# NISHTAR MEDICAL UNIVERSITY, MULTAN

## Research Policy

This Policy document includes;

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# Research Policy of Nishtar Medical University

## Preamble

A collective effort by the faculty and students of a university is fundamental in achieving research excellence. The Nishtar Medical University Multan faculty 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 the 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.

In order to preserve the University's reputation for high standards of scholarly integrity NMU 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 and BASR develop, review and implement these policies. Following are some key Research Policy components at NMU.

### 1. Authorship Policy

1.1.1:

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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 recognised to be the most significant indicator of academic merit at universities.

Relevant international institutions have provided guidelines related to claims of authorship including The International Committee of Medical Journal Editors (ICMJE) has developed 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 integrity of their personal contributions and that of their co-authors. Those not meeting the key criteria should be referred 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 as a whole, from inception to published article."

1.1.2: Data collectors and those who provided laboratory/field/secretarial support, such as providing technical assistance or participating in data collection or helping in typing the manuscript should not claim authorship, but should be acknowledged, with their permission for their work. Field workers, or secretarial/administrative staff may be acknowledged with permission. Unless they have met the above requirements to be eligible for authorship.

1.1.3: For multiple authors, the order of names normally should reflect the contributions made by each of them, with the most significant contributor listed as the first author, and least contributor as second last. The last authorship slot is reserved for the most senior author, who may be or not be the corresponding author. All authors must be ready to submit written documentation of their specific contributions.

1.1.4: The study principal investigator is not always necessarily the first or corresponding author as authorship is based on overall contribution to the work and the publication.

1.1.5: The Corresponding Author should be decided through consensus between authors and will be responsible for communication with editors, journals, and other authors. The Corresponding Author will keep all other authors informed in case of revisions made in the manuscript before it is finally published.

1.1.6: In collaborative research projects resulting in publications, authors should have read, consulted and complied with the University's research policies and guidelines.

1.1.7: Gift, Ghost, or honorary authorship is not acceptable. Ghost/Gift/Guest author is someone who is listed as an author without qualifying for authorship and also someone whose name 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 favours or for encouraging collaboration and maintaining good working relationships. Regardless of the cause, gift authorship is an unacceptable practice at NMU. Ghost authorship is defined as someone whose name is included without their permission, for e.g. senior member of the faculty, contributors who leave the project before its completion. Regardless of the cause, ghost authorship is an unacceptable practice at this University.

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

1.1.9: *"Work undertaken at Nishtar Medical University"* should clearly specify if the author submitted or published the manuscript after leaving NMU or a student who has left the programme 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 oftheir thesis or dissertation research for publication, and the research has been done within a larger project, their supervisor may choose to prepare the work themselvesand will provide appropriate authorship credit to the student in recognition of his/hercontribution to the research. This should preferably be agreed upon with the studentat 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 anyone affiliated with NMU, whether as employee, student, or volunteer, publish data owned by NMU without permission of Copyright Transfer.

## 1.2: Copyright Transfer

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/s reach a different agreement e.g. joint- copyright, the terms of agreement will guide execution of the copyright with assistance from ORIC NMU.

### 1.3: Dispute Resolution

The PI is responsible for resolution of any disputes over order of the authorship, but in collegial consultation with the other investigators. If a dispute or concern arises with respect to authorship, the following steps may be taken for resolution:

- Resolve the dispute within the wider research team. Consult with the research team leader or PI for an amicable resolution. If a discussionwith the PI does not resolve the problem, several avenues of dispute resolution consultation within the relevant departments/entities may be undertaken in the following order: Head of department; Respective Dean, Director, ORIC Principal (of the Institute); and VC, NMU

If a paper is in the process of being published, and the above interventions do not resolve the dispute, a letter indicating a conflict of interest should be sent to the publisher by the PI/corresponding author for final determination on whether to consider work for publication or not.

## 2. Intellectual Property Rights Policy

**Link of IP Policy**

## 3. Publications Policy

This policy defines the procedures for the publication of work produced by members of faculty and staff and, where appropriate, by students. The policy aims to protect the interests of the University and of its members, to support and enhance academic and intellectual freedom, and to enhance the quality of publications associated with the University and its members.

### 3.1: Application

This Policy is applicable to all research related works developed or created in the course of work or study at the University with University support. The application of the policy will be subject to local legislation and international law and conventions.

### 3.2: University Ownership

The University shall own copyrightable works as follows: (a) Works created pursuant to the terms of a University agreement with a third party; (b) Works created as a specific requirement of employment or as an assigned University duty that may be specified, for example, in a written job description or an employment agreement “work for hire”; (c) Works specifically commissioned by the University. The term “commissioned work” refers to a copyrightable work prepared under an agreement between the University and the creator when (i) the creator does not fall under the category of University Personnel or (ii) the creator is a University employee but the work to be performed falls outside the normal scope of the creator's University employment. Contracts covering commissioned works shall specify that the author convey by assignment, if necessary, such rights as are required by the University. (e) Works by student(s): Unless provided otherwise

by written agreement, copyrightable works prepared by students as part of the requirements for a University degree programme shall be the property of the student but are subject to the following provisions: i) The original data and materials (including software) researched for a graduate thesis or dissertation are the property of the University but a copy may be retained by the student at the discretion of the student's principal department. ii) The University 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.

**3.3:** Video recording, Computer Software, Pedagogical Software and Related Classroom Technology: Courses developed and used for teaching at the University belong to the University. Any courses which are video-recorded or recorded using any other media are University property, and may not be further distributed without written permission from the Department Head.

**3.4:** Copyright in Scholarly Works: Unless provided otherwise by written agreement, the University waives its right to claim ownership of Scholarly Works.

**3.5:** Trademarks and series titles

The University owns all rights, title and interest in any Trademarks (registered or otherwise) that relate to the University or relate to a programme of education, service, public relations, research or training by the University. This clause shall be deemed to cover the titles of series of publications sponsored or owned by the University.

**3.6:** Moral rights

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

**3.7:** Assertion of affiliation

The University has the power to authorize the use of its institutional address and the identification of authors as members of its faculty 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.

**3.8:** Faculty are encouraged to be especially mindful of the reputational risk to the University 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 University affiliation. Faculty are encouraged to consult with their Dean or ORIC regarding publications that might be particularly sensitive.

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

**3.10:** Scholarly works

The University recognises the academic freedom of its faculty to publish the results of their work in scholarly journals and other recognised outlets. Such journals and other outlets should have in place effective processes of peer review. Authors are advised to seek advice from the University Librarian and consult with respective dean or ORIC for guidance.

**3.11:** University sponsorship

Where the publication of a work has been subsidized by the University or has been approved for inclusion in a University 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.

**3.12:** University Publications Committee

The Vice Chancellor shall establish a University 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 respective Dean, and Director ORIC, through their Departmental Head.

## 4. Policy on Research Misconduct

Nishtar Medical University aims to stand for high level of integrity in its research activities. NMU builds on common concerns and ensures that the same standards are applied in the conduct and reporting of research. Though unintentional violations of ethical standards remain a possibility in all investigations, a false allegation of misconduct can jeopardize the reputation of the University and its researchers. Hence, this policy is developed with the objective in mind that while having the responsibility to provide a conducive environment to promote integrity in research and quality assurance, NMU has taken steps to ensure that appropriate mechanisms are in place to expeditiously deal with allegations of misconduct in research. The University recognizes the contributions of mentors, project supervisors, department chairs/unit heads, and faculty, which establish the high bar of honesty and integrity required in the conduct of research.

**4.1:** This policy applies to all University employees (*viz*. faculty, residents, students and staff) and also those affiliated with the University (such as trainees, technicians, students, fellows, clinicians, visiting researchers, collaborators, and other staff members) who are engaged in research conducted at or by the University, regardless of the source of funding. If misconduct is discovered after the individual no longer works for/is affiliated with, the University, the case may still be processed and appropriate action taken (such as demand for public apology/retraction of publication/legal action, etc.).

**4.2:** 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.

### 4.3: 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. [Refer to Section 3.0, above, and 5.0, below]

c) Inappropriate use of someone else's intellectual property (without reference, acknowledgment, or permission, as the case may be).

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

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

f) Non-compliance with the University'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) Wilful failure to honour 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 University.

m) Wrongful attribution towards an approving authority (*e.g.*, claiming approval from an Ethics Review Committee [ERC], Ethical Committee for Animal Care & Use [ECACU], biohazard assessment, etc, 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*:

i. unintentional errors in interpretations or judgments of data.
ii. an accidental loss of data or loss of results.
iii. discontinuation of an agreed research collaboration or assigned task due to legitimate reasons, such as ill health or situations beyond one's control.

### 4.4: Plagiarism

The University is uncompromising towards plagiarism and considers it an act of misconduct liable to disciplinary action. In keeping with past practices, the University will adhere to the guidelines issued by the Higher Education Commission Pakistan.

The following types of plagiarism, irrespective of their degree of seriousness, whether committed deliberately or inadvertently, are considered as unethical and illegal:

a) *Complete Plagiarism*: When 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*: When part or whole section(s) are inserted without paraphrasing, with 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*: When 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*: When 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 or group.

e) *Concealing Sources/Denying Acknowledgement*: When the source of the information is not disclosed or acknowledged, or due credit is not given to fellow contributors in a publication or research study (for further clarity, refer to "University Authorship Policy"). Any word-for-word quote must have a reference citation, while written permission of the author and/or the publisher is needed for lengthy quotations.

## 4.5: Finding and/or Reporting of Research Misconduct

The initial reporting of the misconduct may be made in writing or by producing documentary evidence to the respective Dean, Chairperson IRB, or respective Principal, who may direct it to the Director ORIC. Director ORIC shall ask the respective department for verification. Alternatively, upon receiving a report with evidence, he/she will initiate an investigation by setting up an *ad hoc* committee for this purpose. The *ad hoc* committee will submit a full report of the findings and advise penalties, if any, to be imposed.

## 4.6: Confidentiality and Protection

Every effort must be made to maintain confidentiality to protect the interests of the University and those involved in reporting research misconduct. Allegations of research misconduct might originate from outside the University, possibly from other institutions, in learned journals, or in the press. Within the University, allegations of research misconduct might come from members of 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 evaluating and investigating all allegations of misconduct related to research at Nishtar Medical University. Individuals should not undertake investigations of suspected research misconduct on their own. Scientific and research misconduct does not include honest errors or differences of opinion.

a) The Director ORIC, in whose office the allegation charges are filed, will set up an initial inquiry to assess whether or not the matter is research misconduct, as defined in this policy.

b) The faculty 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. 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 investigative process.

c) An *ad hoc* 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 fulfil legal requirements.

d) The *ad hoc* Inquiry Committee may refer to University policies, as well as various international organizations and committees, as resources for its deliberations.

e) The *ad hoc* Inquiry Committee may also consult with faculty, 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 *ad hoc* Inquiry Committee may be shared with the concerned organization or affected individuals, with the consent of the Chair, University Research Council.

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 University 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 University will take appropriate action. The Vice Chancellor upon receiving the recommendations of the Director ORIC, based on the findings of the *ad hoc* 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 Vice Chancellor will review the report and determine whether to accept it as is, or return it to the *ad hoc* Inquiry Committee for further deliberation or fact-finding.

l) The timeline should allow for submission of the report to the concerned sponsor, 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.

## 4.7: Penalty for Research Misconduct

a) In the 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
- Withdrawal of article/proposal or any other dissemination material
- Public/private apology
- A fine not exceeding US$1,000 (One thousand dollars), or equivalent in appropriate local currency
- Disallowance of the work
- Suspension of work/employment
- Termination from job.

b) In cases where the investigation does not confirm the allegations, the *ad hoc* 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 appropriate actions to protect the position and reputation of those who, in good faith, made the allegations. However, if it is revealed that the complainant has brought charges with a malicious intent, he/she should be reprimanded, disciplined and/or penalised 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.

## 4.8: Appeals under the NMU Research Misconduct Policy

1. Either the complainant or the respondent may appeal the decision of the hearing board 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 grounds 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 made a fundamental 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 or not the grounds for appeal are valid. If the Chair, determines that there are no valid grounds under these Procedures for an appeal, then the appeal will be dismissed without a hearing. If the Chair, determines that there may be valid grounds for an appeal, then the appeal hearing will proceed as provided below. The decision of the Chair, with respect to allowing an appeal to go forward is final, with no further appeal.

## 4.9: Appeals Board

4. The appeal board will be constituted by the Vice Chancellor, within twenty one (21) calendar days and will be composed of three senior members of the University or of another academic institution. One member of the appeal board shall be named chair. Individuals appointed to serve on an appeal board shall exclude anyone who was involved in the original hearing of the case.
5. The members of the hearing board will have no actual, apparent, reasonable, 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.
6. 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.

7. The appeal board may, by majority,

   i. Conclude that the appellant received a fair hearing from the original hearing board, and uphold the original decision; or

   ii. Conclude that the appellant did not receive a fair hearing, but that the outcome determined remains appropriate and the original decision is upheld; or

   iii. Conclude that the appellant did not receive a fair hearing, and dismiss or modify the original decision. or

   iv. Order that a new hearing board be struck to re-hear the case. This provision shall be used only in rare cases such as when new evidence has been introduced that could not reasonably have been available to the original hearing board and is in the view of the appeal board significant enough to warrant a new hearing.

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 ask the relevant Senior Administrator 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.

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

9. Not later than **15 days** after a hearing board or an appeal board has completed its deliberations, the chair shall deliver a copy of the report to the Appellant, the Respondent, the relevant head of department, school dean/director, and the Chair.

10. 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.

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

12. 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.

13. 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.

14. NMU 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 investigation 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 Investigation 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:

i. Withdrawal or correction of all pending or published abstracts and papers emanating from the research, where research misconduct was found;

ii. Notification of professional societies, professional licensing board, or other relevant work in the particular project;

iii. Removal of the responsible person from the research project;

iv. Provision of a letter of reprimand;

v. Special monitoring of future work;

vi. Probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment; or research;

vii. Training in the responsible conduct of research;

viii. Restitution of funds to the grantor agency as appropriate;

ix. Notification of law enforcement agencies to prevent such incident in the future.

x. Other action appropriate to remedy the research misconduct.

## 5. Code of Good Research Practice

5.1.1: This code is applicable to all the research and related activities conducted at the Nishtar Medical University, Multan. This Code ensures that the quality and integrity of the research are not compromised and that relevant University policies 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 applies to all research involving human research participants and/or their data across all research disciplines. Strict adherence to research ethical guidelines and conditions is required for all such research. Individuals who fail to maintain the high standards of research practice outlined in this Code of Good Research Practice may be subject to investigation and may ultimately face disciplinary action. The purpose of this Code is to facilitate faculty, students and residents in accessing and using institutional or (outside) researcher data for their research while, at the same time, ensuring that adequate safeguards are in place to protect the confidentiality and the interests of the research participants.

5.1.2: When requesting access to participants' data or entering into a Data Transfer Agreement (DTA) with an external collaborator, the investigators will obtain ethical approval from the Institutional Review Board (IRB), such approval to include the determination that each institute/hospital has human ethics protections equivalent to those of the NMU 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 generated or stored by NMU or its affiliated institutes and all other data collected from within NMU, irrespective of the underlying reason (including research studies), whether in the form of written records or in electronic format, are the property of the University. Access to such data will require explicit approval by the competent authorities, such as the IRB and the Medical Superintendent (for clinic/hospital records), or the VC or the Principal of the of the relevant Institute. In all cases, the identity of the 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 and for updating/maintaining it. Transfer or shipment of bodily fluids and materials require official clearance by accepted University authorities.

c. Researchers generating or collecting participant-related data as a part of their research project shall be responsible for its integrity, security and confidentiality. Any other

person interested in using the data must seek formal consent from the Principal Investigator, the IRB. 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 agreement of the group members, approval from the primary supervisor and acquisition of IRB approval.

e. Each undergraduate student, postgraduate student and postdoctoral fellow or other investigator in a research project should 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 IRB 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 Section/Department Head and the VC or The Principal 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 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 IRB 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 faculty, and students (undergraduate and graduate) and staff 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 respective unit/Department Head before it is submitted to the ORIC. Except for purposes of clinical audit, system or service evaluation, all other studies requiring access to participant data will require an approval from the IRB. 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 IRB approval is necessary prior to the commencement of the study. Principal Investigators are advised to submit a request for exemption from ethical approval from IRB, 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 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. IRB records will similarly be retained for seven (7) 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 IRB.
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 IRB.

## 5.1.5: Retention of Human Biological Materials

a. Biobanks are 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 range of relevant policies of the NMU Department of Pathology 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 acquiring and using human biological materials in research can be considered: firstly when materials are 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 use of 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 IRB ethical review.
f. Sharing of human biological materials would require a Material Transfer Agreement to be signed following an IRB ethical review.

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

a. Portable devices may be needed for the conduct of selected research. Such devices introduce a security risk. In general, research data should only be placed on portable devices when necessary 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): Do not 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 be encrypted as should data sent over the internet. Research which includes a "cloud"[8] 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 (Restricted Funds)

a. All assets purchased from (restricted) research funds are the property of the University.
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.

## 6. Policy on Research Ethics Review

**Link: Research Ethics Policy**

## 7. Policy on Responding to Research Disruption

a. For the purpose of this policy, a *Disruption to Research* occurs when university research activities are *substantially* interrupted or impeded as a result of any event or circumstances beyond the reasonable control of the University and includes but is not limited to; civil disorders, political unrests, protests, strikes, fire, natural disasters, epidemics and government enforced lockdowns.
b. The policy will be applicable to ALL research (ongoing and new) irrespective of the source of funding which have defined timelines and deliverables to report. Besides research, it covers grants which have a development and capacity building component or are classified as consultancies.
c. The foremost priority in responding to crisis situations is the safety of NMU Multan's faculty, students, employees and study subjects.

d. The policy will be applicable only in case of substantial and prolonged disruptions to research. For any temporary / brief disruptions, individual PIs and the NMU entities are in the best position to determine the response.

**7.1: Substantial Disruption:**

A substantial disruption is an unforeseen event which cannot be managed through business as usual structures. The event is declared as national and/or global emergency and is expected to halt university's research activities for 30 working days or more, seriously compromising the University's capability to carry out its research mission and timely accomplishment of research deliverables. Such a disruption has the potential to significantly compromise safety and security of staff, students, and visitors, university's reputation and viability and strategic research objectives. If it is not clear whether the disruption is substantive and merits an institutional response, the Vice Chancellor will make a final decision.

**7.2: Policies Applicable During Research Disruption**

Following policies approved by the University pertaining to research will remain applicable during the disruption; Policy on Research Ethics; Policy on Research Misconduct and Fincial Policy on Research

**7.3: Response to Research Disruption**

**i.** In case of substantive disruption, a **Research Disruption Response Team: RDRT** will be constituted by the Vice Chancellor, which may have the following membership

- Principal of the relevant Institute
- Chair, BASR
- Director ORIC
- Director Finance
- Representative from HR & Legal Office
- Deans of the Institute
- Chair IRB

ii. The Vice Chancellor at his/her discretion or as necessary, may assign an alternate person to act as the chair of the RDRT.

iii. The Chair at his/her discretion or as necessary, may appoint additional members in the Committee depending upon the nature of the disruption.

iv. **MANDATE OF RDRT**

a. To assess the intensity/scope of disruption based on geographic location of the disruption.

b. To determine how conduct/non-conduct of research during disruption will impact NMU's reputation and its contractual obligations under various research agreements.

c. To review and comply, wherever applicable with national and international guidelines/directives on the specific disruption under

consideration.

d. To evaluate impact of disruption on smooth conduct of research activities.

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

f. To ensure that BASR approved policies/procedures /SOPs pertaining to research disruption are disseminated across NMU through various communication channels. During the time when the customized SOPs are being developed and approved, the previous SOPs could apply as applicable. Compliance to the SOPs remains the responsibility of the various entity heads.

g. To ensure that all phases of grant life cycle administration from pre-award to close out continue to function as best as possible during the disruption.

h. To monitor that department/entity heads 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.

i. To facilitate effective supply chain management during periods of disruption for research in wet labs.

j. Work with the Institutional Biosafety Committee (IBC) to ensure safe and secure execution of research and handling of bio-hazardous materials to avoid any possible contamination (as appropriate).

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

l. The Research Disruption Response Team will meet periodically to evaluate the intensity of disruption and may propose a phased approach to restart or ramp-up research operations.

m. When a disruption ends, the Research Disruption Response Team will be dissolved after it submits its deliberations in writing.

## 8. Policy on Use of Animals for Scientific Purposes

The Nishtar Medical University established Animal Care Facility (ACF) as it recognizes the importance of use of Animal Care and Use Program for biomedical sciences to forward its mission of developing human capacities through the discovery and dissemination of knowledge, and application through service. Animals are required for performing pre-clinical research and educational / training endeavors. The Animal Care Facility intends to support the University in the above by catering to the need of laboratory animals for research and education to support biomedical and health sciences. The Program aims to achieve 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 endorsed by the international accrediting agency for animal laboratories, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International, USA. Emanating from these principles, the specific objectives of this policy are:

a. To define its Animal Care Facility for judicious use of animals for scientific purposes including but not limited to research and teaching, encompassing facility construction, maintenance and upgradation for animal-based research, development of standard operating procedures for the use of animals, review of operations, and overall governance.

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

**8.1:**
Implementation of and compliance with this policy is a shared responsibility among the people using laboratory animals for scientific purposes, the Institutional Biosafety Committee, the Animal Facility Committee, BASR and external collaborators performing animal work at NMU.

### 8.2: Animal Facility Committee (AFC)

a. Working under the Office of BASR, this Committee is mandated to manage the animal 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 reports to the Head of the Office of BASR while working to implement relevant regulations and guidelines nationally and internationally.

c. The Committee is headed by the Attending Veterinarian and assisted by a coordinator.

d. The Committee periodically informs and updates BASR about the functioning of the animal facility.

e. *Membership*: The Committee includes the Coordinator of the animal 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.

### 8.3: Institutional Biosafety Committee (IBC)

a. The IBC reviews and approves protocols entailing potential biological hazards. Animal Facility Committee work in accordance with guidelines and relevant operating procedures of the IBC, to ensure safety of personnel and animals.

b. Specific occupational health and biosafety precautions pertaining to laboratory animal-related work are addressed within the umbrella of institutional biosafety.

c. Working closely with the IBC, this section within the Department of Family Medicine is responsible for employee health screening, incident / exposure reporting, and health maintenance, including vaccinations and medical treatment.

## 9. 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. NMU has set up a system of institutional funds that are awarded to eligible groups, individual faculty and graduate students to enable them to pursue research in the priority areas identified by the University and also in any other field that is considered appropriate by the ORIC.

**9.1.2:**
Institutional Research Resources Allocation Committee (IRRAC) is the administrative body which evaluates proposals received for funding from the University for Research and other internal sources that may be allocated. Institutional Research Resources Allocation Committee (IRRAC) funds should be used as a springboard to help faculty get external funding and not used as a main source of funding. It is anticipated that such support would enable the investigators to compete effectively for external grants. This funding also fosters development of capacity for research.

### 9.1.3: Eligibility for ORIC Grant

a. Full-time faculty of the NMU across all affiliated institutes are eligible to apply for ORIC Institutional grants;

b. A PI can re-apply for ORIC grant funding provided 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 when applying for a new 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. Students can also apply for ORIC funding to off-set costs for research activity (e.g. data collection);

d. Involvement of faculty in projects as "investigator" or "co-investigators" should be clearly time-defined, in terms of percentage of time that each co-investigator will spend on the project;

e. ORIC will not fund any application to setup any registries or 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 geared towards obtaining external grants or innovation and commercialization projects;

ii. Approximately 70% of the total yearly ORIC research budget will be allocated for this category;

iii. PIs will have to explain in their applications how their research will help them in obtaining an external grant;

iv. PIs will also be required to suggest names of the funding agencies that they are planning to apply in future;

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

vi. Department head will provide letter of support that the work is important and aligned with departmental goals;

vii. In the support letter the department head will also provide assurance on efficient execution and timely delivery of grant outputs including progress and final reports;

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

b. **Research Support Programme (RSP):** Approximately 30% of the total yearly ORIC 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 personnel for specific needs related to research projects will be considered;

i. Applications may be made on the CBG Application Form. Such applications must be accompanied by a detailed description of the training, and its relationship to existing or future research projects;

ii. Development of research management skills among researchers by providing opportunities through direct exposure or allowing access to offshore training programme;

iii. Training of individuals with aptitude on research management by specifically designed programmes for this purpose;

iv. Development of research managers in the managerial dimension of research, including skills in such areas as risk analysis, priority setting, planning, budgeting, human relations, teambuilding, and developing incentives and rewards;

v. Development of capacity in individual units for the purpose of providing specific service or assistance in research;

vi. Proposals in this sub-category could include well-defined programmes to develop individuals who could meaningfully contribute in research planning covering all aspects (proposal development and execution) and monitoring and evaluation. Organizational development may require creation of new units within or outside NMU with sufficient ability to survive once the grant support is exhausted.

vii. Conference and workshop related expenses may also be supported 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;

viii. Capacity-building projects could be multidimensional and may involve training those who participate in all aspects of the research field

**ix.** 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 entity head of the University 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 will be empowered to sought services of external reviewers in case reviewers are not available in a particular research area at NMU;

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; ORIC will formulate its own TORs.

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

vi. Reviewers will 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 |
| e) Potential | 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 provide confidential comments for Institutional Research Resources Allocation Committee (IRRAC);

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

ix. The reviewers' reports will be shared with the IRRAC and members 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, knowledge of project subject;

xiii. Expedited Review maybe 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 date 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, including 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.

ii) Budget sheet

iii) Budget Justification, itemized

iv) Institutional checklist

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

vi) State the history of funded research and publication during the past 5 years.

vii) The PI, Co-PIs and collaborators must submit a short CV (1 page each) and a list of relevant publications (1 page). C

viii) Co-PIs and collaborators should include a signed letter stating willingness to co-operate and the extent of their involvement.

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

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

### 9.1.8: Project description, background and plan of research

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 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. For the budget justification page, itemize the budget request and justify each item clearly. Please provide an explanation if you have other internal 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 is provided for 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 or graduate students who are involved in approved research and registered at NMU 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. 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 University 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: W*ritten 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 preferably be developed with the assistance of relevant personnel in the Finance Office.

**9.1.11: Reporting guidelines:** These will include;

- Midterm reports
- Closeout report

- Budget report

## 10. Policy on Donor Research Funding

10.1.

Nishtar Medical University aims to seek more national and international collaboration on research including but not limited to capacity building, trainings, and consultancies. For purposes of integrity and consistency, it is important to ensure that donor research funding processes are streamlined, which conform to University policies and comply with all the legal and regulatory requirements. Ultimately the ORIC office with assistance from other departments of the University is required to safeguard the University interests and ensure that grant proposals have undergone institutional review, including where required, the reputation of the funding agency, before its final submission to the sponsor. It is intended that this policy will assist applicants in: preparing better proposals for donor grants; seeking required internal approvals before a research proposal is to be submitted to a funding agency. And NMU 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 University 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 University; Maintain a list of funding agencies relevant to the University and its regions of operation, and make available the same to researchers upon request and through the periodic circulation to the researchers at the University. 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.

### Eligibility To Apply For Funding

All full-time, faculty members and research staff are eligible to apply for research grants but it is important 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 Department/Entity 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 faculty, part-time faculty or a non-faculty 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 faculty, and in exceptional cases staff, are eligible to be Co-Investigators (Co-I). This is subject to approval from the Department/Entity Heads 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 NMU, 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 certifies 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 consultancies.

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

## Submission Of Checklist

The lead person will develop a proposal as per the requirements of the funding agency. He/she or a person authorized by him/her will then fill out the ORIC Checklist and after due approvals from all relevant departments, submit the same 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. To protect the PI and the University's reputation as well as 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 the applicant** regarding the grant proposal and checklist:

It is the responsibility of the lead person to submit the duly filled and 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 the funding agency should include recovery of all 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 University, 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 University 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/Chair (where applicable) must approve the relevant sections of the Checklist;

Human Resources (if personnel are to be hired or there are core personnel being utilised);

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 AKU campus).

In addition to the above approvals, the Checklist must be accompanied by the following 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 authorised 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. The process to be followed is mentioned in section 6.2.[3]

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 OSR.

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 ECACU regarding availability of capacity at AKU 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 usually 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 NMU. Furthermore, the budget and other requirements are checked to see if they concur to what was approved during the initial proposal submission stage. Difference if any are reviewed and if adequate approved. The authorised signatories from the ORIC and Finance subsequently sign the agreement/MoU/Sub-contracts/MTA/DTA and any other arrangements on behalf of the University.

After the agreement is signed by both the funding agency and the University, 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 IRB of the University.

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 NMU 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 university 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 University and Hospital's policies and process for monitoring and evaluating the quality, safety, and ethics of the research.

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16) La Trobe University: 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) A plan for research data management throughout the lifecycle of the research project (http://www.science.gc.ca/eic/site/063.nsf/eng/h_97610.html)

19) Data retention times are set to provide an adequate period to allow any questions about the data to be addressed (*e.g*., accuracy, reproducibility, originality, etc.) and to meet any requirements of the 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 (University of British Columbia, Canadian Institutes of Health Research) or 7 years (NMU, University of Alberta [for financial records]).

20) A *Best Practices for Health Research Involving Children and Adolescents* document developed to complement the

TCPS2, provides guidance (http://www.genomicsandpolicy.org/en/best-practices-2012).

21) Biobank policy is to be developed for NMU.

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

23) York University's Academic Implications of Disruptions or Cessations of University 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-university-business-due-to-labour-disputes-or-other-causes-senate-policy-on-the/

24) Policy on Research Ethics Review, ORGS/008-2018, March 29, 2018. NMU Research Policies https://www.NMU.edu/research/policies/Pages/home.aspx

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

26) Terms of Reference for Animal Facility Committee [of The Aga Khan University].

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