

## **Armauer Hansen Research Institute (AHRI)**

## DATA ACCESS AND SHARING POLICY (DASP)

February 2021



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#### **Preface**

Since the founding of the Armauer Hansen Research Institute (AHRI), the Institute has been engaged in the collection, organization, analysis, compilation, and dissemination of biological data in recognizing the important role of scientific research in transforming medical care and advancing the public health. AHRI strongly supports the view that publicly funded research data are a public good that should be made available with as few restrictions as possible. Greater data sharing could enhance public well-being by maximizing the utilization of gained knowledge, reducing redundant research, and facilitating scientific innovation. Nonetheless, the approach to scientific data access and sharing must be responsible and must recognize legal, regulatory, ethical, and commercial requirements.

For this reason, the Institute formulated a policy to allow appropriate and responsible accessing and sharing of the Institute's research data for scientific research. The policy provides a clear professional direction on the breadth and depth of protecting data, as a national resource and treasure. It also helps all professionals to carry out their duties and responsibilities effectively without compromising ethical values and the public interest of the Ethiopian people.

In the past years, due to the lack of an integrated knowledge management system and appropriate regulations in the Country, the research institute has not been fully exercising it's right of data ownership and capacity to determine the destination of data generated for research. As a result, this policy document will be used to guide collaborations and partnerships in a proper manner that can protect the Institute's and research participant's data.

In general, the policy is a governing document that can be used for all stakeholders, with a detailed implementation manual for data access and sharing.

#### **Section One-Introduction**

#### 1.1. Background about AHRI

Armauer Hansen Research Institute (AHRI) was established in 1970 with the support of Save the Children Organizations of Norway and Sweden in collaboration with the Ethiopian government, to contribute to a better understanding of the pathogenesis and human immune response to leprosy, caused by the bacillus, *Mycobacterium leprae*. A major focus was directed towards improving the diagnostic capacities for leprosy and gaining new knowledge required for the eventual development of a leprosy vaccine.

Upon the emerging demand of the country, the research agenda of AHRI has expanded over the years to include TB, Leishmania, Malaria, HIV/AIDS, Non-communicable diseases, Bioinformatics and Biotechnology, and others. AHRI is also engaged in capacity building activities in the area of clinical research since 2001. As part of capacity building, AHRI has been involved in different short term and long term (MSc and Ph.D.) trainings in collaboration with different National and International Universities and Institutes.

As a result of the expansion of work, several partnerships and collaborations with both national and international organizations became inevitable. These collaborations and partnerships became an immense platform to enforce the institute to give access to data and share scientific findings with partners. However, the absence of an integrated knowledge management system and suitable legislation on data access and sharing, AHRI became unable to fully exercise its right of data ownership and capacity to regulate the fate of the data generated by the Institute. Consequently, developing data access and sharing policy document that can guide stakeholders, during the formation of collaborations and partnerships, in a manner that can benefit the Institute and research participants, became essential.

## 1.2. Purpose and Scope of data access and sharing policy

AHRI considers research data to be a valuable asset that forms the basis for rigorous scientific inquiry, generating evidence through research conduct and a platform to enable new and innovative research in public health. The Institute's primary principle in developing data access and sharing policy is that data are a public good and sharing data is both ethical and beneficial. The definitive goal is to encourage the extensive use of the Institute's data by the scientific community and ultimately make a more meaningful contribution towards promoting societal wellbeing. Nevertheless, we remain mindful of the challenges and complexities of data sharing and will continue to make efforts to create a well-functioning research and innovation infrastructure, supported by Institutes that are committed to protecting the interests of key stakeholders that are integral to a sustainable data sharing environment. To protect the intellectual investment made into its creation, it is important to validate the data is handled in compliance with ethical, contractual and, legal standards. It is indispensable to ensure stakeholders that research data is managed per good research practice.

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The development of this data access and sharing policy is aiming to ensure that AHRI is using high standards in terms of data access, privacy, data sharing, and re-use and ultimately ensures equitable partnership. The application of this policy document envisages all studies conducted by the Institute throughout the world and applies to all AHRI staff researchers, students, partner Institutes, Universities, and national and international collaborators.

## 1.3. Key Stakeholders of the data access and sharing policy

Key stakeholders of AHRI are:

- Ethiopian Federal Ministry of Health
- SIDA, NORAD and other development partners and collaborators
- Local and International Universities
- Ethiopian Public Health Institute
- Research Participants
- Other internal and external communities (staff, directorates and local communities)

# Section Two: Pillars and Values of Data access and sharing Policy

## 2.1. Pillars of data access and sharing policy

The content selection, processing and decision-making process of data access and sharing are based on the following key pillars:

- 1. The 1995 Constitution of the Federal Democratic Republic of Ethiopia,
- 2. The 2005 Criminal Code of the Federal Democratic Republic of Ethiopia,
- 3. The 1960 Ethiopian Civil Code,
- 4. Proclamation No. 958/2016 The Computer Crime,
- 5. Proclamation No. 590/2008The Freedom of the Mass Media and Access to Information,
- 6. Proclamation No. 482/2006 Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation,
- 7. Proclamation No. 123/1995 Concerning Inventions, Minor Inventions and Industrial Designs and,
- 8. Proclamation No. 410/2004 Copyright and Neighboring Rights Protection.
- 9. International Committee of Medical Journal Editors (ICMJE) Recommendation.

## 2.2. Values of data access and sharing policy

To carryout data access and sharing efficiently and effectively, the research institute is equipped with the following professional values:

1. Sense of ownership- AHRI's professionals have the responsibility to administer the data he or she is responsible for, with the sense of ownership. It is also their responsibility to underline the source of data is the Ethiopian people and must

- be valued as a national treasure. Therefore, researchers must ensure an equitable partnership with collaborators and funding agents.
- 2. Collaboration- Researchers (data holders) are expected to work collaboratively with other stakeholders and users to contribute to the well-being of the participants and public health.
- 3. Transparency and accountability- Relationships with all stakeholders must be based on transparency and accountability.
- 4. Equality- This policy must serve all the people of the country equally. Discrimination based on age, gender, religion and, political views of research participants is not allowed.
- 5. Respect- The Institute upholds high value for human beings and their dignity.
- 6. Accuracy- The data generated in researches are free from fraud, mischief and, manipulation.
- 7. Professionalism and ethical conduct- all stakeholders must show at most professionalism and adhere to ethical principles.

## Section Three: Data access and sharing principles

## 3.1. General Principles

The following are the main principles all parties must observe while conveying access or sharing research data.

#### 1. Prioritizing Public Interest

The research institute will put the public interest ahead of all its work and will continue to provide the public with a view to scientific information that will help develop the capacity of the health care system. It must be ensured that the content of data conveys is factual, credible, evidence-based, and benefits the public. The content of data shared or accessed will be evaluated in terms of national and public interest and morals. The Institute will have a pre-disclosure system through the 'offer and acceptance phase" of contract formation so that it can identify contents that are appropriate for the public and future generation.

#### 2. Avoiding conflict of interest

Experts and collaborators should not be tempted to undermine the reputation, independence, and neutrality of the Institute and the public, while sharing and allowing access to the Instituteal data. The Institute should not compromise the dignity and privacy of research participants for the sake of financial benefits.

#### 3. Children, youth and vulnerable population protection

The institute should evade from sharing data that may affect the privacy and mental, emotional, physiological, and moral development of infants, toddlers, youth, vulnerable population.

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#### 4. Intellectual property

The institute must report any intellectual property information in a way that does not infringe on the rights of the owner. The institute must verify by the concerned body that data that appear in print are not copied or removed from the text of another entity.

## Section Four: Data access and sharing Policy

## 4.1. Data categories

This policy refers to the different data categories that are collected as part of research conduct:

- 1. Observational Data- are captured through observation of a behavior or activity. It is collected using methods such as human observation, open-ended surveys, or the use of an instrument or sensor to monitor and record information.
- 2. Experimental Data- are collected through active intervention by the researcher to produce and measure change or to create difference when a variable is altered. Experimental data allows the researcher to determine a causal relationship and is projectable to a larger population.
- 3. Simulation Data- are generated by imitating the operation of a real-world process or system over time using computer test models. This method is used to try to determine what would, or could, happen under certain conditions. The test model used is often as, or even more, important than the data generated from the simulation.
- 4. Derived / Compiled Data- involves using existing data points, often from different data sources, to create new data through some sort of transformation, such as an arithmetic formula or aggregation.
- 5. Diagnostic data- are data generated from the lab diagnostics.
- 6. Genetic data-are data that relates to inherited or acquired characteristics of a natural person which results from the analysis of biological sample particularly chromosomal, DNA or RNA analysis. This could be from human or pathogen (whole-genome or exome sequence data or genotyping data from arrays, as well as from first and next-generation technologies and approaches).

## 4.2. Data Repository and Access Committee (DRAC)

The request for data access and sharing by third parties will be reviewed by the members of the research and innovation directors.

#### 4.2.1. Members of the DRAC

1. The Members of DRAC contains directors from each research and innovation directorate wing and other members who are considered relevant for the task narrated under this clause. The purpose of the DRAC(DRAC) is to review requests and approve for data access for privacy, security, and confidentiality concerns post research approval by ethics committee. They shall also be responsible for the execution, monitoring, evaluation and follow-up of this data access and sharing policy.

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2. To be reviewed at an upcoming meeting of the Data and Repesitory Approval Committee, data access requests to AHRI data base/server or access and privilege request by AHRI's PIs to partner's servers must be submitted at least two (2) weeks in advance of the meeting.

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3. The DRAC are also responsible to decide and regularly monitor the time duration for data retention and destruction.

#### 4.2.2. The responsibilities of the DRAC

The responsibilities of the DRAC are to:

- 1. Ensure the data requests are appropriate and specific to the research objectives and methodology.
- 2. Protect the confidentiality of personal health information of research participants in the custody of AHRI and the privacy of the individual who is the subject of that information.
- 3. Ensure that conditions of data and access are according to the AHRI's agreement with collaborators.
- 4. Uphold standards of data access consistent with the highest levels of security, confidentiality and privacy in Ethiopian legislation, namely:
  - a. To maximize the protection of individual privacy;
  - b. To approve access to linked data files only to nominated researchers involved in specific, approved research projects;
  - c. To approve access by researchers to minimum datasets required for their specific project;
  - d. To provide data to support approved quality review initiatives
  - e. To assure PIs that those data which are their responsibility will be used appropriately and confidentiality and security obligations will be met.
- 5. Ensure that any proposed record linkage is not harmful to individuals or providers and the benefits derived from the record linkage are clearly in the public interest.

## 4.3. Data Access Policy

This policy is concerned with request of data access to internal data that is not publicly available and those data that will be available upon request.

#### 4.3.1. Status of Data and the procedure to access such data

Approaches towards allowing access to AHRI's data depends on the status of data at the time of the request to access.

1. Access to publicly available data (open access to official data)- Open access data (Public use) – is data stored on AHRI's server and other publicly availed server for download, shared to international open databases or made available to everyone with no charge. Wide and easy access to official data is a standing priority of AHRI, as well as the commitment to quality improvement of the service provided. Access to data will be provided using the internet and other



communication technology in order to meet user needs and permit easy access. Recognizing the important needs of users and the importance of timely data, AHRI shall release datasets for public access or share it with the public. Data may be released in phases to ensure that the data have been reviewed and analyzed by the AHRI's researchers to answer research questions and publish findings, before release. The initial release will provide data based on the basic report and subsequent release will be a detailed analysis of specific indicators.

#### Terms and Conditions Governing Use and access to Public Data

- a. Data shall be used for statistical and or evidence generation purposes only and not for investigation of specific individuals or organizations or any other purpose. This is especially related with Meta Data.
- b. No attempt shall be made to produce links among datasets provided by AHRI, or among data from the AHRI and other datasets to identify individuals or organizations.
- c. Any books, articles, conference papers, theses, dissertations, reports, or other publications that employ data obtained from the AHRI's publicly available data should cite the source of data.
- d. Request should be reissued for usage of data that was approved for specific research and a need comes to use it for other in later period.
- 2. **Data avail upon request-** These data are not publicly available but decided by the institute to be available to the requester of the data upon formal request application and review and approval by the DRAC.

## Terms and Conditions Governing use and access to data that will be avail upon request

- a. Access and usage of data avail upon request will be dependent on the validity of the request application and the approval of the DRAC.
- b. Data shall be used for statistical and or evidence generation purposes only and not for investigation of specific individuals or organizations or any other purpose.
- c. No attempt shall be made to produce links among datasets provided by AHRI, or among data from the AHRI and other datasets to identify individuals or organizations.
- d. Any books, articles, conference papers, theses, dissertations, reports, or other publications that employ data obtained from the AHRI's publicly available data should cite the source of data.
- e. Request should be reissued for usage of data that was approved for specific research and a need comes to use it for other in later period.
- 3. **Registered access (Licensed) data related with Intellectual Property** data will be availed to collaborators as per agreement between the collaborators and

AHRI. A collaborator is any party who contributes to the research directly either materially, financially, mentorship and supervision towards a data production process. This includes archived data but does not include personally identified data of research participants.

#### 4.3.2. Obligation of parties

#### **AHRI Obligations**

The obligation of AHRI shall include the following:

- 1. The DRAC shall coordinate the overall distribution of data to external agencies through the use of either data sharing agreements or other dissemination modes.
- 2. AHRI shall release data or grant access to data when it is satisfied that all reasonable steps have been taken into account to safeguard confidential issues. The DRAC should monitor and evaluate such correspondences.
- 3. AHRI shall classify data by their level of sensitivity and risk, taking into account the country's legal framework on freedom of information and data protection, contractual agreements, ethical considerations.

#### **User Obligations**

User obligation shall include the following:

- 1. Any individual or entity may submit a request for data as collected and archived in the AHRI database. Other than for published data, researchers shall disclose the nature and objective of their intended use.
- 2. Any data access preference for organizations that do facilitate specific AHRI data collection by contributing funds, agents, and/or equipment shall be clearly defined and documented. Such arrangements shall receive prior approval by the DRAC.
- 3. Users of AHRI data shall utilize it in a manner consistent with AHRI requirements for security and confidentiality.
- 4. Users shall comply with all requirements as provided by AHRI from time to time.

#### 4.3.3. Access to the network and machines

1. AHRI acknowledges that users may have access to the servers, computers, communications systems, networks, for the purposes outlined in the Data Access Agreement. Notwithstanding, if any data is made available or accessible to a user, its employees, agents or contractors, about AHRI's data, business or financial affairs, or to AHRI's projects, transactions, clients or customers, users shall not store, copy, analyze, monitor or otherwise use that data except for the purposes set forth in the Agreement.

2. Users shall only have access to AHRI's servers, computers, communications systems, network for the specified period of time, according to the institute preserving policy.

- 3. Users should keep all information, credential within AHRI. Any information accessed by users in the due process of executing the Data Access Agreement or other subsequent agreements between the parties shall be confidential and user shall not pass the given access to any third party for technical support or any other purpose.
- 4. Users shall not access or use AHRI data for any purposes what so ever except for the purposes specifically mentioned in the case by case Data Access Agreement. Notwithstanding, access and property right on data generated through future collaborative projects between AHRI and users shall be defined and agreed upon separate project agreements.

#### 4.3.4. Logs

Technical supporters should make all Logs available and traceable to AHRI for the management of user activities as there will be multiple users on the system such as PIs, employees, students, partners and so on, of AHRI. Technical supporters shall help in maintaining logs within the system they have or other recommended tools.

#### 4.3.5. Data Breach

- 1. AHRI further will monitor and test its data safeguards from time to time, and further adjust its data safeguards from time to time in light of relevant circumstances or the results of any relevant testing or monitoring. If AHRI suspects or becomes aware of any unauthorized access to any data by any unauthorized person or a third party, or becomes aware of any other security breach relating to data held or stored by AHRI in connection with the performance of the professional services or other services, AHRI shall immediately notify the party with the unauthorized access, in writing and shall take all necessary measures to prevent or stop such Data Breach.
- 2. In the event of such Data Breach, AHRI shall fully and immediately comply with applicable laws, and shall take the appropriate legal steps to remedy such Data Breach.

#### 4.3.6. Cost Sharing

While AHRI encourages broad use of its data by all stakeholders, it is important to point out that the production of statistical data and information is costly. AHRI is a non-profit organization and provides data at no cost.

#### 4.3.7. Copyright and Citation Requirements

The data users shall acknowledge that any available intellectual property rights, including copyright in the data are owned by the AHRI. The data user is encouraged to provide AHRI with a copy of such a report, paper or article.

#### 4.4. Data access to external storage

As a result of various collaborations and negotiated contracts AHRI can store it's data at collaborator's/partners data storage system/server or at a number of storage



providers. However, the use and access to such storage system of cloud storage solutions must follow the following rules.

- 1. AHRI should maintain the ownership of the data at all times
- 2. Access to such data shall not bar AHRI from accessing the data at any time. Limitation to the period of time towards access shall not be set by any party.
- 3. Logs to AHRI's PIs, researchers, staffs and students must be available at all times.

## 4.5. Data sharing policy

#### 4.5.1. Approach to data sharing

- 1. For each research project conducted by the Institute where a proposal involves the generation of datasets with clear scope for wider research use with external parties, it is the Institute's requirement that Investigators have in place a data sharing plan. This requirement applies to all proposals where the primary goal is to create a database resource. It also includes other research generating significant datasets that could be shared for added value for example, those where the data has clear utility for research questions beyond those that the data generators are seeking to address. This include data stored and archived.
- 2. Data sharing plan would be conceived by investigators in the planning stage. However, the Institute requires that each investigator must have such a plan in place once the project becomes active. For majority of the Institute's proposals, a project becomes active once it secured funding for its proposed activities. Although the Institute researchers can structure their data sharing plan in a manner most appropriate to their research, they are asked to answer the following questions in considering their approach to data sharing:
- a. What data outputs will your research generate and what data will have value to other researchers?
- b. Where will you make the data available?
- c. What documentation will you provide to describe your data?
- d. How will other researchers outside the study be able to access the data?
- e. Are any limits to data sharing required for example, to either safeguard research participants or to gain appropriate intellectual property protection?
- f. How will you ensure that key datasets are preserved to ensure their long-term value?
- g. What resources will you require to deliver your plan?

#### 4.5.2. Data Sharing Processes

- 1. In the first instance, potential requesters are strongly encouraged to approach the relevant study investigators informally to discuss feasibility of data sharing. Study investigators can refer such requests to the Data and Repository Approval Committee.
- 2. A formal outline of the proposed study is to be submitted to the DRAC for consideration by the relevant stakeholders of the project. The Proposal (max 3 pages) must include a clear statement of the background to the proposed data

use, the objectives and details of the methodology proposed, and relevant references. In the outline, Requesters must demonstrate through their peer review publications in the area of interest their ability to carry out the proposed study.

- 3. The PI will decide whether or not to approve the proposal and allow access to the relevant data. Any approval by PI is subject to review by the DRAC as part of their monitoring of data sharing requests.
- 4. Ethics Committee approval from the requester's ethics committee is the requester's responsibility. The Requester may also need to obtain approval from the Research Ethics Committee responsible for the existing Institute study.
- 5. Where demand exceeds the availability of staffing resources to make the data available, access will be prioritized by the DRAC on scientific merit.
- 6. Requesters will be required to cover the costs of administering the data sharing expenses (including legal fees if applicable), retrieving, processing and sending the data. The estimated costs for a particular request will be provided after initial review of the application.
- 7. Access to data in the Collection will only be permitted by application and only under a Data Sharing Agreement.

#### 4.6. Data retention and destruction

Data stored by AHRI will be retained in accordance with the Institutional guidelines for the retention and destruction of research data and any additional contractual or legal requirements.

#### Section Five: General Conditions

#### 5.1. Dissemination of research results and transparency

- 1. The Institute reserves the right to publish the title, the names(s) and affiliations(s) of the PI(s), a lay summary and a scientific abstract of each piece of collaborative research for which access to the data in a Collection has been granted, before identification or publication of results. Requesters who do not wish details of their study to be openly available should state this in their Proposal and give reasons.
- 2. The Institute staff will usually have significant insight into shared data and would usually be able to add value to publications utilizing the data in a Collection. It would be expected that an Institute representative of the original study would be involved as a collaborator on studies resulting from the shared data and be offered co-authorship on resulting publications or presentations. It may be appropriate to acknowledge members of the original study staff who have contributed directly to the original study so that they may claim authorship as members of the study team.
- 3. The Institute's policy and processes on data sharing will be reviewed periodically, and at least every twelve months to keep abreast of the rapidly developing ideas around data sharing globally.

#### 5.2. Data Ownership

- 1. The Ownership to the data shall belong to the AHRI, if it created, invented or generated the data. Both AHRI and collaborators shall have a royalty-free non-exclusive user right to the Project Results.
- 2. Both AHRI and collaborators should retain the data in a secure storage system/infrastructure at such standard as would be reasonably expected for the storage of valuable and proprietary for sensitive/confidential data. The Parties shall refrain from tracing or identifying the identity of any donors who provided the data. The Parties should preserve, at all times, the confidentiality of information pertaining to identifiable donors. The Parties should not give access to data, in whole or part, or any identifiable data derived from the data, to any third party. The Recipient shall limit access to and processing of the data to those employees or other authorized representatives of Parties who:
  - a. need to process such data to conduct their work in connection with the data and the Protocol and
  - b. have signed agreements with the Recipient obligating them to maintain the confidentiality of the data and any information to be derived thereof or disclosed to them.
- 3. The data created or generated jointly by the Parties shall belong jointly to the parties. Where no joint ownership agreement has yet been concluded, each of the joint owners shall be entitled to use the joint Project Results for internal research and teaching purposes on a non-exclusive, non-transferable basis.
- 4. Unless otherwise agreed, the joint owners may only use the jointly owned Project Results for commercial purposes or grant licenses to third parties under the following conditions:
  - a. the other joint owner must give its prior written consent, which shall not be unreasonably withheld; and
  - b. fair and reasonable compensation must be provided to the other joint owner(s), to be negotiated in good faith.
- 5. If the Parties want to secure Intellectual property rights, the Parties shall agree on the specifics in good faith.
- 6. The specifics concerning securing Intellectual property rights, the commercial purpose and the compensation shall be regulated in a separate inter-Institutional agreement.

#### 5.3. Ethics

1. Every data access and sharing procedure and agreement must abide to National Research Ethics Regulations, Policies and Guidelines.

2. Each and every data access and sharing should apply the standards surrounding the protection of personal data of a research participant including subject names, initials, addresses, and genetic information.

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- 3. The confidentiality of records that could identify research participants should be protected, respecting the privacy and confidentiality rules under applicable regulatory requirements.
- 4. AHRI researchers and their project associates and agents should; aim to maximize benefit and minimize harm; respect the privacy, autonomy, diversity, values, and dignity of individuals, groups and communities; act with integrity throughout, employing the most appropriate methods for the research purpose and have regard to their social and professional responsibilities in conducting and disseminating their research.
- 5. Regarding data access and sharing, researchers have the following ethical obligations towards research participants
  - a. Notice- research participants must be informed of how their data will be collected and used.
  - b. Choice- research participants must be able to opt-out of the collection of their data and its transfer to third parties.
  - c. Data transfers-Any transfers of data to third parties must only be to other organizations that have rigorous data-protection policies and with consent by the research participant.
  - d. Security-All reasonable efforts must be made to prevent the loss of any data collected.
  - e. Data integrity-Data must be reliable and relevant to the purpose for which it was collected.
  - f. Access-Subjects must be able to access information about them that is collected and have an opportunity to have this data corrected or deleted if necessary.
  - g. Enforcement-A mechanism must be in place to effectively and consistently enforce these rules.

## 5.4. Intellectual Property (IP)

The institute seeks to protect and maximize the value of IP generated by its researchers, to the benefit of both researchers and the institute. In general, the following three principles apply:

- 1. Where no external contract exists, the institute has ownership of primary data generated in the course of research undertaken by researchers in its employment;
- 2. The institute does not automatically own student/researcher IP, although in some circumstance's students/researcher may be required to assign IP to the institute, for example, where research is carried out under third-party contract or where the data are produced with the significant involvement of institute employees;

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#### 5.5. Publication

- 1. All Parties should secure openness regarding publishing a Research Project. All data from the study shall be sought published, regardless of whether they are favorable or unfavorable to a research hypothesis or theory.
- 2. Unless stated otherwise, the parties have the right to publish results from data collected within their Institute unless such a publication will disclose confidential information, trade secrets or in other ways weaken the potential presence of the study significantly compared to publication of the results in a broader context. Each Party shall notify the other about planned publications from research utilizing the Material and/or Data, and the other Party shall be allowed to suggest changes and scope of the publication in favor of a broader and more representative presentation of the results.

#### Section Six: Miscellaneous Provision

## 6.1. Implementation of the data access and sharing policy

This policy shall take effect from the date of approval by the relevant body. The members of research and innovation directorates shall establish a system for monitoring and evaluating the policy's implementation. The policy will have the following manuals that will help in the implementation process.

- a. Data Sharing guideline
- b. Data access guideline
- c. Data transfer guideline

## 6.2. Revision of the data access and sharing policy

This policy shall be revised on a Three-year basis. However, if need arises, the Director General shall authorize its revision. Changes necessitating revision shall include changes in technology, statutory regulations and any other reasons as may be determined from time to time.

## 6.3. Violation of the data access and sharing policy

Any person engaging in unauthorized use, disclosure, alteration, or destruction of data in violation of this policy shall be subject to appropriate disciplinary action, including dismissal or prosecution under applicable state and/or federal laws.

Done at Addis Ababa, this 10th day of February, 2021

#### APPROVED BY:

- 1. DR. ABEBE GENETU, DIRECTOR GENERAL
- 2. DR. ALEMSEGED ABDISSA, DEPUTY DIRECTOR GENERAL FOR RESEARCH AND INNOVATION
- 3. YAMEROT ANDUALEM, DEPUTY DIRECTOR GENERAL FOR DEVELOPMENT AND ADMINISTRATION

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## **Appendices**

- 1. Annex A: Data Sharing guideline
- 2. Annex B: Data access guideline
- 3. Annex C: Data transfer guideline
- 4. Annex D: Data access agreement
- 5. Annex E: Data transfer agreement
- 6. Annex F: Application/Request form for data sharing
- 7. AHRI Specimen Management Policy
- 8. Related Institute policies



#### Reference

- The Federal Democratic Republic of Ethiopia Ministry of Communication & Information Technology. Consultation on the Recommendations and Working Text of the National Open Data Policy of the Government of Ethiopia. JANUARY 2018
- 2. NATIONAL INSTITUTE FOR MEDICAL RESEARCH. the United Republic of Tanzania, RESEARCH POLICY, GUIDELINES AND REGULATIONS
- 3. Ethiopian Public Health Institute Guideline for Data Management and Sharing, December 2016, Addis Ababa, EPHI
- 4. The 1995 Constitution of the Federal Democratic Republic of Ethiopia, 8 December 1994, Addis Ababa, Negarit Gazeta
- 5. The 2005 Criminal Code of the Federal Democratic Republic of Ethiopia, 9 May, 2005, Addis Ababa, Negarit Gazeta
- 6. The 1960 Ethiopian Civil Code, 05 May 1960, Addis Ababa, Negarit Gazeta
- 7. Proclamation No. 958/2016 The Computer Crime, 07 July 2016, Addis Ababa, Negarit Gazeta
- 8. Proclamation No. 590/2008The Freedom of the Mass Media and Access to Information, 04 December 2008, Addis Ababa, Negarit Gazeta
- 9. Proclamation No. 482/2006 Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, 27 February 2006, Addis Ababa, Negarit Gazeta
- 10. Proclamation No. 123/1995 Concerning Inventions, Minor Inventions and Industrial Designs, 10 May 1995, Addis Ababa, Negarit Gazeta
- 11. Proclamation No. 410/2004 Copyright and Neighbouring Rights Protection, 10 July 2004, Addis Ababa, Negarit Gazeta
- 12. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, International Committee of Medical Journal Editors (ICMJE) Recommendation, December 2019

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