Lahore Medical Research Center, Lahore

Lahore Medical Research Center

Research Policy

Office of Research, Innovation and Commercialization

This Policy document includes.

1. **Authorship Policy**
2. **Intellectual Property Rights Policy**
3. **Publications Policy**
4. **Policy on Research Misconduct**
5. **Code of Good Research Practice**
6. **Policy on Research Ethics Review**
7. **Policy on Responding to Research Disruption**
8. **Policy on Use of Animals for Scientific Purposes**
9. **Policy on Institutional Research Funding**
10. **Policy on Donor Research Funding**

Research Policy of Lahore Medical Research Center

Preamble

A collective effort by the supervisors and students of a LMRC is fundamental in achieving research excellence. The Lahore Medical Research Center supervisors and students are committed to pursue their task by working within a framework based on high sets of ethical guidelines and principles. These guidelines and principles cover wide range of practical and conceptual aspects, which include protection against violations of human rights and misrepresentations of data whether intentionally or unintentionally. All research work should maintain high standards in terms of integrity, responsibility and without prejudice to any ethnic or religious group. This policy document is subject to review when needed based on new guidelines or requirements due to changing global scenario in research.

To preserve the LMRC's reputation for high standards of scholarly integrity LMRC has developed policies that define offenses like fabrication of data, plagiarism, abuse of confidentiality, dishonesty in publication, intellectual property violations, claim to authorship and contribution and research misconduct and how to address them. ORIC develop, review and implement these policies. Following are some key Research Policy components at LMRC.

1. Authorship Policy

1.1.1 : This Authorship policy will determine the authorship for all scholarly publication, i.e. developing manuscripts, applying for grants, making presentations, and other electronic or non-electronic communications. Authorship of scholarly, scientific or research publication is recognized to be the most significant indicator of academic life. Relevant international institutions have provided guidelines related to claims of authorship including The International Committee of Medical Journal Editors (ICMJE) has developed the following guidelines recommending that to qualify as an author, one should have made:

1. Substantial intellectual contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

2. Drafting the article or revising it critically for important intellectual contribution

3. Evidence of author approval of the final version of the submitted manuscript.

4. Agreement to be accountable for accuracy and integrity of the work.

Authors should meet conditions 1, 2, and 3. Authors should have confidence in the integrity of their personal contributions and that of their co-authors. Those not meeting the key criteria should be referred to in acknowledgment. ICMJE also states that: “Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take the responsibility for the integrity of the work, from inception to published article.”

1.1.2 : Data abstractors and team members who supported in laboratory/field/secretarial fields, for example provision of technical guidance or participation in the fields of data collection or their assistance in writing manuscript do not qualify for authorship. However, these team members must be acknowledged as per ICMJE guidelines, after their formal permission. Field staff, or secretarial/administrative support team members should also be acknowledged with their permission, unless they meet the above-mentioned pre-requisites to claim authorship.

1.1.3 : For manuscripts involving different authors, the order of names must be reflected by the contribution of each team member and first author must be the one who has significantly contributed in study planning, execution of research work, conduct of study, writing and editing of draft of manuscript and least contributor should be listed as second last author. The senior most author / supervisor should be listed as last author which may or may not be the corresponding author. Every author should also disclose their written documentation revealing their contribution in specific terms.

1.1.4 : Principal Investigator of the study may not always be the first author or corresponding author as order of authorship should be based on overall contribution of each team member in conduct of research work and writing of publication.

1.1.5 : The name of Corresponding Author may be decided by mutual understanding of authors, and he/she will be responsible for communication with offices, editors of the Journal and other authors. The Corresponding Author is also responsible for keep all authors informed regarding revisions to be made in the manuscript before it is finally accepted.

1.1.6 : Research publications resulting from collaborative research projects, all authors must have read, consulted and shown their compliance with the LMRC's research policies and guidelines.

1.1.7 : Gift, Ghost, or honorary authorship will not be acceptable. Ghost/Gift/Guest authors is someonewhoislistedasanauthorwithoutqualifyingforauthorshipandalsosomeonewhosename is included without permission but meant to be acknowledged. Gift authorship is defined as co-authorship assigned to an individual who has not contributed significantly to the research project. Senior researchers assign gift authorship as repayment for favors or for encouraging collaboration and maintaining good working relationships. Regardless of the cause, gift authorship is an unacceptable practice at LMRC. Ghost authorship is defined as someone whose name is included without their permission, for e.g. senior member of the supervisors, contributors who leave the project before its completion. Regardless of the cause, ghost authorship is an unacceptable practice at this LMRC.

1.1.8 : All sources of internal or external resources funding should be acknowledged.

1.1.9 :"Work undertaken at Lahore Medical Research Center" should clearly specify if the author submitted or published the manuscript after leaving LMRC or a student who has left the program after graduation.

1.1.10 : Students/Residents:

Students are expected to publish their theses or dissertations work. In those cases where a student explicitly chooses not to engage in the preparation of their thesis or dissertation research for publication, and the research has been done within a larger project, their supervisor may choose to prepare the work themselves and will provide appropriate authorship credit to the student in recognition of his/her contribution to the research. This should preferably be agreed upon with the student at the earliest possible moment. If the student prepares independent research under supervision that they do not publish, and a supervisor deems the data and findings publishable, a written agreement must be reached with the student. Authorship must be credited to the student who as co-author must read and approve the final manuscript as per authorship requirements. The order of authors is decided in mutual agreement with the supervisor and/or the principal investigator. A student can be the Corresponding Author with the approval of the supervisor. Under no circumstance should any one affiliated with LMRC, whether as employee, student, or volunteer, publish data owned by LMRC without permission of Copyright Transfer.

1.2: Copyright Transfer

The copyright of a manuscript is generally transferred to a publisher when the Lead Author or Corresponding Author signs a copyright transfer agreement on behalf of all authors after due consultations. Thereafter, the manuscript, and all contained content are no longer the property of authors and no part of the manuscript (including figures, tables, etc.) can be submitted or published by any author without prior approval of the publisher. In such cases, where the publisher and author reach a different agreement e.g. joint- copyright, the terms of agreement will guide the execution of the copyright with assistance from ORIC LMRC.

1.3: Dispute Resolution

Overall, the Principal Investigator is mainly responsible for resolution or consensus of any disputes over the order of the authorship, however it shall be with mutual consultation. Alternatively in case a dispute or concern arises with respect to authorship, the following steps may be taken for resolution:

- Dispute may be resolved within the wider research team. Consult with the research team leader or PI for a mutual resolution. If such measures does not resolve the problem, the following order of intervention may be used: Head of department, Director ORIC, Director (of the Institute).
- If a research paper is in the process of publication, and the above interventions do not resolve the dispute, a letter showing a conflict of interest may be sent to the publisher by the PI/corresponding author for final determination on whether to consider work for publication or not.

- **Intellectual Property Rights Policy**

Link of IP Policy

2. Publications Policy

2.1: This policy defines the procedures and processes for the publication of the work produced by the members of the supervisors and students. The objective of this policy is to protect the interests of the LMRC and of its staff or supervisors, and to enhance academic and intellectual freedom, and to improve the quality of the publications. This Policy is applicable to all the research related, works which are developed or created during work or study at the LMRC, with or without LMRC support. The application of the policy will be subject to national legislation and international law or conventions.

2.2: LMRC Ownership

The LMRC shall own all the copyrightable works as follows: (a) all the work created pursuant to the terms of a LMRC agreement with a third party; (b) all the work created as requirement of employment or duty; (c) all the works specifically commissioned by the LMRC. Commissioned work includes such as; a copyrightable work prepared under an agreement between the LMRC and the creator when (i) the creator is not a LMRC Personnel or (ii) the creator is a LMRC employee but the work to be performed falls outside the normal scope of the creator's LMRC employment. Contracts covering such commissioned works shall specify that the author convey, if necessary, such rights as are required by the LMRC. (e) Works by student(s): Unless provided otherwise by the written agreement, the copyrightable works prepared by the students as part of the requirements for a LMRC degree program shall be the property of the student but are subject to the following provisions: i) The original data and the materials (including software) researched for a graduate thesis or dissertation are the property of the LMRC but a copy may be retained by the student at the discretion of the student's principal department. ii) The LMRC reserves the right, as a condition of awarding the degree, to retain, use and distribute a limited number of copies of the thesis, royalty- free, together with the right to require its publication for archival and/or educational use.

2.3: Video recording, all types of Computer Software's, Related Classroom Technology and the Courses developed and/or used for the teaching at the LMRC belong to the LMRC. Any such courses which are video-recorded or recorded using any media are the property of the LMRC and may not be further distributed without written permission from the Department Head.

2.4: The LMRC owns the copyright in Scholarly Works.

2.5: The LMRC owns all the rights, title and interest in any Trademarks (registered or otherwise) that are related to the LMRC or relate to a program of the education, service, public relations, research or training by the LMRC.

2.6: The individual author shall in all cases retain moral rights in his or her scholarly and other works.

2.7: The LMRC has the power to authorize the use of its institutional address and the identification of authors as members of its supervisors or staff. Such authorization will be deemed to have been granted in respect of all scholarly works. In other cases, specific permission must be sought.

2.8: supervisors are encouraged to be especially mindful of the reputational risk to the LMRC when publishing in the public domain on topics of particular sensitivity. When writing on topics of that fall outside of their areas of professional expertise, they should consider not using their LMRC affiliation. supervisors are encouraged to consult with their Dean or ORIC regarding publications that might be particularly sensitive.

2.9: The LMRC reserves the right to withdraw its affiliation in scholarly papers published in predatory journals. LMRC may also reject support for papers intended to be published in expensive journals without adequate senior consultation prior to submission.

2.10: Scholarly works: The LMRC recognizes the academic freedom of its supervisors in publishing the results of their work in scholarly journals and publication forums. Such journals and other forums should have effective processes of peer review in place. Authors are advised to seek advice from the LMRC Librarian and consult with respective dean or ORIC for guidance.

2.11: LMRC sponsorship: In case a publication of a work is subsidized by the LMRC or has been approved for inclusion in a LMRC series, it shall be reviewed by a formal process established within each academic entity. This process will include provision for external review by independent experts in the relevant field. The head of the entity shall be responsible for establishing an appropriate mechanism for this purpose.

2.12: LMRC Publications Committee: The Director establish a LMRC Publications Committee to formulate procedures and guidance within the scope of this policy and to take decisions on approval of series titles and other strategic issues related to publications. If a dispute or concern arises with regard to the application, efforts should be made to resolve it through

informal discussion. If the dispute persists, the aggrieved party may refer the dispute for resolution to the Director ORIC.

3. Policy on Research Misconduct

Lahore Medical Research Center aims to stand for high level of integrity in its research activities. LMRC ensures that high standards are applied during the conduct and reporting of research. LMRC shall take steps to ensure that relevant appropriate processes are in place to expeditiously deal with the allegations of misconduct in the research. The LMRC also recognizes that the contributions of the mentors, project supervisors, department heads, and the supervisors, which establish a high bar of the honesty and integrity required in the conduct of research.

3.1: This policy applies to all the LMRC employees and also those affiliated with the LMRC, who are engaged in the research conducted at or by the LMRC, regardless of the source of funding. If misconduct is discovered after the individual no longer works for/is affiliated with, the LMRC, the case may still be processed and appropriate action taken (such as demand for public apology/retraction of publication/legal action, etc.).

3.2: The minimum time-limit for the retention of research data and records will be seven (7) years from the end of the data collection for the research project, the last publication/report emanating from the research, or when a degree is awarded to a student for the research work (whichever is last).Research records include all forms of results captured in the course of the research (laboratory notebooks, questionnaires, interview and similar notes, etc). The primary purpose for the retention is to preserve the ability to validate the research findings and/or to permit the work to be repeated or extended into new scholarship.

3.3: Definitions:

Misconduct in research includes any, some, or all of the following acts:

a) Fabrication and/or falsification of research-related data, or in reported research outcomes.

b) Plagiarism in all research-related matters, including publications, appropriation of someone else's ideas, processes, results, outputs, or words, without giving appropriate credit.

c) Inappropriate use of someone else's intellectual property, without reference, acknowledgment, or permission.

d) Denial of individual rights such as authorship to collaborative partners in research publications.

e) Non-compliance with the LMRC's policies on "*Conflict of Interest",* "*Intellectual Property Rights*" and "*Authorship Policy*".

f) Non-compliance with the LMRC's "*Policy on Code of Good Research Practice and Access to Participant Data*."

g) Deliberate misuse of institutional or sponsored funds for financial gains.

h) Willful failure to honor an agreement or contract with the funding agency, to perform certain tasks.

i) Publishing any data or results that are against the internationally accepted general principles of research and scholarly activities.

j) Deliberate destruction of one's own or others' research data, records, or research-related property.

k) Making use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

l) Violation of (or non-compliance with) the code of ethics for research as established by the LMRC.

m) Wrongful attribution towards an approving authority (*e.g*., claiming ethical approval from the Institutional Review Board, Ethical Committee for Animal Care & Use, Institutional Biosafety Committee, when such approval does not exist).

n) Inappropriate use of technology (*e.g*., misinformation resulting from manipulation of images through photo-editing technology or software)

Misconduct does not include unintentional errors in interpretations or judgments of data, an accidental loss of data or loss of results, and discontinuation of an agreed research collaboration or assigned task due to legitimate reasons, such as ill health or situations beyond one's control.

3.4: Plagiarism

The LMRC has a strong commitment against plagiarism and considers it an act of misconduct, which is liable to disciplinary action. LMRC will adhere to the guidelines issued by the Higher Education Commission Pakistan, and relevant international organizations. The following types of plagiarism, irrespective of their degree of seriousness, whether committed deliberately or inadvertently, are considered unethical and illegal:

a. Complete Plagiarism: In case the whole document, manuscript, or research idea, is copied verbatim from one or more sources, even if the source is disclosed in the reference section.

b. Partial Plagiarism: In case a part or whole section(s) are inserted without paraphrasing, with a few or only cosmetic changes to the text, without giving appropriate reference. It also applies to insertion of figures/photos, diagrams, illustrations, graphs, or charts, from various sources without prior approval of the author(s) and/or publisher(s), as may be the case.

c. Self-Plagiarism: In case one's own published work is re-sent for publication to another journal, without the permission of the original publisher, even if the publication is translated into another language.

d. Plagiarism of Ideas: In case the ideas or documented work of others are presented as one's own, in any form whatsoever, and at any forum whatsoever. This includes proposed research studies on specific topics previously conceived by another individual orgroup.

e. Concealing Sources/Denying Acknowledgement: In case the source of the information is not disclosed or acknowledged, or due credit is not given to fellow contributors in apublication or research study. Any word- for-word quote must have a reference citation, while written permission of the author and/o r the publisher is needed for lengthyquotations.

3.5: Finding and/or Reporting of Research Misconduct

The first reporting of the misconduct may be made in writing or by producing documentary evidence to the respective Dean, Chairperson IERC, or respective Principal,

who may direct it to the Director ORIC. Director ORIC shall ask the respective department for verification. Alternatively, upon receiving such report with an evidence, he/she will initiate an investigation by setting up an Adhoc committee for this purpose. The Ad hoc committee will submit a full report of the findings and advise penalties, if any.

3.6: Confidentiality and Protection

Effort must be made to maintain confidentiality for the protection of the interests of the LMRC and those who are involved in reporting research misconduct. Allegations of research misconduct might originate from outside the LMRC, possibly from other institutions, in learned journals, or in the press. Within the LMRC, allegations of research misconduct might come from academic, research or technical staff, or from students and residents. Under no circumstances will an anonymous complaint be the basis for a formal proceeding.

Procedure of Inquiry: (Details in Appendix: "Procedures for resolving disputes and allegations of misconduct in research")

The Office of ORIC is responsible for evaluation and investigation of all the allegations of misconduct related to the research at Lahore Medical Research Center. Individuals should not undertake the investigations of a suspected research misconduct on their own. It is pertinent to mention that scientific and research misconduct does not include honest errors or differences of opinion.

a) The Director of ORIC (Chair), in whose office an allegation charge is filed, will set up an initial inquiry to assess whether or not the matter is research misconduct, as defined in this policy.
b) The supervisors member or an employee whose research work is the subject of investigation shall be notified about the nature of the complaint without disclosing the identity of the initiator. The evidence relevant to the complaint must be securely placed with the respective head of the department or institute, and only duplicates shall be used for the investigation process.
c) An Adhoc Inquiry Committee shall be appointed by the Director ORIC to conduct the investigation; the Committee will submit a written report of the inquiry

proceedings. All activities and proceedings of the meetings must be recorded in audio and transcribed, to fulfill legal requirements.

d) The Adhoc Inquiry Committee may refer to LMRC policies, as well as various international organizations and committees, as resources for its deliberations.

e) The Adhoc Inquiry Committee may also consult with supervisors, students, or any other individual who has knowledge of the alleged research misconduct in question.

f) If an outside sponsor or collaborator is involved in the research, the report of the Adhoc Inquiry Committee may be shared with the organization concerned or affected individuals, with the consent of the Chair

g) The entire inquiry process from initiation, post-allegation, to submission of the inquiry report to the Chair, (or a relevant/appropriate authority), must be completed in sixty (60) calendar days.

h) An appropriate extract of the report shall be provided to the accused for rebuttal.

i) If the alleged misconduct is not substantiated, diligent efforts will be undertaken, where appropriate, to restore the reputation of those under investigation. The research records will be restored appropriately as well. No further action will be taken by the LMRC and no reports will be made to funding agencies unless they are specifically required under the circumstances of the allegation, or unless the funding agency is aware of the allegation.

j) If misconduct is proven, the LMRC will take appropriate action. The Vice Chancellor upon receiving the recommendations of the Director ORIC, based on the findings of the Adhoc Inquiry Committee and any statement of rebuttal by the accused, shall take a final decision with respect to the action to be taken and will formally notify all parties, including the sponsor of the research.

k) The final investigation report must be in writing and submitted to the Vice Chancellor in a timely fashion. The Chief Scientific Officer will review the report and determine whether to accept it as is or return it to the Adhoc Inquiry Committee for further deliberation or fact-finding.

l) The timeline should allow for the submission of the report to the sponsor concerned, if required, no later than 120 days from the date the investigation began, in cases where misconduct is found.

m) Copies of the inquiry report, along with all supporting documents and decisions must be retained for seven (7) years.

3.7: Penalty for Research Misconduct

a. In an event that a researcher is found guilty of misconduct, the Ad hoc Inquiry Committee shall impose a penalty, taking into account the severity of the misconduct. Penalties may include: a reprimand, public/private apology, withdrawal of article/proposal or any other dissemination material, fine not exceeding US$1,000 (One thousand dollars), or equivalent inappropriate local currency, suspension of the work/employment and termination from job.
b. In cases the investigation does not confirm the allegations, the Adhoc Inquiry Committee shall recommend the same to the Chair, who shall undertake appropriate efforts to ensure that the reputation and integrity of the individual is not harmed.
c. The higher authorities shall also take suitable actions to guard the position and reputation of those who, in good faith, made the allegations. However, if it is discovered that the complainant has brought charges with a malicious intent, he/she should be reprimanded, disciplined and/or penalized as may be deemed fit.
d. If a student commits plagiarism in his/her thesis, that student may be judged to have failed the thesis.

3.8: Appeals under the LMRC Research Misconduct Policy

1. Either the complainant or the respondent may appeal the verdict of the hearing board (adhoc committee) and/or the penalty imposed by delivering to the Chair a written notice of appeal within thirty (30) days of receipt of a copy of the hearing board report. The notice should

   Include a written statement of appeal that indicates the proof on which the appellant intends to rely, any evidence the appellant wishes to present to support those grounds, and (where relevant) what remedy or remedies the appellant believes to be appropriate.

2. An appeal will be considered only on one or more of the following grounds:

   a. That the original hearing board had no authority or jurisdiction to reach the decision or impose the sanction(s) it did.

   b. That there was a reasonable apprehension of bias on the part of a member or members of the original hearing board.

c. That the original hearing board (ad hoc inquiry committee) made a basic procedural error that seriously affected the outcome.

d. That new evidence has arisen that could not reasonably have been presented at the initial hearing and that would likely have affected the decision of the original hearing board.

3. Upon receipt of a notice of appeal, the Chair, or designate will review the record of the original hearing and the written statement of appeal and determine whether the ground for appeal is valid. If the Chair, determines that there are no valid basis under these Procedures for an appeal, then the appeal will be dismissed without a hearing. If the Chair determines that there may be a valid basis for an appeal, then the appeal hearing will continue as provided below. The decision of the Chair, with respect to allowing an appeal to go forward is final, with no further appeal.

3.9: Appeals Board

i. The Appeal Board will be formulated by the Vice Chancellor, within twenty-one (21) calendar days and will be composed of three senior members of the LMRC, with one from another academic institution. One member of the appeal board shall be named by the chair (Director ORIC). Individuals appointed to serve on an appeal board shall exclude anyone who was involved in the original hearing of the case.

ii. The members of the hearing board will have no real, clear, perceived, or potential conflict of interests or bias and will jointly have appropriate subject matter expertise and administrative background to evaluate the complaint and the response to it. The complainant and the respondent will be advised of the composition of the hearing board and will have seven (7) calendar days to advise the Chair, of the intent to challenge the suitability of any member of the hearing board based on a reasonable apprehension of bias against the complainant's or respondents' case.

iii. After all questions have been answered and all points made, the Appeal Board will meet in camera to decide whether to uphold, overturn or modify the decision of the original hearing board. The deliberations of the Appeal Board are confidential.

iv. The Appeal Board may, by majority as following; conclude that the appellant received a fair hearing from the original hearing board, and uphold the original decision; or conclude that the appellant did not receive a fair hearing, but that the outcome determined remains appropriate and the original decision is upheld; or conclude that the appellant did not receive a fair hearing, and dismiss or modify the original decision, or order that a new hearing board be struck to re-hear the case. A new hearing board decision shall be used only in cases such as when a new evidence is introduced, in original hearing board.

v. The chair of the Appeal Board shall prepare a report of the board's deliberations that shall recite the evidence on which the board based its conclusions and state any penalty imposed or withdrawn. The report shall be delivered to the Chair and distributed.

vi. If the decision of a hearing board is successfully appealed, the chair of the appeal board shall suggest the Vice Chancellor to take all reasonable steps to repair any damage that the appellant's reputation for academic integrity may have suffered by virtue of the earlier finding of the hearing board.

vii. The findings and ruling of the appeal board shall be final with no further appeal.

viii. Not later than **15 days** after a hearing board or an appeal board has completed its deliberations, the chair of the Appeal Board shall deliver a copy of the report to the Appellant, the Respondent, the Chief Scientific Officer and the Director ORIC

ix. If there is more than one Appellant or Complainant, reasonable efforts will be made to provide each with parts of the report that are pertinent to him/her.

x. Records pertaining to complaints that result in disciplinary action will be retained in the respondent's official file in accordance with existing LMRC policies, procedures and collective agreements.

xi. No record of a complaint will be kept in the complainant's official file except the record of disciplinary action resulting from a complaint that is made in bad faith.

xii. Subject to the provisions of the Research Misconduct Policy and the requirements of law, any and all records pertaining to charges and/or hearings and/or sanctions under these Procedures are confidential and should be kept in

a file accessible only to the Chair, and their confidential assistants for a period of 10 years or while any legal or official proceedings are pending. After this time, the records may be destroyed. These records are strictly confidential and will be disclosed only when disclosure is required by law or by a legal or official proceeding. The Chair shall make them available to hearing boards and appeal boards as required.

xiii. LMRC shall take appropriate administrative actions against research misconduct which has been substantiated. If the Chair, determines that research misconduct is substantiated by the findings of the inquiry committee, he or she shall decide on the appropriate actions to be taken, after consultation with the Legal/Human Resource Office and consideration of the recommendations in the Inquiry Committee report. The Chair, has the sole discretion and responsibility to determine, decide, and stipulate the final sanctions against any individual who has been found to have engaged in research misconduct under this policy. The administrative actions may include, but are not limited to, the following: withdrawal or correction of all pending or published abstracts and papers emanating from the research, where research misconduct was found; notification of professional societies, professional licensing board, or other relevant work in the particular project; removal of the responsible person from the research project; provision of a letter of reprimand; special monitoring of future work; probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment; or research; training in the responsible conduct of research; restitution of funds to the grantor agency as appropriate; notification of law enforcement agencies to prevent such incident in the future or any other action appropriate to remedy the research misconduct.

4. Code of Good Research Practice

5.1.1 : This code is applicable to all the research and related activities conducted at the Lahore Medical Research Center, Lahore. This code shall ensure the standards of research in terms of quality

and integrity and relevant policies of LMRC such as Intellectual Property Rights, Authorship Policy and The Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule) (the last for health domain studies) are followed in letter and spirit. This policy applicable to all the research involving human research participants and/or their data. Strict compliance with the research ethical guidelines and conditions is required for all such research. Individuals who fail to uphold the high standards of research practice outlined in this Code of Good Research Practice, may be subject to investigation and which may ultimately lead to disciplinary action. The purpose of this code also includes to ensure that adequate safeguards are in place to protect the confidentiality and the interests of the research participants and researchers.

5.1.2 : In case there is a request for accessing participant's data or entering into a Data Transfer Agreement (DTA) with an external collaborator, the investigators will obtain ethical approval from the Institutional Review Board (IERC), such approval to include the determination that each institute/hospital has human ethical protections and that the institute/hospital complies with the HIPAA Privacy Rule for health domain studies.

5.1.3 : Ownership and Access to Data

a. Any data which is generated or stored or collected by LMRC or its affiliated institutes, irrespective of the underlying reason (including research studies), whether in the form of written records or in electronic format, are the property of the LMRC. Access to all such data will require explicit approval by the competent authorities, In all cases, the identity of the research participants must at all times be kept confidential.

b. The physical form of the data, including participant medical records and biological samples, may be kept within the department(s) responsible for generating the data andforupdating/maintainingit.Transferorshipmentofbodilyfluidsandmaterials require official clearance by accepted LMRC authorities.

c. Researchers who are generating or collecting data from the participants, as a part of their research project shall be accountable for its integrity, protection and confidentiality. Any other person interested in using the data must seek formal consent from the Principal Investigator, the IERC. The use of electronic data capture and retention requires special care.

d. Access to data should normally not be denied to any member of a research group

which collected the data. However, the formation of writing groups should follow the publications policy specified for the project. Individuals outside the research group should be allowed access to data only after the agreement of the group members, approval from the primary supervisor and acquisition of IERC approval.

e. Each undergraduate or postgraduate student or other investigator in a research project must come to an understanding with the primary supervisor or Principal Investigator, preferably in writing, about which parts of the project he/she might continue to explore after leaving the research project. Such an understanding should specify the extent to which a copy of the research data may be taken and should stipulate the need for IERC approval for such further data use. In all cases, there must be no data security breach. Co-investigators at other institutions are entitled to access the data if they participated in its generation. In all such cases, prior permission of the ORIC Department and Chief Scientific Officer will be required for patient data in the health domain. Where the supervisor or other collaborators and the student have jointly generated data and/or results that have been published, the student may incorporate the data in his/her dissertation or thesis, for which he/she will have the copyright, with the permission of the other data co-owners. Permission to use the data in the student's thesis, however, does not give the student the right to use the data for other purposes without permission from the primary supervisor. The primary supervisor will ensure that applicable rules (such as IERC approval) are followed prior to granting such permission.

f. All communications and publications generated out of students' work must at all times state the student's supervisor as the corresponding author. The student will, however, remain the principal author of all such publications.

g. All student-related projects/assignments and/or elective studies whether a part of regular curricula or optional, which require access to clinical data or participants' interaction, must be coordinated through the primary supervisor and relevant authority.

h. All supervisors, and students who intend to use patient medical records, other participant data or any other source of participant information, such as computer-generated data for research, must fill in the request form available from the ORIC. The form must be duly signed by the Head of Department before it is submitted to ORIC. Except for purposes of clinical audit, system or service evaluation, all

other studies requiring access to participant data will require approval from the IERC. However, if the intention is to publish the clinical audit, system or service evaluation (Quality Assurance/Quality Improvement (QA/QI)) study as a research publication, then IERC approval is necessary prior to the commencement of the study. Principal Investigators are advised to submit a request for exemption from ethical approval from IERC, if the study qualifies for exemption.

5.1.4 : Retention of Research Data and Records

a. The researcher should put in place a Data Management Plan to describe the collection, handling, sharing, and storage of data through the lifecycle of the research project and beyond. Researchers will follow the best practices for data management and the expected standards within their discipline.
b. The Data Management Plan will stipulate the form in which the data will be retained (typically, the original form of the collected data will be retained up to the minimum retention time-limit–see following sections); after that, electronic copies may be acceptable for longer-term retention of the data.
c. The minimum time-limit for the retention of research data and records will be seven (7) years from the end of the data collection for the research project, the last publication/report emanating from the research, or when a degree is awarded to a student for the research work (whichever is last).Research records include all forms of results captured in the course of the research (laboratory notebooks, questionnaires, interview and similar notes, etc).The primary purpose for the retention is to preserve the ability to validate the research findings and/or to permit the work to be repeated or extended into new scholarship.
d. IERC records will similarly be retained for five (5) years beyond the last year in which the research protocol was active.
e. Data from clinical trials must be retained for twenty-five (25) years.
f. Where the research requires only anonymized data, identifiable data should be anonymized as soon as possible after it is generated.
g. Where data involve participants who are children and/or adolescents, appropriate guidelines must be adopted as approved by the IERB.
h. Where the research or data-matching studies require the data to remain identifiable, the identifier key should be kept separate from the research data and, if transmitted, sent

independently. For both the data and the identifier key, encryption should be utilized as part of the Data Management Plan.

i. Access to the retained research data will require ethical approval from IERB.

5.1.5 : Retention of Human Biological Materials

a. Biobanks are very important research assets. In the same way that data preserved for possible future research work may support new insights, human biological materials could also support future research projects. The time of retention of such specimens should be decided, in part, by the stability of the material under the appropriate storage conditions.

b. Storage conditions for the human biological materials could be guided by the variety of relevant policies of the LMRC or by the standard practices typically followed in a given field of study where the materials are routinely used or studied.

c. Two main approaches to getting and using human biological materials in research can be considered: firstly, when materials are going to be collected for research purposes, ethical approval is required in advance. Related to that approval, is the use of a consent form for the research participants, agreeing to the collection of the tissue for the specified research purpose; secondly when tissues acquired for clinical and similar purposes may result in excess material (otherwise discarded) that could be saved in a Biobank. Subsequent proposed useof these materials for a research purpose requires ethical approval.

d. In the case where someone other than the person(s) who established the Biobank, wishes to use the materials for research, a new ethical approval is needed.

e. Whether the biological materials are "identifiable" *versus* anonymous is important for the IERC ethical review.

f. Sharing of human biological materials would require a Material Transfer Agreement to be signed following an IERB ethical review.

5.1.5 : Data Security when Electronic Devices and/or the Internet are used in Research

a. Portable device sare usually needed for the conduction of selected research. Such devices introduce security risk. In general, research data should only be placed on portable devices when essential for the needs of the research project.

b. The portable devices should be protected through the use of a password and/or data

encryption.

c. If the use of the portable device in research includes travel, travel precautions should be taken including the following (in addition to the password and encryption precautions): Donot transport sensitive information unnecessarily; Safeguard the device from theft or damage; Use the latest (patched) software; Avoid wireless connections when accessing sensitive data; Prepare for border searches or the need to report a loss/theft.
d. Data stored on a computer that is connected to the internet should been crypted as should data sent over the internet. Research which includes a "cloud" service, is subject to the same data management practices (*e.g.*,security, access,etc.) as other research activities that involve use of the internet.
e. Data repositories or registries to be used for the storage of sensitive data must be assessed for the adequacy of their security.
f. Research conducted on the internet remains subject to a number of debates regarding ethical considerations. Researchers should follow the currently accepted approaches and practices in their research domain. The design of internet research should consider distinguishing between public and private information (and the related need for ethics review) and, for those studies where ethics review is needed, obtaining free and informed consent, the protection of children & adolescents, pseudonyms & confidentiality, validity & reliability of data, anonymity & confidentiality, and risks of follow-up. Research using questionnaires on the interned may not have shortcomings greater than those of other methods and may be able to be subjected to the same evaluation criteria.

5.1.6 : Assets Purchased through Research Grants (RestrictedFunds)

a. All assets purchased from (restricted) research funds are the property of the LMRC.
b. Department Heads are responsible for coordinating the acquisition planning, procurement, and the ongoing effective and efficient stewardship of assets, including safeguarding, utilization (possible re-assignment/relocation), maintenance and disposal.

5.1.7 : Dispute Resolution

Any dispute related to access of data or misuse of data shall be referred to the ORIC who will be the final arbiter. Disputes related to authorship and intellectual property shall be resolved according to the procedures outlined in the respective policy document.

5. Policy on Research Ethics

Link: Research Ethics Policy

6. Policy on Responding to Research Disruption

a. As per this policy, a Disruption to Research is defined as when the LMRC research work or activities are substantially interrupted or impeded, which may as a result of an event or circumstances, beyond the reasonable control of the LMRC and includes but is not limited to; civil disorders, protests, strikes, fire, natural disasters, epidemics and government enforced lockdowns. The policy will be applicable to ALL research (ongoing and new), or consultancies, funded or unfunded, having defined timelines and deliverables to report. The prime concern in responding to such crisis situations is the life and safety of LMRC Lahore's supervisors, students, employees and study subjects.
b. The policy is relevant only in case of a substantial and prolonged disruption to research. For any brief disruptions, individual PIs and the departments or institutes are in the best position to determine there action.

6.1: Substantial Disruption:

A substantial disruption is defined as an unforeseen incidence or event, which are not manageable as routine measures. The "event" is usually declared as national and/or global emergency and which halts the LMRC's research activities for more than 30 working days, badly compromising the LMRC's capacity to carry out its research activities and timely completion of research deliverables. Such a disruption has commonly the potential to significantly risk the safety and security of staff, students, and visitors, LMRC's reputation and viability and strategic research objectives. In case it is not clear to decide that disruption is substantive and needs an institutional response, the Vice Chancellor will make a final decision.

6.2: Policies Applicable during Research Disruption

The relevant policies of the LMRC related to the research are applicable during the disruption; Policy on Research Ethics; Policy on Research Misconduct and Financial Policy on Research.

6.3: Response to Research Disruption

i. In case the LMRC faces a substantive disruption, **Research Disruption Response Team (RDRT)** will be constituted by the Chief Scientific Officer, which may have the following membership

- Principal of the relevant Institute
- Director ORIC
- Director Finance
- Representative from Legal Office
- Chair IERC
- Additional relevant members (May be appointed by the CSO)

ii. The CSO may assign an alternative person to act as the chair of the RDRT.

iii. **Mandate of RDRT**

a. To evaluate the nature and intensity of disruption, and to establish how conducting or non-conducting of the research during the disruption will impact LMRC's repute and its contractual obligations under various research agreements.

b. To appraise and conform with national and international guidelines on the disruption under consideration, and to evaluate the impact of the disruption on conduction of the research activities.

c. To develop Standard Operating Procedures (SOPs) depending on the nature of the disruption for complete/partial conduct of the research or suggesting its complete halt as found appropriate.

d. To ensure that BASR approved policies/procedures /SOPs pertaining to research disruption are disseminated across LMRC through various communication channels. During the time when customized SOPs are being developed and approved, the

previous SOPs could apply as applicable. Compliance to SOPs remains the responsibility of the various entity heads.

e. To ensure that the research grant administration continues to work as best as possible during the disruption.

f. To monitor that head of department or institute work with respective principal investigators to evaluate if any of their project timelines, staffing needs or technical deliverables require alteration/ modification (cost/no cost extensions) negotiations with granting agencies/sponsors.

g. To work with the Institutional Biosafety Committee (IBC) to make sure safe and secure execution of the research and handling of biological hazardous materials to evade any possible contamination.

h. Facilitate the Chair, IERB to guarantee ethical compliance of the research to avoid any possible deviation of ethical standards during times of disruption. The IERC should develop relevant procedures to ensure compliance to best ethical practices during times of disruption.

i. The RDRT will meet regularly to evaluate the intensity of the disruption and so it may propose a an appropriate approach to restart or ramp-up research operations.

j. When a disruption ends, the RDRT will stand dissolved after it submits its deliberations in writing.

7. Policy on use of Animals for Scientific Purposes

The Lahore Medical Research Center established Animal Care Facility (ACF)as it recognizes the importance of use of Animal Care and Use Program for Biomedical Sciences so as to promote its duty of developing the human capacities through a process of the discovery and dissemination of knowledge, and its application. Animals are essential for doing the pre-clinical research and educational or training activities. The Animal Care Facility intends to maintain the needs of the

LMRC these tasks, by catering to the requirement of laboratory animals for the research and education to support the biomedical and health sciences. The policy will achieve the standards of animal care and use comparable to those described in the Guide for the Care and Use of Laboratory Animals (8th ed. 2011, National Research Council, National Academies Press) and the Guide for the Care and Use of Agricultural Animals in Research and Teaching (3rd ed. 2010, Federation of Animal Science Societies)and will be endorsed by the international accrediting agency for animal laboratories, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, USA. Based on these principles, the objectives of this policy include:

a. To define and establish LMRC's Animal Care Facility for sensible use of animals for scientific purposes, which may include research and teaching. This policy also defines how shall be facility constructed, maintained and upgraded for animal-based research, and shall also defines and apply standard operating procedures for the use of the animals.

b. To make available a framework for ensuring compliance in the use of animals at LMRC with internationally and nationally accepted guidelines or principles of animal welfare and ethics.

7.1: Implementation of and the compliance with this policy will be a shared responsibility of the people using the laboratory animals for scientific purposes, the Institutional Biosafety Committee, the Animal Facility Committee, BASR and external collaborators performing animal work at LMRC.

7.2: Animal Facility Committee (AFC)

a. Working under the Office of BASR, the AFC has the mandate to manage the animal care facility, including procurement, housing, feeding, breeding, screening, day-to-day care, health care, dispensing to users, and monitoring of use of laboratory animals.

b. AFC shall report to the Head of the Office of BASR while working to implement relevant regulations and guidelines nationally and internationally.

c. The AFC shall be headed by the Attending Veterinarian and assisted by a coordinator.

d. The AFC periodically shall inform and updates BASR about the functioning of Animal Care Facility (ACF).

e. Members of the AFC include the Coordinator of the Animal Care Facility, and a representative from the Institutional Biosafety Committee. A representative from the Pathology Department and a Chair Animal Care Facility are ex-officio members.

7.3: Institutional Biosafety Committee (IBC)

a. The IBC shall formulate, approve and implement the protocols entailing potential biological hazards. Animal Facility Committee shall work in harmony with the guidelines and the relevant SOPs of the IBC, so as to ensure safety of the personnel and the animals involved.

b. Relevant occupational health and biosafety precautions related to laboratory animal-related work will be addressed within the umbrella of institutional biosafety.

c. Working closely with the IBC, the Department of Medicine will be responsible for the employee health screening, incident / exposure reporting, and health maintenance, including vaccinations and medical treatment.

d. Composition of IBC: Head of Pharmacology Department, Head of Pathology Department, Head of Medicine Department, Representative of District Health Officer, Assistant Registrar of the LMRC and Environment Protection department of the Government. The quorum shall be 4 members.

8. Policy on Institutional Research Funding

9.1.1: The ORIC follows the vision of the Higher Education Commission Pakistan regarding research for creation of knowledge and its applicability in solving the health and related problems of the community. LMRC has established a system of institutional funds which are awarded to the eligible groups, or individual supervisors and the students to enable them to pursue research in the priority areas based on national policies and identified by the LMRC and

also in any other field which is considered appropriate by the ORIC and BASR.

9.1.2 : Institutional Research Resources Allocation Committee (IRRAC) is an administrative body which evaluates the research proposals received with request for the funding from the LMRC and other internal sources which may be allocated. Institutional Research Resources Allocation Committee (IRRAC) funds will be used as a catalyst to help the supervisors to get external funding and shall not be used as a main source of funding. It is expected that this support would permit the investigators to compete effectively for the external grants. This funding shall also fosters the development of the capacity for the research.

9.1.3 : Eligibility for ORIC Institutional Grant

a. Full-time supervisors of the LMRC across all affiliated institutes are eligible to apply for ORIC Institutional grants.

b. A PI may re-apply for the ORIC Institutional grant funding, provided the previous progress report was submitted and one year has passed since the completion of the previously ORIC funded project. However, the track record of the PI would be a consideration while applying for a new ORIC institutional grant and the completed project would have been evaluated for quality of research in terms submission of final report and other scholarly outputs; *Note: This clause does not apply in cases where the PI is submitting application as student's supervisor. A supervisor can submit at the most two applications on behalf of a student or a resident.*

c. The students of the LMRC can also apply for ORIC Institutional funding to compensate the costs for the research activity(e.g. data collection)

d. The involvement of the supervisors in projects as "investigator" or "co-investigators" should be clearly time-defined, in terms of proportion of time that each co-investigator will spend on the project.

e. ORIC will not fund a request for financing to setup a registries or a tissue bank.

9.1.4 : Categories of Research Support:

Applications will be accepted under two categories:

a. Commercialization and Donor Oriented Programme (CDOP)and

b. Research Support Programme (RSP).

a. Commercialization and Donor Oriented Programme (CDOP)

i. CDOP will include application that are preparing towards obtaining external grants or innovation and commercialization projects.

ii. Approximately 50% of the total yearly ORIC institutional research budget will be allocated for this category.

iii. PIs will be required to explain in their applications that how their research project will help them in obtaining an external grant or better impact factor.

iv. PIs will also be required to mention the names of the funding/donor agencies that they are preparing to apply in future or in which reputable scholarly journal they are planning to publish, as the case may be.

v. Departmental Research Committee (DRC) will peer review each application before it is submitted to ORIC.

vi. Department head will submit a letter of support that the work is important, relevant and has potential impact in terms of knowledge generation or commercialization and aligned with departmental goals. In the support letter the departmental head will also provide assurance on the efficient execution and a timely delivery of grant outputs including progress and final reports. The departmental head shall also provide information on the availability of the researcher during the whole time period of the projects.

vii. Projects in this category may receive funding which will be decided on case to case basis and subject to the availability of funds.

b. **Research Support Programme (RSP):**

- Approximately 50% of the total yearly ORIC Institutional budget will be allocated for this category. RSP programme will accept application related to research funding to research projects which have potential to impact the current practices and contributes to the existing knowledge pool.

c. Capacity Building Grants (CGB): Grants for the training of the personnel for specific needs related to research projects will be considered;

i. Applications may be submitted on the CBG Application Form. Such

applications must accompany a detailed description of the training, and its relationship to existing or future research projects.

ii. The applications may be related to the training of the individuals who have an aptitude on research management by specifically designed programmes, and development of research managers in the managerial dimension of research or the skilled personal training for specific research purposes.

iii. Conference and/or the workshop related operating expense may also be supported in this category provided that the project has a research/ capacity building component. The department submitting such applications will have to bear half of the cost of the project.

iv. Projects in this category may receive funding which will be decided on case to case basis and subject to availability of funds.

9.1.5 : Review of Applications

i. ORIC will contact each departmental/institutionl head of the LMRC to obtain lists of Reviewers to review research proposals for ORIC. A 6-monthly report will be given to the entity heads so that the contribution of these reviewers can be duly recognized at the time of annual appraisal.

ii. ORIC is empowered to seek the services of the external reviewers in case reviewers are not available or there may be conflict of interest, in a particular research area at LMRC.

iii. Applications will be reviewed double-blind, so that PIs and the reviewers are anonymous to each other.

iv. All applications will preferably be reviewed by at least two reviewers and ORIC will formulate its own TORs.

v. External reviewers may be requested to evaluate the applications if appropriate expertise is not available at the LMRC;

vi. Reviewers may use the following scale based scoring to provide a summary of the proposal specifying the strengths and weaknesses and will rate them based on the scale below (10 being highest):

a) Feasible	1	2	3	4	5	6	7	8	9	10
b) Impact	1	2	3	4	5	6	7	8	9	10
c) Novel	1	2	3	4	5	6	7	8	9	10
d) Ethical	1	2	3	4	5	6	7	8	9	10

(Potential for extramural funding, how clear and likely to get funding on scientific merit)

vii. The reviewers will also submit confidential comments for the Institutional Research Resources Allocation Committee (IRRAC). IRRAC shall include the Director/Additional Director ORIC, a Research Advisor, a Co-opted Member from Concerned Department, One Member from Finance department of the LMRC. IRRAC shall be responsible for submitting the recommendation to the VC regarding financial or other resources allocation to a project. Its decision shall be based on relevance, rationale, innovation, feasibility and impact of the proposed research. It shall ensure transparency in funds utilization. The IRRAC has the right to recommend or refuse the funding request without assigning any reason.

viii. IRRAC will evaluate the submitted applications based on the markings or/and the comments provided by the reviewers in the periodic IRRAC meetings.

ix. The reviewers' reports will be shared with the IRRAC and members, who will use them to prioritize the proposals for better, efficient and informed decision making.

x. IRRAC in their meetings will rate the applications as 'approved', approved with minor changes' or 'not approved'.

xi. A feedback system will be created for the applicants to evaluate the review process and the reviewers' comments.

xii. IRRAC must also comment on the following factors related to the Principal Investigators including research history competence, experience, and knowledge of project subject.

xiii. Expedited Review may be available in case of applications that are time sensitive.

9.1.6 : Frequency & Deadlines of ORIC Funding Calls

a. The URC extends invitation for research grant proposals two times a year. Deadlines for yearly closing of funding calls as follows; (In case the deadline falls on a holiday, applications will be accepted till the following working day)

1st Cycle:	December 31	Every year
2nd Cycle:	August 31	"

9.1.7 : Application guidelines

The following should be included with each application:

i) ORIC application form, which includes summary statement of proposed research, describing (a) its significance in your field, (b) how the results could enhance the potential for obtaining external grants, or provide the basis for larger grant applications or may help in creating new knowledge, resulting in better citations and impact factor.

ii) Budget sheet with justification (itemized)

iii) Institutional checklist

iv) Details of the Researcher; Name, Affiliation, and Contact details

v) Details of the previous funded research and publications in past five years.

vi) Short CVs (one page) of the PI, Co-PIs and collaborators and one page publication details of each.

vii) Co-PIs and collaborators must submit a signed letter stating willingness to co-operate and the extent of their involvement.

viii) For multi-disciplinary, multi-investigator projects: The roles of investigator or group should be stated.

ix) **Appendices:** These should include information critical for evaluating the proposal. They should be numbered consecutively.

9.1.8 : Project description, with background and plan of research conduction and analysis:

The research plan should be organized into the following sections:

a) Objectives and hypothesis: This should be in outline form, with the objectives stated for the period of this project only.
b) Background and Rationale: This should be a brief, critical review of the context of the proposal, evaluating current knowledge in the field. The bibliography should cite only the most relevant references. A multi-disciplinary committee, including people from outside your field of expertise should be able to understand why this research is important.
c) Methods: Provide sufficient detail for the committee to assess your understanding of the experimental design, specific procedures, justification of sample size and methods of data analysis.

9.1.10 : Budget guidelines

a. Request the minimum amount of the funds that will allow you to conduct the research. PKR for Institutional and United States Dollar (USD) for Donor/ External Funding should be used on the Budget Form.

b. Provide itemized budget justification and justify each item clearly. Please provide an explanation if you have other institutional or external funding.

c. Details in Budget Report of expenses must be submitted to ORIC office for the audit purposes at the end of project, within 3 months of completion of project..

d. Allowable expenses vary depending on the project. Salary for the PI is not an allowable expense.

e. The following is a general guideline:

    a. Consumables and supplies: Support will be given for the consumables and supplies related to equipment, office stationery, data processing; animal costs and animal maintenance; unavoidable cost involving human subjects; and unusual computer time requirements.

b. Stipends: Research fellows/Associate or graduate students who are involved in approved research and registered at LMRC may be eligible to receive a stipend.

c. Postdoctoral fellows, Research Assistants and Technicians*:* Salaries may be requested to support postdoctoral fellows, research assistants in all disciplines and technicians in Basic and Clinical Sciences. A request for fringe benefits may be included, where applicable.

d. Travel: Travel will be considered when it is essential to achieve project goals. The nature of the travel must be clearly explained in the proposal. In extraordinary circumstances, other travel may be supported.

e. Equipment: Although the ORIC discourages funding equipment in its grants, applicants may include a small proportion of the overall funds in the budget for equipment, however the LMRC may allow the use of existing equipment for research project. In such case the chemicals of reagents or other kits used in such existing equipment may be provided. This must be justified on the basis of a specific need defined in the research proposal. All consumables/ supplies required to run the equipment for experimental purposes must be included under the list of consumables for the research project. The total cost of equipment should include handling charges freight and accessories. As this is a LMRC funded item the equipment must be utilized with utmost care and returned after the expiry of the grant in good working condition except for normal wear and tear compatible to careful use. The ORIC will allow other eligible grantees to use the same equipment hence it reserves the right to provide used equipment to the grantees as long as it can satisfy the needs of project.

f. Dissemination cost: Written application should include support cost of publication of research papers as well as cost related to the dissemination of research reports.

g. The budget should be developed with the help of relevant personnel in the Finance Office.

h. The funds shall be transferred to the PI in a joint account with The VC/Director ORIC/Manager Research/Manager I&C or funds shall be utilized via finance department of LMRC, as the case may be.

i. The funds may be release in two phases at the beginning and after midterm report after assuring the safe practices.

j. In case a PI and his team fails to complete the financed research, and publish it. An inquiry Committee shall be composed by the The VC, including Two Deans, Director ORIC and a Member Finance of IRRAC. This Committee shall decide about the cause of the failure to complete the research and recommend the actions including banning for further research funding, recovery of the financing or any other. The recommendations shall be sent to the VC, and the decision of the VC will be final.

9.1.11 : Reporting guidelines: These will include;

- Midterm reports
- Closeout report
- Budget report

9. Policy on Donor Research Funding

10.1. Lahore Medical Research Center aims to seek more national and international collaboration on research including but not limited to capacity building, training, funding and consultancies. For the purposes of integrity of research and consistency of the work, it is important to ensure that donor research funding processes are streamlined, which match LMRC policies and conform with all the national and international legal and regulatory requirements. Ultimately the ORIC office, along with BASR and with the assistance from other departments of the LMRC is required to uphold the LMRC research interests and ensure that the grant proposals have undergone institutional review, assess where required, the reputation of the donor agency, before its final submission to the sponsor. It is

anticipated that this policy will assist funding applicants in: preparing the better research proposals for donor grants; seeking the required internal approvals before a research proposal is to be submitted to a funding agency and LMRC will help in establishing requirements for sponsors of research to ensure their commitment to the conduct of ethical research in accordance with the applicable laws and regulations. The applicant or the lead person for the project for which funding is sought (Principal Investigator (PI) in case of research grants, or Project Lead or Director in case of other activities) can have preliminary discussions about a proposed project including exchange of emails with the funding agency, however no written proposal (paper or electronic), which binds the LMRC to a legal or moral responsibility can be submitted until an internal approval is obtained in writing. ORIC shall periodically disseminate information on grant funding opportunities across the LMRC and maintain a list of funding agencies relevant to the LMRC and its regions of operation, and make the same available to researchers upon request and through the periodic circulation to the researchers at the LMRC. ORIC shall make any and all internal policies available to researchers, both general and specific, and gives advice, where sought, on completing the pre-award checklist and other documents.

10.2: Eligibility to Apply for Funding

- All full-time supervisors members and research staff are eligible for applying for such donor funded research grants but it is essential for PIs to have the necessary qualification, experience and commitment to take the project to a successful completion. This is subject to approval from the Departmental Head certifying that there is no other reason for ineligibility, including, but not limited to other committed responsibilities, long leave, approaching end of contract, resignation, and disciplinary action. In exceptional circumstances, contract supervisors, part-time supervisors or a non-supervisors can be the lead person of a project and will require prior approval of the Vice Chancellor Office.The same criteria of eligibility strictly apply to Co-Principal Investigators (Co-PIs) as they will be held equally

responsible for everything that the PI does.

- All supervisors, and in exceptional cases staff, are eligible to be Co-Investigators (Co-I). This is subject to approval from the Departmental Head certifying that there is no other reason for ineligibility, including, but not limited to other responsibilities, leave, resignation, disciplinary action, etc. To qualify as Co-Is, they must provide significant demonstrable intellectual input to the research project. In addition the researchers external to LMRC, such as members of other institutions can be Co-Is, subject to written approval by competent authority of their parent institution. Graduate students, postdoctoral fellows and research staff hired on a specific project cannot apply for extramural funding as PI. However, students can become a Co-I with their supervisor's approval in the project(s).

- The head of the department must certify that they will allow the PIs and Co-Is sufficient time to participate in the project. The supervisor takes responsibility for graduate students conduct while working in a project led by them.

- **Conflicts of interest (COI)** or perceptions of conflicts may occur when there is a convergence of an investigator's personal interests with his or her research interests, such that an independent observer might reasonably question whether the investigator's professional actions or decisions are inappropriately influenced by considerations of personal financial gain. Such conflicts are common in universities and do not question the character or actions of any individual. Such conflicts of interest can also arise in non-research grants including consultancy.

The investigator may be required to disclose significant personal financial interest related to his/her institutional responsibilities. This disclosure must be done through a section entitled 'Conflict of Interest' in the "Checklist".

When LMRC reasonably determines that the significant financial or other interest could directly and significantly affect the design, conduct, or reporting of the research, LMRC will take steps either to manage or to eliminate any COI from the project. The PI agrees to fully cooperate with the LMRC in this regard.

Submission of Checklist

The lead person or the PI will develop a research proposal as per the requirements of the funding organization. He/she or a person who is authorized by him/her will then fill out the ORIC Checklist and after due approvals from all the relevant departments, submit the application to the ORIC for processing. The concept note and/or LOI cannot be submitted directly to funding agency. ORIC must be informed before submitting such concept note or LOI, in written form. It is advised that to protect the PI and the LMRC's reputation or to avoid any legal liability that may ensue, identical or similar proposals must not be made to different sponsors nor should duplicate funding be solicited from any institution. To avail funding opportunity, a PI can apply an identical or similar proposal to different sponsors; provided that sponsors are made aware in writing of submissions to the other agency.

Responsibilities of applicant regarding the grant proposal and checklist:

It is the prime responsibility of the PI or lead person to submit the duly filled application and relevant supporting documents to the approving departments, satisfy their queries, and seek their approval well ahead of time.

Recovery of costs: To the best extent possible, the budget submitted to a funding agency should include recovery of all the costs, both direct and indirect, in a transparent and compliant manner. In addition to direct expenses and core recoveries, the budget should aim to recover indirect costs of the LMRC, as approved from time to time to the extent allowable by the funding agency. This recovery may be done either through

a straight charge to the grant (up to the extent allowed by the funding agency's policy), and by charging allowable core LMRC costs as direct expenses to the grant. Naturally, the above options should be chosen and executed in a transparent manner, and based on guidelines/policies of the respective Funding Agency.

Review and Endorsements

The following departments/individuals review and approve the proposals;

- The head of department (whereapplicable) must approve the relevant sections of the Checklist;
- Human Resources (if personnel are to be hired or there are core personnel being utilized);
- Finance (to ensure that Institutional financial policies are adhered to and project budgets are reasonably accurate and adequate ensuring full cost recovery as allowed by the sponsor. PI is responsible for the scientific basis of the budget);
- Legal Department
- Registrar (only in case of student sponsorships, and/or funding of academic programmes) to ensure that fees are accurately depicted.
- Safety & Security for off-campus research sites (only if project activities are to be performed anywhere outside the LMRC campus).

In addition to the above mentioned approvals, the Checklist must be accompanied by the following relevant documents:

- A profile of external collaborator(s), if any;
- **Letter of Support**: Individual support letters from any Collaborators

and/or external Co- Investigators indicating their willingness to participate and that they are authorized to do so in the project, along with the extent of their involvement in the proposed study, as well as their budget (if any). In case of a budget, a due diligence may be required.

- Copy of the proposal that is to be submitted to the funding agency. If any changes are required to the proposal after submission, it would require explicit approval of the ORIC.

- Copy of the financial budget with justification.

The following information for records and data analysis.

- Brief objectives of the project
- Anticipated impact
- Research Design
- Laboratory space needs.
- Animal requirements. PI to take advise from the Animal Care Facility regarding availability or the capacity at LMRC to complete the planned deliverables in the grant.

- **IBC approval**: To ensure biosafety of all projects involving activity in the research lab or handling biological or hazardous materials, proposal has to be reviewed by the Institutional Biosafety Committee.

- Intellectual property, data retention, publications, confidentiality and other rules also apply in all relevant cases.

- The funding agency commonly prepares the final agreement. Once the final agreement, or its draft, is received from the funding agency, it is reviewed by Finance, the Legal Office, and the ORIC (and other department, if and as relevant) to ensure that the terms and conditions mentioned in the agreement are acceptable to LMRC. Furthermore, the budget and other requirements are checked to see if they concur to what was approved during the initial proposal submission stage.Differenceif any are reviewed and if adequate approved. The authorized signatories from the ORIC and Finance

subsequently sign the agreement/MoU/Sub-contracts/MTA/DTA and any other arrangements on behalf of the LMRC.

- After the agreement is signed by both the funding agency and the LMRC, the grant is considered as an approved project. However, in case of projects involving interaction/study on human subjects or human tissues, the PI must obtain an ethical approval from the IERC of the LMRC.

- It should be especially noted that the internal approval process is mandatory in all cases, prior to final submission of proposal even where funding agencies require only the PI and/or the concerned head of department to sign the proposal form. Agreements are between institutions and not individuals hence all agreements/contracts will be signed for LMRC by the relevant authorized signatories. Should you receive any agreement in your own name, you must immediately contact the ORIC for further guidance.

Requirements f Donors, and Contract Research Organizations (CRO)

In compliance with the LMRC and hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of research, the investigator will work with the sponsors, in case the sponsors or donors are a commercial organization or a CRO involved in the clinical research, to ensure:

- Research teams used by the sponsor are trained and qualified to conduct the research.
- Privacy and confidentiality of subject data is maintained.
- Research data are reliable and valid, and the results and reporting are statistically accurate, ethical, and unbiased.
- Patient or researcher incentives do not compromise the integrity of the research.

In case the sponsor is transferring its duties, functions and responsibilities to the CRO, the investigator will ensure that the following requirements are met:

- A written contract clearly delineating this transfer of responsibilities.
- The contract should specify that the CRO or sponsor is also responsible for compliance with LMRC and Hospital's policies and process for monitoring and evaluating the quality, safety, and ethics of the research.

References:

1) AmericanPsychologicalAssociation.4thEd,1994.PublicationManualoftheAmerican PsychologicalAssociation.Washington, DC: USA.
2) Hemmings,A.Greatethicaldivides:Bridgingthegapbetweeninstitutionalreviewboardand theresearchers. *Educational Researcher,* 2005; *35*(4):12-18.
3) *IntellectualPropertyRightsPolicy*.KenyattaLMRC,Nairobi:Kenya(May2 010).
4) *IntellectualPropertyRightsPolicy*.AgaKhanLMRC(February2019).
5) International Committee of Medical Journal Editors. Guidelines on Authorship. BMJ. 1985;291:722.
6) Research policies. Aghakhan Medical LMRC, Karachi. Available at: *https://www.aku.edu/research/policies/Pages/home.aspx*
7) Prevalence of Honorary and Ghost Authorship in Cochrane Reviews. *JAMA*. 2002; 287:2769-71.
8) *Research Policy Guidelines*.Muhimbili LMRC of Health and Allied Sciences, DaresSalaam,Tanzania.(August2011).
9) American Psychological Association. Research Misconducthttp://www.apa.org/research/responsible/misconduct/index.aspx retrieved April 11,2012
10) Higher Education Commission Pakistan "The Little Book of Plagiarism"http://beta.hec.gov.pk/InsideHEC/Divisions/QALI/QADivision/Documents/ Plagiarism%20Policy.pdfretrieved April2012

11) Kenyatta LMRC (May 2010). Intellectual Property Rights Policy. Nairobi,Kenya

12) Muhimbili LMRC of Health and Allied Sciences (August 2011). Research Policy Guidelines. Dar es Salaam, Tanzania

13) Muhimbili LMRC of Health and Allied Sciences (August 2011). Intellectual Property Policy and Guidelines. Dar es Salaam,Tanzania

14) Agres T. NIH Misconduct Rules Reviewed, Professional Societies Support Revisions To Rules On Whistle-Blowers And Research Misconduct. The Scientist April 26,2004

15) DeFrancesco L. Researcher Seeks Whistle-Blower Protection. The Scientist, November 1, 2002.http://www.biomedcentral.com/news/20021101/04/

16) La Trobe LMRC: The Academic Misconduct Policy.http://www.latrobe.edu.au/policies

17) Canadian Tri-Council Policy Statement 2, http://www.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf

18) Aplanforresearchdatamanagementthroughoutthelifecycleoftheresearchproject (http://www.science.gc.ca/eic/site/063.nsf/eng/h_97610.html)

19) Dataretentiontimesareset toprovideanadequateperiodtoallowanyquestionsaboutthedatatobeaddressed(*e.g.*,accuracy, reproducibility, originality, etc.) and to meet anyrequirements ofthe sponsors or applicable laws or regulations. Research data and related financial data must both be considered. Retention times vary: some institutions rely on a statement similar to the preceding; others state 3 years (Oxford, Memorial Sloan Kettering), 5 years (LMRC of British Columbia, Canadian Institutes of Health Research) or 7 years (LMRC, LMRC of Alberta [for financial records]).

20) A*BestPracticesforHealthResearchInvolvingChildrenandAdolescents* documentdevelopedtocomplementtheTCPS2, provides guidance:http://www.genomicsandpolicy.org/en/best-practices-2012

21) Aga Khan LMRC – Policy on responding to Disruption of Academic Programming:https://www.aku.edu/admissions/Documents/policy-disruption-of-academic-programme-042.pdf#search=disruption.

22) York LMRC's Academic Implications of Disruptions or Cessations of LMRC Business Due to Labour Disputes or Other Causes, Senate Policy on the: https://secretariat-policies.info.yorku.ca/policies/academic-implications-of-disruptions-or-cessations-of-LMRC-business-due-to-labour-disputes-or-other-causes-senate- policy-on-the/

23) Policy on Research Ethics Review, ORGS/008-2018, March 29, 2018. aku Research Policieshttps://www.aku.edu/research/policies/Pages/home.aspx

24) Policy on Research Misconduct, ORGS/002-2018, Oct 11, 2018. aku Research Policies. https://www.aku.edu/research/policies/Pages/home.aspx