المجلس الصحي السعودي
Saudi Health Council
الأمانة العامة ١٥٧

Rules Governing Data Sharing Activity in Health Research

Saudi Health Council

Health Research and Studies Center

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Contents

Revision History

Prepared/Revised by	Type of Update	Date	Version
A Scientific Supervisory Committee, comprising representatives of various official health-related bodies embodied in the membership of the Saudi Health Council, in addition to the National Bioethics Committee, was set up for the purpose of formulating unified regulatory rules for the management, preservation, sharing and use of, and facilitating access to, health data and biological material for research purposes.			

Introduction

These rules draw on one of the objectives of the Saudi Health Council set forth in the Health Law (issued by Royal Decree No. M/11, dated 03/23/1423 AH, pursuant to item (3) of Article (11) of The Ministerial Cabinet Resolution No. (11), dated 14/01/1434AH), which entitles the Center for Health Research and Studies the right to propose professional and ethical guidelines for national health research, and to follow up on their implementation once they have been approved by the Saudi Health Council. The ultimate goal would be to enhance coordination and integration among various bodies of health authorities, thereby maximizing yield from available resources.

The Center for Health Research and Studies set out to prepare these rules as part of its mission to coordinate with other health authorities in establishing a system for health research and studies that is effective, sustainable, and helpful in outlining and implementing evidence-based national health strategies.

Hence, a scientific committee comprising the representatives of the various bodies of health authorities in the Saudi Health Council, the Food and Drug Authority, the Cooperative Health Insurance Council, the National Bioethics Committee, the National Center for Health Information, and the Health Research and Studies Center was formed to take on the task of

formulating these rules. This effort reflects one of the tasks assigned by Saudi Health Council to the Center for Health Research and Studies; namely to regulate the preservation and sharing of health data for research purposes.

المملكة العربية السعودية
Kingdom Of Saudi Arabia
المجلس الصحي السعودي
Saudi Health Council
إدارة تنسيق أعمال المجلس
Department of Council Coordination

Definitions

Article One:

The following terms – wherever mentioned in these rules – have the definitions individually juxtaposed, unless the context requires otherwise:

The Council	The Saudi Health Council
The Center	The Health Research and Studies Center at the General Secretariat of the Saudi Health Council
The Rules	Rules Governing Data Sharing Activity in Health Research
Data Sharing Agreement (DSA)	An agreement on data or information sharing that is concluded between the data applicant and the data controller, conclusively covering all aspects relevant to the researcher's obligation to share data after its processing has been completed.
Data management	All the administrative and technical procedures through which data is retrieved from databases while maintaining its integrity during collection and sharing.
Research/Study	A systematic experimental investigation (data collection and analysis) that aims to advance the biological sciences, or to enrich general knowledge, using living creatures or parts thereof.
National Committee of Bioethics (NCBE)	The National Committee of Bioethics mentioned in the Law of Ethics of Research on Living Things, issued by Royal Decree No. M/59 dated 09/14/1431 AH.

Data controller	The natural or legal person who determines, alone or in association with others, the purposes and means of data processing.
The source	The person (patient and/or healthy), who has given consent, for himself/herself or on behalf of others, to provide data or samples of biological material for research purposes.
Biological material	Material collected from living creatures without recorded objection from the source (where applicable) for the purpose of research. This includes, but is not limited to, cell strains, viruses, bacteria, expired bags of donated blood, or old umbilical cord blood (stored in blood banks). The term also includes any data that may be of use presently or in the future.
Health research data (RD)	Health research data previously collected by licensed researchers.
Data management and sharing plan (DMSP)	A plan that describes how to manage, archive, and share research data with interested professionals (such as researchers and government agencies).
Institutional Review Board (IRB)	The committee formed in the establishment to review and approve research in accordance with the Law of Ethics of Research on Living Things, issued by Royal Decree No. M/59 dated ١٤/٠٩/1431 AH.
Data processor	The natural or legal person who processes data on behalf of the data controller. The researcher can also be considered a data processor.
Data processing	Any operation, or set of operations, that is performed on data, or on data sets, such as: use of processing methods (like collection, registration, organization, installation, storage, conditioning, change, retrieval, consulting, use, or disclosure by transmission or publication), making accessible, merging, collecting, restricting, deleting, or destroying.
Data Protection Officer (DPO)	The person appointed by the data controller to provide advice on compliance with the rules and regulations in force and with the present rules.

Data sharing	Making research data and biological samples findable, accessible, interoperable, and reusable for research purposes.
Overseer of the sharing and protection of research data and biological materials	The legal person that operates as an independent supervisory body withing the establishment to perform the task of monitoring research data and biological material in full coordination with the National Committee of Bioethics.
Protection period	The period requested by the researcher to shield data from sharing for the purpose of making use of the protected data as outlined in his data management and sharing plan (DMSP) presented with the new research proposal.
New research proposal	The proposal submitted by the researcher to make use of data gathered in previous research or studies.
FAIR Enabling Principles	The four basic principles that must be followed by all establishments that collect data for health research purposes, namely, making data findable, accessible, interoperable, and reusable.

Goals and Scope of the Rules

Article Two:

These rules aim to provide an official framework to regulate the exchange of health research data and biological materials through coordination and integration between authorities concerned with health research in order to achieve the following:

A. Promote health research in the Kingdom of Saudi Arabia.

B. Regulate the use of health research data.

C. Ensure the transmission of health research data between researchers and the concerned authorities.

Article Three:

These rules apply to those dealing with health research data, such as: the overseer of the sharing and protection of research data and biological materials, the data processor, the data controller, and the data protection officer.

Governance

Article Four:

A permanent committee shall be formed under the umbrella of the SHC carrying the name "The National Committee for Monitoring the Sharing and Preservation of Research Data and Biological Materials", to be assigned with the following responsibilities:

A. Coordinating with bodies concerned with health research in regulating the sharing and preservation of research data and biological materials and following up on their implementation.
B. Approving the implementation mechanisms for the rules.
C. Appointing an overseer for the sharing of research data and biological materials and enabling him/her to perform their duties as specified in Article Five herein.
D. Coordinating with bodies concerned with health research to approve the nomination of a person responsible for controlling research data and biological materials and linking him/her with the overseer of data sharing.
E. Spreading awareness among researchers in sharing research data and biological materials.
F. Providing consultations to help in the implementation of these rules.

G. Submitting semi-annual reports on the results of the committee's work to the SHC.

Article Five:

The overseer of sharing and protecting research data and biological materials shall coordinate with the Research Ethics Monitoring Office of the National Committee of Bioethics on the following:

1. Monitoring the implementation of the responsibilities of the data controller, the data protection officer (DPO), and the data processor as outlined in these rules.
2. Organizing the sharing and preservation of research data and biological materials and coordinating with local committees to verify the following:
   A. Ensuring that all health research funded or supported by government agencies includes a data management and sharing plan (DMSP) that is in line with the policies of the entity that is conducting the research. The following requirements must be considered:
   - The plan should outline how the Four FAIR Principles (Findable, Accessible, Interoperable, Reusable) are to be implemented.
   - The plan should account for any potential conflict of interest.

- The plan should include mechanisms to protect research data or biological materials from leakage or exchange with any party not specified in the plan.
- The plan should point to any obstacles that may arise during the sharing of data and provide explanations for them (e.g., implementing restrictions or limitations on data sharing).

Article Six: Responsibilities of the Data Controller:

1. Taking the necessary measures to protect data in accordance with ethical and regulatory standards and in line with the Law of Ethics of Research on Living Things and the applicable laws and guidelines.
2. Ensuring that all data held by the controller, which were collected for previous research, consider the four FAIR principles as defined in the context of these rules, namely:

a) Principle 1: Rendering data findable:

All research databases and biological materials available to the data controller must be disclosed and announced in a clear and transparent manner to those interested in research. The announcement will include a list of research

projects with a list of data collected for each project including the keys to graphic variables in order to allow for ease of access to and use of all or part of the data.

b) Principle 2: Rendering data accessible:

The data controller should declare specific and clear conditions for access to research data and biological samples that guarantee integrity, fairness, and transparency. These conditions should include requests for approval by local committees (IRBs/IECs) and contract terms under which the data will be transferred.

c) Principle 3: Rendering data interoperable:

The stored data must be ready for integration – when needed – with other data sets, whether the integration is carried out by the researcher or by statistical software (algorithms).

d) Principle 4: Rendering data reusable:

Data keys should be well defined to allow researchers to plan to duplicate and/or merge them to fit the needs of the new research proposal.

3. Ensuring that approved standards are met for processing data and biological materials.
4. Obliging researchers not to share research data and/or biological materials without the explicit and valid approval of the local committees. Such approval includes reviewing and accepting the data management and sharing plan (DMSP) in accordance with the four principles mentioned in these rules.

5. Taking all necessary measures to subject all research data and biological materials to fair use. The data controller has the right to request financial compensation for the use of the data in accordance with the rules to be laid down by the National Committee for Monitoring the Sharing and Preservation of Research Data and Biological Materials.
6. Studying requests from the data processor to extend the protection period, provided that the required extension does not exceed the protection period which was approved in the new research proposal.
7. Ensuring that the data is encrypted to protect the identities of the source. This should include names or any other identifiers that may compromise their identities.
8. Ensuring that policies and procedures are in place to prevent leakage of data that may identify the source in any form. Any such leaks should be reported within a specified period.
9. If the data processor or the new researcher requests unencrypted data, the objectivity of the request must be verified, i.e., that the new research can only be conducted through the unencrypted data, and that the encrypted data alone is not sufficient.
10. Identifying the person responsible for data protection in the facility. This includes:

    A. Ensuring the clarity of the responsibilities that fall upon the person responsible for data protection in the facility and upon the data processor.

B. Assuring independent lines of communication between the person responsible for data protection and the overseer of sharing and protecting research data and biological materials.

11. Communicating any obstacles that may arise from the application of these rules to the National Committee for Monitoring the Sharing and Preservation of Research Data and Biological Materials, or to the National Committee of Bioethics – as the case may be.

Article Seven: Responsibilities of the Data Protection Officer (DPO):

A. Ensuring that the research data and biological materials kept by the data controller are accurate and up to date.
B. Reviewing all data processing methods annually to ensure that the data and/or biological materials being processed remain in compliance with these rules and the Data Management and Sharing Plan (DMSP).
C. Ensuring that internal and external audit processes are carried out according to an agreed upon policy that guarantees compliance with these rules.
D. Evaluating the risks of leakage or mishandling by the data processor (such as failure to comply with what was agreed upon in the new research proposal) by reviewing the data processing records annually.
E. Evaluating the likelihood of any other risks associated with specific types of research data, such as genetic, criminal, or psychological data, among others. Such types of data need to be handled with specific care since they may lead to personal, family, tribal, or community stigmatization.
F. Reviewing and updating research data and biological materials that the data controller handles, when necessary, and ensuring that the data is accurately described, facilitating benefit for future use.
G. Communicating any data breaches or leaks to both the data controller and the overseer of sharing research data and biological materials.

Article Eight: Responsibilities of the Data Processor:

A. Disclosure of any actual or potential conflicts of interest regarding the uses of research data and biological materials.
B. Limiting work with biological data and materials to the scope of the approved research project whose purpose is clarified in the Data Management and Sharing Plan (DMSP) and the agreements approved in the new research proposal.
C. Ensuring that the data-sharing plan is activated in the new research proposal and that the processed data resulting from that proposal is delivered to the data controller to make it available (in accordance with the four enabling principles) after expiration of the protection period that was approved in the new proposal.
D. Refraining from dealing with a third party unless there is a prior explicit mention of it in the approved new research proposal.
E. Refraining from making any changes to the previously approved data processing plan. In the event that a change is needed, the data processor must ensure that that the proposed change is approved by the local ethics committee and by the data controller.
F. Taking the necessary measures to protect data from database breaches, or any other potential risks to individuals or groups.
G. Ensuring that the data obtained is sufficient and relevant to the purpose for which it is being processed.

General Provisions

Article Nine:

Subject to the provisions of the Law of Ethics of Research on Living Things, all health-related research must adhere to these rules.

Article Ten:

These rules are to be enforced once approved by the Saudi Health Council. The Centre has the responsibility of disseminating the entirety thereof to all pertinent parties.

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