refer Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017)](https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf)   1. (Before commencement of Category I GE experiments, the investigator should intimate the IBSC about the objective and experimental design of the study along with organisms involved.   IBSC should review the same as and when convened for record or action if any. It is desirable to designate a separate area in the facility with proper labelling for Category I GE experiments to avoid any chances of contamination)   1. (All category II GE experiments require prior authorization from IBSC before the commencement of the experiments through submission of information in the prescribed proforma. It is desirable to designate a separate area in the facility with proper labelling for Category II GE experiments to avoid any chances of contamination.) 2. (All category III and above GE experiments require prior authorization from IBSC and subsequent approval from RCGM before commencement of the experiments through submission of information in the prescribed proforma) |
| **Research involves Microorganisms.**  **If Yes**   1. Risk Group 2 and below 2. Risk Group 3 and above | [(refer Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017)](https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf)   1. (Within the purview of Rules 1989 of Environment (Protection) Act 1986, Institutional Biosafety Committees have been empowered to take adequate precautionary measures for research conducted on risk group 1 and 2 organisms. Biosafety Level 2 (BSL-2) will be applicable for: i. Isolation, cultivation and storage of RG 2 microorganisms. ii. Handling of environmental samples collected from environment that is unlikely to contain pathogens. Isolation of microorganisms from those samples and subsequent experiments. iii. Experiments on RG 2 microorganisms or isolates from environment mentioned above, provided that the experiments will not increase environmental fitness and virulence of the microorganisms.) 2. (The approval from Review Committee on Genetic Manipulation is required for experiments involving risk group 3 and 4 organisms. **Biosafety Level 3 (BSL-3)** will be applicable for: i. Isolation, cultivation and storage of RG 3 microorganisms. ii. Handling of environmental samples collected from environment that is likely to contain pathogens of potential disease consequences. Isolation of microorganisms from those samples and subsequent experiments. iii. Experiments on RG 3 microorganisms or isolates from environment mentioned above provided that the experiments will not increase environmental fitness and virulence of the microorganisms. **Biosafety Level 4 (BSL-4)** is the maximum containment laboratory. BSL-4 will be suitable for: i. Isolation, cultivation and storage of RG 4 microorganisms. ii. Handling of samples collected from environment/patients that are likely infected with RG 4 organisms with serious/fatal health effects. iii. Experiments on RG 4 microorganisms or isolates from environment/patients mentioned above to find remedial measures. iv. Category III and above genetic engineering experiments on microorganisms involving introduction of nucleic acids (recombinant or synthetic) into RG 4 microorganisms or exotic agents.) |
| **Research involves Animal Studies**  **If Yes**   1. Small Animals 2. Large Animals | [(refer Compendium of CPCSEA)](http://cpcsea.nic.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf)   1. (Compliance required as per Compendium of CPCSEA and approval of Institutional Animal Ethic Committee (IAEC)) 2. (Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) approval) |
| **Biomedical and Health Research involving Human Participants**  **If Yes**   1. International Collaboration in Biomedical and Health Research involving Human Participants and/or transfer of Human Biological Material (Samples): | [(refer Guidelines for International Collaboration/Research Projects in Health Research: MoUs and HMSC Procedure)](https://main.icmr.nic.in/content/guidelines)   1. (Health Ministry's Screening Committee (HMSC) approval) |
| **Research Involves Import/Export/Transfer**  **If Yes**   1. Import/ export/ transfer of Micro-Organisms upto Risk Group 2 2. Micro-Organisms upto Risk Group 2 and products derived from them not specified or covered in Revised Simplified Procedures/ Guidelines on Import, Export and Exchange of GE organisms and products thereof for R&D purpose, OM No. BT/BS/17/635/2015-PID dated 17.01.2020 3. Import/ export/ transfer Micro-Organisms of Risk Group 3 and above 4. Import of Exotic Agricultural Pests 5. Export of Indian Bioresource and Traditional Medicine Bioresources 6. Export of SCOMET items | 1. [Compliance required as per Revised Simplified Procedures/ Guidelines on Import, Export and Exchange of GE organisms and products thereof for R&D purpose, OM No. BT/BS/17/635/2015-PID dated 17.01.2020 and approval of Institutional Biosafety Committee (IBSC)](https://ibkp.dbtindia.gov.in/PageContent/ShowBrowsedFile?FileName=20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf&FPath=E:\\DBT_Content_Test\CMS\Guidelines/20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf) 2. [Review Committee on Genetic Manipulation (RCGM) approval](https://ibkp.dbtindia.gov.in/PageContent/ShowBrowsedFile?FileName=20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf&FPath=E:\\DBT_Content_Test\CMS\Guidelines/20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf) 3. [Review Committee on Genetic Manipulation (RCGM) approval](https://ibkp.dbtindia.gov.in/PageContent/ShowBrowsedFile?FileName=20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf&FPath=E:\\DBT_Content_Test\CMS\Guidelines/20200423124040845_Revised%20simplified%20procedure%20guidelines.pdf) 4. Directorate of Plant Protection Quarantine & Storage (DPPQ&S) approval 5. [National Biodiversity Authority (NBA) approval (refer Biological Diversity Rules, 2004)](https://www.forests.tn.gov.in/tnforest/app/webroot/img/document/legislations/01_Biological%20Diversity%20Rules%202004.pdf) 6. [Export License from DGFT is required](https://content.dgft.gov.in/Website/append3_0.pdf) |
| **Research Involves Radioactive Material:**  **If Yes** | Radiological Safety Division (RSD), Atomic Energy Regulatory Board (AERB) approval |
| **Confined Field Trials for Genetically Engineered Plants.**  If Yes | Genetic Engineering Appraisal Committee (GEAC) approval |