REPUBLIQUE DU BENIN
MINISTERE DE L'ENSEIGNEMENT SUPERIEUR ET DE LA RECHERCHE SCIENTIFIQUE
UNIVERSITE D'ABOMEY-CALAVI
CENTRE DE RECHERCHE POUR LA LUTTE CONTRE LES MALADIES INFECTIEUSES TROPICALES (CReMIT)
TROPICAL INFECTIOUS DISEASES RESEARCH CENTER (TIDRC)
UNITE ENVIRONNEMENT, GESTION DES DONNEES ET FORMATION UNIVERSITAIRE (UEGDFU)
01BP526 COTONOU ; IFU : 4202239622770 ; Tél : (+229) 0195324577

RECORD KEEPING & DATA MANAGEMENT POLICY

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TIDRC/UAC RESEARCH GRANTS MANAGEMENT OFFICE

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KEY GUIDELINES

The following guidelines are provided for good practices in Record Keeping and Data Management for the Tropical Infectious Diseases Research Center of University of Abomey-Calavi:

Data Ownership: This refers to who has the legal rights to the data and who retains it after the project is completed, including the researcher's right to transfer data between institutions and individuals.

Data Collection and Analysis: This involves collecting project data in a consistent and systematic manner (i.e., reliability) and establishing an ongoing system for evaluating and recording changes to the project protocol (i.e., validity). It also involves to how raw data are chosen, evaluated, and interpreted into meaningful and significant conclusions that other researchers and the public can understand and use.

Data Storage and Protection: This concerns the amount of data and how it should be stored. The amount of data stored should be enough so that project results can be reconstructed. Written and electronic data should also be protected from physical damage and data integrity, including

damage from tampering or theft and natural causes. Electronic media data should be updated periodically in line with technological advancements to prevent obsolescence.

Data Retention: This refers to the length of time one needs to keep the project data according to the Center's guidelines. It also includes safeguarded destruction of data where absolutely necessary, with permission from TIDRC/UAC.

Data Sharing: This refers to the dissemination of project data and research results to other researchers and the general public, as well as the circumstances under which data should not be shared.

Data Reporting: This pertains to the publication of the results of the research findings, during the course or after the project is completed.

1. OWNERSHIP OF DATA

Ownership of research is a complex issue that involves the Principal Investigator (PI) of the research, the sponsoring institution, the funding agency, and any participating human subjects. In many cases, the institution/organization owns the project data, but the PI and the funding agency have "rights" to access and use the data. Usually, the PI has physical custody of the data on behalf of the organization. However, these rules vary with institutions and also depend on the funding source. The following recommendations are provided for the Tropical Infectious Diseases Research Center:

1.1 The Center:

TIDRC/UAC has the right of ownership to any research conducted under its auspices. Consequently, It has responsibilities for ensuring that research is reliably and ethically conducted. For example, the Center should have direct interest in budget management and disbursement procedures, regulatory compliance, contractual obligations and data management and therefore the rights and obligations to retain control over the data. Within TIDRC/UAC, a Principal Investigator (PI) may be granted stewardship over the project data and may control the direction, publication, patenting and copyright of any innovative results from the research, subject to the TIDRC/UAC's own institutional review and policies.

Researchers cannot automatically assume that they can take their data with them should they leave the services of the TIDRC/UAC and move to another institution. TIDRC/UAC may continue to maintain ownership of project data as long as the PIs are employed by TIDRC/UAC.

- **Transfer of data in the event a researcher leaves TIDRC/UAC:**

When individuals involved in research projects at TIDRC/UAC leave the center, TIDRC/UAC may decide whether they can take away copies of research data for projects on which they have worked. The PI must, however, retain original data at TIDRC/UAC.

If a PI leaves TIDRC/UAC, and a project is to be moved to another institution, ownership

of the data may be transferred with the approval of TIDRC/UAC with written agreement from the PI's new institution that guarantees:

a) Its acceptance of custodial responsibilities for the data and

b) TIDRC/UAC should continue to retain the ownership of the data, and the PI granted access to it should that become necessary.

1.2 The Funding Agency:

Many research projects are funded by Government agencies, Philanthropic organizations and/or Private industries. These agencies often have specific regulations governing how data should be retained and disseminated, such as whether to publish the project's results or market a resulting product. The PI and TIDRC/UAC should understand the funding agency's regulations regarding a research project and the data it produces.

- **Research grants:**

These can be described as assistance funding usually awarded to do some projects that enable the researcher to address some specific needs. The PI retains control over the agreed scope of the research.

- **Research contract**:

These can be described as procurement funding or provision of money in order to acquire a product, property, or service. Like a contractual agreement between a buyer and a seller, contracted research is often subject to strict regulations, requirements, and expectations. For instance, the PI must coordinate project goals and decisions with the funding agency, which assigns a project officer to oversee the project and to make sure that the agency's goals are met. Funding may be disbursed in instalments. Also, the data typically belongs to the funding agency, unless otherwise stipulated in the agreement.

1.3 The Principal Investigator:

In addition to being the steward of a project's data, a PI may retain some ownership of the data.

2. DATA COLLECTION AND RECORDING:

a) Different types of research call for different data collection techniques.

There are, however, four important considerations that will help ensure the overall integrity of both the process and the information collected.

i. **Appropriate methods**.

Reliable data are vitally dependent on trustworthy methods.

Proposals/projects should pre determine/indicate appropriate methods and designs/statistical tests available for analyses of data to be collected. Researchers should ensure they are using the most appropriate and reliable technology possible.

ii. **Methods can be compromised by bias**

Choosing one method or set of experimental conditions so that a particular conclusion can be drawn. Whatever the origin, the use of inappropriate methods in research compromises the integrity of research data and should be avoided. Responsible research is conducted using appropriate, reliable methods.

iii. **Attention to detail**.

Quality research requires attention to detail. Experiments must be set up properly and the results accurately recorded, interpreted, and published. Failure to pay attention to detail can result in mistakes that will later have to be corrected and reported. Once errors are detected, the researcher is obligated to make corrections. However, if the errors are coming from the design, then it means the whole experiment is damaged and one will have to

redesign the experiment.

iv. **Authorized.**

Researchers have the responsibility to know when permission is needed to collect or use specific data in their research. If one is not sure whether permission is needed, it is necessary to check before proceeding with data collection.

The following provides examples of types of data collection which need authorization before proceeding:

- Human and animal subjects in research;
- Hazardous materials and biological agents;
- Information contained in some libraries, databases, and archives;
- Information posted on some Web sites;
- Published photographs and other published information; and
- Other copyrighted or patented processes or materials.

b) **The final step in data collection is the physical process of recording the data in some type of notebook (hard copy), computer file (electronic copy), or other permanent "record" of the work done**.

The physical formats for recording data vary considerably, from measurements or observations to photographs or interview tapes. Whatever type of data recorded, it is important to keep in mind that the purpose of any record is to document what was actually done and the results that were achieved.

In recording data, the following two simple rules should be borne in mind to avoid problems later:

i. **Hard-copy evidence should be entered into a numbered, bound notebook so that there is no question later about the date the experiment was run, the order in which the data were collected, or the results achieved**.

Loose-leaf notebooks or simply collecting pages of evidence in a file should be avoided. Records in a bound notebook should not be changed without noting the date and reasons for the change.

ii. **Electronic evidence should be validated to assure that it was actually recorded on a particular date and not changed at some later date.**

It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. If data is electronically collected; it should be possible to demonstrate that they are valid and have not been changed. The data to be authenticated can be printed out and, signed by the research team.

iii. **Best Practices for Record Keeping**:

Diligent record keeping is essential to ensuring the integrity of research data. To help maintain data validity and reliability, the following best practices are recommended when planning or completing data collection:

Include notes: Records should provide information which could account for what occurred during the course of research and also make it possible to reconstruct and justify the findings. It is important therefore that records should include notes about what methods did or did not work, observations, and commentary on the project's progress. Notes should be kept according to the research team's predetermined communications plan.

- . **Personal notebooks**: For smaller projects using handwritten data, each team member should have his or her own personal notebook for recording project

data, observations, etc. Entries should be made in a chronological and consistent manner -- for instance, each new workday should begin on a new page dated and blank lines should not be left between entries.

- **Noting errors**: A consistent system for noting errors or adjustments should be used. In written records, entries should be made in indelible ink so

that records cannot be altered or damaged. If any information must be changed or amended,
one solid line should be marked through the entry and initialled and the change dated. The records can thus reflect what has occurred during the course of a project.* CORRECTION FLUID SHOULD NEVER BE USED.

- **Recording information**: Record anything that seems relevant to the project, its data, and the standards of the project. At a minimum, records should include the following information:

- **Date and time**
- Names and roles of any team members who worked with the data
- Materials, instruments, and software used
- Identification number(s) to indicate the subject and/or session
- Data from the experiment and any pertinent observations from the data's collection.

*It may also be helpful to include a summary of the day's data collection activities and a task list for the next day.

- **Transferring information**: When records are to be transferred from written to electronic format, a double entry system should be used to reduce rates of
incorrectly entered electronic data. For, example this could be done by using two different Research Assistants to enter all of the raw data into the software program, then cross-check the data to identify and remedy inconsistencies at the time of data entry.

3. **DATA PROTECTION, STORAGE AND RETENTION**

Once collected, data must be properly protected, because they may be needed later:

- To confirm research findings,

- To establish priority, or

- To be re-analysed by other researchers.

If the data are not properly protected, the investment, whether public or private, could become worthless. The responsible handling of data begins with proper storage and protection from accidental damage, loss, or theft:

- Lab notebooks should be stored in a safe place.

- Computer files should be backed up and the backup data saved in a secure place that is physically removed from the original data.

- Samples should be appropriately saved so that they will not degrade over time.

- Care should be taken to reduce the risk of fire, flood, and other catastrophic natural events.

- The primary data should not be destroyed after completion of the research so that it can be re-analyzed and re-interpreted in the future.

- Directors are also obliged to keep the data on behalf of the Center.

The data can also be stored with identifiable institutions or responsible individuals outside TIDRC/UAC.

- Data should be kept as long as possible. After 10 years in the store, it should be moved into the museum/ archives.
- Units should try to create storage facilities for keeping data.

- Some can be converted into a softcopy and stored electronically.

a. Confidentiality:

Some data are collected with the understanding that only authorized individuals will use them for specific purposes. In such cases, care should be taken to assure that privacy agreements are honoured. This is particularly true of data that contain personal information that can be linked to specific individuals. It is also true of confidential information about protected processes and materials. If a company shares confidential

data about a process with a researcher prior to seeking a patent on that process, the researcher must take care to make sure the data are kept confidential.

Data that are subject to privacy restrictions must be stored in a safe place that is accessible only to authorized personnel. Random codes to identify individual subjects, rather than names or social security numbers should be used to further protect private information. Access to these codes can then be restricted to provide a double layer of protection. Whatever the method used to protect private or confidential information, the researcher who collects or uses the information has the primary responsibility for its protection.

b. Period of retention:

Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common

definition of a reasonable period of time.

Given the different reasons data could be useful over long periods of time, researchers should give some thought to retaining data longer than some minimum period required by specific regulations. How long is reasonable will vary from discipline to discipline and institution to institution. Nevertheless, it is important to have a clear retention policy that balances the best interests of society with those of TIDRC/UAC and the individual researcher. Before throwing out notebooks, cleaning out files, or erasing computer memory, careful consideration should be given to who might benefit from or ask to see the data in the future.
Thorough data collection accomplishes the following:

i. Enables those involved in the research to be more accurate in the analysis and assessment of their work.

ii. Allows independent researchers to replicate the process and evaluate results.

iii. Impresses upon research team members the importance of data management.

iv. Details the rationale behind a research project.

v. Provides justification to sponsors for expenditures and project decisions.

4. **DATA PRIVACY**

a) Researchers should be encouraged to release their work to RGMO and be assured of its security.
b) Expertise should be recognized and respected. Wherever possible, experts in the relevant fields should be identified for collaborative and interdisciplinary research.
c) The person responsible for the research (usually the PI) should keep a proper record of all the data.
d) The Director and Deputy Directors should be responsible for monitoring

research and use of funds.

5. **PROCEDURES AND RELEASE OF INFORMATION**

Every research work should obtain the approval of TIDRC/UAC to ensure some protection of data when necessary.

6. **DATA SHARING AND PUBLICATION/DISSEMINATION**

It is widely agreed that research data should be shared, but deciding when and with whom raises questions that are sometimes difficult to answer.

Researchers are not expected to and, in most instances, should not release preliminary data (i.e., data that have not been carefully checked and validated). An exception to this rule would be preliminary data that could potentially benefit the public. A researcher who has strong preliminary indications of a major threat to public health, such as unexpected side effects from a drug or an unrecognized environmental health problem, may have good reason to share this information with the public and other researchers before it is fully

validated. Data that have no such immediate public benefit, in most instances, is best held until the researcher is confident that the results will stand.

Provided no agreements have been made to the contrary, keeping data confidential prior to publication is a commonly accepted practice that most researchers and funding agencies accept.

Once a researcher has published the results of an experiment, it is generally expected that all the information about that experiment, including the final data, should be freely

available for other researchers to check and use. Some journals formally require that the data published in articles be available to other researchers upon request or stored in

public databases. There is considerable support for sharing data with other

researchers and the public unless there are compelling reasons for confidentiality. Data should however not be shared without the permission of TIDRC/UAC.

7. **ACADEMIC AUTHORSHIP**

a) Copies of all published articles and research works should be deposited at the TIDRC/UAC's library.

b) People who do not actively participate in the research should not be listed as authors. Experienced senior members supervising students in a research work as mentors should not necessary be the first author. They can however be named as the first author(s) if they contribute at least two-thirds (2/3) of the whole research work.

c) Young senior members should be encouraged to be first authors, with the experienced senior members being corresponding authors.

d) If a student's research work forms part of a major research project, the student's contribution should be acknowledged.

8. **RESEARCH MISCONDUCT**

a) Forgery of data

b) Research proposals that do not go through the process of approval by TIDRC/UAC.

c) Proposals submitted without the consent of all listed researchers.

d) Taking research ideas from others without attribution or recognition.

e) Use of research data for personal/ individual gain.

f) Publications listing individuals who have not been actively involved in the research work.

g) Research work published without the authorization of TIDRC/UAC.

h) Multiple submissions of the same research work for publication in different journals.

9. **RESEARCH TEAM MEMBERS**

Although titles, roles, and responsibilities vary by organization or institution, it is recommended that research teams at TIDRC/UAC should be made up of at least the following 5 key members:

a) Principal Investigator:

The Principal Investigator (PI) is ultimately the individual responsible for a project and its research. S/He is the main authority on all scientific, medical and other relevant issues related to the project. By obtaining funding and seeing that a project has the right team members, proper resources, and guidance, a PI must ensure the success of the project. A project may

have more than one PI, and they are Co-Principal Investigators.

b) Research Director (Project Director)

The Research Director controls the project. She/he directs the protocol for how the research and data collection are carried out, and thus may often know more about the day-to-day

operations of the project than the PI. The Research Director is responsible to the PI and should work closely with him/her to both report on and redirect research.

c). Research Associate (Project Coordinator)

Under the guidance of the Research Director and the PI, the Research Associate coordinates the project. This individual carries out the research itself, collecting data and assessing the effectiveness of project protocol, suggesting changes to the methodology as needed.

d) Research Assistant

Research Assistant(s), may normally be the least experienced member(s) of a research team who carries out the project work. A Research Assistant performs the

day-to-day tasks of a project, including collecting and processing the data and maintaining equipment.

e) Statistician

The Statistician analyzes the data that are collected during the project. In some projects, the statistician may simply analyze and report on the data (under the guidance of another team member) after data collection has been completed. In other projects, a statistician is involved in the construction and analysis of research throughout the entire course of a study.

f) Other Team Members

Additional team members may be involved in research studies, including clinical research specialists, laboratory technicians, interns or student researchers, grant administrators, and others. Their roles should be defined by the PI at the outset of the project.

10. RESEARCH TEAM RESPONSIBILITIES

a. Data Management Responsibilities of the PI and Research Director

Most of the specific tasks of data management fall to the PI and Research Director. For instance, these individuals are usually responsible for the following:

i. Ensuring that every person who is involved in the project knows his or her rights regarding data ownership

ii. Ensuring that the protocol is meticulously planned and that staff is thoroughly trained to maintain the integrity of the data collected.

iii. Determining how to best store, protect, analyze, and disseminate the data.

iv. Developing a plan for addressing research misconduct and data mismanagement

b.) Responsibilities of the Other Team Members

Management of the primary data is the responsibility of the Research Associate and Research Assistant and is usually in data collection: ensuring the reliable and valid collection of the data and protecting the data that they have collected. Statisticians are primarily responsible for ensuring comprehensive and accurate data analysis. All research team members are responsible for letting the PI or Research Director know if they suspect data fraud, manipulation, or other misconduct. The PI and Research Director are usually responsible for most of the tasks related to data management. Research Associates and Research Assistants are primarily responsible for data collection, while Statisticians are responsible for analysis.

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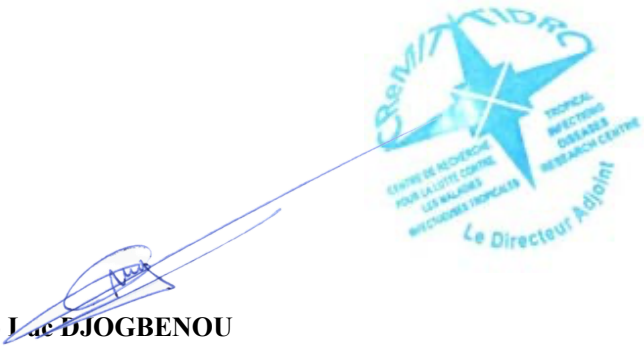
Approval & adoption

This Record Keeping & Data Management Policy, code: TIDRC/DM/RKDMP-01 is hereby formally approved and adopted as the official policy of the Tropical Infectious Diseases Research Center/University of Abomey-Calavi, effective February 18, 2026



Salako Luc DJOGBENOU
Head of Environment Data Management
and University Training Unit (UEGDFU)
Deputy Director of Tropical Infectious
Diseases Research Center (TIDRC/UAC)