Jawaharlal Institute of Postgraduate Medical Education and Research Puducherry - 605 006

Institution of National Importance under Ministry of Health and Family Welfare, Government of India

2014

Standard Operating Procedures for Institutional Biosafety Committee (IBSC)

Contents

CODE: JIPMER-IBSC 2014

Prepared by:	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **1 of 23**
Dr. G. K. Pal Member Secretary, JIPMER, IBSC	**Title: Establishing and Constituting the Institutional Biosafety Committee**	**Category IBSC**	

1. PURPOSE

To establish and constitute IBSC, JIPMER.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

Director (Head of the Institute) is responsible for implementing this SOP.

4. PROCEDURE

4.1. Director will select and nominate the Chairman and Member Secretary for JIPMER, IBSC.

4.2. The IBSC will be constituted by the Director in consultation with the Chairman.

4.3.The IBSC shall have the following members (Document 3):

i. Head of the organization or his designate (a suitable senior officer) as the Chairperson

ii. Three or more scientists engaged in rDNA work or molecular biology with atleast one outside expert in the relevant discipline.

iii. A member with medical qualifications - Biosafety Officer (in case of work with pathogenic agents/large scale use).

iv. A nominee of DBT.

4.4. Director will invite the members to join IBSC by sending the official request letter (Document 1)

4.5. Members will confirm their acceptance to the Director by providing all the required information for membership (Document 2)

4.6. The Director will ensure that the IBSC is established in accordance with the applicable laws and regulations of Department of Biotechnology, Ministry of Science and Technology, Government of India

4.7. Director will designate and instruct Chairman of IBSC or his representative to conduct the regular proceedings of IBSC for the institute

4.8. At regular intervals, Director will review the functioning of IBSC.

4.9. The request for registration of IBSC is submitted to DBT in prescribed proforma (Document 5). DBT then nominates appropriate representative as a DBT nominee and communicates the same to IBSC Chairperson.

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER** **Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **2 of 23**
	Title: Procedure for appointing members for the IBSC	**Category IBSC**	

1. PURPOSE

To appoint suitable members for the IBSC, JIPMER**.**

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

Director (Head of the Institute) and Chairman are responsible for implementing this SOP.

4. PROCEDURE

4.1. Director in consultation with Chairman will nominate the members of IBSC, who have the qualification and experience to review and evaluate research proposal related to the area of interest.

4.2. IBSC may use qualified experts/ consultants from within or outside organization for advice and information, as and when required.

4.3. The appointment of an IBSC member will be for 3 years.

4.4. Director may renew the appointment on the basis of the member's contribution.

4.5. Membership can be annually reviewed by the IBSC Chairperson and Head of the organisation and appropriately modified based upon participation.

4.6. Member will have the right to discontinue from membership of IBSC after giving written notice at least one month in advance.

4.7. Director can replace the member of IBSC as and when required.

4.8.There is no limit to the number of terms a member may serve as an IBSC member

4.9. Any changes in IBSC membership/composition including the Chairperson will be notified by the IBSC Chairperson/Member Secretary to DBT within two weeks of the new appointment/ discontinuation.

4.10. Each member is required to sign the declaration and confidentiality agreement regarding IBSC activities (Document 7)

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by:	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **3 of 23**
Dr. G. K. Pal Member Secretary, JIPMER, IBSC	**Title: Responsibilities and training requirement of members of IBSC**	**Category IBSC**	

1. PURPOSE

To define the general responsibilities of the members of IBSC including training requirement**.**

2. SCOPE

Applicable to IBSC members, JIPMER.

3. RESPONSIBILITY

Director (Head of the Institute), Chairman and members of the IBSC are responsible for implementing this SOP.

4. PROCEDURE

4.1. IBSC members are expected to attend all the IBSC meetings. Information should be provided at least one week before, if a member is unable to attend an IBSC meeting.

4.2. All members of the IBSC should receive initial mandatory and refresher training on biosafety, the Rules,1989, rDNA guidelines and related regulations and familiarise themselves with IBSC guidelines and institutional policies. In addition, IBSC members should receive refresher training on any changes to national guidelines. All IBSC members must familiarize with the DBT guidelines for research involving GMOs, LMOs and rDNA materials.

4.3. IBSC members are expected to assess in detail the proposals allotted to them and attend the convened meetings with their prepared report that highlights the deficiencies and suggest improvements in design or execution of the study

4.4. All IBSC members are expected to declare competing conflicts of interest with respect to research proposals or investigators, if any, before commencement of each meeting.

4.5. IBSC members are expected not to be present during presentation of proposals in which they are co-investigators, unless requested to answer clarifications; they may present proposals if they are principal investigators, but in both situations should leave the room before IBSC discussions and decisions.

4.6. Members should not make copies of any material provided to them and ensure destruction or return of all materials sent for review (CD containing research proposals and supporting documents) after the IBSC meetings.

4.7. Training is imparted to IBSC members by holding workshops on regular basis.

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **4 of 23**
	Title : Procedure for convening and conducting IBSC meetings	**Category IBSC**	

1. PURPOSE

To hold regular IBSC meetings.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

The Chairman and Member Secretary are responsible for implementing this SOP.

4. PROCEDURE

4.1. The Member Secretary in consultation with the Chairman may convene the IBSC meeting once in every six months or as and when required.

4.2. Additional review meetings can also be held with short notice and will be planned in accordance with the need of the work load.

4.3. All the IBSC meetings will be held regularly on scheduled dates that are announced and notified in advance.

4.4. The meetings would discuss

i. Action taken on the decisions of earlier IBSC meetings.
ii. Assessment of work elements and approval as per risk category of organism involved
iii. Evaluation of projects and direction for submission to appropriate agencies for statutory approvals
iv. Inspection of containment facilities, unit process areas, greenhouses and preparation of reports for regulatory agencies.
v. Review the medical reports of employees
vi. Examining and recommending procedures and other approval requirements

4.5. All the proposals will be received at least three weeks before the meeting, checked for completeness

4.6. Members will be given not less than 10 days time in advance to review study proposals and the relevant documents.

4.7. Attendance of members at IBSC meetings is mandatory. At least 50% of the IBSC members along with DBT nominee must be present to conduct the meeting.

4.8. The final approval or disapproval of non-exempt projects of GMOs/LMOs/rDNA materials requires a majority vote by IBSC members and DBT nominee.

4.9. Minutes of the IBSC meetings, all the proceedings and deliberation will be documented.

4.10. Signatures of the Chairman and DBT nominee will be obtained on the minutes of the meeting document, without which it is invalid.

4.11. Principal investigator may be invited to present the proposal or elaborate on specific Issues.

4.12. Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality

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Approved by:	**Dr. S. C. Parija** **Dean, (Research)** **Chairman, JIPMER, IBSC**	**06.01.2014**

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER** **Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **6 of 23**
	Title : Procedure for submission of research project for review by IBSC	**Category IBSC**	

1.PURPOSE

To submit a research proposal for review by IBSC.

2. SCOPE

Applicable to Principal Investigators.

3. RESPONSIBILITY

All investigators are responsible for implementing this SOP. Every protocol or amendment submitted for review to IBSC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.

4. PROCEDURE

4.1. The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IBSC (Document 8). All research proposals must be submitted in English language only.

4.2. Application can be submitted to the office of the Member Secretary, IBSC, JIPMER, Pondicherry on any working day.

4.3. All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IBSC meeting.

4.4. Ten hard copies and a soft copy of the research proposals should be sent to Member Secretary. The hard copies should be typed as per format.

4.5. Receipt of the application will be acknowledged by the IBSC office.

4.6. Every application will be allotted an IBSC registration number to be used for all future correspondence and reference

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **7 of 23**
	Title : Procedure for initial scrutiny of proposals	**Category IBSC**	

1. PURPOSE

To check the research proposals submitted by the investigators for completeness.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

The office of Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1. Every proposal will be collected and compiled by IBSC office.

4.2. An office staff nominated by the Member Secretary will verify the proposals for completeness..

4.3. In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit.

Approved by: **Dr. S. C. Parija**
Dean, (Research)
Chairman, JIPMER, IBSC
06.01.2014

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **8 of 23**
	Title : Procedure for reviewing the research proposals	**Category IBSC**	

1. PURPOSE

To review the research proposals submitted by the investigators.

2. SCOPE

Applicable to JIPMER.

3. RESPONSIBILITY

All members of IBSC are responsible for implementing this SOP.

4. PROCEDURE

4.1. Every proposal will be sent not less than 10 days before the meeting to all members of IBSC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IBSC review.

4.3. IBSC has to review all recombinant research carried out by an organisation depending upon the category of experiments, IBSC can simply note the information provided by investigator, give permission before start of the experiments or forward it to RCGM for approval as per the Recombinant DNA Safety Guidelines.

i. Category I experiments involving self cloning, using strains and also inter species cloning belonging to organism in the same exchanger group etc. are exempt for the purpose of intimation and approval.

ii. Category II experiments falling under containment levels II, III and IV, large scale use of recombinants made of self cloning in systems belonging to exempt category etc. require prior intimation to IBSC.

iii. Category III experiments involving toxin gene cloning, cloning of genes for vaccine production, use of infectious animals and plant viruses, self fusion experiments, field testing and release of GMOs etc. require review and approval of IBSC before commencement.

4.4. Expert opinion of additional members would be obtained if necessary.

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **9 of 23**
	Title : Procedure for decision making regarding the research project	**Category IBSC**	

1. PURPOSE

To make a decision regarding approval of the submitted research proposal.

2. SCOPE

Applicable to the IBSC of JIPMER.

3. RESPONSIBILITY

All members of IBSC are responsible for implementing this SOP.

4. PROCEDURE

4.1. Member having a conflict of interest will indicate to the Chairman prior to the review of application and same will be recorded in the minutes.

4.2. Where there is a conflict of interest, member will withdraw from the decision making procedure.

4.3. A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. Investigator) from the meeting.

4.4. Decision will only be taken at meetings when quorum is complete.

4.5. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.

4.6. Only IBSC members who participated in review and discussion will participate in decision making.

4.7. Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.

4.8. Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.

4.9. Rejection of proposal will be supported by clearly stated reasons

4.10. IBSC can simply note the information provided by Principal investigator, give permission before start of the experiments or forward it to RCGM for approval.

4.11. RCGM grants approval as per format (Document 9).

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER** **Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **10 of 23**
	Title : Procedure for communicating the decision of IBSC to the Principal Investigator	**Category IBSC**	

1. PURPOSE

To communicate the decision of IBSC to the applicant.

2. SCOPE

Applicable to the IBSC of JIPMER.

3. RESPONSIBILITY

Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1. A decision of the IBSC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format (Document-4). All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

4.2. The communication of the decision will include:

- Name and address of IBSC.
- The date and place of decision.
- The name and designation of the applicant.
- Title of the research proposal reviewed.
- The clear identification of protocol no., version no., date, amendment no., date.
- A clear statement of decision reached.
- Any advice by the IBSC to the applicant.
- In case of conditional decision, any requirement by IBSC, including suggestions for revision, approval of RCGM and the procedure for having the application re-reviewed.
- In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
- Signature of the member secretary with date

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER** **Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **11 of 23**
	Title : Procedure for follow-up of research projects IBSC	**Category IBSC**	

1. PURPOSE

To carry out follow-up of the research proposals.

2. SCOPE

Applicable to the IBSC of JIPMER.

3. RESPONSIBILITY

All members of the IBSC and the investigators are responsible for implementing this SOP.

4. PROCEDURE

4.1 IBSC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.

4.2. Progress of all the research proposals will be followed at a regular interval of at least once a yea But in special situations, IBSC will conduct the follow up review at shorter intervals basing on th need, nature and events of research project.

4.3. All the requirements and procedures for follow up review will be similar to that of initial and mair review.

4.4. Following instances and events will require the follow-up review:

i. Any protocol amendment likely to affect safety of research subject of conduct of study.

ii. Any event or information that may affect the benefit/risk ratio of the study.

4.5. A decision of a follow up review will be issued and communicated to the applicant indicating modification/ suspension/termination / continuation of the project.

4.6. In case of premature suspension /termination, the applicant must notify the IBSC of the reasons for suspension/termination with a summary of results.

4.7. Applicant must inform the time of completion of study and must send the result summary to IBSC. IBSC must receive a copy of final summary of study completed from the applicant.

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, IBSC, JIPMER

Prepared by: **Dr. G. K. Pal** **Member Secretary,** **JIPMER, IBSC**	**Institutional Biosafety Committee, JIPMER** **Standard Operating Procedure**	**Date** **06.01.2014**	**Page** **12 of 23**
	Title : Procedure for reporting, documentation and archiving of documents and communications of IBSC	**Category IBSC**	

1. PURPOSE

To archive the study related documents, proceedings and communications.

2. SCOPE

Applicable to the IBSC of JIPMER.

3. RESPONSIBILITY

The Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1. IBSC submits annual report to RCGM (Document 6), provides information to biosafety websites

4.2. Only persons, who are authorized by the Chairman of IBSC will have the access to the various documents.

4.3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.

4.4. No document (except agenda) will be retained by any IBSC member.

4.5. At the end of each meeting, every member must return all the research proposals and documents to IBSC office staff. They will archive one copy in IBSC office and other copies will be destroyed after one year.

4.6. Following documents will be filed and archived with proper label on the top of file for easy identification of proposal.

i. The constitution, written standard operating procedures of the IBSC, and communications to RCGM.
ii. The curriculum vitae of all IBSC members.
iii. A record of all income and expenses if any, of the IBSC.
iv. The published guidelines for submission established by the IBSC.
v. The minutes of the IBSC meetings.
vi. One copy of all material submitted by an applicant.
vii. A copy of the decision and any advice or requirements sent to an applicant.
viii. All written documentation received during the follow-up.
ix. The notification of completion, premature suspension, or premature termination of study.
x. The final summary or final report of the study.

Approved by:	**Dr. S. C. Parija** **Dean, (Research)** **Chairman, IBSC, JIPMER**	**06.01.2014**

CODE: JIPMER-IBSC 2014

Prepared by:	Institutional Biosafety Committee, JIPMER Standard Operating Procedure	Date 06.01.2014	Page 13 of 23
Dr. G. K. Pal Member Secretary, JIPMER, IBSC	Title: Procedure for monitoring research facilities	Category IBSC	

1. PURPOSE

To monitor research facilities.

2. SCOPE

Applicable to IBSC of JIPMER.

3. RESPONSIBILITY

IBSC Members, Principal investigator are responsible for implementing this SOP.

4. PROCEDURE

4.1. Routine laboratory inspections are carried out by, relevant authorised personnel, such as IBSC members, as well as representatives and officers authorised by the regulatory authorities using IBSC checklists. Inspection reports are filed.

4.2. The Principal investigator and all associated personnel are held responsible for the security of GMOs/LMOs/rDNA and are accountable for them. Access to biological materials is limited to authorised personnel only.

4.3. The Principal investigator, depending on the risk group of GMOs/LMOs and rDNA materials, should develop a plan to protect the security of the material in question.

4.4. IBSC may review the disposal methods as potentially hazardous biological materials and should be disposed of in a manner consistent with rDNA safety guidelines.

Approved by: **Dr. S. C. Parija** **06.01.2014**
Dean, (Research)
Chairman, JIPMER, IBSC

Letter Ref. No: Date:

From,
The Director
JIPMER
Puducherry.

To

Sub: Constitution of Institutional Biosafety Committee - Reg.

****

Dear Sir / Madam,

On behalf of Jawaharlal Institute of Postgraduate Medical Education and Research, an institution approved for conducting clinical research in genetically modified organisms (GMOs)/living modified organisms (LMOs) and rDNA materials, I request your concurrence for possible appointment as a member of Institutional Biosafety Committee of this institute. Kindly send your written acceptance in the enclosed format and provide the necessary information requested. On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Signature:

Name:

From,

To
The Director
JIPMER
Puducherry-6.

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg.
Ref: Your Letter No: dated:

****

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IBSC of JIPMER. I shall regularly participate in the IBSC meeting to review and give my unbiased opinion. I shall be willing for my name, profession and affiliation to be published. I shall not keep any literature or study related document with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel. I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature Date:
Name of the Member
Address:

Telephone No: (Off) (Res) email:
JIP-IBSC Ref. No.:

Date:

OFFICE ORDER

I herewith establish and constitute an Institutional Biosafety Committee of Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, to regulate and monitor research activity related to genetically modified organisms.

The following members will constitute the Institutional Biosafety Committee

1. Chairman
   Designation_____ Affiliation
2. Member secretary
   Designation_____ Affiliation
3. DBT Nominee
   Designation_____ Affiliation
4. Biosafety Officer
   Designation_____ Affiliation
5. External Member
   Designation_____ Affiliation
6. External Member
   Designation_____ Affiliation
7. Internal Member
   Designation_____ Affiliation
8. Internal Member
   Designation_____ Affiliation
9. Internal Member
   Designation_____ Affiliation
10. Internal Member
    Designation_____ Affiliation

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The tenure of this membership will be for a period of 3 years from the date of appointment.

Signature
Director, JIPMER

Institutional Biosafety Committee
JIPMER

Review letter No IBSC/JIP/ Date:

To,

The _____ meeting of the Institute Biosafety Committee IBSC for the year _____ was held in _____, JIPMER on _____ under the chairmanship of _____. Besides the Chairman, _____ (Member Secretary), _____ (Member), _____ (Member), attended the meeting.

After the proceedings, the proposals listed for the meeting were taken up for discussion. After deliberations, the following decisions were arrived:

No. of proposals reviewed - _____

No. of proposals approved - _____

No. of proposals approved subject to corrections - _____

The recommendations made by the committee are given below.

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to _____, Member-Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairman of committee.

The recommendations of the committee to each proposal are detailed below:

Sl No.	Reg. No.	Name of the Principal Investigator (Department)	Title of proposal	Name of Co-investigators	Recommendations of the committee

Any change, modification or deviation in the protocol, or any serious adverse event must be informed to committee within fourteen days. Any protocol modification or amendment must receive IBSC approval. Investigator should conduct the study as per the recommended guidelines.

Member Secretary
Institute Biosafety Committee

Chairman
Institute Biosafety Committee

Name:

Signature:

Date:

APPLICATION FOR REGISTRATION OF AN INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)

Name and address of the Organisation:

Phone, fax & email:

2. Head of the Organisation:
(Please provide contact details including postal address, phone, fax and e-mail)

Phone, fax & email:

3. Contact Person/(Proposed Member Secretary):
(Please provide contact details including postal address, phone, fax & e-mail)

Phone, fax & email:

4. Proposed activities/projects to be undertaken:

5. Indicate the list of organisms/genetically engineered organisms to be used:

6. Category of biosafety level as per the Recombinant DNA Safety Guidelines, 1990 issued by Department of Biotechnology:

7. Containment facilities available for rDNA activities:
a. Laboratory set up

b. Greenhouse/ nethouse (Details may include structure, size, size of the mesh etc.):

c. Any other specialized facility

8. Proposed composition of IBSC:

9. Suggestion for suitable experts (3 nos.) working in similar area who could be identified as DBT nominee:

10. Please provide a brief write up about your organisation including details of infrastructural facilities available to carry out r-DNA activities in not more than 500 words:

Date: **(Head of the Organisation)**

ANNUAL REPORT OF THE INSTITUTIONAL BIOSAFETY COMMITTEE TO RCGM

1. Name of the Organisation:

2. DBT Office Memorandum No.:

3. Date of IBSC constitution:

4. Composition of IBSC:

Chairperson:
Member Secretary:
DBT Nominee:
Members:
Outside Experts: Biosafety Officer/ Medical Officer:

5. Changes in IBSC composition during the year, if any:

6. Details of IBSC meetings during the year:

a. Number of meetings held:
b. Dates of each meeting:
c. Whether the minutes have been sent to RCGM:
Yes □ No □
d. Whether the details have been posted on the http://dbtbiosafety.nic.in:
Yes □ No □

7. Examination & Clearance of the proposals during the period:

8. Import/ Exchange of material for Research/Training

9. Pilot operations/confined field trials conducted during the period

10. Whether all projects approved by IBSC are being carried out:
Yes □ No □

11. Whether all projects approved by RCGM are being carried out:
Yes □ No □

12. Training programmes related to biosafety:

a) Programmes conducted in-house
b) Participation in national/international programmes

13. Yearly health surveillance (as applicable) conducted:
Yes □ No □

14. Whether the appropriate waste treatment & disposal facilities are being used in all projects to avoid risks to the environment?:
Yes □ No □

15. Accidents, if any & emergency measures taken:

16. Any other relevant information:

Date **(Head of the Organisation)**

CONFIDENTIALITY AGREEMENT WITH IBSC MEMBERS INCLUDING DBT NOMINEE

As a member of the Institutional Biosafety Committee (IBSC) constituted by the_____ (Name of Organisation) as per provisions of “Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989” notified by the Ministry of Environment and Forests (MoEF), Government of India under the Environment (Protection) Act, 1986.

I hereby declare that I am aware of my obligations to respect confidentiality of applications, issues and other matters placed before the IBSC and discussed thereupon, during my entire tenure of membership of IBSC. I hereby solemnly agree and undertake to maintain the confidentially of the proposals and other related information made available to me for review, reference or discussion. I hereby further agree and undertake not to divulge any confidential or Intellectual Property (IP) or commercial business information (CBI) of the organisation/institute acquired as a result of my review of such proposals and subsequent discussions arising there from. I shall also respect the confidential nature of the opinions expressed by other IBSC members or experts during discussions in meetings or provided in written form and would not divulge the same to any person, press or media. I also agree that I would avoid any conflict of interest such as relationship with any applicant, financial interest and providing any consultancy, advice, services as an individual/ scientist to any applicant except of the academic, scientific and intellectual nature.

Executed at: _____on (Date) _____

Signature :

Name & Address:

JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH, PUDUCHERRY - 605 006
(Institution of National Importance under Ministry of Health and Family Welfare, Government of India)

INFORMATION TO RCGM TO CARRY OUT RESEARCH INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR DEVELOPMENT OF rDNA PRODUCTS FOR HEALTHCARE AND INDUSTRIAL USE

1. Name of the Applicant:_
   Designation
   Address:
   Telephone No.
   Fax No.:_____
   e-mail:_____
2. DBT Office Memorandum No.:_____
3. Application for : _____
   - 3.1 Purpose: (not more than 100 words) _____
   - 3.2 New Yes No
   - 3.3 Ongoing Project Yes No
     If yes, No. & Date of permission letter issued :
   - 3.4 Category (Biosafety level) of experiments as per the Recombinant DNA safety Guidelines, 1990 issued by DBT
4. Description of the GMOs/LMOs proposed to employed in the research proposal:
   (in scientific terms; for new application only)
   - 4.1 Description of GMOs/LMOs
   - 4.2 Description of the target gene(s)
   - 4.3 Number of copies of the genes incorporated
   - 4.4 Description of the target product(s)
5. Details on :
   - 5.1 Source of nucleic acid(s) :
   - 5.2 Nucleic acid sequence (Please enclose the nucleic acid sequence map of the target gene) :
   - 5.3 Vector(s) (Please enclose the map of the vector gene) :
   - 5.4 Host(s) that carrying the vector(s)/ target gene(s) :
   - 5.5 Manipulative procedures :
   - 5.6 Anticipated functions of product(s)
6. Summary of the proposed work plan utilizing GMOs:
   (please check it from the following areas and provide the details of work plan).
   - 6.1 Basic transformation and laboratory work to assess the expression of the target gene
   - 6.2 Standardization of fermentation/production procedures _____
7. Site/ Location of the research work :
8. Proposed containment facility (Please indicate the level of containment pro-posed):

9. Decontamination and disposal mechanisms:
10. Risk management (Emergency plan):
11. Any other relevant information:
12. Declaration:

I declare that the information provided in the above format is correct and accurate to the best of my knowledge. The "Safety Guidelines" brought out by the Department of Biotechnology, Ministry of Science & Technology, Govt. of India will be and is being strictly followed. In case any untoward incident occurs, the Chairman of the IBSC and the Member-Secretary of the RCGM will be informed immediately.

Date: Signature of the Applicant

Forwarded:

The proposal set out above has been considered and approved by the "Institutional Biosafety Committee" in its meeting held on _____ and is forwarded to RCGM for further necessary action.

Date: Signature and name of the Chairman, IBSC

Note:
1. Please submit 10 copies of the application along with the enclosures to the Member Secretary, RCGM, Department of Biotechnology for consideration by RCGM.

2. Enclosed: (Kindly tick the enclosures)
   - Sequence map of the gene
   - Vector Map
   - Copy of the permit, if issued earlier
   - Copy of the minutes of IBSC meeting in which the proposal was approved

INFORMATION ON RECORD TAKEN BY RCGM FOR RESEARCH INVOLVING GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR DEVELOPMENT OF rDNA PRODUCTS FOR HEALTHCARE AND INDUSTRIAL USE

PERMIT NUMBER:

DATE OF ISSUE: _____
DATE OF EXPIRY: _____

Applicant: _____

Name of Organisation: _____

Address:

_____

Phone, fax & e-mail:

_____

Subject: Information submitted vide letter No. _____ dated _____

1. This is to inform that the application to Review Committee on Genetic Manipulation (RCGM) on the following projects was considered and noted by the RCGM in its meeting held on _____.

i) _____

ii) _____

2. Additional information sought by RCGM, if any should be separately included.

3. You are required to comply with the r-DNA Safety Guidelines-1990 of DBT.

4. Please provide the information on the above projects for updation on http:// www.igmoris.nic.in as per details on the website

(Member Secretary, RCGM)