RAWALPINDI MEDICAL UNIVERSITY

Research Data Management & Protection Policy (Version 1.0)



Research Data Management & Protection Policy

Of

Rawalpindi Medical University

Approved by Institutional Research Ethics Forum RMU on 27.10.2018

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Policy Statement

Rawalpindi Medical University fully acquaints with the value and importance of protecting personal, medical and research related information. It is fully committed to encourage and endorse transparency and accountability by demonstrating compliance with principles set out in its regulations.

A robust Research Data Management Policy is mandatory for validation and establishment of of good research practice and procedures. It will not only ensure proper recording, maintenance, storage and security of research data and its appropriate access but also will make evident that intellectual property rights (IPR) are protected.

At present no comprehensive data protection legal framework exists at the national level or even at any university level¹. However, only a draft of "Personal Data Protection 2018" at national level available on line, at the website of Ministry of Information and technology that still needs to be tabled for its approval². The policy and regulations of the Rawalpindi Medical University even though are pertinent to research but still pledges in accord with it.

The Rawalpindi Medical University will adopt the following policy on Research Data Management. The policy outlines the requirements and responsibilities for the Institute and for researchers as recognized and implemented. The current version of the policy was approved at the monthly meeting of Institutional Research and Ethics Forum of Rawalpindi Medical University held on Saturday, 27th October, 2018. It will be reviewed annually and amendments will be approved by the Institutional Research and Ethics Forum of Rawalpindi Medical University.

- Stakeholder Report Universal Periodic Review 28th Session-Pakistan. "The Right to Privacy in the Islamic Republic of Pakistan". Privacy International. March 2017: Available at https://privacyinternational.org/sites/default/files/2017-11/UPR28 Pakistan.pdf
- 2. Personal Data protection Bill 2018. Draft. Ministry of Information and Technology Pakistan. Available at http://www.moitt.gov.pk/userfiles1/file/PERSONAL-DATA-PROTECTION-BILL-July-18-Draft.pdf

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Purpose:

The purpose of the policy is to:

- Ensure conformity to the ethical, funders and other legal requirements related to personal and medical information, research data and data management.
- Enable staff, faculty and researchers to effectively and securely manage all kind of data.
- Ascertain and demonstrate the veracity of research.
- Preserve eligible data for reuse.
- Ensure that faculty, staff and researchers of the Rawalpindi Medical University understand and fulfil their responsibilities in relation to governance of research data management.
- Ensure that the university's responsibilities for research data management are clearly expressed and enunciated.
- Create model research data management practices for all researchers at the Rawalpindi Medical University.
- Promote onus for research data management through the development of research data management plans.

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Definitions:

In this Policy, the terms have the following meanings, unless otherwise indicated:

- **1."Researcher"** means any person undertaking research or involved in collecting, generating or creating Research Data, for or on behalf of the university which shall include but not be limited to faculty, employees, workers, visiting researchers, external research collaborators, postgraduate trainees conducting research, undergraduate researchers, internees and the principal investigator.
- **2.** "Principal Investigator (PI)" refers to the Institute's employee primarily tasked with delivering a programme of research on behalf of the university, whether or not he/she is referred to as such in a research grant. If the research project is a collaborative project and the formal PI belongs to another institution, then the PI refers to the lead researcher at the Rawalpindi Medical University.
- **3.** "Research Data" refers to any information in digital, computer-readable format or paper-based that: is contained or presented in various ways including notes, facts, figures, tables, images (still and moving), audio or visual recordings; and
- 3-A. which is collected, generated or obtained during the course of or as a result of undertaking research (which includes interventional or experimental studies, trials, surveys, interviews, focus groups or analysis of data); and
- 3-B. which is subsequently used by the Researcher as a basis for making calculations or drawing inferences or conclusions to develop, support or revise theories, practices and findings.
- **4. "Repository"** means the repository or repositories which the Rawalpindi Medical University owns or controls and makes available to Researchers for the storage of Research Data.

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Policy scope:

This policy applies to all research data in digital, computer-readable format or paper-based form that is collected, during the course of or as a result of undertaking research at the Rawalpindi Medical University or on behalf of university. It will also be applicable to all personal, medical or socio-demographical data that will be collected during any research process.

This policy applies to all Researchers collecting, generating or creating Research Data, for or on behalf of the university and will include faculty, employees, workers, visiting researchers, external research collaborators, postgraduate trainees conducting research, undergraduate researchers, internees and the principal investigator.

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Data Protection Principles

Rawalpindi Medical University delineates following principles of Data Protection that must be reinforced and followed stringently, during data creation and collection by the researchers:

- 1. **FAIRNESS:** The research data will be collected and processed with a fair approach. The procedures involved in the collection of the data will not have an adverse effect on the individuals.
- 2. **TRANSPERANCY:** The researchers will be transparent about their purposes and regarding the procedures of data collection and its handling.
- 3. <u>LAWFULLNESS</u>: It will be ensured that there will be a legitimate ground for collecting and using the information and nothing unlawful will be ever attempted with the information gathered in the form of research data.
- 4. **PURPOSE LIMITATION:** The research data will be collected for specified and legitimate purposes and will not be further processed in a manner that is incompatible with those purposes.
- 5. **DATA MINIMISATION:** Only relevant and adequate information will be gathered pertinent to the specified purpose and objectives of the research. The data collected and processed will not be held or further used unless this is essential for reasons that were clearly stated in advance.
- 6. <u>ACCURACY:</u> It will be ensured that the data is accurate, consistent and unambiguous. Researchers will identify the right and accurate data sources and the necessity to update the information.
- 7. **STORAGE LIMITATION:** The researchers will keep the data only for the length of period specified and will not be retained longer than the period specified in the plan. At the completion of the study, when the data is no longer required, it will be ensured that data will be deleted securely.
- 8. <u>INTEGRITY:</u> Data will be processed in a manner that its consistency, accuracy, and trustworthiness prevail over its entire life cycle. Appropriate technical and organisational measures will be taken against unauthorised or unlawful processing, alteration, loss, damage or destruction of data.
- 9. **CONFIDENTIALITY:** Measures will be stringently taken to ensure confidentiality, to prevent sensitive information from leaking to unintended authorities.

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Data Management Policy:

- 1. All the research data created and collected by Researchers and PIs will be owned by the university (or funder) and remain with the university's repository, even if the researcher being employee, post graduate, Undergraduate, internee or faculty of university leaves the university. Unless it is a condition of a grant or agreement, exclusive rights to research data must not be assigned, licensed or transferred to external parties.
- 2. Data management plans must be prepared according to researcher's and funders' requirements. Legal, ethical and commercial constraints on the release of research data must be recognized and addressed appropriately as a documented plan, during the planning phase of the study and must be stringently followed through the whole period of research.
- In case of collaborative or funded research, all parties will agree on a plan and the procedures data management at the time of settlement of contract or agreement.
- 4. Appropriate resources (time and financial resources) for data management should be allocated in grant proposals, where possible.
- 5. Principal investigator (PI) will be primarily responsible for the management of data produced during the whole research process. If the researcher is a post graduate trainee, internee or undergraduate, then his/her supervisor in research will be responsible for the data management. In case of collaborative project, a lead will be identified at the Rawalpindi Medical University to take responsibility for management of data.
- 6. Every Researcher who will collect research data, or any personal, medical or socio demographic information during the research process must have formal Ethical approval from the Institutional Research and Ethics Forum of RMU. In

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case of visitor researchers or collaborative research projects, PI must ensure that they also have secured Ethical appraisal from their parent institutions.

- 7. No research data will be collected or generated without the assurance of Informed verbal or written consent of the study participants. The researchers must have clearly informed participants about how research data will be stored, preserved and used in the long-term, and how confidentiality will be maintained. Protection. Personal research data should be fully anonymous that ensures the confidentiality of the participant.
- 8. The data storage will be secured, safe and backed up regularly. It is stored in a manner that is compliant with legal obligations and the requirements of funding bodies and project-specific guidelines. Locking cabinets for participant records, use of password protected programmes, and limited access to personal information will be ensured. Confidentiality will be protected by identifying all subjects by ID numbers only with their names kept in a locked file cabinet. The data will be saved electronically, encrypted and password-protected on Institute's computers. Secured process (involving shared drives) will be adopted while transferring data to avoid any disclosure of information.
- 9. The research data must be retained in an appropriate format and storage facility for at least 3 years after the completion of the study at the Rawalpindi Medical University or more according to the duration specified in the protocol exceeds 3 years. The retention of this research data must also comply with any requirements specified by the collaborative partners or funder of the research.

 Data acquired in postgraduate or undergraduate or projects will be retained for at
 - least 1 year after the completion of the study at the Rawalpindi Medical University and the supervisor of that researcher will be responsible for its storage.
- 10. Any deletion of data must also comply with the protocols already identified by the researchers at the time of planning in concordance with the Pl's or collaborators or funders.

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- 11. The deliberate or reckless mismanagement of research data will constitute unacceptable research conduct and should be reported to Institutional Research and Ethics Forum of RMU.
- 12. Every researcher must ensure that the data collected will be accurate, authentic and reliable, identifiable and retrievable when needed or checked by Institutional Research and Ethics Forum of RMU.
- 13. All research data produced by researchers should be made openly available with as few restrictions as possible in a timely manner. Personal research data may be made available only if it is anonymous and there is informed consent for it to be shared. Sharing of research data will be restricted when the rights of individual researchers/and or subjects would be compromised or if the research has an Intellectual Property opportunity arising from it or if it includes secondary data that you may have had the right to use as part of your research, but do not have the right to share with others.
- 14. Research data will be managed to the highest standards throughout the research data lifecycle as part of the Rawalpindi Medical University commitment to research excellence.