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1. Governance and Structural Mandate of the SIMS IRB/ERC

SIMS shall maintain a centralized Institutional Review Board (IRB) / Ethical Review Committee (ERC) operating at the institutional level rather than at departmental level. This arrangement promotes neutrality, consistency, transparency and a uniform standard of ethical review across basic sciences, clinical sciences, medical education, public health and community-based research.

Governance Element	Institutional Policy Position
Centralized review	All human-subject research protocols submitted under SIMS shall be reviewed through a centralized IRB/ERC or its authorized review pathway.
Independence and impartiality	Members shall review proposals independently, disclose conflicts of interest and recuse themselves from review where required.
Scope	The IRB/ERC shall review faculty, student, postgraduate, clinical, community-based, collaborative, industry-supported and foreign-funded research involving human participants, personal data or biological materials.
Institutional reporting	The IRB/ERC shall maintain records of applications, decisions, minutes, approvals, amendments, adverse events and continuing review where applicable.

1.1 Composition and Tenure

- Membership: The committee shall comprise 13 to 15 members, including scientists, healthcare professionals (physicians and nurses), legal experts, religious scholars, and laypersons/ethics experts representing the community.
- Tenure: Members are nominated by the Principal of SIMS for a period of two years.
- Quorum: A meeting quorum requires at least 1/3rd of the membership, including at least one member whose primary area is non-scientific and at least one member who is independent of SIMS.

1.2 Meeting Schedule and Review Records

- The IRB/ERC shall meet as per protocol load, typically monthly or quarterly, and may convene special meetings for urgent regulatory or safety matters.
- Meeting minutes shall document attendance, agenda, decisions, deferred items, required modifications, recusals due to conflicts of interest, and action points.
- Protocol decisions should be recorded as approved, approved with modifications, deferred for clarification, not approved, exempted from full review, or referred for full-board review.

2. Regulatory Alignment and Applicable Legal Framework

The SIMS IRB/ERC shall operate in alignment with applicable national bioethics requirements, PMDC ethical standards, institutional research governance policies and internationally accepted ethical principles including the Declaration of Helsinki. Regulatory references shall be applied according to the type of research, so that clinical trials and therapeutic-goods research are not confused with routine observational, educational or quality-improvement work.

Reference / Standard	Application
National Bioethics Committee (NBC) requirements	Applicable to human-subject research, foreign-funded research, biological materials, sample storage/export and projects requiring national bioethics clearance.
PMDC ethical standards and professional conduct requirements	Applicable to ethical conduct of doctors, faculty, trainees and researchers; supports integrity, confidentiality, participant welfare and professional accountability.
Declaration of Helsinki	International ethical reference for medical research involving human participants, informed consent, risk-benefit balance and participant protection.
Bio-Study Rules, 2017	Applicable where research involves clinical trials, bioavailability/bioequivalence studies, investigational products, medical devices or therapeutic goods regulated by DRAP.

DRAP Act, 2012 and relevant provisions of Drugs Act, 1976	Applicable to regulated therapeutic goods, investigational products, clinical trials and DRAP-regulated approvals; apply where relevant to the protocol.
National Guidelines for Collection, Usage, Storage and Export of Human Biological Materials 2020	Applicable to collection, storage, use, etc. of human biological materials, with NBC approval and MTA/export requirements where applicable.
Punjab public-sector service and disciplinary laws including PEEDA Act 2006	Applicable to disciplinary proceedings involving Punjab public-sector employees, misconduct, inefficiency and accountability issues.
Funder and collaborator requirements	Applicable to externally funded research including NIHR/Imperial and other international collaborations, subject to approved agreements and local law.

3. Ethical Review Framework, Technical Review and Protocol Review Categories

All research protocols submitted to the SIMS IRB/ERC should address the core ethical questions of relevance, scientific robustness, community need, fair participant selection, risk minimization, informed consent, confidentiality, biological materials, dissemination and post-research obligations. This framework is consistent with national bioethics expectations and international research ethics practice.

3.1 Scientific and Technical Review Before Ethical Review

Where required, research proposals should undergo scientific and technical review before final ethical approval. The purpose of technical review is to assess relevance, methodology, feasibility, sample size, tools, budget, project team capacity, institutional resources, safety considerations and whether the proposal is ready for ethical review. The technical review process shall support the ERC but shall not replace independent ethical review.

Review Category	Appropriate Use	Decision Pathway
Exempt review / exemption determination	Educational, anonymized, negligible-risk or quality-assurance activities where no identifiable personal data are recorded and where the ERC determines that full review is not required.	Chair/Secretary or designated reviewers may issue an exemption determination according to SOP.
Expedited review	Minimal-risk research such as anonymized questionnaires, surveys, record reviews or non-	Chair and designated member(s) may review,

	invasive procedures where appropriate.	with reporting to the full committee.
Full-board review	Clinical trials, interventional studies, vulnerable populations, identifiable sensitive data, biological materials, sample export, higher-than-minimal risk or complex ethical issues.	Full IRB/ERC discussion and documented decision in minutes.
Continuing review / amendment review	Protocol extensions, major amendments, safety issues, adverse events, annual reports, MTA/sample transfer updates or funder-required updates.	Review pathway determined by risk and nature of amendment.

4. Informed Consent, Vulnerable Populations and Participant Protection

- Consent shall be a voluntary, informed and ongoing process, not merely a signature on a form.
- Participant information should be provided in Urdu, Punjabi or another locally understandable language, avoiding unnecessary technical jargon.
- Written consent is preferred. Thumbprint or witnessed consent may be accepted where literacy is limited, provided that the process is justified and documented.
- Participants must be informed about study purpose, procedures, risks, benefits, confidentiality, voluntary participation, right to withdraw and contact persons for questions or complaints.
- Special protections apply for minors, incapacitated persons, refugees, prisoners, survivors/victims of violence, economically dependent participants or others who may have reduced autonomy.
- Research involving minors should include parental/guardian consent and age-appropriate assent where applicable.
- Research involving biological materials must include specific consent provisions for collection, storage, future use, and anonymization /coding and withdrawal options where feasible.

5. Research Integrity, Plagiarism, Conflict of Interest, Publication and Misconduct

SIMS shall promote responsible conduct of research, including honesty, accountability, accuracy of data, transparent authorship, responsible supervision, protection of participants and proper management of funds and records.

Area	Institutional Policy
Research misconduct	Includes fabrication, falsification, plagiarism, unethical authorship, suppression or manipulation of data, breach of confidentiality, misuse of funds, undeclared conflicts of interest and serious protocol violation.

Plagiarism / similarity	As an institutional quality-control benchmark, manuscripts, theses or reports showing similarity above the approved threshold, currently 19%, shall be returned for correction, justification, review or inquiry according to the nature of similarity.
Conflict of interest	Investigators shall disclose financial or non-financial interests that may affect or appear to affect study design, recruitment, supervision, procurement, funding, analysis, publication or participant protection.
Disciplinary action	For public-sector employees, violations may be referred to the competent authority under applicable service rules, including PEEDA Act 2006 where applicable.
International best practice	For international collaborations, SIMS may additionally align with collaborator/funder research integrity requirements such as UK/NIHR/Imperial requirements, while ensuring consistency with Pakistani law.

5.1 Publication, Authorship and Affiliation Policy

All publications arising from SIMS research should follow accepted authorship criteria, acknowledge relevant institutional affiliation, disclose funding sources and conflicts of interest, and avoid predatory or non-recognized publishing routes. Manuscripts should include accurate SIMS/Services Hospital affiliation where institutional resources, participants, data, supervision or funding support have been used. Funder acknowledgements, trial/project identifiers, IRB/ERC approval numbers and data/material acknowledgements shall be included where required by the approved protocol or agreement.

6. Data Governance, Confidentiality, Repository and International Data Transfer

Research data shall be handled according to applicable Pakistani law, NBC requirements, SIMS institutional confidentiality standards, participant consent, approved research protocol, collaborator/funder agreements and internationally accepted data protection principles. If Pakistan enacts a comprehensive Personal Data Protection Act, this manual should be updated accordingly.

- Research data should be collected only for approved protocol purposes and limited to what is necessary for the research question.
- Identifiable data must be stored securely with role-based access, password protection and appropriate physical/electronic safeguards.
- Data should be coded, de-identified or anonymized where possible, especially before analysis or sharing with collaborators.

- International transfer of data must be consistent with the approved protocol, informed consent, NBC/IRB requirements, data sharing agreements and funder/collaborator agreements.
- Data retention and destruction timelines should be documented in the protocol and institutional repository SOP.
- Any breach of confidentiality or unauthorized access should be reported according to institutional procedure and reviewed for corrective action.

6.1 Research Data Repository and Project Registry

SIMS should maintain an institutional research registry/repository to document approved projects, ongoing projects, completed projects, student projects, publications, presentations, funded studies, collaborations and annual research output. The registry may be maintained electronically through the Research Office, IRB/ERC Secretariat, relevant departments or an authorized institutional repository. Access to identifiable data shall remain restricted; the registry should primarily support monitoring, reporting, inspection evidence, research planning and institutional memory.

7. Human Biological Materials and Biobanking:

Research involving human biological materials requires additional safeguards because it may involve privacy, genetic information, future use, export control, biosafety and participant rights. SIMS shall follow the legal requirements set out by National Bioethics Committee of Ministry of Health Research Institute, National Institutes of Health –NIH and will follow due processes specified therein before storage of human biological materials.

8. International Research Grants, Collaborations and Institutional Agreements

International research governance at SIMS shall focus on institutional credibility, ethical compliance, financial transparency, funder trust and successful delivery of approved project targets. This section should be read with Sections 2, 5, 6 and 7; it avoids repetition of ethics, data and biological-material requirements already stated above.

8.1 Institutional Approval and Signing Authority

All international research collaboration agreements, grant sub-agreements, institutional MOUs, data sharing agreements shall be reviewed through the relevant academic, ethical, administrative, financial and legal channels before signature. Agreements creating institutional, financial, legal, ethical, or data-sharing shall be signed or endorsed by the Principal, SIMS, or another formally authorized institutional representative. Principal Investigators may sign technical forms, protocol documents and progress reports within their approved project role, but institutional commitments shall require competent-authority approval.

8.2 Financial Governance and Grant Handling

Foreign-funded research grants shall be received, recorded, utilized and audited through approved institutional or government-recognized financial mechanisms. Where applicable, DEER Foundation may serve as the transparent and auditable grant-management vehicle for diabetes, endocrinology and related research projects at SIMS. All expenditures shall follow the approved budget, donor/funder conditions, institutional authorization, supporting documentation, bank reconciliation, asset/inventory records and external audit requirements.

8.3 Reporting, Due Diligence and Funder Readiness

International projects shall maintain periodic scientific, ethical, administrative and financial reporting according to the approved agreement and applicable local requirements. Reports may be submitted to SIMS leadership, IRB/ERC, national regulatory bodies, funders/collaborators, DEER/Finance Office and other authorities where required. SIMS shall retain project files containing agreements, approvals, progress reports, correspondence, expenditure records, audit evidence, data/sample transfer documents and final outputs, so that the institution remains inspection-ready and eligible for future international grants.

8.4 Responsibilities of PI and Project Team

The Principal Investigator shall be responsible for scientific leadership, protocol compliance, participant protection, data quality, team supervision, project delivery and communication with collaborators. Project managers/research coordinators shall support day-to-day operations, documentation, logistics, staff coordination, field monitoring, report compilation and issue escalation. Project risks, deviations, delays, safety issues or reporting gaps shall be escalated to the PI and relevant institutional authority in a timely manner.

9. Research Advisory Structures, Project Registry and Institutional Oversight

To support the PMDC research standard and to strengthen institutional research culture, SIMS should maintain a Research Advisory Board or Institutional Research Committee in addition to the IRB/ERC. The advisory/research committee may guide institutional research priorities, interdisciplinary collaboration, annual research output review, grant readiness, research training, and coordination between basic sciences, clinical sciences, medical education, public health and hospital departments.

A Technical Review Committee or designated technical reviewers may assess scientific merit and feasibility before ethical review. Departmental research focal persons may maintain departmental project lists, publication lists, student research records and evidence for annual research reporting. These structures should have notifications, terms of reference, membership lists, meeting minutes and action records.

Body / Mechanism	Primary Role
Research Advisory Board / Technical Review Committee	Institutional research planning, research culture, collaborations, annual output review, grant readiness and PMDC inspection evidence. Scientific, methodological and feasibility review before ethical review where required.
IRB/ERC	Independent ethical review and participant protection.
Research Cell	Research coordination and facilitation.
Departmental research focal persons	Department-wise publications, projects, student research and evidence compilation.
Research registry/repository	Central record of projects, approvals, publications, grants, collaborations, trainings and outputs.

10. Student Research Electives, Training and Capacity Building

SIMS should maintain a student research/elective policy for undergraduate and postgraduate learners. Student projects shall be supervised by approved faculty, registered at departmental or institutional level, reviewed for scientific and ethical requirements, and completed with a written report, presentation, poster, manuscript or other defined output. Students should receive orientation on research methodology, ethics, informed consent, data confidentiality, plagiarism, referencing and responsible publication practice.

SIMS should also maintain an annual research capacity-building calendar covering research methodology, biostatistics, literature search, reference management, IRB/ERC submission, scientific writing, clinical audit, quality improvement, grant writing, data management, publication ethics, plagiarism, community-based research and international collaboration requirements. Attendance sheets, certificates, program flyers and photographs should be retained as PMDC inspection evidence.

11. Post-Approval Monitoring, Field Research Safety and Record Retention

Approval of a research protocol does not end institutional oversight. Approved studies may require progress reports, amendment approvals, protocol deviation reporting, adverse event reporting, annual/continuing review, study closure reports and publication/output reporting depending on risk and project type. The IRB/ERC or Research Office may request monitoring evidence from investigators to confirm that the approved protocol is being followed.

For field research, community camps, mobile health unit activities or home-based follow-up, project teams shall maintain safety plans appropriate to the setting. These may include travel planning, female staff safety, infection prevention, emergency contacts, equipment safety, sample transport safeguards, adverse event response, community permissions and escalation procedures. Field teams shall document site

permissions, participant flow, consent process, data collection, referrals, incidents and corrective actions.

Research records shall be retained in institutional files for the period required by local law, IRB/ERC approval, funder agreement, sponsor requirements or institutional SOP. Essential records include protocols, approval letters, consent forms, data collection tools, correspondence, progress reports, deviation reports, financial records, sample transfer documents, publications and closure reports. Records should be retrievable for inspection, audit, collaborator review and institutional reporting.

12. Whistleblowing, Complaints and Non-Retaliation

SIMS shall maintain a confidential pathway for reporting research misconduct, participant complaints, ethical concerns, data breaches, financial irregularities, harassment or coercion in research. Good-faith complainants and whistleblowers shall be protected from retaliation according to applicable federal/provincial law, public-sector service rules, PEEDA Act 2006 where applicable, and institutional confidentiality procedures.

- Reports may be submitted to the IRB/ERC Chair/Secretary, Research Office, Head of Department, Principal or another designated institutional authority according to the nature of the complaint.
- The identity of complainants should be kept confidential to the maximum extent possible during assessment and inquiry.
- Frivolous or malicious complaints may be dealt with under applicable institutional and public-sector disciplinary procedures.
- Serious safety concerns, participant harm, suspected fraud, coercion or breach of confidentiality should be escalated promptly to the competent authority.

13. Reference Sources and Legal Alignment Notes

- Drug Regulatory Authority of Pakistan (DRAP): Clinical trials are regulated under the Bio-Study Rules, 2017 for therapeutic goods / investigational products.
- Drug Regulatory Authority of Pakistan Act, 2012 and Drugs Act, 1976: apply where research involves regulated therapeutic goods, investigational products, drugs, medical devices or related clinical trials.
- National Guidelines for Collection, Usage, Storage and Export of Human Biological Materials 2020: relevant to collection, storage and export of human biological materials.
- Punjab Employees Efficiency, Discipline and Accountability Act 2006: applicable to disciplinary proceedings for Punjab public-sector employees where relevant.
- PMDC professional ethics framework, National Bioethics Committee requirements and Declaration of Helsinki: foundational references for ethical conduct of medical research involving human participants.

- Concordat to Support Research Integrity and other collaborator/funder standards/agreements may be used as international best-practice references for externally funded collaborations, without treating them as Pakistani law.