Ethiopian Public Health Institute

Revised Guideline for Data Management and Sharing

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Addis Ababa, Ethiopia

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ABBREVIATIONS AND ACRONYMS

DG	Director General
DDG	Deputy Director General
EHNRI	Ethiopian Health and Nutrition Research Institute
EPHI	Ethiopian Public Health Institute
FMOH	Federal Ministry of Health
IT	Information Technology
NDMC	National Data Management Center for health
PHEM	Public Health Emergency Management
PI	Principal Investigator
RTT	Research and Technology Transfer
SERO	Scientific and Ethical Review Office

ACKNOWLEDGEMENTS

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Moreover, EPHI Management team gave incredible inputs at all levels of preparing this guideline. Thus, we would like to thank the team for their inputs and comments including to the final document. Last but not least, we would like to thank institutions who helped us in sharing their similar data sharing documents that guided us to learn about minimum information required in preparing this important document.

In 2019, the guideline has been revised following the establishment the National Data Management Center for health (NDMC). The center is responsible for creating data repository, data processing, managing data, analyzing and synthesizing health and health related data and providing input for policy and decision. The center is responsible for updating data sharing guidelines, processing data sharing requests and data governance. This guideline revision was made taking into consideration the structural and functional changes on data management system of the institute following the establishment of the center.

INTRODUCTION

The Ethiopian Public Health Institute (EPHI) is the technical wing of the Federal Ministry of Health (FMoH) in which its mandate is revised following a business process re-engineering (BPR) in 2009. The thematic areas are conducing problem-solving research on priority public health and nutritional issues, national laboratory capacity building system and Public health emergency preparedness and response. Additionally, training of public health professionals on priority programs.

The Council of Ministers Regulation issued in January 2014 confirmed the establishment of EPHI with new mandates resumed according to BPR. As stipulated by the regulation, the objectives and main powers and duties of the EPHI are to:

1. Undertake research, based on national public health research agenda, on priority health and nutrition problems, and generate, absorb and disseminate scientific and technological knowledge to improve the health of the general public"

2. Conduct surveillance – notably to early detect, alert on, and prevent public health emergencies, and help prepare and respond to these emergencies

3. Strengthen its laboratory services (notably in relation with public health emergencies and threats, referral diagnostics and tests).

In all aspects, the Institute is engaged in generating national public health and nutrition data obtained using either survey or surveillance as well as laboratory tests. Thus, establishing appropriate data management and sharing system is a vital step. This system ensures efficiency and productiveness of utilizing research for action.

RELEVANCE AND RATIONALE

Data sharing is an important way to increase the ability of researchers, scientists and policy-makers to analyze and translate data into meaningful reports and knowledge. Sharing data discourages duplication of effort in data collection, prevents the waste of resources, and encourages diverse thinking and collaboration, as others are able to use the data to answer questions that the initial data collectors may not have considered. Sharing data also encourages accountability and transparency, enabling researchers to validate one another's findings as well as allowing for

comparisons and conversations across departmental and national lines.[1] Sharing data with partners involved in collecting, analyzing, or utilizing data both improves the quality of EPHI's data and the consistency of data across the Ethiopian public health sector. Because of EPHI's constant activity with a wide variety of types of data and Biological Specimens, both human and non-human, it is crucial that formal guidelines are developed for the Institute in order to uphold EPHI's commitment to both high quality data as well as prompt and proper dissemination for the benefit of national policy makers, the public health sector, and general public. In addition, EPHI as the leader of public health research for swiftly changing country of Ethiopia must set the stage in terms of data and bio specimen sharing, which will increase with the country and health sector's development.

SECTION I: GENERAL PROVISIONS

ARTICLE 1: DEFINITIONS

1.1. WHAT IS DATA?

According to this guideline, data are a collection of facts, measurements, or observations used to make inferences about health and related issues. Data may be numerical, descriptive or visual; it can range from material created in a wet laboratory, such as an electrophoresis gel or a DNA sequence, to the content of filled-out questionnaire, videotapes, and photographs. Data can be specimen on microscope slides or membranes or other carriers, cell lines, DNA sequences, other biological samples climate patterns, soil samples etc. and also be processed data which is made up of analyses, descriptions, and conclusions prepared as a report or paper. Custom software or hardware and specialized methods can be data as well.[2]

Upholding this definition, this guideline applies to all Biological Specimens and samples, both human and non-human, that includes but is not limited to blood and other body fluids, tissues, serums, microorganisms, nucleic acids, and other biological products. Subsets of these materials and derivatives such as extracted DNA or derived cell lines are considered independent Biological Specimens (example: DNA, RNA, PBMC, and serum deriving from the same parent Biological Specimen (blood) shall be considered four separate Biological Specimens).

1.2. RESTRICTED DATA

This category covers both personal and sensitive data and seeks to clarify which subcategories of data require additional measure or controls in their use. There are ethical requirements that when using restricted data the individual who is the subject of the data has to consent and he/she has the right to know who holds their data and how such data are or will be processed, including how such data are to be shared. Furthermore, greater emphasis is attached to sensitive personal data and any processing of sensitive personal data may only take place in an anonymous format or by persons duly authorized to access such data.

1.3 .UNRESTRICTED DATA

This category relates to provision of information or services that do not require partners to know anything about the individual making the contact. This category includes anonymous and aggregated data that may be used for segmentation or research purposes. To safeguard data subjects and to manage the risk associated with this type of data, aggregated data which comprise less than five individual records should not be used or disclosed without senior management approval, unless such aggregated data can in no way be matched to identify individual data subjects.[5]On the basis that anonymous and aggregated data do not identify individual data subjects, the processing of such data are not regulated.

1.4. TYPES OF DATA

i. **Anonymous data**: Anonymous data are individual data records from which the personally identifiable fields have been removed.[6]

ii. **Aggregated data:-** Aggregate data area multiple combination of at least two or more abstract data.[7]

iii. Personal data:- Personal data are data which relates to a living individual comprising personal details like name, address, telephone number, date of birth, age etc..[8]

iv. **Sensitive data** certain types of data are referred to as "sensitive personal data". These are data which relate to the data subject's details like racial or ethnic origin, religious belief, physical or mental health or condition etc.[9]

v. Numerical data: -Values or observations that can be measured using numbers.[10]

vi. **Biological data:-** Biological data" or Biological Specimens" are data or measurements collected from biological sources, which are often stored or exchanged in a digital form. Biological data are commonly stored in files or databases. Examples of biological data are DNA base-pair sequences.

ARTICLE 2: PURPOSE

The purpose of this guideline is to ensure that EPHI maintains a comprehensive and systematic data storage mechanism and consistently provides data to its partners for appropriate public health purposes and all data efficiently released without compromising ethical commitments, privacy concerns, federal and regional confidentiality concerns, proprietary interests, national security interests, or law enforcement activities.[11]

ARTICLE 3: SCOPE

The scope of this guideline includes both electronic data and sample/specimen storage and management process at EPHI as well as the sharing of all data generated and sample/specimen storage by EPHI and collaborators on research, survey/surveillance and epidemiological studies, public health emergency management and laboratory data as well as biological specimens/products. In addition to this, data generated on technology transfer, policy briefs, laboratory equipment and maintenance will be considered as resources to be managed and shared. Data can be shared with those who fulfill the requirement of data sharing guideline.

This guideline doesn't cover the routine activities of the Institute Directorates as between themselves or with third parties. Data requested for public health response by Ministry of Health and other humanitarian agencies can be shared directly by PHEM. Surveillance data can be also shared to WHO as per the IHR 2005 through PHEM center.

ARTICLE 4: GUIDING PRINCIPLES

The core guiding principles of the data sharing and management are to ensure transparency, efficiency, accountability, confidentiality, equal opportunity and quality.

SECTION II: DATA STORAGE AND MANAGEMENT

ARTICLE 5: SOURCES OF DATA

There are various sources and nature of data at EPHI. Overall, the major data sources at EPHI are:

- Research and Technology Transfer (RTT) data
- Public Health Emergency Management (PHEM) data
- National Laboratory System data

Data from RTT could be obtained from survey, lab-based surveillance from EPHI and health facilities and community knowledge. Data from PHEM could be from day to day rumors and intelligence reports from health facilities and other sources of routine and outbreak nature.

Laboratory data comes from regional laboratories and companies on instruments and equipment. In fact, each source has various nature and request for data access might also be addressed accordingly. The processes involved and flow chart in each category of data sources is outlined and approaches for handling the request is presented. (**Annex 1**).

ARTICLE 6: DATA MANAGEMENT

6.1 RESEARCH DATA

Research data are collected, observed, or created, for purposes of analysis to produce original research results. Research starts from proposal development of the protocol which should be scientifically valid and ethical in compliance with internationally available consensus. During the implementation of the research project, valuable data are normally collected in the field as numerical data or biological specimens. Alternatively, data can be generated in a laboratory from samples and/or specimens collected for various purposes. Research data can further be analyzed and this can provide a set of data with defined interpretation of result. Technical report and publications provide written account of the project outcome that can be consumed by scientific community, policy makers and the general public. Research findings in general lead to provision of evidence -based information or product development that can be produced at industrial scale for mass production for use by the community.

6.2. PHEM DATA

PHEM obtains public health surveillance data on priority diseases from public and private health facilities (health posts, health centers, hospitals, clinics) through weekly routine surveillance, case based and line lists from outbreak areas. Data are also collected from sentinel surveillance sites on regular bases on selected diseases. PHEM also collect clinical and laboratory data. All data collected by PHEM are primary to follow the trend of cases, detect upsurge of cases and respond to any outbreaks. The data are being collected by health facilities and reported to woreda health office and then to zonal health department, region health bureaus and finally to EPHI. These data are stored at EPHI's server by PHEM data Manager who has access privileged. The PHEM data can be analyzed

and used for outbreak management, planning, resource distribution, policy change, situational awareness, and for different health program evaluations. The surveillance data can be further analyzed, triangulated, interpreted and disseminated to humanitarian agencies on regular bases for actions. Row data are also expected to be shared with WHO as per the IHR 2005. The non-sensitive and unclassified data can be further analyzed and published on peer reviewed journal for further dissemination and maximize the utilization of surveillance data for different programs.

6.3 Laboratory Data

Data from diagnostic referral laboratory services provided at EPHI, analytical tests done on water food and environmental samples as well as laboratory data from regional laboratories and other health facilities including quality assurance and laboratory equipment maintenance are sets of data require storage for further reference.

Article 7: Responsibilities of Directorates

All data collected by respective EPHI directorates shall be submitted to EPHI's local server, which is managed by the National Data Management Center for health (NDMC) and ICT unit. The data storage chart for Research, PHEM and Laboratory is shown in Annex 1.

ARTICLE 8: THE NATIONAL DATA MNAGMENT CENTER FOR HEALTH (NDMC)

Data obtained from different EPHI directorates shall be managed by NDMC according to data management protocol. This include facilitating data access upon obtaining approval as per the relevant procedure considered in this guideline. The NDMC is responsible for vetting data sharing requests forwarded by the DG are properly submitted, checking the requests are in line with article 9 of this data sharing guideline.

SECTION III: DATA ACCESS AND SHARING

ARTICLE 9: ELIGIBILITY

9.1 AGENCIES OR PERSONS ELIGIBLE FOR DATA ACCESS

EPHI data is potentially shared with but not limited to researchers, clinicians, postgraduate students, health bureaus, professional associations, partners, universities, humanitarian agencies, line ministries, and industries.

9.2 AGENCIES OR PERSONS INELIGIBLE FOR DATA ACCESS

1. Those who are not willing to fulfill the prescribed procedures in utilizing the raw data indicated in the "Form for Requesting Access to Raw Data or Biological Specimens" that outlines background, intent, and usage constraints;

2. If there is a prior information that the agency/person requesting access to raw data could use it un-ethically or un- professionally.

ARTICLE 10: OBLIGATIONS OF ORGANIZATION/PERSON REQUESTING ACCESS TO DATA AND BIOLOGICAL SPECIMEN

1. The organization/person requesting access to raw data should submit the data request form to NDMC briefly describing for what purpose the data is requested;

2. The organization/person requesting access to biological specimen should submit a brief written proposal for Scientific and Ethical review that that shows how the data will be utilized and for what purpose;

3. The organization/person granted access to the raw data should not summarize and produce any information below the intended reporting level other than indicated in the survey design;

4. The organization/person granted access to the raw data should not transfer the raw data it obtained with or without fee to third party without a written consent from EPHI

5. The organization/person granted access to the raw data should not use the data it obtained with possible identification of individuals or households or establishments. The NDMC at EPHI should anonymize and de-identify the data before sharing.

6. Students of higher education institutions and researchers who are allowed to have access to the raw data without charge are obliged to provide a copy of their data analysis report.

ARTICLE 11: PROCEDURE FOR DATA ACCESS

- In order to obtain data from EPHI's central data repository, the following steps should be followed (see the flow chart at Annex 2)

- First, a brief data sharing/access request should be submitted to the Director General (DG) office and the DG forwards the request to the NDMC and a copy to respective deputy directors office.
- Second, the NDMC will inform data requesters to submit formal data sharing request by filling out the institute's data request form. Then the center evaluates the data request in accordance with the institute's eligibility for data sharing/access and other relevant criteria. A data request which is found to be eligible and fulfilled relevant criteria will be forwarded to data generating directorate.
- Third, data generating directorate will be requested by NDMC to provide technical input and consultation to the data sharing/access request.
- Fourth, the NDMC will approve the data access/sharing request. Then, data sharing agreement format should be filled out, signed and stamped by the two parties (EPHI designated officer and data requesting institution/person (**Annex 2**).
- Finally, an officially delegated individual will be authorized to access data based on objectives of the project.

The NDMC is responsible for Data Governance, management and will be accountable to the Director General and supported by the input of EPHI's various directorates (**Annex 2**). This unit will be responsible for the management of the national health and health related data.

ARTICLE 12: ROLES AND RESPONSIBILITIES OF KEY DECISION MAKERS DURING DATA ACCESS

For processing data sharing/access requests, the following EPHI units are involved having critical roles and responsibilities. (Annex 2)

12.1 ROLES AND RESPONSIBILITIES OF DIRECTOR GENERAL DURING DATA ACCESS

- Receive the data access request and pass it to NDMC and a copy to respective deputy director's office
- Approve the final decision based on the feedback given from NDMC and in accordance with the EPHI revised data sharing guideline

12.2 ROLES AND RESPONSIBILITIES OF NDMC DURING DATA SHARING/ACCESS

- Receive data sharing/access request from the DG and initiate the process
- Inform data requester to fill out and submit the EPHI's formal data request form and other relevant documents (if necessary). These include data requesting party should produce evidence that the study is Ethically and Scientifically approved, if the data is requested for research purpose
- Evaluate the submitted data sharing/access request in accordance with the EPHI's revised data sharing guideline and other relevant criteria

- Forward valid data sharing/access requests to data generated directorate/relevant directorate for their technical input and consultation.
- Facilitate the signing of formal data sharing agreement between EPHI's designated official and data requesting institute/person for a request having favorable response from data generated directorate
- Inform respective deputy director for a request having unfavorable response from data generated directorate to reconcile decisions
- Make sure that data access/sharing fee has been paid before signing of the agreement for paying individuals/organization
- Anonymize and de-identify the data to be shared, prepare it in appropriate format and provide access to the dataset
- Follow up whether the shared data are used in accordance with the signed agreement. Any deviation from the agreement shall be handled in accordance with pertinent national laws as stipulated in the data sharing contractual agreement.

12.3 ROLES AND RESPONSIBILITIES OF DATA GENERATING/RELEVANT DIRECTORATE DURING DATA ACCESS

- Check the question can be addressed using the requested data set
- Check the appropriateness and relevance of the request
- Check for conflict of interest between data requester and principal investigator
- Provide feedback to NDMC based on the finding from the discussion with the study team

ARTICLE 13: DATA ACCESS FEE

13.1 AGENCIES OR PERSONS HAVING ACCESS TO DATA FREE OF CHARGE

- Policy-making Government Institutions/Organizations;
- Students of Ethiopian higher education institution who request access to raw data for the partial fulfillment of their degree
- Organizations/Institutions financially and technically supported the operation of the survey/census from which the raw data has been generated.

13.2 AGENCIES OR PERSONS CHARGED TO ACCESS DATA

- Except those mentioned in article 13.1, others shall be charged
- The institute will set certain amount of fee taking into account local and international practices.
- Upon approval of the data sharing request, the data requester should pay the fee to EPHI's finance department/designated account to effect the signing of the data sharing agreement

ARTICLE 14: TIMING OR STAGE FOR DATA ACCESS

EPHI give access to data/share data following the submission the first technical report/dissemination. However, data can be shared before dissemination as required for those who technically and financially supported. This is time for institutions involved from designing to generating report.

Article 15: THE DATA SHARING AGREEMENT

15.1: DEFINITION AND PURPOSE

A data sharing agreement is a formal contract that clearly documents what data are being shared and how the data can be used. Such an agreement serves two purposes. First, it protects the agency providing the data, ensuring that the data will not be misused. Second, it prevents miscommunication on the part of the provider of the data and the agency receiving the data by making certain that any questions about data use are discussed. Before any data are shared, both the provider and receiver should talk in person or on the phone to discuss data sharing and data use issues and come to a collaborative understanding that will then be documented in an agreement.[14] This applies to all three sources of data aforementioned including laboratory, RTT, and PHEM.

15.2: CONTENTS OF THE AGREEMENT

The agreement between EPHI and the party interested to accessing data must at least comprise but not limited to the following components including:

1.**Period of agreement** that clearly defines when EPHI will give the data or samples to the receiver and how long the receiver will be able to use the material and what will happen the data afterwards (i.e., deleted, destroyed, or returned).

2. **Intended use** of the data that states as specifically as possible how the receiver will use the data including the studies will be performed, questions will be asked, and the expected outcomes. In addition, this section of the agreement should address whether or not the receiver can use the data to explore additional research questions without approval of the provider.

3.**Constraints on use** of the data which lists any restrictions on how the data/Biological Specimens or findings can be used including whether or not the receiver is required to document how the data are used, if the receiver can share, publish, or disseminate data/biological specimen findings and reports without prior approval from EPHI, if the receiver can share, sell, or distribute data findings on any party of the database, and if the receiver publishes a report based on the data who the report will belong to.

4. **Data confidentiality** which describes the required processes that the receiver must use to ensure that data remain confidential. Because some data may contain information that can be

linked to individuals, it is important to put safeguards in place to ensure that sensitive information remains private. Personal information should remain confidential and should not be disclosed verbally or in writing to an unauthorized third party, by accident or otherwise.

5. **Data security** which describes the methods that the receiver must use to maintain data security. Hard copies of data should be kept in a locked cabinet or room and electronic copies of data should be password protected or kept on a secure disk. Biological Specimens should be kept in a secure location that is protected from unauthorized persons. This section will note who at the receiver agency will have access to the data, which will not, how it will be protected, and what will happen to the data sharing period ends.

6. **Methods of data sharing** which identifies the way in which data will be transferred from the provider to the receiver (ie physically or electronically, encrypted or not).

7. **Financial costs** of data sharing which clarifies who will cover the monetary costs of sharing the data. This may include transportation or postal costs.[15]

8. **Termination of agreement** - If one of the agreement will not be fulfilled from data receiver, EPHI has full right to terminate the agreement with/without notice with 2 weeks time.

15.3 ADDITIONAL CONCERNS

Additional concerns may be relevant to the particular dataset, organic matter, or provider agency. These additional concerns should be addressed in the agreement to facilitate clear communication and establish additional safeguards if necessary. EPHI's Data Sharing Agreement and its Biological Specimen Material Transfer Agreement can be found at the end of this document in the annex. EPHI's Legal Service shall provide the agreement format to customers.

ARTICLE 16: SHARING SENSITIVE DATA

Based on factors including rarity, controversy, and traceability, the types of data and bio-specimens described above will be designated either "restricted" or "unrestricted" by the PI of the project, case team leader and directorate director. These types of data may be related to epidemics, sexuality, controversial behavioral data, or rare specimens. How to handle and share such type of data will be addressed as explained in **article 1** (definition of restricted data).

SECTION IV: MISCELLANEOUS

ARTICLE 17: AUTHORSHIP AND INTELLECTUAL PROPERTY RIGHT

Data collected and information generated by EPHI staffs is the property of the Institute. It belongs to EPHI, which is also held accountable for the integrity of the data even after the researchers leave the Institute.16 Reasonable access to data, however, should normally not be denied to any member of the research team. But expected to fill request format and commitments expected to be fulfilled.

17.1: AUTHORSHIP AND INTELLECTUAL PROPERTY RIGHT

According to the International Committee of Medical Journal Editors (ICJME) an "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. Accordingly, authorship must be based on contribution and responsibility for the following activities:

i. Conception and design of project;
ii. Analysis and interpretation of research data;
iii. Drafting significant parts of the work or critically revising it so as to contribute to the interpretation.
iv. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

A researcher can claim authorship when he/she is actively involved in at least one of the first three and the fourth activities.

As mentioned before, all research data obtained in studies performed at EPHI and/or by its employees are not property of the researcher, but that of the Institute. If there is any possibility that a copyright or patent application might emerge from the project, a written agreement within the group should specify the rights, if any, of each member of the group to the intellectual property.

Any data accessed and used from EPHI's data repository should be properly acknowledged using acceptable and standard statement.

17.2: INTELLECTUAL PROPERTY RIGHT

Intellectual property right issue which may arise as a result of this data sharing processes will be dealt with according to national available rules and regulation or international conventions.

ARTICLE 18: ETHICAL CONSIDERATIONS

Data, particularly Biological Specimens, from study participants (human or non-human and including microorganisms and plants) must be handled according to the highest ethical and

scientific standards to maintain the public's trust, to preserve and protect the specimens and the substantial investment these resources represent, and to facilitate research by maximizing the use of the specimens. Ethical issues will be addressed according to standard procedures of EPHI's Scientific and Ethical Review Office (SERO). SERO will examine biological Specimens request and its project to see if there is a separate ethical section in the protocol that address ethical rules of respect for person, beneficence and justice.

ARTICLE 19: LEGAL CONSIDERATIONS

Overall, this guideline shall be implemented in accordance with all relevant laws related to information sharing laws issued by the Government of Ethiopia. Without prejudice to this statement, EPHI data sharing and utilization must be considered and conducted in accordance with the following documents including,

- EPHI Establishment Regulation Number 301/2013, Addis Ababa, 2014.
- Institute of Biodiversity Conservation and Research Establishment Proclamation 120/1998 and 381/2004 as amended.
- Ethiopian Science and Technology Policy and Ethiopian Science and
- IPR office establishment proclamation 320/2003GC.
- National Research Ethics Review Guideline, FDRE Ministry of Science and Technology, September 2014, Fifth Edition, Pp. 95

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9. National Institute of Health (2013). National Institutes of Health- Biological Specimen Working Group,Guidelines for Human Biological Specimen Storage and Tracking within the NIH Intramural Research Program, 2013
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11. WP (2008). Warwickshire Partnership, Agreement for Sharing Data Between Partners of the Warwickshire Direct Partnership, 2008.
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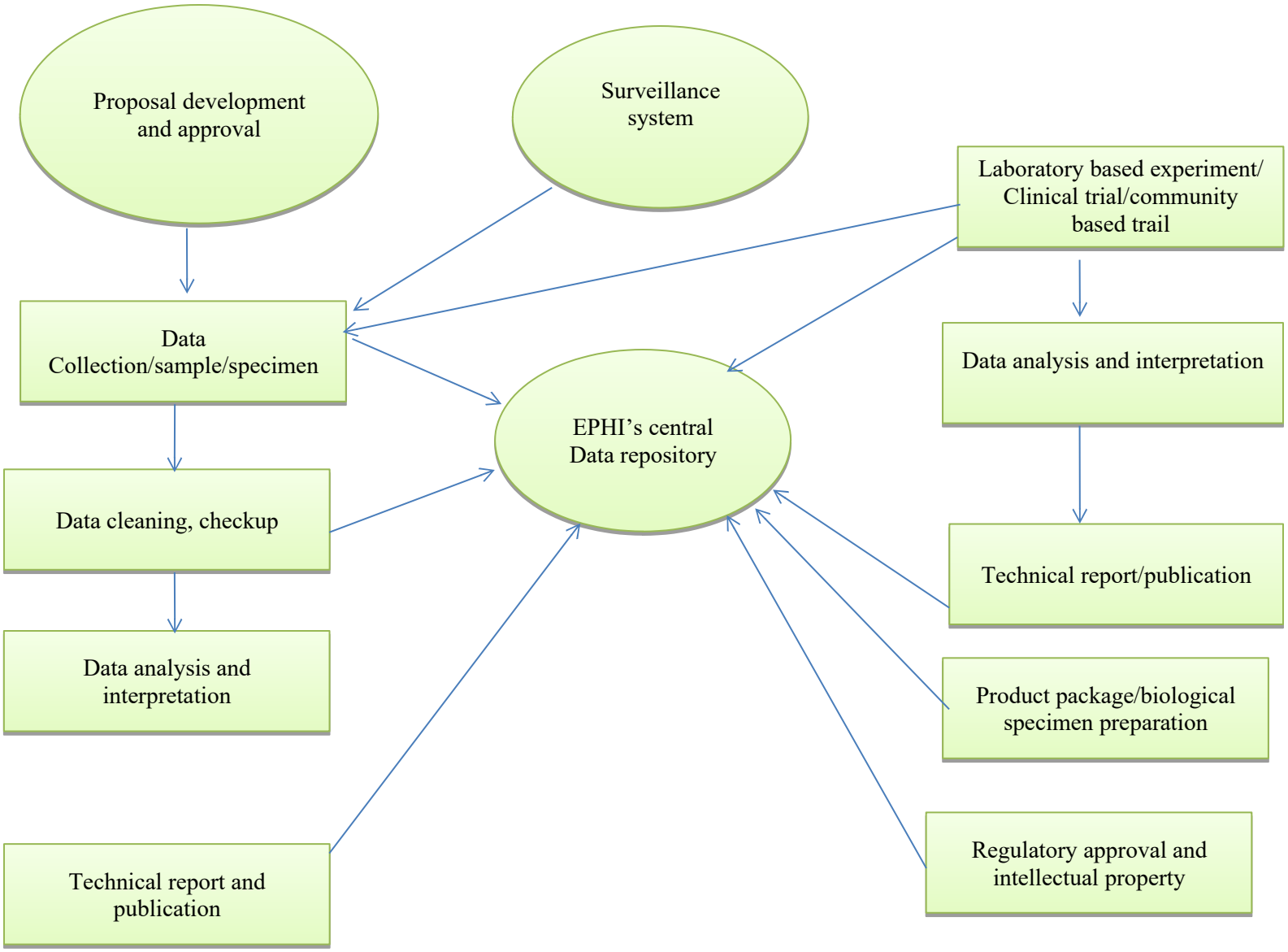
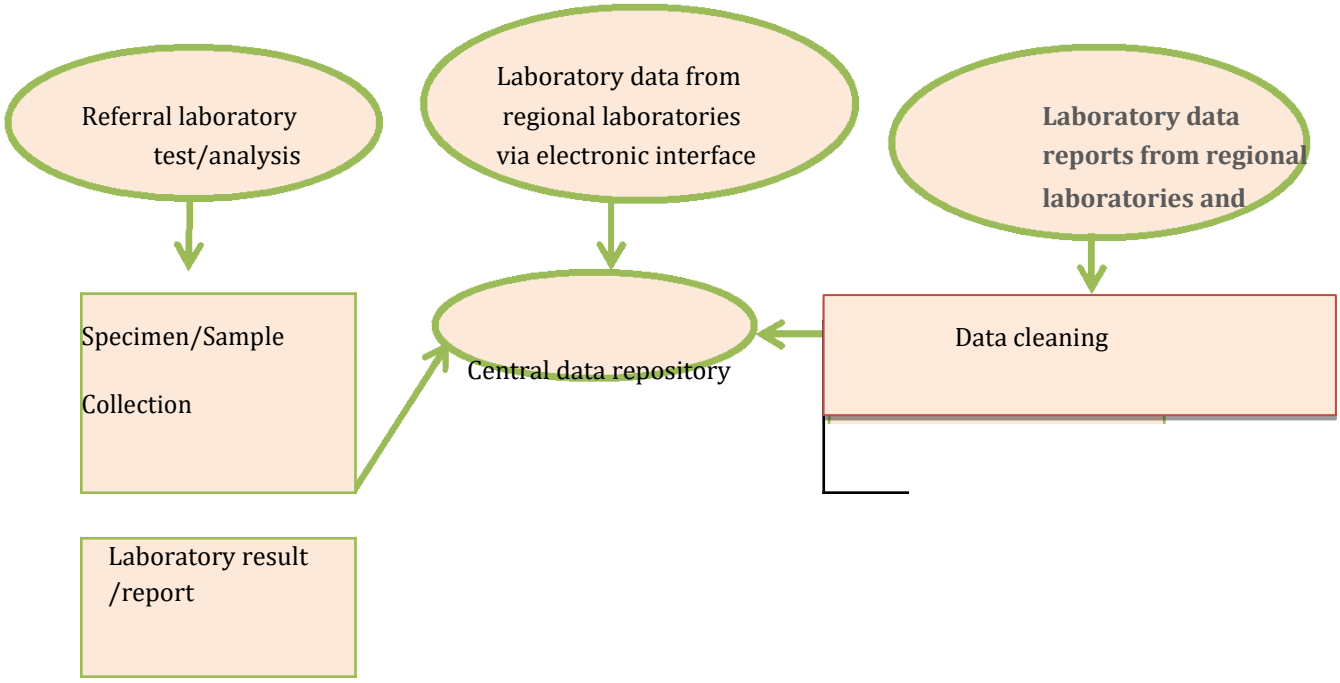
ANNEX 1: FLOW CHART FOR EPHI's DATA ARCHIVING

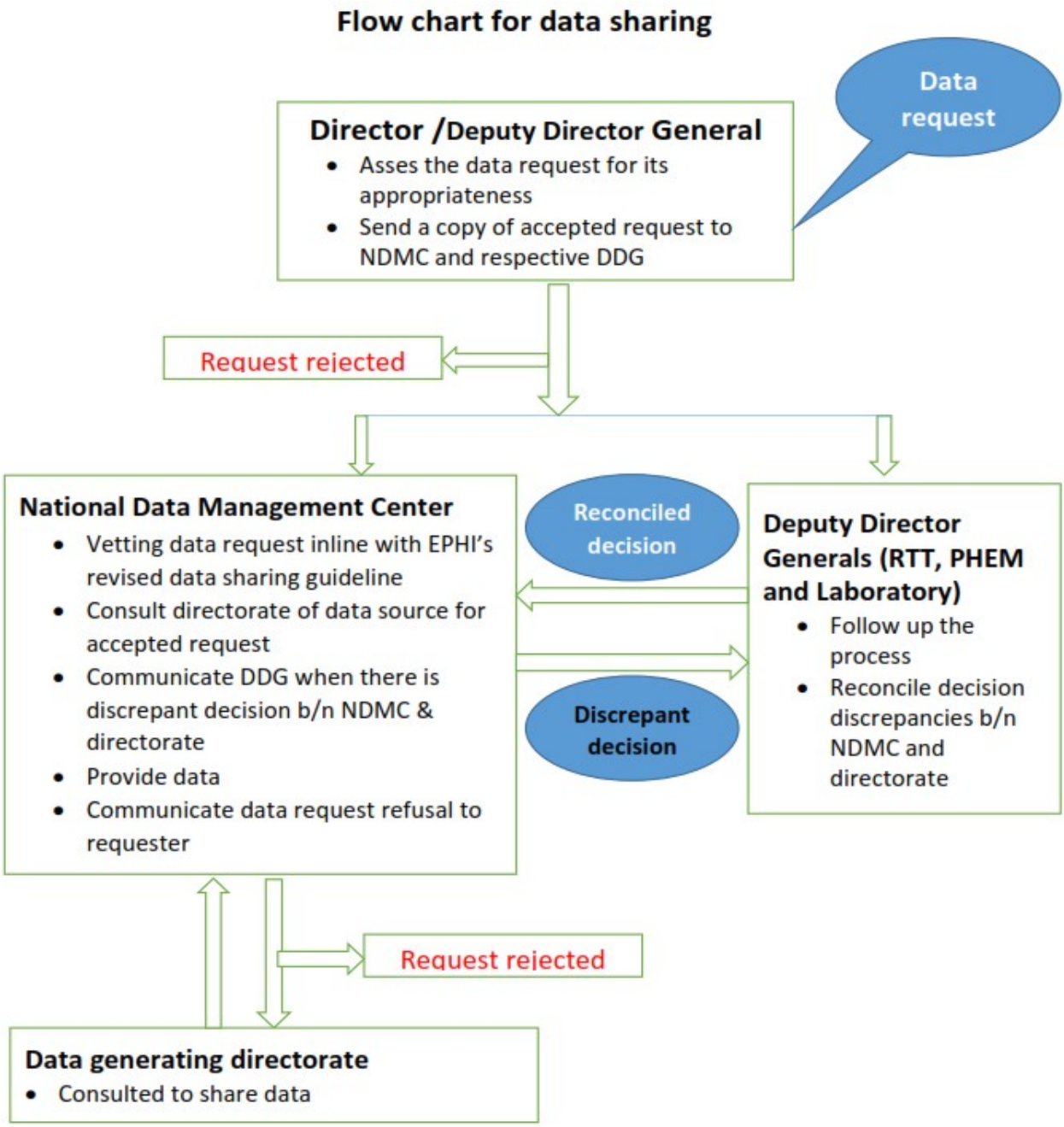
i. FLOW CHART for RESEARCH, SURVEILLANCE and PHEM DATA



ii. FLOW CHART AND STORAGE FOR LABORATORY DATA



ANNEX 2: DATA SHARING FLOW CHART



ANNEX 3: STANDARD OPERATING PROCEDURE FOR ACCESSING DATA AT EPHI

i. Standard operating procedure for accessing data at EPHI
ii. Data request form
iii. Biological Specimen Material Transfer Agreement form
iv. Data transfer agreement form
v. Data delivery/acceptance receipt form

I. Standard operating procedure for accessing data at EPHI

1. Data request should be first submitted to DG/DDG
2. Data request form for data sharing/access must be made on the standard data request format and submitted to NDMC
3. The party requesting data should produce evidence that the proposal is Ethically and Scientifically approved to NDMC
4. The party receiving the data and EPHI will complete set formalities and sign contractual agreement.
5. Individuals/institutes not fee exempted for sharing/accessing data should pay designated fee prior signing of the data sharing contractual agreement
6. Data will be provided to the receiver upon signing the data sharing contractual agreement acceptance form
7. The data receiver upon completion of the data analysis should submit a copy of the report to EPHI. In the case of biological specimen request, project proposal should be properly written and submitted to the Director General Offices
8. Project proposal review will be made for biological specimens according to the standard procedure of the Institute's SERO
9. If a request is approved by SERO access to biological specimens will be authorized.

ANNEX 4: FORMAT TO BE USED

PHI reference no. :_____

I. EPHI DATA REQUEST FORM

This form is for organizations or persons, both domestic and foreign, who seek data originated from EPHI. Please read EPHI's guideline on data management and sharing before completing this form. This form is applicable for all types of EPHI (administrative, laboratory, RTT, and PHEM).

- Please allow two weeks for a response
- Completed data request forms should be emailed to NDMC with the form as word or pdf attachments.
- For biological specimen request please attach the project's full-length proposal
- Questions about request processing can be sent to NDMC

Please complete the form below and return it to EPHI at the previously-mentioned email addresses.

Name			
Organization			
Contact person-1			
Contact person-2			
Date requested		Date required	

*please be aware that due to our own work commitments, we require that requests are submitted much in advance of the date that data are needed. please submit your request at least four weeks in advance of the date that you require the data in order to avoid possible disappointment.

Data requested: Please be as specific as possible with your data requirements.
Data type (Laboratory, Research, or Public health emergency):
Brief description of the requested data and its intended use
Who will have access to this data/how will it be kept secure?
In the case of blood, serum, microorganisms, etc., please state amount needed per unit (amount per sample).

Please attach the project's full-length proposal for biological specimen request or complete the data request form for data request. Note any ethical considerations and project's overall budget.

TO BE COMPLETED BY EPHI

Received by:		**Completed by:**	
Date request received:		**Date request completed:**	
Comments			

EPHI reference no. :_____

II. DATA SHARING AGREEMENT FORMAT

DATA SHARING AGREEMENT between The Ethiopian Public Health Institute and

_____

This Agreement is made and entered into this ____ day of _____, 20___ between the Ethiopian Public Health Institute (EPHI) and *(name of party)* _____, collectively known as the "parties."

EPHI is conducting or has conducted a study or sample collection known as _____.

And, EPHI has developed a set of data pertaining to the study subjects, practices, and results involved in the said research. EPHI is the full owner of such data that exists from the said project

1. **Description of data :** Recipient obtains data from EPHI *(short information of the research data requested)*

_____

_____

_____

_____

2. **Recipient's Use of Data.** The EPHI provides the Data to Recipient solely for the research or evaluation, and publication or distribution described in the Data Request Form or research proposal submitted to the Research Review Committee and for no other purpose. Recipient may not publish or distribute, or conduct any other research or evaluation involving the Data in any way, without making a request to and procuring the consent of the EPHI regarding such other research or evaluation.

3. **Restrictions on Recipient's Use of Data.**

3.1 Recipient agrees to use or disclose the Data exclusively for the purposes set forth in Section 2 above or as required by law.

3.2 Recipient agrees to use appropriate safeguards to protect the Data from misuse and unauthorized access or disclosure, including, without limitation, (i) maintaining adequate physical controls and password protections for any server or system on which the Data may reside and (iii) taking any other measures reasonably necessary to prevent any use or disclosure of the Data other than as provided in this Agreement.

3.3 Data recipient agrees to report (within ten (10) days of discovery) to the EPHI any Use or Disclosure of the Data Set (or components) not provided for by this Agreement, including

without limitation, any Disclosure of the Data Set (or components) to an unauthorized subcontractor.

3.4 Recipient will ensure that any agents, including subcontractors, to whom it provides the Data, agree to the same restrictions and conditions set forth in this Agreement.

3.5 Recipient will not attempt to identify the individuals whose information is contained in any Data transferred from the EPHI or attempt to contact those individuals.

3.6 All data transferred to shall remain the property of EPHI and shall be returned / Destroyed upon termination of the Agreements.

3.7 The recipient shall not under any circumstance distribute, reprint, alter, sell, assign, edit, modify or created derivative works or any ancillary materials from or with the Data, including but not limited to, question and answer forms, without obtaining the prior written permission of the School District.

3.8 The recipient agree to report results, findings, and conclusions originating from the shared data at the conclusion of the study in *(approximate date of study's conclusion)*_____.

3.9 The recipient shall not share the data to third party without the knowledge of EPHI

3.10 All data will be transferred in an encrypted format with the encryption key stored separate from the dataset. Each party agrees to maintain this dataset either on the supplied CD or on a secure server. In the case of Biological Specimens, sample transport and security will be determined by EPHI's *(appropriate directorate)* _____ and the recipient in accordance with material transfer agreement which should be attached to this Agreement.

3.11 Recipient agrees to the boundary conditions of the original proposal was initially submitted by under which data sharing was initiated.

3.12 This Agreement shall be in full force and effect from the first date written above for a period of _____. This Agreement may be terminated upon thirty (30) days written notice by either party or mutual agreement of the parties. Termination of the agreement will terminate (name of party) _____'s access to EPHI's data.

3.13 This Agreement is expressly made subject to all laws and regulations of the Federal Democratic Republic of Ethiopia, without regard to any choice of law principles.

3.14 The terms and provisions of this Agreement represent the entire understanding of the parties with respect to the subject matter of this Agreement.

3.15 The undersigned individuals represent that they are fully authorized to execute this Agreement on behalf of the respective parties, perform the obligations under this Agreement, and make all representations, warranties, and grants as set forth herein.

IN WITNESS WHEREOF, the Parties have caused this agreement to be executed effective as of the first date written above.

EPHI Director General _____ Date_____

Party Representative _____ Date_____

EPHI reference no. :_____

III. MATERIAL TRANSFER AGREEMENT FORMAT

BIOLOGICAL SPECIMEN MATERIAL TRANSFER AGREEMENT

Between

The Ethiopian Public Health Institute

and

_____

This Material Transfer Agreement (MTA) outlines the manner of collaboration between the Ethiopian Public Health Institute (EPHI) and *(name of party)* _____, collectively

known as "the Parties" and pertains to laboratory data. EPHI is known as "provider" and *(name of party)* _____ is known as "recipient" in this document. This agreement will compliment

EPHI's Data Sharing Agreement form that is to be filled out by and signed by both parties and to which this biological specimen MTA agreement should be attached.

1. Provider agrees to transfer to the recipient investigator the following research material:

_____

_____ which is categorized as *(data type i.e., administrative, PHEM, etc.)* _____ data.

2. This/these biological specimen(s) listed above will only be used for investigational purpose of

outlined in *(name of party)* _____'s project proposal that was submitted with the data request form. Recipient agrees to comply with EPHI rules and regulations applicable to the research project and the handling of research material and all parts of the Data Transfer Agreement attached to this agreement which is unique to Biological Specimen-sharing.

___

3. The materials will be used by the recipient solely in connection with the research project

entitled " _____ ". And in achieving the main objective of research project,

any unused Biological Specimens will be returned to EPHI.

4. In all disseminations (oral presentations, written publications, etc) of the knowledge generated and skills developed concerning the research project, recipient shall abide to guideline of national planning and coordinating committee for clearing manuscripts on _____

_____

5. The Biological Specimens will be physically transferred by _____ and paid for by _____.

6. After the completion of the recipient's project in _____, 20____, the Biological Specimens will be _____.

7. The recipient shall compile investigational data, analyze, interpret and submit overall technical report to EPHI.

8. This research material is provided as to sort out solution for the health problem in the community and is considered as the property (proprietary)of the provider. The recipient investigator therefore agrees to retain control over the research material, and further agrees not to transfer to others not under his/her direct supervision without advance written approval of provider.

9. Both the recipient and provider shall retain patent or other intellectual property rights in inventions made in course of the research project.

10. The undersigned provider and recipient expressly certify and affirm that the contents of any statement made herein are truthful and accurate

DECLARATION OF AGREED AND ACCEPTED PARTNERS

On behalf the organization specified below, I agree to the provision and management of data in accordance with the conditions laid out in the "agreement for the sharing of data between partners of the Warwickshire direct partnership".

Recipient Coordinator: I have read and understand the conditions outlined in this agreement, and I understand that I must abide by them to receive and use the research material.

Name: ----------

Signature: ---------- Date ----------

Authorized Official for Recipient

Name: ----------

Signature: ---------- Date ----------

Provider Coordinator (Director of responsible directorate):

Name: ----------

Signature: ---------- Date ----------

EPHI Director General

Name: ----------

Signature: ----------Date----------

EPHI reference no. :_____

Ethiopian Public Health Institute

IV. DATA AND BIOLOGICAL SPECIMENS RECEIPT FORM

This form must be filled out and signed upon the delivery and acceptance of EPHI's data or Biological Specimens. This form should then be faxed or emailed to EPHI. *This form applies to laboratory, RTT, and PHEM data.*

To be completed by recipient

Name:			
Organization:			
Type of data (laboratory, RTT, or PHEM)			
Date initial proposal/request was sent to EPHI:		**Date data were received:**	

Data or Biological Specimen received. Please be as specific as possible with the data you have received. Interims of Biological Specimens like blood serum etc.. Provide amount received as well as method of delivery.

To be completed by EPHI

Date this form was received from data recipient:		Date that shared data agreement will expire (please refer to EPHI-recipient data sharing agreement):	
Principal Investigator of these data:		Monitoring Directorate of these data:	
Comments:			

V. DOCUMENT HISTORY, MARCH 2014-NOVEMBER 2016, EPHI

ACTIVITIES	DELIVERABLES	DATE
Management Team identified a team	DG approved	March 2014
Identifying and collecting source documents as Reference	Institutions with similar experience at local and international level identified From local institutions Armauer-Hansen Research Institute (AHRI) Ethiopian Agricultural Research Institute (EARO) School of Public Health, Addis Ababa University Central Statistics Agency (CSA) From international experience WellCome Trust Sanger Institute National Institute of Health National Cancer Institute	March 2014
Compiling documents Collected	Preparing **Zero draft**	March 2014
Retreat to Bishoftu town	Enriching and finalizing the document the Guideline	11- 13April 2014
Submission of the first draft	Input from Research and Technology Transfer Deputy Director General Comment and input from Management Team	April 29, 2014
Submission of final draft	Consider mandate of the Institute and	June 2016

	establishment document into account	
Presentation to Management Team	Guideline approved and a small team assigned to clean contents ready for approval by DG	November 2016
NDMC presented the need for revision to management team and the team approves the request	Taking into consideration the structural and functional changes on the data management system of the institute, the management team approved NDMC proposal to revise the 2016 guideline	May 2019
NDMC team revised the guideline	The NDMC team revised the guideline taking inputs from different directorates and directors and inline with its working guideline	May to August 2019
Presentation of the revised guideline to the management team	Management team approved the revised guideline	August 2019