بسم الله الرحمن الرحيم

Kingdom of Saudi Arabia
Ministry of National Guard
Health Affairs

المملكة العربية السعودية
وزارة الحرس الوطني
الشؤون الصحية

APP

MINISTRY OF NATIONAL GUARD - HEALTH AFFAIRS
ADMINISTRATIVE POLICY AND PROCEDURES

NUMBER	:	**1441-03**
TITLE	:	**DATA ACCESS AND OWNERSHIP FOR RESEARCH PURPOSES AT MNG-HA**
STEWARD DEPARTMENT	:	**KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH CENTER (419801)**
ORIGINAL DATE	:	**OCTOBER 2019**

1. PURPOSE

To provide the process governing data ownership, authorization and maintaining security for data used for research purposes within Ministry of National Guard-Health Affairs (MNG-HA) and all its affiliated facilities.

2. APPLICABILITY

To all personnel involved in research within MNG-HA and all its affiliated facilities.

3. RELATED REFERENCES

3.1 APP 1419-05: Research Proposal, Submission, Processing and Approval

3.2 APP 1426-02: Institutional Review of Researches by IRB

3.3 APP 1426-14: Human DNA Banking and Research

3.4 APP 1433-37: Conducting Research Studies

3.5 APP 1436-01: Research Authorship and Publication Conduct

3.6 APP 1436-04: Intellectual Property, Innovation and Technology Transfer Management

NA

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المملكة العربية السعودية

3.7 APP 1438-02:Access to and Use of Research Laboratory Core Services At King Abdullah International Medical Research Center (KAIMRC)

3.8 APP 1439-05 : Use of Animals for Research and Education Purposes

3.9 Joint Commission International Accreditation Standards for Hospitals, 6th Edition (2017) - MOI.6

4. DEFINITIONS

4.1 **Database** refers to a collected, organized data, texts, references or images in a standard format, stored in a computer system for multiple applications.

4.2 **Data collection** refers to the process of extracting data from subject, charts or clinical records by research professional or highly specialized personnel.

4.3 **Data ownership** refers to both the possession of and responsibility for data. Ownership implies power as well as control. The control of data includes not just the ability to access, create, modify, package, derive, benefit from, sell or remove data, but also the right to assign these access privileges to others.

4.4 **Extramurally Funded Research** refers to a research study sponsored or funded by the non-MNG-HA organization, establishments or governmental institution, external sponsor or individuals.

4.5 **International Conference on Harmonization/Good Clinical Practice (ICH/GCP)** refers to the international ethical and scientific quality standard for designing, conducting, recording and reporting research involving the participation of human subjects.

4.6 **Institutional Review Board (IRB)** refers to an independent body composed of medical, scientific and non-scientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in research studies.

4.7 **Institutional Animal Care and Use Committee** refers to the governing body that reviews and recommends the approval of research proposals involving the use of animals; reviews the guidelines, policy and procedure for the ethical handling and use of animals for experimental research, teaching/education or training, testing, forensic and breeding purposes, and act in accordance to the charges outlined in the committee formation order (CFO) number KAIMRC-05-14.

4.8 **Principal Investigator (PI)** refers to an individual or group of individuals, who prepares, develops and submits research proposals for review and are responsible for conducting the research study according to the research proposal process, ICH/GCP guidelines and other applicable regulatory authority requirements.

4.9 **Program** refers to the Ministry of National Guard– Health Affairs (MNG-HA) and all its affiliated facilities.

4.10 **Research Data Management** refers to a unit at King Abdullah International Medical Research Center (KAIMRC) that is responsible for providing data management services for research projects.

4.11 **Research Data** refers to clinical or biological data related to the research participant or patient data that intended to be used for research, either hard or soft format including but not limited to diagnosis, treatment, images, and socio-economic status, in addition to data created or generated during the course of performing research, whether funded by MNG-HA or external funding entities. It may include computer software, electronic systems, computer databases (developed by KAIMRC or by the funding entity), paper forms or transmitted form of source documents. It's also covers modified or unmodified biological specimen taken from human subjects or animal subjects stored at KAIMRC and MNG-HA laboratories or facilities, as well as researcher notes, statistics and findings on the research subject.

5. POLICY

5.1 King Abdullah International Medical Research Center (KAIMRC) owns any collected data at the Program meant to be used for research purposes including data that are collected at the departmental or individual level.

5.2 The Principal Investigator (PI) is the custodian of the research data collected and processed during the course of their research project.

5.2.1 The ownership and control of research data of extramurally funded projects must be in accordance with the duly signed contract between KAIMRC and the external sponsor.

5.2.1.1 The Program's interest must be protected in the contractual relationship with extramural research sponsor.

5.2.1.2 KAIMRC must ensure that the collected research data for extramurally funded research are treated confidentially and consistent with existing Program policies and procedures.

5.3 Collected research data must be offered confidential treatment at all times and must not be shared or transmitted from the Program premises for research purposes without a valid Institutional Review Board (IRB) approval.

5.4 For any IRB approved research project, there must be no hindrances or interference at departmental or individual level when a PI requests access to/collects data relevant to their research project.

5.5 KAIMRC has the right to take custody of research data from the PI in case of research misconduct, conflict of interest or when determine intellectual property rights according to APP1436-01.

5.6 When another research institution or entity has joint ownership rights of data ownership, such joint ownership must be agreed in writing prior to the creation of the data.

5.6.1 The cost and benefits of data sharing must be viewed in ethical, institutional, legal and professional dimensions.

5.7 The IRB must resolve any conflict regarding requests for research data and when necessary through the Authorship and Publication Conduct Committee.

5.8 The PI and KAIMRC must protect the confidentiality aspects of the research data.

5.9 Researchers must not disclose any research data or results to any party before publication without written permission from KAIMRC.

5.10 All collected data must remain the property of KAIMRC as stipulated in APP 1426-02.

5.10.1 All original documents/raw data must remain in Program premises or stored in Program computers and not on personal devices.

5.10.1.1 The investigators can use appropriate data summaries for subsequent analysis or have a masked version of the data that eliminates any identifiable data.

5.10.2 Clinical records, original laboratory reports and collected biological specimens remain the property of KAIMRC and must not be removed from the premises unless there is an IRB approved agreement between the PI and any collaborator stating otherwise. All such materials are retained and stored in the Program location where normally kept.

5.10.3 Any storage facility within the Program must be linked or supervised according to KAIMRC regulations.

5.10.4 Any storage of data that is meant for current or future research purposes must be according to APP 1419-05 and 1426-14 and must be at KAIMRC facilities or under KAIMRC supervision/custody.

5.11 Utilization of data for research purposes or publication must have an IRB approval.

5.12 KAIMRC must ensure that the PI accordingly submits and/or endorses all collected data upon separation from the Program.

5.13 The collected data related to the approved research project are protected for the PI for three (3) years from the study closure date to give the PI enough time to publish.

5.13.1 After three (3) years from the study closure, collected data are retained by KAIMRC and can be used by other PI(s) upon the IRB approval of a new protocol.

5.13.2 The PI can request for an extension of the three (3) years protection period for the research data subject to the approval of the IRB and Executive Director, KAIMRC.

5.14 Research data must not be released to non-MNG-HA researchers without contractual agreement approved by the Executive Director, KAIMRC.

5.15 Any unauthorized release of research data must be reported to the IRB and Research Authorship and Publication Conduct Committee for appropriate disciplinary action in accordance with APP 1436-01.

5.16 The PI must protect the integrity of the research data as well as its security. A backup system must be in place to ensure the data are not completely lost when storing systems failed.

5.17 Destruction of any research data for any reason must be done with the full knowledge and dual written approval of both the IRB and Executive Director, KAIMRC.

6. PROCEDURES

6.1 Researchers who are interested in obtaining research data from the Program's database for research purpose will submit a research proposal in accordance to APP 1419-05.

6.2 The IRB will review and approve the proposed research involving human subjects in accordance with the provisions of APP 1426-02.

6.3 The Institutional Animal Care and Use Committee (IACUC) will review and recommend the approval of research involving the use of animals. Final approval of the IRB will be in accordance with the provisions of APP 1439-05.

6.4 Upon receipt of the IRB approval, PI will prepare the required documentation for submission to the concerned data keeper at the Program to obtain the relevant research data as following:

6.4.1 Requested biological samples data will be in accordance to APP 1426-14 for samples are stored in the Biobank; or by coordinating with the leadership of the relevant department

6.4.2 Request for raw data will be granted according to APP 1426-02

6.4.3 Request for clinical data will be in accordance with the existing policies and procedures at Research Data Management unit at KAIMRC

6.4.4 Other research data meant for research purpose will be requested directly from the concerned data keeper at the relevant department.

6.5 When utilizing Research Laboratory Core Services at KAIMRC, all data and specimen ownership will be identified according to the contractual agreement with PI or the requester as stipulated at APP 1438-02.

6.6 The PI is responsible, along with the concerned data keeper, for ensuring that sound plans are in place to safeguard the identity of all study subjects as well as the confidentiality of the collected data.

6.7 During the research study, the PI will fulfill all requirements as stipulated in APP 1433-37 regarding record management, accountability, retention and documentation of communication.

6.8 Upon completion of the research study, the PI will ensure that all requirements for the management of records are accomplished and submitted in accordance with the relevant provisions of APP 1433-37.

6.9 After three (3) years from the research study closure date, the raw data can be requested by another PI from the concerned data keeper upon approval by IRB.

6.9.1 Concerned data keeper will inform requester on the availability of the requested data or the reason(s) for disapproval of the request.

6.9.2 For the requested research data that are protected for the original PI, concerned data keeper will inform the requester of the protection period.

6.10 The original PI will accordingly return the research data to the concerned data keeper after the end of the protection period, which is (3) years from the research study closure or at the end of the extended protection time.

7. RESPONSIBILITY

7.1 King Abdullah International Medical Research Center and all other related departments are responsible for the implementation of and adherence to the provisions of this APP.

7.2 Internal Audit will randomly monitor implementation of the provision within this APP.

8. APPROVALS

PREPARED BY:

21 OCT 2019

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29 OCT 2019

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