Academic Integrity and Ethics Policy

Jain VishvaBharati Institute

(Declared Deemed-to-be University Under Section 3 of The UGC Act, 1956)

Ladnun - 341306 (Raj.)

Approved in the meeting of the Academic Council on

Jain VishvaBharati Institute

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Preamble

Scientific researches involve the cooperation and coordination of different people to achieve goals that have impact on society and are essential for overall development in all areas. Research requires experimentation, data analysis, writing research papers and grant proposals and educating future scientists. Thus, it is essential that research is carried out in ways that are ethically correct.

The administrative apparatus of the JVBI shall envisage an Institutional Ethics Committee for effectuating the said preamble.

Institutional Ethics Committee (IEC)

The IEC shall be entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved programs to foresee the compliance of the ethics during the period of the project.

The basic responsibility of the IEC shall be to ensure a competent review of all ethical and technical aspects of the project proposals received by it in an objective manner. IEC will 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. The major aspects that IEC shall focus on the following aspects:

A. To protect the dignity, rights and well-being of the potential research participants.

B. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

C. To assist in the development and the education of a research community responsive to local health care requirements.

Submission and Review of applications

Applications for ethical committee clearance would be submitted in the prescribed format to the Member Secretary along with the necessary documents. The applications will be then scrutinized by the Chairperson and the Member Secretary and will be categorized among the three categories as described in the guidelines.

The applications shall be then forwarded to IEC members, who will have a minimum period of 3 weeks for review. The Committee shall evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and other legal issues. Following the receipt of comments from the IEC members, the faculty/Principle Investigator will be invited to present and defend his/her proposal in front of the IEC.

An investigator cannot decide whether her/his protocol falls in the exempted category without approval from the IEC.

The IEC shall meet periodically at frequent intervals, to review new proposals, evaluate annual progress of ongoing projects, to review serious adverse event (SAE) reports and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate.

Checklist of documents for submission of applications

1. Duly filled and signed application in the prescribed format

2. Detailed CV of PI and collaborators involved in the work and a clearly defined role of each investigator

3. Participant recruitment procedures, brochures, inclusion exclusion criteria for entry of participants

4.Volunteer information sheet.

5. Consent forms in English and native language (Rajasthani/Hindi) of the participant. (Including assent forms where young adults or children are proposed as human participants-if any).

6. Ethical clearance certificate for the project from the participating Institute/Organization (if applicable) format.

7. MoU/MoA signed between PIs and collaborators outside JVBI (if applicable)

8. Material Transfer Agreement (MTA) for international projects which may involve exchange of human material or data.

9. A statement of conflicts of interest (if any)

10. Periodic review report

Monitoring

Once the IEC gives a certificate of approval; it shall be the duty of the IEC to monitor the approved studies. Therefore, an oversight mechanism shall be put in place. Actual site visits could be made especially in the event of reporting of adverse events or violations of human rights. Additionally, periodic status reports shall be asked for appropriate intervals, based on the safety concerns as specified in the SOP's of the IEC.

The Policy : Various Dimensions of the Institutional Approach

Guidelines for research ethics would be laid in such a way that concerns of Jain Vishva Bharati Institute and individuals are simultaneously addressed. Also, it is important to adhere to these ethical guidelines in order to preserve the dignity, rights and welfare of researchers and research participants. Based on area of research and subjects involved, guidelines for carrying research has been defined by various agencies. All the researchers at the JVBI are expected to follow the Ethics of research as described in the guidelines. Some of the guidelines are given below:

Biomedical Research on Human Participants: The Nuremberg Code formulated in 1947, was the first international statement on ethics of medical research using human subjects. Over the years, various international and national advisory bodies have revised and laid down principles for scientific research involving human beings. Clinical research is required for better understanding of science and developing drugs, vaccines, diagnostics, instruments and materials which can enhance quality of human health. However, it is important to give credit to individuals who volunteer to participate in biomedical research. To protect the interest of participants in biomedical research, ethical guidelines are established. In India, the Indian Council of Medical Research

(ICMR), Govt. of India, has set ethical guidelines for biomedical research involving human participants. Research on human subjects follows the principles of essentiality of the research, voluntariness, informed consent, non-exploitation, confidentiality, accountability and transparency. Although, right now the JVBI has not undertaken such research projects; however, in future if any project shall be undertaken, the said ICMR guidelines would be adhered to.

Working with Laboratory Animals: The Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA), has laid down guidelines to assure quality maintenance and humane care of laboratory animals while conducting scientific experiments. These guidelines also set rules for proper procurement, quarantine and rearing of laboratory animals. At present, no research programme has been undertaken where use of living animals is required. However, in future such experiments if undertaken, JVBI administration would be taking all precautions to conduct experiments by way of erecting separate animal house and adhere to the protocols, as stated above.

Working with Chemicals: The Bureau of Indian Standards, Govt. of India, has recommended a code of safety for all chemical laboratories in India. It involves guidelines for recognizing potential chemical hazards and employing corrective actions in order to expeditiously minimize accidents. Every researcher at JVBI has been directed to follow the guidelines especially with the hazardous chemicals.

Radiation Safety: These guidelines have been set by the Department of Atomic Energy, Govt. of India, which apply to practices adopted and interventions applied while working with radiation sources in Indian laboratories. They ensure that the ionizing radiation and nuclear energy does not cause any risk to the health of researcher and the environment. At present no such experiment has been undertaken, where radiation occurs; however, in future, if such experiments would be undertaken, a close monitoring by institutional radiation safety committee shall be made in order to seek help in ensuring compliance to these guidelines so that the exposure to all sources of ionizing radiation is ensured as low as reasonably achievable.