



KRISTU JAYANTI
(DEEMED TO BE UNIVERSITY)
Under Section 3 of UGC Act 1956
A CMI INSTITUTION | BENGALURU | INDIA

Centre for Research and Development

Institutional Review Board January 2026-December 2028

About IRB

Kristu Jayanti University is committed to upholding the highest standards of ethical conduct in all research activities involving human participants. The Institutional Review Board (IRB) has been established in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, issued by the Indian Council of Medical Research (ICMR), and in compliance with applicable national and international regulations.

The IRB serves as an independent body responsible for reviewing, approving, and monitoring all research involving human participants conducted under the auspices of Kristu Jayanti University. This policy document outlines the framework, procedures, and standards that govern the ethical review process at the institution.

1. Overview

The Institutional Review Board (IRB) of Kristu Jayanti (Deemed to be University) is established to ensure that all research involving human participants upholds the highest ethical standards and complies with both national and international guidelines. The University is committed to safeguarding the rights, welfare, dignity, safety, and privacy of all individuals participating in research conducted under its auspices.

The IRB serves as an independent body responsible for reviewing, approving, and monitoring all research involving human participants conducted under the auspices of Kristu Jayanti University. *Research involving medical, clinical, or biological materials, or animal subjects, does not fall within the jurisdiction of the IRB.* Such studies shall be directed to the respective Human Ethics Committee or Institutional Biosafety Committee, or Animal Ethics Committee of Kristu Jayanti (Deemed to be University).

The IRB operates in accordance with the three fundamental ethical principles outlined in the Belmont Report — Beneficence, Justice, and Respect for Persons. Adherence to these principles ensures that research conducted by faculty, research scholars, students, and collaborators reflects academic integrity, social responsibility, and a culture of respect for research participants.

Maintaining these ethical standards is essential to preserving the trust of the academic community, funding agencies, and the public in the quality and integrity of research at Kristu Jayanti (Deemed to be University). Researchers are required to ensure that potential risks to participants are minimized and that informed consent is obtained in an appropriate, transparent, and voluntary manner. (See “Guidelines” for further details.)

All research involving human participants will undergo an appropriate level of ethical review. The IRB will evaluate critical elements of research protocols, including participant selection, voluntariness, informed consent, risk–benefit assessment, confidentiality in data management, and—where relevant—provisions for participant compensation. Proposals will be reviewed before the initiation of the study, and the IRB may conduct periodic reviews throughout the project to ensure ongoing compliance.

1.1 Legal and Regulatory Framework

This policy is developed in consonance with:

- ✦ National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (ICMR)
- ✦ Good Clinical Practice Guidelines
- ✦ National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017
- ✦ Information Technology Act, 2000 and subsequent amendments
- ✦ Digital Personal Data Protection (DPDP) Act 2023
- ✦ Biological Diversity Act, 2002
- ✦ International ethical guidelines, including the Declaration of Helsinki, CIOMS Guidelines, Belmont Report principles (1979), and United States Federal Policy for the Protection of Human Subjects (1991; revised 2018) —known as the Common Rule (45 CFR 46, Subpart A)

2. Institutional Commitment

Kristu Jayanti University acknowledges that research involving human participants is crucial for advancing scientific knowledge and enhancing health outcomes. However, such research must be conducted with the utmost respect for human dignity, rights, safety, and well-being. The University commits to:

- ✦ Protecting the rights, safety, dignity, and well-being of research participants
- ✦ Ensuring the scientific and social value of research
- ✦ Maintaining transparency and accountability in research conduct
- ✦ Promoting research integrity and preventing misconduct
- ✦ Building capacity for ethical research practices
- ✦ Fostering a culture of responsible research

3. Vision and Mission

3.1 Vision

To be a center of excellence in ethical research governance, fostering innovative and socially relevant research while ensuring the highest standards of protection for human research participants, thereby contributing to the advancement of science upholding integrity and compassion.

3.2 Mission

The Institutional Review Board of Kristu Jayanti University is committed to:

1. **Safeguarding Participant Welfare:** Ensuring that the rights, safety, dignity, and well-being of all research participants are protected through rigorous ethical review and continuous monitoring.
2. **Promoting Research Excellence:** Facilitating high-quality, scientifically sound, and ethically conducted research that addresses relevant health and social challenges.
3. **Ensuring Regulatory Compliance:** Maintaining adherence to national and international ethical guidelines, regulatory requirements, and institutional policies.
4. **Building Research Capacity:** Providing education, training, and guidance to researchers, students, and staff on ethical principles and responsible conduct of research.
5. **Fostering Transparency:** Operating with transparency, accountability, and independence in all review processes and decision-making.

6. **Encouraging Community Engagement:** Promoting meaningful engagement with communities and stakeholders in research planning, conduct, and dissemination.
7. **Upholding Social Justice:** Ensuring equitable access to research participation and fair distribution of research benefits and burdens.

3.3 Core Values

The IRB of KJU will operate on the following core values:

1. **Respect for Persons:** Acknowledging autonomy and providing protection to those with diminished autonomy
2. **Beneficence:** Maximising benefits and minimising harms
3. **Justice:** Ensuring fair distribution of research benefits and burdens
4. **Non-maleficence:** Avoiding harm to participants
5. **Integrity:** Maintaining honesty, transparency, and accountability
6. **Confidentiality:** Protecting participant privacy and data security
7. **Social Responsibility:** Conducting research that benefits society

4. Scope and Applicability

4.1 Applicability

This policy applies to all research activities conducted by:

- ✚ Faculty members, research scholars, students, and staff of Kristu Jayanti University
- ✚ Researchers affiliated with the University through collaborative agreements
- ✚ External researchers using University facilities or resources
- ✚ Research conducted on University premises or under University sponsorship

4.2 Types of Research Requiring IRB Review

All research involving human participants or sensitive personal information will require IRB review and approval before initiation.

This includes but is not limited to:

4.2.1 Health Research (With No Risk or Minimal Risk or Minor increase over Minimal Risk)

- ✚ Epidemiological studies
- ✚ Public health research
- ✚ Health systems and services research
- ✚ Behavioural and psychological interventions
- ✚ Nutrition and dietary studies
- ✚ Health education research
- ✚ Quality improvement studies with research components

4.2.2 Social and Behavioural Research with Health Implications (With No Risk or Minimal Risk or Minor increase over Minimal Risk)

- ✦ Studies involving non-sensitive health information
- ✦ Research on health behaviours and risk factors
- ✦ Community-based participatory research

4.2.3 Database and Registry Research (With No Risk or Minimal Risk or Minor increase over Minimal Risk)

- ✦ Research using existing records
- ✦ Database research with identifiable information
- ✦ Registry-based studies

4.3 Types of Research that do not fall within the jurisdiction of the IRB

Research involving Biomedical, Clinical, Biological materials, Animal subjects, Vulnerable populations, Radioactivity, OR meets the criteria for more than minimum risk

This includes but is not limited to:

4.3.1 Biomedical & Clinical Research

- ✦ Clinical trials of drugs, vaccines, and medical devices
- ✦ Surgical and therapeutic interventions
- ✦ Diagnostic procedures and tests
- ✦ Biological sample collection and analysis
- ✦ Genetic and genomic studies
- ✦ Stem cell research
- ✦ Reproductive health research
- ✦ Studies involving radiation or radioactive material

4.3.2 Health Research (with more than minimal Risk)

- ✦ Epidemiological studies
- ✦ Public health research
- ✦ Health systems and services research
- ✦ Behavioural and psychological interventions
- ✦ Nutrition and dietary studies
- ✦ Health education research
- ✦ Quality improvement studies with research components

4.3.3 Social and Behavioural Research with Health Implications (with more than minimal Risk)

- ✦ Studies involving sensitive health information
- ✦ Research on health behaviours and risk factors
- ✦ Mental health research
- ✦ Research involving vulnerable populations
- ✦ Community-based participatory research

4.3.4 Database and Registry Research (with more than minimal Risk)

- ✚ Research using existing medical records
- ✚ Secondary analysis of biological specimen
- ✚ Database research with identifiable information
- ✚ Registry-based studies

4.4 Multi-site and Collaborative Research

For multi-institutional research:

- ✚ The IRB will review research where Kristu Jayanti University is the coordinating centre
- ✚ For collaborative research, IRB review may be obtained from a single IRB through authorization agreements
- ✚ Site-specific issues must still be reviewed and approved by the local IRB
- ✚ International collaborative research must comply with the regulations of all participating countries

5. Constitution and Composition of IRB

5.1 IRB Structure

The IRB shall consist of at least ten members with diverse backgrounds to promote complete and adequate review of research activities. The Kristu Jayanti IRB consists of internal members drawn from multiple academic disciplines within the University and external experts from the medical, legal, and ethics domains. This diverse representation ensures balanced evaluation and ethical oversight across various fields of study.

5.2 Membership Composition

5.2.1 Required Members

1. **Chairperson or Co-Chairperson:** A senior faculty member (Affiliated/ non-affiliated) with substantial research experience and expertise in biomedical or health research ethics (non-scientist or scientist)
2. **Member Secretary:** A faculty member (Affiliated) responsible for administrative coordination and record-keeping. Should be motivated and have good communication skills.
3. **Basic Medical Scientist:** A person (Affiliated/ non-affiliated) with expertise in basic medical sciences (anatomy, physiology, biochemistry, pharmacology, microbiology, pathology)
4. **Clinical Expert:** Should be an individual/s (Non-affiliated) with a recognised medical qualification, expertise, and training
5. **Legal Expert:** A person (Affiliated/ non-affiliated) with legal knowledge, preferably with expertise in medical law or human rights
6. **Social Scientist:** Should be an individual (Non-affiliated) with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
7. **Lay Person/Community Representative:** A literate person (Non-affiliated) from the public or community, has not pursued a medical science/health-related career in the last 5 years, may be a representative of the community from which the participants are to be drawn, aware of the local language, cultural and moral values of the community. Desirable: involved in social and community welfare activities.

8. **Internal experts:** Faculty members from multiple academic disciplines with expertise in bioethics or moral philosophy.

5.2.2 Additional Members (as needed)

- ✦ Subject matter experts for specific research areas
- ✦ Public health specialist
- ✦ Biostatistician
- ✦ Patient/participant representative
- ✦ Representative from non-governmental organizations

5.2.3 Requirements for EC members

Every IRB member must:

- ✦ Provide a current signed CV along with training certificates in human research protection and GCP guidelines, where applicable.
- ✦ Either be trained in human research protection and/or GCP at the time of induction into the IRB, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy).
- ✦ Commit to ongoing professional development and skill enhancement throughout their service as an IRB member.
- ✦ Be aware of relevant guidelines and regulations.
- ✦ Review and commit to the IRB's Conflict of Interest policy, declaring any applicable conflicts as required.
- ✦ Sign a confidentiality and conflict of interest agreement/s.
- ✦ Agree to place her/his full name, profession, and affiliation to the IRB in the public domain.
- ✦ Recognise the importance of conducting quality research while prioritising the safety and well-being of all research participants.

5.3 Member Qualifications

All IRB members must:

- ✦ Have appropriate professional qualifications and experience
- ✦ Demonstrate commitment to ethical research practices
- ✦ Be available for regular meetings and reviews
- ✦ Complete required training in human subjects' protection and research ethics
- ✦ Maintain confidentiality of all review materials
- ✦ Declare conflicts of interest

5.4 Appointment and Tenure

1. **Appointment:** Members shall be appointed by the Vice-Chancellor/competent authority based on recommendations from a selection committee
2. **Term:** Members serve for a term of three years, renewable once
3. **Staggered Terms:** Appointments shall be staggered to ensure continuity

4. **Removal:** Members may be removed for cause, including non-attendance, conflict of interest, or breach of confidentiality

5.5 Independence and Conflict of Interest

- ✚ The IRB shall function independently and be free from undue influence
- ✚ Members shall not participate in the review of protocols in which they have a conflict of interest
- ✚ No member shall receive financial benefits from research approval decisions
- ✚ The majority of members shall not be from the same professional discipline
- ✚ At least three members shall be from outside the institution
- ✚ The IRB shall not consist entirely of members of one gender

5.6 Quorum Requirements

- ✚ A quorum requires the presence of at least 50% of members plus one
- ✚ Quorum must include:
 - ✓ At least one scientist member
 - ✓ At least one non-scientist member
 - ✓ At least one member from outside the institution
 - ✓ Both genders must be represented
 - ✓ Preferably, the lay person should be part of the quorum.
- ✚ No meeting shall be held without a quorum
- ✚ No decision will be valid without the fulfilment of the quorum.

6. Roles and Responsibilities

6.1 Institutional Responsibilities

Kristu Jayanti University shall:

- ✚ Provide adequate resources for the functioning of IRB including:
 - ✓ Suitable meeting space
 - ✓ Administrative support staff
 - ✓ Office equipment and supplies
 - ✓ Electronic database systems
 - ✓ Training opportunities for members
- ✚ Ensure IRB independence and authority
- ✚ Support IRB decisions and not override disapprovals
- ✚ Implement policies for research misconduct investigation
- ✚ Maintain liability insurance for research participants
- ✚ Ensure compliance with IRB requirements
- ✚ Report to regulatory authorities as required

6.2 IRB Responsibilities

The IRB shall:

1. **Review Protocols:** Conduct an ethical review of all research involving human participants

2. **Approve or Disapprove:** Make decisions on protocol approval, modification requirements, or disapproval
3. **Monitor Research:** Conduct continuing review and monitor ongoing research for compliance
4. **Review Adverse Events:** Assess serious adverse events and take appropriate action
5. **Review Amendments:** Evaluate protocol modifications and revised consent documents
6. **Suspend or Terminate:** Suspend or terminate research not conducted in accordance with IRB requirements
7. **Maintain Records:** Keep detailed records of all reviews and decisions
8. **Report:** Submit required reports to institutional authorities and regulatory bodies
9. **Provide Guidance:** Offer consultation to researchers on ethical issues
10. **Training:** Conduct training programme on research ethics

6.3 Principal Investigator Responsibilities

The PI shall:

- + Submit complete protocol and supporting documents for IRB review
- + Obtain IRB approval before initiating research
- + Conduct research according to approved protocol
- + Obtain and document informed consent
- + Report all serious adverse events promptly
- + Submit continuing review reports as required
- + Request IRB approval for all protocol modifications
- + Maintain research records for the specified period
- + Report protocol deviations and violations
- + Ensure all research personnel are trained
- + Protect participant confidentiality
- + Report any conflicts of interest
- + Comply with all IRB decisions and requirements
- + Submit final report upon study completion

6.4 Research Team Responsibilities

All research personnel shall:

- + Complete the required training in protection of human subjects
- + Understand and comply with the approved protocol
- + Follow informed consent procedures
- + Maintain participant confidentiality
- + Report safety concerns to PI immediately
- + Maintain accurate and complete records
- + Participate in IRB audits and inspections

6.5 Participant Responsibilities

While participants have no obligations, they are encouraged to:

- + Provide accurate information during screening
- + Ask questions about the research

- ✦ Follow study procedures if enrolled
- ✦ Report any adverse events or concerns
- ✦ Inform researchers of the decision to withdraw

6.6 Roles and Responsibilities of Key Members

6.6.1 Chairperson

- ✦ Presides over all IRB meetings
- ✦ Ensures fair and efficient conduct of reviews
- ✦ Assigns reviewers
- ✦ Signs approval documents and official correspondence
- ✦ Represents the IRB in institutional administration and external agencies
- ✦ Ensures compliance with policies and regulations
- ✦ Handles emergencies requiring expedited decisions

6.6.2 Member Secretary

- ✦ Schedules and coordinates meetings
- ✦ Maintains all IRB records and documents
- ✦ Receives and logs all submissions
- ✦ Distributes materials to members
- ✦ Prepares minutes of the meeting
- ✦ Manages correspondence
- ✦ Tracks continuing review and compliance
- ✦ Maintains training records

6.6.3 Primary Reviewers/Experts

- ✦ Conduct a detailed review of the assigned application and protocol
- ✦ Present a brief report to the full board
- ✦ Recommend approval, modifications, or disapproval
- ✦ Follow up on modifications requested

7. Types of Risk and Review process

7.1 Categories of Risk

7.1.1 Less than minimal risk:

The probability of harm or discomfort anticipated in the research is nil or not expected.

This includes but is not limited to:

- ✦ Research on anonymous or non-identified data/samples, data available in the public domain for meta-analysis or systematic review, etc*.
- ✦ Recording observations of people's public conduct without personally identifying details, provided that disclosing these observations would not negatively impact those individuals
- ✦ Conducting quality control and quality assurance audits to evaluate institutional performance

- ✦ Analysis of various teaching techniques, curriculum designs, and strategies for managing the classroom environment (The intervention should not negatively affect student learning outcomes or the validity of educational assessments. Additionally, classroom instructors must be excluded from the study team)
- ✦ Research investigating consumer preferences regarding flavour profiles and food quality standards[#]
- ✦ Public health programmes operated by government agencies often include evaluation and monitoring components aimed at programme improvement. When these activities don't require individual identification, and they fall outside certain regulatory requirements.

**Data retrieved from websites or platforms that require authentication are not regarded as publicly available. When dealing with social media platforms specifically, the data extraction practices must comply with the platform's own privacy policies*

[#]The tested products must be wholesome foods, either free of additives or containing additives only at levels deemed safe by the Food Safety and Standards Authority of India (FSSAI)

7.1.2 Minimal risk:

Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population, or during the performance of routine physical or psychological examinations, where the occurrence of serious harm or an adverse event (AE) is unlikely

This includes but is not limited to:

- ✦ Research involving routine questioning or history taking, observing, physical examination, etc.
- ✦ Research involving documentation materials that are non-identifiable (data, documents, records)
- ✦ Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus groups, programme evaluation, human factors evaluation, or quality assurance methodologies where disclosure of responses would not reasonably place subjects at risk.

7.1.3 Minor increase over minimal risk/Low risk:

The probability of harm or discomfort rises only marginally above the minimal risk threshold.

This includes but is not limited to:

- ✦ Use of personal identifiable data in research
- ✦ Research leading to Social risks, psychological harm and discomfort
- ✦ Research resulting in stigmatizing a group or exposing its members to discrimination
- ✦ Research results in certain fields (e.g, epidemiology and sociology) which present risks to the interests of communities, societies, families, or racially or ethnically defined groups.
- ✦ Outcomes of research indicating that a group has a higher than average prevalence of alcoholism, mental illness, or sexually transmitted disease, or that it is particularly susceptible to certain genetic disorders

7.1.3 Vulnerable population:

Vulnerable people are those with reduced or absent ability to protect themselves, whether due to personal constraints, environmental challenges, social disadvantages, powerlessness, communication barriers, or restrictive circumstances. Individuals who are illiterate, marginalized by virtue of their social status or behaviour, or living in an authoritarian environment, may have multiple factors that make them vulnerable. These individuals often exhibit common characteristics as listed:

7.1.3.1 Characteristics of vulnerable individuals/populations/groups

Individuals may be considered to be vulnerable if they are:

- ✦ Socially, economically or politically disadvantaged and therefore susceptible to being exploited
- ✦ Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example, unconscious people, differently abled;
- ✦ Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions
- ✦ Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent.

7.1.3.2 Example of vulnerable individuals/populations/groups

1. **Women:** Although the general population of women should not be presumed vulnerable, certain research environments or conditions may render women vulnerable in ways such as:
 - ✓ Studies with female or transsexual sex workers
 - ✓ Research on sexual and intimate partner violence
 - ✓ Studies with trafficked women, refugees asylum seekers
 - ✓ Studies of abortion in jurisdictions where abortion is illegal
 - ✓ Research with women who live in a cultural context where they are not permitted to consent on their own behalf for participation in research, but require permission from a spouse or male relative
 - ✓ Study may cause risks to the fetus
 - ✓ Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare)
2. **Institutionalised persons:** Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, mentally compromised adults, under trials and prisoners), residents of nursing homes, mental institutions, and prisons (prisoners under trial)
3. **Other potentially vulnerable individuals:** Members of groups that have traditionally been considered vulnerable:
 - ✓ People receiving welfare benefits or social assistance, economically and socially disadvantaged [unemployed individuals, orphans, abandoned individuals, homeless persons, nomads, refugees, displaced persons, persons below the poverty line, political asylum, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.]
 - ✓ People who perceive participation as the only means of accessing medical care
 - ✓ People unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent
 - ✓ Some ethnic and racial minorities
 - ✓ People living with disabilities, afflicted with mental illness, and cognitively impaired individuals, differently abled –mentally and physically disabled
 - ✓ People with incurable or stigmatized conditions or diseases
 - ✓ People facing physical frailty, e.g., age and comorbidities, politically powerless individuals
 - ✓ Members of communities unfamiliar with modern medical concepts.

- ✓ Children (up to 18 years of age)
- ✓ Tribal and marginalized communities
- ✓ Refugees, migrants, homeless persons, or populations in conflict zones, riot areas, or disaster situations
- ✓ Terminally ill or are in search of new interventions, having exhausted all therapies

7.1.4 Highly Sensitive Research Proposal:

This includes but is not limited to:

- ✚ 'race', social group, caste, civilization, or culture
- ✚ Political judgement or view
- ✚ Religious, spiritual, or other beliefs
- ✚ Sexuality
- ✚ Children or adult abuse
- ✚ Nudity and the body
- ✚ Criminal activities
- ✚ Conflict states
- ✚ Individual/ community violence

7.2 Type of Review

Normally, there are three types of review

7.2.1 Exempt Review

Research may be exempt from full IRB review if it meets the criteria of less than minimal risk
The probability of harm or discomfort anticipated in the research is nil or not expected.

This includes but is not limited to:

- ✚ Research on anonymous or non-identified data/samples, data available in the public domain for meta-analysis or systematic review, etc*.
- ✚ Recording observations of people's public conduct without personally identifying details, provided that disclosing these observations would not negatively impact those individuals
- ✚ Conducting quality control and quality assurance audits to evaluate institutional performance
- ✚ Analysis of various teaching techniques, curriculum design, and strategies for managing the classroom environment (The intervention should not negatively affect student learning outcomes or the validity of educational assessments. Additionally, classroom instructors must be excluded from the study team)
- ✚ Research investigating consumer preferences regarding flavour profiles and food quality standards[#]
- ✚ Public health programmes operated by government agencies often include evaluation and monitoring components aimed at programme improvement. When these activities don't require individual identification, and they fall outside certain regulatory requirements.
- ✚ Quality assurance and program evaluation activities without research intent
- ✚ Studies involving only observation of public behavior without recording identifiable information
- ✚ Research involving minimal risk with adult participants providing informed consent

**Data retrieved from websites or platforms that require authentication are not regarded as publicly available. When dealing with social media platforms specifically, the data extraction practices must comply with the platform's own privacy policies*

#The tested products must be wholesome foods, either free of additives or containing additives only at levels deemed safe by the Food Safety and Standards Authority of India (FSSAI)

7.2.1.1 Exempt Review Process

- ✦ Investigator submits exemption request with protocol summary
- ✦ Designated reviewer or IRB Chair evaluates request
- ✦ Decision communicated within 14 working days
- ✦ Exemption letter issued if approved
- ✦ Research is still subject to institutional oversight

Note: Even an exempt research

- ✓ Must adhere to ethical principles and good research practices.
- ✓ Must be submitted to the IRB for determination of exempt status

7.2.3 Expedited Review

Research involving no more than minimal risk may qualify for expedited review

This includes but is not limited to:

- ✦ Modification or amendment to an approved protocol, including administrative changes or correction of typographical errors, and a change in researcher(s)
- ✦ Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- ✦ Minor deviations from originally approved research causing no risk or minimal risk
- ✦ Progress/annual reports where there is no additional risk, for example, activity limited to data analysis
- ✦ Expedited review of SAEs/unexpected AEs will be conducted by the SAE subcommittee
- ✦ For multicentre research where a designated main IRB/EC among the participating sites has reviewed and approved the study, a local IRB/EC may conduct only an expedited review for site-specific requirements in addition to the full committee common review
- ✦ Research during emergencies and disasters

7.2.3.1 Expedited Review Process

- ✦ Application and protocol assigned to experienced IRB member(s) or Chair
- ✦ Reviewer(s) conduct detailed review
- ✦ Reviewer may:
 - ✓ Approve the research
 - ✓ Require modifications to secure approval
 - ✓ Refer to full board review
- ✦ Decision communicated within 28 working days
- ✦ Full board notified of expedited approvals

7.2.4 Full Board Review

All research proposals presenting minimal risk or minor increases over minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, provided the proposal does not involve any clinical, Biological material, or genetic modification or biohazards or vulnerable individuals/populations/groups or highly sensitive matter.

This includes but is not limited to:

- ✦ Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine physical or psychological examinations, where the occurrence of serious harm or an adverse event (AE) is unlikely
- ✦ For example:
 - ✓ Research involving routine questioning or history taking, observing, physical examination, etc.
 - ✓ Research involving documentation materials that are non-identifiable (data, documents, records)
 - ✓ Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus groups, programme evaluation, human factors evaluation, or quality assurance methodologies where disclosure of responses would not reasonably place subjects at risk
- ✦ The probability of harm or discomfort rises only marginally above the minimal risk threshold.
- ✦ For example:
 - ✓ Use of personal identifiable data in research
 - ✓ Research leading to social risks, psychological harm and discomfort
 - ✓ Research resulting in stigmatizing a group or exposing its members to discrimination
 - ✓ Research results in certain fields (e.g, epidemiology and sociology) which present risks to the interests of communities, societies, families, or racially or ethnically defined groups
 - ✓ Outcome of research indicates that a group has a higher than average prevalence of alcoholism, mental illness or sexually transmitted disease, or that it is particularly susceptible to certain genetic disorders

7.2.4.1 Full Board Review Process

1. **Submission:** PI submits a complete application to IRB office
2. **Administrative Review:** IRB staff conduct an administrative review for completeness (3-5 working days)
3. **Assignment:** Application and protocol assigned to primary and secondary reviewers
4. **Initial Review:** Reviewers conduct a detailed evaluation (minimum 15 days before meeting)
5. **Agenda Preparation:** The IRB office prepares the meeting agenda and distributes materials (minimum 7 days before the meeting)
6. **Board Meeting:** Protocol presented and discussed
 - ✓ Primary reviewer presents protocol
 - ✓ Board discusses scientific merit, risks, and benefits
 - ✓ PI may be invited to clarify issues
 - ✓ Board deliberates and votes
 - ✓ Decision recorded in minutes
7. **Decision Categories:**
 - ✓ Approved
 - ✓ Approved with minor modifications (to be verified by Chairperson)
 - ✓ Deferred (modifications required, re-review needed)
 - ✓ Disapproved

- ✓ Tabled (insufficient information)
- ✓ Decision communicated within 90 working days
- 8. **Notification:** Decision communicated in writing within 5 working days of the meeting
- 9. **Approval Period:** Initial approval is valid for one year unless specified otherwise

7.3 Review Criteria

The IRB evaluates all protocols using the following criteria:

7.3.1 Scientific and Social Value

- ✚ Research addresses an important scientific or social question
- ✚ The study design is appropriate to answer the research question
- ✚ Research has the potential to generate useful knowledge
- ✚ Benefits justify the risks

7.3.2 Scientific Validity

- ✚ Study design is scientifically sound
- ✚ Sample size is justified and adequate
- ✚ Statistical methods are appropriate
- ✚ Research objectives are achievable
- ✚ Investigators have the necessary expertise and resources
- ✚ Study is feasible

7.3.3 Fair Subject Selection

- ✚ Selection is equitable and justified
- ✚ Vulnerable populations are not included in the study
- ✚ Inclusion/exclusion criteria are appropriate
- ✚ Recruitment procedures are fair and non-coercive
- ✚ Benefits and burdens are fairly distributed

7.3.4 Favorable Risk-Benefit Ratio

- ✚ Risks are minimized through sound research design
- ✚ Risks are reasonable in relation to anticipated benefits
- ✚ Procedures are consistent with sound research design
- ✚ Alternative procedures with less risk are considered

7.3.5 Informed Consent

- ✚ Consent process is adequate and appropriate
- ✚ Information provided is complete and understandable
- ✚ Consent is voluntary and free from coercion
- ✚ Documentation is appropriate
- ✚ Special provisions for vulnerable populations

7.3.6 Privacy and Confidentiality

- ✚ Adequate provisions to protect privacy
- ✚ Data confidentiality measures are robust
- ✚ Data security plans are adequate
- ✚ Provisions for breach notification exist

7.3.7 Monitoring and Compliance

- ✚ Adequate provisions for data and safety monitoring
- ✚ Plans for reporting adverse events
- ✚ Provisions for ongoing review and oversight

8. Standard Operating Procedures

8.1 Protocol Submission Requirements

Before applying to the IRB member secretary, all the proposals, along with protocol and required documents, must be approved by the department or Ph.D advisory committee (as applicable).

8.1.1 Required Documents

All submissions must include:

1. **Cover letter to Member Secretary:** mentioning the Type of review requested
2. **IRB Application Form:** Completed initial institutional review form with all required information
3. **Protocol Document:** Detailed protocol including:
 - a) **Title and version date:** The face page carrying the title of the proposal with signatures of the investigators
 - b) **Background and rationale:** Why a human study is needed to answer the research question
 - c) **Brief summary/ lay summary**
 - d) **Research objectives and hypotheses:** Clear research objectives and endpoints (if applicable)
 - e) **Detailed study design and methodology :**Including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection and management, statistical analysis plan, timeline
 - f) **Study population and sample size calculation:** Justification
 - g) **Recruitment procedures:** Inclusion and exclusion criteria with Justification
 - h) **Risk assessment and mitigation:** Benefit–risk assessment, plans to withdraw
 - i) **Ethical considerations:** Plan to maintain the privacy and confidentiality of the study participants
 - j) **Plans for publication of results:** Positive or negative – while maintaining confidentiality of personal information/ identity
 - k) **References**
4. **Informed Consent Documents (ICD):**
 - ✓ Participant Information Sheet
 - ✓ Consent Form (The correct version of the ICD in English and the local language)
 - ✓ Assent form (if applicable)

- ✓ Translated versions (if applicable)
- ✓ Translation and back translation certificates (if applicable)

5. ***Investigator Documents:***

- ✓ CV of Principal Investigator and co-investigators
- ✓ Training certificates in research ethics (preferably within 5 years)
- ✓ Any other research ethics/other training evidence, if applicable, as per IRB SOP
- ✓ Conflict of interest disclosure
- ✓ List of ongoing research studies undertaken by the principal investigator (if applicable)
- ✓ Undertaking with the signatures of the investigators

6. ***Recruitment Materials:***

- ✓ Advertisements
- ✓ Flyers
- ✓ Social media content
- ✓ Scripts for verbal recruitment

7. ***Data Collection Instruments:***

- ✓ Questionnaires
- ✓ Interview guides
- ✓ Case report forms
- ✓ Scales and assessment tools

8. ***Supporting Documents:***

- ✓ Regulatory approvals (if obtained)
- ✓ Funding approval letter
- ✓ Collaboration agreements
- ✓ Data safety monitoring plan
- ✓ Previous IRB approvals (for multi-site studies)
- ✓ MoU in case of studies involving collaboration with other institutions (if applicable)

8.1.2 Submission Process

- ✚ Investigator completion of all documents by investigator
- ✚ Getting the approval from the departmental or Ph.D. advisory committee, whichever is applicable
- ✚ Submit the documents electronically through the IRB portal or in hard copy to member secretary
- ✚ The IRB office acknowledges receipt within 2 working days
- ✚ Administrative review for completeness within 5 working days
- ✚ Incomplete submissions are returned with clarifications needed
- ✚ Complete submissions assigned for review

8.2 Review Timeline

1. ***Exempt Review:*** 15 working days from complete submission
2. ***Expedited Review:*** 15 working days from complete submission

3. **Full Board Review:**

- ✓ Next scheduled quarterly meeting (materials due 14 days before meeting)
- ✓ Decision communicated within 5 working days of meeting
- ✓ Total timeline: 15-105 days from complete submission

8.3 IRB Meeting Procedures

8.3.1 Meeting Frequency

The IRB shall meet quarterly, or more frequently as workload demands.

8.3.2 Meeting Preparation

- + Agenda prepared and distributed at least 7 days before the meeting
- + Application, protocol document and review materials distributed electronically
- + Primary and secondary reviewers complete evaluation forms
- + Members review material before the meeting

8.3.3 Conduct of Meeting

- + Meeting called to order; quorum verified
- + Review and approval of previous minutes
- + Review of protocols:
 - ✓ New submissions
 - ✓ Continuing reviews
 - ✓ Protocol amendments
 - ✓ Adverse event reports
- + Discussion and voting (if required)
- + Review of correspondence and reports
- + Training and education items
- + Any other business

8.3.4 Voting Procedures

- + Only members without a conflict of interest may vote
- + A member with conflict must leave the room during discussion and voting
- + Simple majority required for approval
- + Chair votes only to break a tie
- + Votes recorded in minutes

8.3.5 Documentation

- + Minutes to be prepared, including:
 - ✓ Attendance
 - ✓ Protocols reviewed
 - ✓ Decisions made
 - ✓ Votes taken
 - ✓ Conditions or modifications required

- ✓ Rationale for disapprovals
- ✚ Minutes reviewed and approved at subsequent meeting
- ✚ Minutes archived securely

8.4 Communication of Decisions

8.4.1 IRB Approval Letter

Includes:

- ✚ IRB approval number
- ✚ Protocol title and version
- ✚ Approval date and expiry date
- ✚ Approved enrolment number
- ✚ Conditions of approval
- ✚ Continuing review requirements
- ✚ Reporting requirements

8.4.2 Modification Required Letter

Includes:

- ✚ Specific modifications required
- ✚ Rationale for modifications
- ✚ Process for resubmission

8.4.3 IRB Disapproval Letter

Includes:

- ✚ Reasons for disapproval
- ✚ Ethical concerns
- ✚ Right to appeal
- ✚ Appeal procedures

8.5 Protocol Amendments

8.5.1 Types of Amendments

Minor Amendments (Administrative changes):

- ✚ Contact information updates
- ✚ Correction of typographical errors
- ✚ Administrative personnel changes
- ✚ Minor clarifications

Major Amendments (Substantive changes):

- ✚ Changes to study design or objectives
- ✚ Changes to risk level

- ✦ Changes to study population
- ✦ Changes to consent procedures
- ✦ Addition of study sites
- ✦ Changes to data collection methods

8.5.2 Amendment Review Process

- ✦ PI submits an amendment request with:
 - ✓ Amendment description
 - ✓ Justification for change
 - ✓ Revised documents
 - ✓ Impact assessment
- ✦ IRB staff conducts an administrative review
- ✦ Minor amendments reviewed by Chair
- ✦ Major amendments reviewed by the full board
- ✦ Decision communicated within:
 - ✓ 7 days for minor amendments
 - ✓ 15-30 days for major amendments
- ✦ Amendments cannot be implemented until IRB approval

8.6 Continuing Review

8.6.1 Frequency

- ✦ Research approved for more than a year or less requires annual continuing review (every 6 months)
- ✦ Depending on the risk associated, some research may require more frequent review (every 3 months)
- ✦ Review will be scheduled before approval expiration

8.6.2 Continuing Review Requirements

PI submits:

- ✦ Continuing review report including:
 - ✓ Number of participants enrolled
 - ✓ Number of participants completed
 - ✓ Adverse events summary
 - ✓ Protocol deviations
 - ✓ Updated risk-benefit assessment
 - ✓ Any new information
 - ✓ Current consent documents
 - ✓ Publications or presentations
- ✦ Updated protocol (if changes made)
- ✦ Current investigator documents

8.6.3 Continuing Review Process

- ✦ IRB reviews ongoing research
- ✦ Determines if continuation is appropriate
- ✦ May require modifications
- ✦ May increase monitoring frequency

- ✦ Issues continuation approval or requires study closure

8.6.4 Lapse in Approval

If approval expires:

- ✦ All research activities must stop
- ✦ No new participants can be enrolled
- ✦ Only interventions necessary for participant safety may continue
- ✦ PI must submit continuing review immediately
- ✦ Lapse to be reported to institutional authorities

8.7 Adverse Event Reporting

8.7.1 Reporting Requirements

1. **Serious Adverse Events (SAEs)**: Report within 24 hours of awareness
2. **Unanticipated Problems**: Report within 7 days
3. **Protocol Deviations**: Report within 15 days
4. **Protocol Violations**: Report immediately

8.7.2 SAE Report Content

- ✦ Participant identifier (coded)
- ✦ Description of event
- ✦ Date of onset and resolution
- ✦ Severity grade
- ✦ Relationship to research procedures
- ✦ Expectedness
- ✦ Action taken
- ✦ Outcome
- ✦ PI assessment

8.7.3 IRB Review of Adverse Events

- ✦ IRB reviews all SAE reports
- ✦ Determines if the event was:
 - ✓ Related to research
 - ✓ Unanticipated
 - ✓ Suggests research poses greater risk
- ✦ May require:
 - ✓ Protocol modifications
 - ✓ Consent form updates
 - ✓ Additional participant notification
 - ✓ Increased monitoring
 - ✓ Study suspension or termination

8.8 Study Closure

8.8.1 Final Report Requirements

PI submits final report within 30 days of study completion, including:

- ✚ Study completion date
- ✚ Final enrollment numbers
- ✚ Summary of findings
- ✚ Adverse events summary
- ✚ Protocol deviations summary
- ✚ Publications or presentations

8.8.2 Early Termination

If the study terminates early, the report must include:

- ✚ Reason for termination
- ✚ Actions taken for participant safety
- ✚ Data security measures
- ✚ Plan for result dissemination

9. Informed Consent Process

9.1 Principles of Informed Consent

Informed consent is based on:

1. **Voluntariness:** Free from coercion or undue influence
2. **Adequate Information:** Complete and understandable information provided
3. **Comprehension:** Participant understands information
4. **Competence:** Participant has the capacity to make a decision
5. **Documentation:** Consent properly documented

9.2 Elements of Informed Consent

9.2.1 Required Elements

The consent document must include:

1. **Study Title and Purpose:** Clear statement of research nature and objectives
2. **Study Procedures:** Detailed description of what participation involves, including:
 - ✓ Duration of participation
 - ✓ Frequency of visits
 - ✓ Procedures to be performed
 - ✓ Randomisation (if applicable)
 - ✓ Blinding (if applicable)
3. **Risks and Discomforts:** Comprehensive description of:
 - ✓ Physical risks
 - ✓ Psychological risks

- ✓ Social risks
- ✓ Economic risks
- ✓ Known and potential risks
- 4. **Benefits:** Realistic description of:
 - ✓ Direct benefits to participant (if any)
 - ✓ Benefits to society
 - ✓ Statement if no direct benefit expected
- 5. **Alternative Procedures:** Other available options
- 6. **Confidentiality:** How privacy will be protected, including:
 - ✓ Data security measures
 - ✓ Who will have access to data
 - ✓ How long data will be stored
 - ✓ De-identification procedures
- 7. **Compensation:** Information about:
 - ✓ Payment for participation (if any)
 - ✓ Reimbursement of expenses
 - ✓ Treatment for injuries
 - ✓ No compensation if no payment
- 8. **Voluntary Participation:** A clear statement that:
 - ✓ Participation is voluntary
 - ✓ Refusal to participate involves no penalty
 - ✓ May withdraw at any time without penalty
 - ✓ Care/benefits will not be affected by the decision
- 9. **Right to Withdraw:** Process for withdrawal and consequences
- 10. **Contact Information:**
 - ✓ PI contact details
 - ✓ IRB contact details
 - ✓ Emergency contact (if applicable)
- 11. **Future Use of Data/Samples:** If applicable, information about:
 - ✓ Storage duration
 - ✓ Future research use
 - ✓ Right to withdraw samples
 - ✓ Commercialization potential
- 12. **IRB Approval Statement:** Statement that IRB has approved the research (with IRB approval No)
- 13. **Individual consent is important:** required, even if the community permits participation in a research study

9.2.2 Additional Elements (when applicable)

- ✚ Anticipated circumstances under which participation may be terminated
- ✚ Additional costs to participant
- ✚ Consequences of withdrawal
- ✚ New findings that may affect willingness to continue
- ✚ Number of participants in study
- ✚ Commercial implications
- ✚ Conflict of interest disclosure

9.3 Consent Process

9.3.1 Process Requirements

1. **Setting:** Private, quiet, comfortable location
2. **Language:** Use simple, non-technical language; avoid jargon
3. **Comprehension Assessment:** Use teach-back or other methods to verify understanding
4. **Time:** Provide adequate time for questions and consideration
5. **Opportunity for Questions:** Encourage and answer all questions
6. **Witness:** Independent witness present for illiterate participants
7. **Translation:** Use certified translators for non-English speakers
8. **Documentation:** Properly document consent in research records

9.3.2 Who May Obtain Consent

- ✦ Principal Investigator or trained designee
- ✦ The person must be knowledgeable about research
- ✦ The person must be trained in consent procedures
- ✦ Person must be listed on IRB-approved protocol

9.3.3 Consent for Participants with Limited Literacy

- ✦ Information read aloud by trained staff
- ✦ Independent witness present throughout
- ✦ Participant signs or provides thumbprint
- ✦ Witness signs attesting to proper process
- ✦ Participant receives copy of consent

9.3.4 Consent in Emergency Situations

If immediate intervention is necessary and consent is not possible:

- ✦ Exception from informed consent pre-approved by IRB
- ✦ Legally authorised representative provides consent if available
- ✦ Retrospective consent obtained when the participant is able
- ✦ Community consultation conducted before the study
- ✦ Public disclosure of study and exception

9.4 Waiver or Alteration of Consent

9.4.1 Criteria for Waiver

IRB may waive consent if:

- ✦ Research involves no more than minimal risk
- ✦ Waiver will not adversely affect participants' rights and welfare
- ✦ Research could not practicably be carried out without a waiver, and the waiver is scientifically justified
- ✦ Whenever appropriate, participants were provided with additional information after participation
- ✦ Retrospective studies, where the participants are de-identified or cannot be contacted

- ✦ Certain types of public health studies/surveillance programmes/programme evaluation studies
- ✦ Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. An attempt should be made to obtain the participant's consent at the earliest

9.4.2 Examples of Waiver Situations

- ✦ Chart review studies
- ✦ Anonymous surveys
- ✦ Observational studies of public behaviour
- ✦ Secondary analysis of de-identified data
- ✦ Emergency research with community consultation

9.4.3 Waiver of Documentation

IRB may waive written documentation if:

- ✦ The consent document is the only a record linking the participant to research
- ✦ Research involves minimal risk
- ✦ Oral consent is obtained and documented
- ✦ Participants have given written information about the research

9.5 Consent Documentation

9.5.1 Required Elements

- ✦ Participant signature and date
- ✦ Person obtaining consent signature and date
- ✦ Witness signature (if required)
- ✦ Each page is initialled
- ✦ Version date on each page

9.5.2 Record Keeping

- ✦ Original signed consent in research file
- ✦ Copy provided to participant
- ✦ Consent tracked in enrollment log
- ✦ Retained as per retention policy

9.6 Re-consent

Re-consent will be required when:

- ✦ Significant new information emerges
- ✦ Risk level changes
- ✦ Major protocol amendments are done
- ✦ Participant's capacity changes
- ✦ Long-term studies (periodic re-consent) are placed
- ✦ Participant reaches the age of majority

10. Data Safety and Monitoring

10.1 Data Safety Monitoring Plans

10.1.1 Requirements

All research involving human participation must have a data safety-monitoring plan appropriate to:

- + Level of risk
- + Size and complexity of study
- + Nature of study population
- + Study phase

10.1.2 Components of the Monitoring Plan

1. **Who will Monitor:**
 - ✓ Principal Investigator (minimal risk studies)
 - ✓ Independent monitor
2. **What will be Monitored:**
 - ✓ Participant safety
 - ✓ Data quality and integrity
 - ✓ Protocol compliance
 - ✓ Adverse events
 - ✓ Interim efficacy
3. **How Often:** Frequency of monitoring activities
4. **Stopping Rules:** Criteria for early termination
5. **Reporting:** Who receives reports and when

10.2 Data Safety Monitoring Board (DSMB)

10.2.1 When DSMB Required

For studies involving:

- + Significant risk to participants
- + Large multi-site trials
- + Blinded trials
- + Sensitive personal information
- + Studies likely to have broad impact

10.2.2 DSMB Composition

- + At least 3 members
- + Independent of research team and sponsor
- + Expertise in relevant disciplines
- + Biostatistician
- + Ethicist (for complex ethical issues)

10.2.3 DSMB Responsibilities

- ✦ Review safety data at regular intervals
- ✦ Recommend study continuation, modification, or termination
- ✦ Monitor interim efficacy
- ✦ Review protocol deviations
- ✦ Assess risk-benefit ratio
- ✦ Make recommendations to the sponsor and the IRB

10.3 Adverse Event Monitoring and Reporting

10.3.1 Definitions

Adverse Event (AE): Any unusual, unexpected, or inappropriate, often with a negative or unpleasant connotation occurrence in a participant

Unanticipated Problem: Any incident that:

- ✦ Was unexpected in nature, severity, or frequency
- ✦ Related or possibly related to research
- ✦ Suggests research places participants at greater risk

10.3.2 PI Responsibilities

- ✦ Monitor participants for adverse events
- ✦ Document all adverse events
- ✦ Assess relationship to research procedures
- ✦ Report SAEs to IRB within 24 hours
- ✦ Report to sponsor per agreement
- ✦ Report to regulatory authorities as required
- ✦ Take appropriate action for participant safety

10.3.3 IRB Assessment of Adverse Events

IRB reviews each report to determine:

1. **Expectedness:** Was the event anticipated?
2. **Severity:** How serious was the event?
3. **Relationship:** Event related to research procedures?
4. **Frequency:** Rate higher than expected?
5. **Action Required:**
 - ✓ Continue as approved
 - ✓ Require protocol modifications
 - ✓ Require consent form updates
 - ✓ Notify enrolled participants
 - ✓ Suspend enrollment
 - ✓ Terminate study

10.3.4 Aggregate Review

IRB reviews aggregate adverse event data at continuing review to identify:

- + Patterns or trends
- + Risk profile changes
- + Need for protocol revision

10.4 Protocol Deviations and Violations

10.4.1 Protocol Deviation

Unintentional departure from protocol that does not significantly affect:

- + Participant safety
- + Participant rights or welfare
- + Data integrity

Reporting: Document in study file; report to IRB at continuing review

10.4.2 Protocol Violation

Departure from protocol that:

- + Affects participant safety
- + Compromises data integrity
- + Represents non-compliance
- + Is wilful or repetitive

This includes but is not limited to:

- ✓ Enrolment of an ineligible participant
- ✓ Failure to obtain informed consent
- ✓ Failure to report SAE
- ✓ Performing unapproved procedures

Reporting: Report to IRB within 5-7 days; describe corrective actions

10.4.3 IRB Review of Violations

IRB may:

- + Accept the corrective action plan
- + Require additional training
- + Increase monitoring frequency
- + Suspend research
- + Terminate approval
- + Report to institutional authorities

11. Compliance and Quality Assurance

11.1 Audit and Monitoring Program

11.1.1 Types of Audits

1. For-Cause Audits: Triggered by:

- ✓ Serious non-compliance reports
- ✓ Participant complaints
- ✓ Pattern of protocol violations
- ✓ Concerns about data integrity

2. Random Audits: Random selection of active studies for quality assurance

3. Targeted Audits: For first-time investigators

11.1.2 Audit Process

1. Planning:

- ✓ Audit team selected
- ✓ Audit scope defined
- ✓ PI notified

2. Conduct:

- ✓ Document review
- ✓ Site visit
- ✓ Staff interviews
- ✓ Participant interviews (with consent)
- ✓ Facility inspection

3. Audit Areas:

- ✓ Informed consent process
- ✓ Protocol compliance
- ✓ Record keeping
- ✓ Data management
- ✓ Safety reporting
- ✓ Regulatory documentation

4. Report:

- ✓ Findings documented
- ✓ Non-compliance identified
- ✓ Recommendations made
- ✓ Report to IRB and institution

5. Follow-up:

- ✓ Corrective action plan required
- ✓ Implementation verified
- ✓ Re-audit if necessary

11.2 Non-Compliance

11.2.1 Categories

1. Minor Non-Compliance: Does not significantly affect:

- ✓ Participant rights, safety, or welfare
- ✓ Integrity of data
- ✓ Participant's willingness to participate

2. Serious Non-Compliance: Significantly affects or has potential to affect:

- ✓ Participant rights, safety, or welfare
- ✓ Integrity of data

3. Continuing Non-Compliance: Pattern of non-compliance

11.2.2 Examples of Non-Compliance

1. Minor:

- ✓ Administrative documentation errors
- ✓ Minor deviations from IRB-approved procedures
- ✓ Late submission of continuing review

2. Serious:

- ✓ Conducting research without IRB approval
- ✓ Failure to obtain informed consent
- ✓ Enrollment of ineligible participants
- ✓ Failure to report SAEs
- ✓ Unauthorized protocol changes
- ✓ Breach of confidentiality

11.2.3 IRB Response to Non-Compliance

1. **Investigation:** IRB conducts a thorough investigation
2. **Actions May Include:**
 - ✓ Warning letter
 - ✓ Corrective action plan
 - ✓ Increased monitoring
 - ✓ Mandatory training
 - ✓ Suspension of research
 - ✓ Termination of research
 - ✓ Restriction on future research
 - ✓ Report to institutional authorities
 - ✓ Report to regulatory authorities
3. **Documentation:** All actions documented in IRB records
4. **Follow-up:** Ensure corrective actions are implemented

11.3 Research Misconduct

11.3.1 Definition

Fabrication, falsification, plagiarism, or other serious deviation from accepted practices in:

- ✚ Proposing research
- ✚ Conducting research
- ✚ Reviewing research
- ✚ Reporting research results

11.3.2 Reporting Misconduct

- ✚ Allegations reported to IRB and institutional authorities
- ✚ Preliminary inquiry conducted

- ✦ Formal investigation if warranted
- ✦ Due process for the accused
- ✦ Report to funding agencies and regulatory authorities
- ✦ Institutional action as appropriate

11.4 Conflict of Interest

11.4.1 Types of Conflicts

1. **Financial Conflict:** Financial interest in the research outcome

- ✓ Equity in the sponsor company
- ✓ Consulting fees
- ✓ Intellectual property rights
- ✓ Royalties

2. **Non-Financial Conflict:**

- ✓ Personal relationships
- ✓ Academic competition
- ✓ Institutional pressures

11.4.2 Disclosure Requirements

All investigators must disclose:

- ✦ Financial interests in research
- ✦ Relationships with sponsors
- ✦ Intellectual property interests
- ✦ Other potential conflicts

11.4.3 Management of Conflicts

IRB reviews disclosures and may require:

- ✦ Public disclosure to participants
- ✦ Independent monitoring
- ✦ Modification of consent process
- ✦ Recusal from specific activities
- ✦ Divestiture of interests
- ✦ Disqualification from research

11.5 Record Retention

11.5.1 IRB Records

Retained for at least five years after completion of research:

- ✦ Protocol applications and documents
- ✦ Meeting minutes
- ✦ Correspondence
- ✦ Review documentation
- ✦ Continuing review records
- ✦ Adverse event reports

- ✚ Audit reports

11.5.2 Investigator Records

Retained for period required by regulations (typically 10 years):

- ✚ Protocol and amendments
- ✚ IRB correspondence
- ✚ Informed consent documents
- ✚ Study data
- ✚ Safety reports
- ✚ Final report

12. Appeals and Grievance Redressal

12.1 Investigator Appeals

12.1.1 Grounds for Appeal

Investigators may appeal IRB decisions based on:

- ✚ Procedural irregularities
- ✚ Misinterpretation of regulations or guidelines
- ✚ Inadequate consideration of information
- ✚ New information not available at initial review

12.1.2 Appeal Process

1. Submission: Written appeal within 30 days of the decision

- ✓ Specific grounds for appeal
- ✓ Supporting documentation
- ✓ Requested action

2. Review: Appeal reviewed by:

- ✓ IRB Chair and institutional authority (if disagreement with IRB decision)
- ✓ Independent reviewer or appeals committee

3. Hearing: The investigator may request a meeting to present the case

4. Decision:

- ✓ Appeal committee reviews materials
- ✓ May consult experts
- ✓ Decision final within 60 days
- ✓ Decision communicated in writing

5. Outcomes:

- ✓ Uphold original decision
- ✓ Modify decision
- ✓ Reverse decision
- ✓ Remand to IRB for reconsideration

12.1.3 Appeal Does Not Stay Decision

Research remains suspended/not approved during the appeal process except for participant safety concerns.

12.2 Participant Complaints

Complaint Channels

Participants may lodge complaints through the IRB office or the institutional authorities

12.2.2 Complaint Process

1. **Receipt:** Complaint received and logged
2. **Assessment:** Seriousness and urgency assessed
3. **Investigation:**
 - ✓ Relevant documents reviewed
 - ✓ Interviews conducted
 - ✓ Site visit if warranted
4. **Resolution:**
 - ✓ Corrective actions implemented
 - ✓ Participant informed of actions
 - ✓ Follow-up to ensure resolution
5. **IRB Notification:** IRB notified of:
 - ✓ Nature of complaint
 - ✓ Investigation findings
 - ✓ Actions taken
6. **Action:** IRB determines if further action is needed

12.3 IRB Member Concerns

12.3.1 Dissenting Opinions

Members who disagree with the IRB decision may:

- ✚ Have dissent recorded in minutes
- ✚ Provide a written statement for the record
- ✚ Request protocol reconsideration

12.3.2 Ethics Concerns

Members concerned about the IRB processes may:

- ✚ Raise concerns with Chair
- ✚ Report to institutional authorities
- ✚ Report to regulatory authorities
- ✚ Seek external guidance

13. Documentation and Record Keeping

13.1 IRB Documentation System

13.1.1 Documentation Requirements

IRB maintains comprehensive documentation, including:

1. **Administrative Documents:**
 - ✓ IRB charter and policies

- ✓ SOPs
- ✓ Member roster and CVs
- ✓ Training records
- ✓ Conflict of interest disclosures

2. *Protocol Files:*

- ✓ Application and all submissions
- ✓ Review documentation
- ✓ Approval letters
- ✓ Correspondence
- ✓ Amendments
- ✓ Continuing reviews
- ✓ Adverse event reports
- ✓ Audit reports
- ✓ Closure documents

3. *Meeting Records:*

- ✓ Agendas
- ✓ Minutes
- ✓ Attendance records
- ✓ Voting records

4. *Regulatory Documents:*

- ✓ Registration certificates
- ✓ Inspection reports
- ✓ Correspondence with authorities

13.1.2 *Electronic Records*

1. *Electronic systems must:*

- ✓ Ensure data integrity
- ✓ Provide audit trails
- ✓ Restrict unauthorized access
- ✓ Allow retrieval and review
- ✓ Have backup systems

2. *Electronic signatures permitted if:*

- ✓ System validated
- ✓ Security adequate
- ✓ Compliant with regulations

13.2 Minutes of IRB Meetings

13.2.1 *Required Content*

Minutes must document:

- 1. *Date, time, location***
- 2. *Members present and absent***
- 3. *Members recused for conflicts***
- 4. *Guests present***
- 5. *Protocols reviewed with:***
 - ✓ Title and IRB number

- ✓ Type of review
- ✓ Discussion summary
- ✓ Vote results (if applicable)
- ✓ Decision with conditions
- ✓ Minority opinions if any

6. *Other business conducted*

13.2.2 Approval of Minutes

- ✚ Draft prepared within 10 days
- ✚ Distributed to members
- ✚ Reviewed at next meeting
- ✚ Corrections made
- ✚ Approved by the signature of the Chair

13.3 Investigator Files

Investigators must maintain:

1. **Regulatory Binder:**

- ✓ Protocol and amendments
- ✓ IRB approvals
- ✓ Consent documents
- ✓ CVs and licenses
- ✓ Training certificates
- ✓ Delegation log

2. **Participant Files:**

- ✓ Screening logs
- ✓ Enrollment logs
- ✓ Informed consent forms
- ✓ Case report forms
- ✓ Source documents
- ✓ Correspondence

3. **Safety Records:**

- ✓ Adverse event logs
- ✓ SAE reports

4. **Administrative Records:**

- ✓ Correspondence
- ✓ Deviation/violation reports
- ✓ Training logs

13.4 Confidentiality of Records

1. **Access Control:**

- ✓ Limited to authorised personnel
- ✓ Access logs maintained
- ✓ Secure storage (physical and electronic)

2. **Participant Privacy:**

- ✓ Identifiers protected
- ✓ Coded identification used
- ✓ Master link list secured separately

3. Third-Party Access:

- ✓ Regulatory inspections allowed
- ✓ Auditors with authorized access
- ✓ Release requires IRB approval or participant consent

14. Training and Education

14.1 Mandatory Training

All investigators listed on a research project are required to complete the **Online Research Ethics and Responsible Conduct Training** offered by Kristu Jayanti (Deemed to be University).

A **training completion certificate** must be submitted along with the IRB application. If the certificate is pending, the applicant must provide a **written undertaking** to submit it within **three months** from the date of application. This requirement ensures that all members of the university's research community uphold ethical and responsible research practices.

14.1.1 IRB Member Training

All IRB members must complete training in:

- ✚ Research ethics principles
- ✚ Regulatory requirements
- ✚ IRB procedures and SOPs
- ✚ Conflict of interest
- ✚ Privacy and confidentiality
- ✚ Special population protections

Frequency:

- ✚ Initial training before joining IRB
- ✚ Annual refresher training
- ✚ Update training when regulations change

14.1.2 Investigator Training

All investigators and research staff must complete training in:

- ✚ Human subjects protection
- ✚ Good Clinical Practice (GCP)
- ✚ Informed consent process
- ✚ Protocol compliance
- ✚ Safety reporting
- ✚ Data management
- ✚ Ethical principles

Frequency:

- ✚ Before initiating any research
- ✚ Every 3 years renewal
- ✚ Protocol-specific training as needed

14.2 Training Programmes

14.2.1 Training Modalities

Online Courses:

- ✓ CITI program - Collaborative Institutional Training Institute (Paid course)
(<https://about.citiprogram.org/en/homepage/>)
- ✓ ICH-GCP certification
- ✓ ICMR courses
- ✓ NIH Research ethics training module (free course)
(<https://researchethics.od.nih.gov/CourseIndex.aspx>)
- ✓ Research Ethics online training by Global Health Training Centre (Free course)
(<https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>)
- ✓ Introduction to research ethics: Working with people by University of Leeds via Future Learn platform (Free Course) (<https://www.classcentral.com/course/research-ethics-an-introduction-12091>)
- ✓ Research Ethics Training Curriculum by FHI. (Free Course)
(<https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/RETCTraditional/intro.html>)
- ✓ Any other ethics course dealing with human participant research with due approval from the Centre for Research.

2. Workshops and Seminars:

- ✓ IRB-conducted workshops
- ✓ External training programmes
- ✓ National/international conferences

3. Mentorship:

- ✓ New investigators paired with experienced mentors
- ✓ Observation of the consent process
- ✓ Supervised protocol development

14.2.2 Training Content

1. Core Topics:

- a) History of research ethics
- b) Ethical principles (Belmont Report, Declaration of Helsinki)
- c) Indian regulations and guidelines for research
- d) IRB review process
- e) Informed consent
- f) Privacy and confidentiality
- g) Vulnerable populations
- h) Risk assessment and minimization
- i) Research misconduct
- j) Cultural sensitivity

2. Advanced Topics:

- a) Complex study designs
- b) Biobanking ethics
- c) Genomic research
- d) International research
- e) Community-based participatory research

- f) Emergency research
- g) Precision medicine ethics

14.3 Capacity Building

14.3.1 Institutional Initiatives

1. **Research Ethics Committee:** Regular meetings to discuss ethical challenges
2. **Case-Based Learning:** Analysis of actual cases and scenarios
3. **Mock IRB Reviews:** Practice sessions for new investigators
4. **Ethics Consultation Service:** Available for researchers
5. **Resource Library:** Maintain updated library of ethics resources

14.3.2 Student Education

- ✦ Integration of research ethics into the curriculum
- ✦ Mandatory courses for research students
- ✦ Ethics component in thesis defence
- ✦ Student representation in ethics discussions

14.4 Continuing Education

14.4.1 For IRB Members

- ✦ Quarterly educational sessions during meetings
- ✦ Annual ethics symposium
- ✦ Subscriptions to ethics journals
- ✦ Participation in national forums

14.4.2 For Investigators

- ✦ Half-yearly research ethics seminars
- ✦ Newsletter on ethics topics
- ✦ Case discussions
- ✦ Updates on regulatory changes

14.5 Training Documentation

- ✦ Training certificates maintained in files
- ✦ Training database for tracking
- ✦ Renewal alerts sent before expiry
- ✦ Non-compliance for expired training

15. Amendments and Revisions

15.1 Policy Review

15.1.1 Review Schedule

This policy shall be reviewed:

- ✦ Annually by IRB leadership
- ✦ When regulations change
- ✦ When problems are identified
- ✦ At the request of institutional authorities

15.1.2 Review Process

- ✦ IRB committee reviews policy
- ✦ Identifies needed changes
- ✦ Draft amendments
- ✦ Circulates to stakeholders for feedback
- ✦ Incorporates feedback
- ✦ Obtains institutional approval
- ✦ Implements changes
- ✦ Communicates changes to the community

15.2 Amendment Process

15.2.1 Types of Amendments

1. *Minor Amendments:*

- ✓ Typographical corrections
- ✓ Formatting changes
- ✓ Updated contact information
- ✓ Clarifications without substantive change

2. *Major Amendments:*

- ✓ Changes to procedures
- ✓ Changes to requirements
- ✓ Changes to review categories
- ✓ New regulatory requirements

15.2.2 Approval Authority

1. *Minor Amendments:* Approved by IRB Chair

2. *Major Amendments:* Approved by:

- ✓ IRB full board
- ✓ Institutional authorities
- ✓ Communicated to the entire research community associated with the University

15.3 Version Control

- ✦ Each version is numbered and dated

- ✚ Change history maintained
- ✚ Previous versions archived
- ✚ Current version posted on website
- ✚ All users notified of updates

15.4 Effective Date

This policy is effective from 01.01.2026 and supersedes all previous versions.

16. Glossary of Terms & Abbreviations

16.1 Key Terms

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Participant/Subject: A living individual about whom a researcher conducting research obtains data through intervention or interaction or obtains identifiable private information.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.

Intervention: Physical procedures, manipulations of the subject or subject's environment, or drug/device administration conducted for research purposes.

Interaction: Communication or interpersonal contact between researcher and subject, including surveys, interviews, and focus groups.

Identifiable Private Information: Private information for which the identity of the subject is or may be ascertained by the researcher or associated with the information.

Informed Consent: A voluntary decision made by a competent person to participate in research after being informed about its purpose, methods, demands, risks, benefits, and rights.

Vulnerable Population: Groups whose ability to provide informed consent may be compromised, including children, pregnant women, prisoners, mentally challenged persons, economically disadvantaged, and critically ill patients.

Serious Adverse Event (SAE): Any untoward medical occurrence that results in death, is life-threatening, requires hospitalization, results in persistent or significant disability, or is a congenital anomaly.

Protocol Deviation: An unplanned excursion from the protocol that does not affect participant safety or data integrity.

Protocol Violation: A deviation that affects participant safety, rights, or data integrity, or represents willful non-compliance.

Data Safety Monitoring Board (DSMB): An independent group of experts that reviews safety and efficacy data during clinical trials.

Investigator: The person responsible for the conduct of the research study at the site.

Sponsor: An individual, organisation, or entity that initiates and takes responsibility for a clinical trial.

Continuing Review: Periodic review of ongoing research by the IRB to ensure continued ethical conduct.

Expedited Review: Review of research by the IRB chairperson or designated experienced reviewers rather than the full board.

16.2 Abbreviations

- CIMOS: Council for International Organisations of Medical Sciences
- CITI: Collaborative Institutional Training Institute
- Co-PI: Co-Principal Investigator
- DSMB: Data Safety Monitoring Board
- EC: Ethical Committee
- GCP: Good Clinical Practice
- ICD: Informed Consent Documents
- ICF: Informed Consent Form
- ICMR: Indian Council of Medical Research
- IRB: Institutional Review Board
- LAR: Legally Authorised Representative
- MoU: Memorandum of Understanding
- NIH: National Institutes of Health
- PI: Principal Investigator
- PIS: Participant Information Sheet
- SAE: Serious Adverse Event
- SOP: Standard Operating Procedure
- WHO: World Health Organisation

17. Implementation and Compliance

17.1 Institutional Commitment Statement

Kristu Jayanti University is committed to implementing this policy in letter and spirit. All members of the university community engaged in research involving human participants must comply with this policy. Non-compliance will be addressed through institutional mechanisms and may result in suspension or termination of research privileges.

17.2 Acknowledgment

All investigators, research staff, and IRB members must sign an acknowledgement form indicating they have read, understood, and agree to abide by this policy.

17.3 Questions and Support

For questions or clarification regarding this policy, contact:

IRB Office Kristu Jayanti University

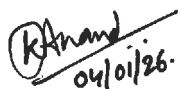
Email: irb@kristujayanti.com

Phone:

17.4 Approval and Signatures

Prepared by:

Name: Dr. Kushi Anand


04/01/26

Signature and Date:

Name: Mr Jaheer Mukthar K.P


04/01/26

Signature and Date:

This policy has been reviewed and approved by:

Director (Research & Development):



Date: 04/01/2026

RAC Chairperson and Dean (Research & Development):



Date: 04/01/2026

Registrar:



Date: 04/01/26

17.5 Document Information

Version: 1.0 **Effective Date:** 01.01.2026 **Next Review Date:** 01.01.2027 **Document Owner:** IRB Chairperson **Approved By:** University Academic Council, KJU

This document is a living document and will be updated as regulations evolve and institutional practices mature. All users are responsible for ensuring they are using the most current version available on the institutional website.

Appendices

Appendix A: KJU policy, National and international Guidelines and References

1. Kristu Jayanti University IRB policy and complete Guidelines version 1.0
2. ICMR National Ethical Guidelines, 2017
3. Handbook on ICMR Ethical Guidelines 2018
4. Declaration of Helsinki_1964-2013
5. CIOMS International Ethical Guidelines_2016
6. ICH-GCP Guidelines_2025
7. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants
8. United States Federal Policy for the Protection of Human Subjects (1991; revised 2018) — commonly known as the Common Rule (45 CFR 46, Subpart A)

Appendix B: Standard Forms and Templates

1. Initial IRB Review Application Form
2. Application Form for Expedited Review
3. Continuing Review/ Annual report format
4. Application or Notification form for Amendments
5. Protocol Violation or Deviation Reporting Form (Reporting by case)
6. Serious Adverse Event Reporting Format
7. Application Form for Socio-Behavioural and Public Health Research
8. Premature or Termination or Suspension or Discontinuation Report Format
9. Study completion Final report format
10. Format for Curriculum Vitae for Investigators
11. Generic form for Project extension
12. Initial Review Multicentric Research
13. Informed Consent Template/sample

Appendix C: Quick Reference Guides (Types of Review Decision Tree)

Appendix C: Quick Reference Guides

