STANDARD OPERATING PROCEDURES

for Institutional Ethics Committee

Babasaheb Bhimrao Ambedkar University, Lucknow

1. OBJECTIVES

The IEC is responsible for reviewing research involving human participants at this institution, to ensure that subjects' safety, rights, and welfare are protected in conformity with applicable regulations and guidelines issued by the ICMR Indian state and local laws and regulations where such laws or regulations provide protection for human subjects that exceed the protection afforded under national law. A number of studies pursued in BBAU include biological sample (blood / tissue/ stored sample) collected from diseased and normal subjects for research purposes; and non-invasive studies on speech and language deficit in cases of neurological damage, aphasia studies, dyslexia and developmental disorders of language etc. Non invasive studies also include socio-psychological, socio-cultural studies involving human participants. All such studies on biological samples, stored samples, behavioural data samples and socio-cultural-psychological data samples involving human participants need ethical clearance by IEC. All such studies require IEC clearance before the commencement of the study.

This Standard Operating Procedures (SOP) is to outline the development, approval, organization, implementation and management of all Human Research protocols to be conducted in Babasaheb Bhimrao Ambedkar University. The IEC is entrusted not only with the initial review of the proposed research protocols prior to the initiation of the project; in case of adverse effects reported by the PI /participants, the Board is also mandated to review and fix compensations/reimbursement. All adverse effects/ injury /damage/ loss /death must be reported immediately to the IEC, death to be reported within 24 hours, as per GOI/CDSCO norms.

In case of modifications in research tools & procedures during the course of the study, reported by the PI/ participants, the Board is also mandated to review and accept/reject the modifications proposed as the case may be.

2. ROLE AND RESPONSIBILITIES OF THE INSTITUTIONAL ETHICS COMMITTEE

The basic responsibility of IEC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IEC shall provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Departmental Research Committee of the University.

The mandate of the committee will be to review all research projects involving human subjects/materials to be conducted in different departments at the University. The Committee will review all research proposals involving human subjects, submitted by faculty members and research students (through their respective Supervisors). Each investigator shall be responsible, for proving the benefit of placing human subjects at risk, and assure the review committee about appropriate Informed Consent Process and Subject Confidentiality. All studies need to be approved before the study procedures begin and provide details of primary data/secondary data/stored samples/cell lines/ Buying data to the review committee in her/his presentation; also assure the review committee about appropriate IC process & subject confidentiality before the commencement of the study. No completed studies or those already being pursued will be reviewed by the Ethics Committee.

3. OPERATING PROCEDURES

3.1 CONSTITUTION OF IEC.

As per ICMR, guidelines, the IEC should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an Institutional Ethics Committee. The members should be a mix of medical/ non-medical professionals, legal experts, experts from sciences and social sciences and humanities, philosophers and activists, internal and external, also including lay persons from NGO's to represent the civil society. (See appendix B for relevant sections of ICMR guidelines) A panel of names in each one of the categories specified below, approved by the EC, will serve as the Institutional Ethics Committee- BBAU.

Constitution of IEC -

1. Chairperson (External)
2. Scientist from Medical Practice (External)
3. Scientist from Basic Sciences (External)
4. Scientist from Basic Sciences (BBAU)
5. Social Scientist / Philosopher / Social Activist (External)
6. Social Scientist / Philosopher / Activist (External)
7. Member of another IEC (ICMR / AIIMS / any other)
8. Legal Advisor (External)
9. Legal Advisor (Internal)
10. Lay Persons (NGOs representatives of Civil Society/lay persons).
11. Member Secretary (BBAU)

As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental organization / philosopher / ethicist / theologian or a similar person
5. One lay person from the community

**As foot note/ end note*

Link for Drug trials-norms &guidelines to be provided

Link for genetic studies on human samples may be provided

Link for Radiological investigations-norms &guidelines to be provided

3.2. COMPOSITION OF A REVIEW COMMITTEE.

The number of persons in an ethics committee should be 8 to 12, drawn from the panel of names approved by the EC, as specified above. The Chairperson, IEC will approve the names of the members of a review committee, at least one from each category, depending on the nature of the research proposal to be reviewed.

(Appendix A for the current Panel of Experts in the IEC-BBAU).

3.2.1. APPOINTMENT, RESIGNATION AND RECONSTITUTION

For appointment to the committee, a candidate should have had at least 10 years of work experience at positions of significant responsibility. Professional integrity and commitment to human welfare would be important criteria for inclusion as members.

After the initial constitution, subsequent appointment to the committee shall be guided by the quorum requirements and activity of the members involved. As per ICMR guidelines, the appointee will be informed of the rights and duties of the committee, and that the external members will receive honorarium for every consultative meeting held on the campus.

All Committee members shall sign a confidentiality agreement at the time of appointment, the terms of which shall be binding on them even after the term expires. Co-opted members are also expected to sign confidentiality agreement. All members, except the Chairperson and Member Secretary, shall serve a maximum of a two-year term on the committee, after which a fresh panel of three names in the same category will be submitted to the IEC, BBAU so that one out of the three may be appointed in place of the retiring person. For the sake of continuity, the Chairperson and the Member- Secretary will have a term of two/three years. Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.

Members may voluntarily resign from the Committee at a month's notice citing appropriate reasons, and incase of internal members, their membership would be considered withdrawn, if they resign from the University. A member who has direct involvement or self affirmed conflict of interest with a proposal being considered, shall not form a part of the quorum.
If a member is found to have a conflict of interest with the results of decision and fails to declare the same, or is found to have drawn direct benefit arising out of the results of the research, or has involved self-interest with the sponsor(s) or investigators, his/her membership shall be terminated with provision of appropriate legal proceedings.
In case a member breaches the confidentiality, his/her membership shall be terminated and the institution may initiate appropriate legal proceedings.

3.2.2. HONORARIUM

External members of the IEC, and experts invited (if any) shall receive appropriate compensation for the time and effort expended for the purpose.

3.3. PROCEDURE FOR SUBMISSION AND REVIEW

The IEC will meet at twice a year or more if required, to review all the applications, including proposals for M.Sc, Ph.D; also including research proposals submitted by the faculty involving human subjects materials for any kind of data. All proposals shall be reviewed as per the applicable guidelines given in Appendix C. (see Research and Protocol Organization Guidelines in Appendix C.) Exact meeting date shall be notified at least 15 days in advance so that all members can make themselves available for the purpose. The Chairperson / Member -Secretary shall be the convener with responsibility of laying out the agenda for the meeting. All material relevant to the agenda shall be made available to IEC at least 1 week in advance. Before they are circulated to the external members the Member Secretary of the committee together with one or two internal members, will screen the proposals, to see if it needs (i) exemption from review, or (ii) expedited review or (iii) full review, see appendix B, for relevant excerpts from ICMR guidelines.

All protocols should be submitted in the format prescribed in *Appendix C*. The proposals shall be addressed and submitted to the office of the **Member Secretary, IEC, Room no. 15, Dept. of Biotechnology, Babasaheb Bhimrao Ambedkar University, Lucknow-226025**. Ten copies each of the documents should be submitted. An application should be submitted at least 10 days

weeks prior to the next review meeting. A unique submission number shall be assigned to proposals submitted for review.

3.3.1. **To Review MA/ M.Sc/ M.Tech/ M.Phil proposals:**
The constitution of the committee to review students' proposals will be as under:
1. Chairperson or his nominee
2. Two external members
3. At least one legal expert member
4. Two or three internal members
5. Member - Secretary
Further the committee will review MSc. /Ph.D. proposals in a time bound manner, meeting at least twice a year. This committee will take full responsibility of all the decisions. Ph. D proposals will be reviewed in the main committee along with the faculty research proposals.

3.3.2. Recommendation of the Committee:
After discussion, the committee may make one of the following recommendations:
 Approval - indicating that the proposal is approved as submitted;
 Approval after clarifications - indicating that the proposal is approved if the clarification(s) requested are provided to the satisfaction of designated committee members;
 Approval after amendment(s) - indicating that the proposal is approved subject to the incorporation of the specified amendment(s) verified by designated committee members;
 Deferment - indicating that the proposal is not approved as submitted but it can be reassessed after revision to address the specified reason(s) for deferment;
 Disapproval - indicating that the proposal is not approved for the reasons specified.

Format for the Ethical clearance certificate will be as given in the Appendix C.

3.4. DOCUMENTS FOR SUBMISSION OF THE PROPOSAL:
1. Protocol of the proposed research in the prescribed format which includes:
1.1 Rationale / Background information
1.2. A description of the ethical considerations involved in the research
1.3. Case report forms and other questionnaires intended for research participants
1.4. Summary of safety, pharmacological, pharmaceutical, and toxicological data available on the study product, wherever applicable
1.5. Statement of agreement to comply with ethical principles
1.6. Statement of conflict of interest
1.7. Name and address of the Sponsor/Funding agency
1.8. Insurance Statement (Wherever required)
2. Investigator's Brochure Including Report of Prior Investigations
3. Investigator(s)'s curriculum vitae
4. Informed Consent
5. In case of students' proposals, synopsis of the MPhil/Ph.D research as approved by the Centre/ School.
3.4.1. Regarding no.-4 above, a template is given in the annexure- C. which may be modified depending on the nature of participation expected from the study participants.