Charter du Centre de Ressources Biologiques de la Martinique
CeRBiM

CeRBiM is certified by Euro Quality System

NF S 96-900 standard
April 12, 2017: initial cycle
March 19, 2020: renewal

☐ **ISO 9001 and ISO 20387 standards**
March 29, 2023: initial cycle

EURO-QUALITY SYSTEM
ISO 20387
ISO 9001

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CHARTER MANAGEMENT RULES

Revision: The entire document is reviewed and, if necessary, updated annually by the Quality Manager, for example during the management review, but it may also be modified following significant changes to the organization, the inclusion of new activities, or following audit recommendations.

The document is managed by the Quality Manager. Distribution is handled by the CHUM communications department.

1. PREAMBLE

The charter presents the Centre de Ressources Biologiques de la Martinique (CeRBiM) of the CHU de Martinique and governs the relationship between CeRBiM and the people who use its services.
This is done in compliance with the ethical principles governing the collection of human body parts, and with the legal and regulatory provisions governing the collection, processing and storage of said parts and associated information.
It provides a guarantee of transparency and a commitment to continuous quality improvement, by setting out how CeRBiM is organized and how its collections are managed.

It's a training and communication tool.

The Centre de Ressources Biologiques de la Martinique (CeRBiM) was created in 2007 by the Laboratoire de Virologie-Immunologie to meet the needs generated by the clinical research activity of the Hôpital Pierre Zobda Quitman (PZQ): the management of biological samples collected as part of these studies had to be entrusted to a specialized structure, able to guarantee traceability, compliance with the operating procedures defined for each study and safe storage conditions.

Located in the Virology-Immunology Laboratory, then in the House of Research (level -1 of the EFS), CeRBiM has been responsible since its creation for preparing, storing and making available biological fluids collected as part of clinical studies by the medical-scientific community of the PZQ hospital.
The PZQ Tumorotheque, integrated into the Pathological Anatomy Department, joined the Biotheque in January 2018 giving birth to the Martinique Biological Resource Center Platform. Within the Platform, the two units remain distinct, each retaining its own activity, in line with the nature of the samples managed, but the interaction of dedicated staff is continuous and the approach to the quality management system is common.

The joint quality approach, initiated in 2014, led to NF S96-900 certification in January 2017, which will be renewed in January 2020.
Excluding Chapter 7.3.3: Dedicated spaces
Chapter 10.3: duplication of biological resources (insufficient storage capacity and lack of demand in current projects)

□Le CeRBiM has been certified to ISO 9001 and ISO 20387 standards since March 29, 20223.

Since September 2021, CeRBiM has been a unit attached to the Laboratories Unit of Martinique University Hospital.

2. REFERENCES, ABBREVIATIONS AND DEFINITIONS

a. References

Norme NF S 96-900 " Qualité des Centres de Ressources Biologiques (CRB) -Système de management d'un CRB et qualité des ressources biologiques ".

Standard NF EN ISO 20387 "Biotechnology - Biobanking - General requirements for biobanking" (September 2020)

Standard NF EN ISO 9001 "Quality management systems - Requirements".

b. Definitions

Annotations: information associated with biological material.

EDM: Document management software

Catalog: documentary tool for listing available biological resources.

Biological Resource Center (BRC): an organization that carries out at least the activities of receiving, preparing, conserving and making available biological resources, in particular for research, education and industrial development purposes. Biological resources of human origin may be derived from diagnostic activities.

Collection: A set of biological samples or materials assembled according to common characteristics, taken from individuals for the purpose of scientific research.

Critical: all elements (purchasing, materials, methods, steps, etc.) that have an impact on the quality of biological resources, stakeholder satisfaction and personnel safety are considered "critical".

Reservation period: period starting from the meeting of the number of samples predetermined in the study or necessary for the start of the study, during which the Offeror has the right to oppose any access by a third party.

Depositor : Organization to which the individual carrying out, or under whose responsibility, the sampling to constitute or participate in the constitution of a collection to be deposited at CeRBiM belongs.

Quality manual: CeRBiM's reference document for implementing the requirements of this document. It provides a precise description of the scope and perimeter of the quality management system adopted by CeRBiM.

The perimeter represents the locations where the BRC activities covered by the QMS are carried out.

Biological materials: for the purposes of the BRC, biological materials include human biological fluids (blood, plasma, serum, urine, cerebrospinal fluid, etc.), tissue biopsies of human origin and any other product derived from the human body.

Project initiator : The natural person behind the scientific project requiring the creation of a collection, in other words the *initiator of the collection*.

Biological resources: A generic term for biological samples and the data associated with them.

Collection referent: This is the collection's clinical referent, who may be the initiator or the project leader.

CeRBiM's Quality Management System (QMS): The QMS represents all the measures established, documented, implemented and maintained to control the identified processes and thus guarantee the supply of compliant SR. This system must enable the implementation of CeRBiM's quality policy.

User (or applicant) : An individual whose research project requires the use of biological resources stored at CeRBiM. The user may be the project leader himself, or a different individual.

Interested parties: These include anyone involved in the operation of the CRB.

3. EXCLUSIONS

ISO 9001 standards :
Chapter 8.3 design and development of products and services

4. REGULATIONS

CeRBiM has made an **initial declaration** to the French Ministry of Higher Education and Research, concerning the activity of conserving and preparing elements of the human body for scientific purposes.

CeRBiM holds an **authorization** from the French Ministry of Higher Education and Research, covering the conservation and preparation of human body parts with a view to their transfer for scientific use for the Tumor Library and the Biolibrary.

☐ Updates and follow-up are regularly carried out by a DRCI employee dedicated to this activity.

5. CERBIM'S MISSION

CeRBiM's main mission is to help researchers set up bio-collections as part of their research projects. Its activities consist in helping to set up the logistics surrounding the collection of samples to constitute, transform, conserve and make available the biological resources it houses, while guaranteeing the consent and/or information of the subject, compliance with regulations, protection of individuals, as well as the quality and traceability of biological samples.
In order to fulfil its missions and respect the best practices related to its activities, CeRBiM applies a rigorous quality approach, respecting the following standards:

- ISO 9001: Quality management system - Requirements
- ISO 20387: Biotechnology - Biobanking - Biobanking requirements

The Tumorotheque preserves tumor and/or healthy tissues collected in a care setting, but which can be requalified for research or collected specifically for research purposes.
The Biothèque stores biological fluids collected as part of health collections or research projects.

6. FINANCING

CeRBiM receives financial support from its supervisory bodies in several forms: staff salaries, operating budget and assistance with equipment purchases.

CeRBiM also receives funding from :

- Organizations that support research projects for which it provides the desired services on biological resources.
- Industrial developers
- Specific calls for projects (e.g. national cohort) to which it responds,
- By invoicing services rendered.

Since 2020, CeRBiM has included the study of the costs of operating, managing and providing biological resources, as well as services provided for research purposes, in its practices.

Newly accepted projects must therefore take this pricing system into account. The financial conditions are set out in the contract signed between the CRB and the interested party.

7. QUALITY POLICY AND STRATEGY

CeRBiM's Quality Policy is :

- Written by the Coordinator and the Quality Manager
- Approved by CHUM management (Direction Générale et de la Recherche)
- Reviewed at least once a year.

CeRBiM's quality policy aims to meet the following objectives:

- Maintain and improve the Quality Management System
- Improving the quality and efficiency of biological resource management
- Satisfy the needs and expectations of interested parties while complying with legal and regulatory requirements
- Improve organization and work tools

8. DOCUMENTATION SYSTEM

CeRBiM's activities and quality policy are supported by documentation that ensures the availability of the information needed to carry out its activities.

Where necessary, procedures describe all or part of the processes presented in this Quality Manual. Protocols and operating procedures describe how activities are carried out. Finally, proof of activities performed or results obtained is provided by quality records.

☐ **CeRBiM's document system is gradually integrating electronic document management.**

9. HOW CERBIM WORKS

CeRBiM has a dual management structure, one at strategic level and the other at operational level.

- Strategic level: CHU Martinique's management, via the Research Department, is responsible for validating the organization's development policy and promoting its overall strategy.

- Operational level: Operational management is responsible for running the facility. The structure's Medical and Scientific Coordinator is in charge of routine operations, in liaison with the Laboratories Division.

Research Director

Its mission:

- Implementing the Research strategy
- Organizing collection declarations
- Position yourself as an interlocutor for interested parties

Medical and Scientific Coordinator

Its mission:

- Coordinate and organize CeRBiM's activities through staff meetings
- Prepare and distribute the annual project and annual activity report
- Internal and external communications
- Deploy the quality policy
- Validate quality documents
- Comply with current legislation

Quality

□Depuis 2015 a Clinical Research Associate (CRA) from the Clinical Research and Innovation Delegation, had the role of Quality Manager.
Since May 2023, CeRBiM's quality consultant, with support from the division's quality unit and CHUM's quality department, has been responsible for this mission.

Its mission:

- Ensure that the BRC's quality management system and objectives are implemented, maintained and improved.
- Report to management on the operation, effectiveness and appropriateness of the quality management system, monitoring improvement actions and preparing the management review in conjunction with the medical and scientific coordinator and the quality consultant.

Regulatory Affairs

Is carried out by a DRCI agent

CeRBiM staff

CeRBiM staff are qualified and competent. Technical staff are only assigned to a research project after having received specialized training (internal or external), attained the appropriate level of training for the job and been judged competent by an assessment (habilitation).

Individual responsibilities are defined in job descriptions, and all staff are bound by professional secrecy.

All new staff are welcomed by the scientific and medical coordinator, the health executive and the Quality Manager.
The training program for all new arrivals is defined according to the tasks they perform. The entire team is actively involved in the training of new arrivals.

10. ORGANIZATION

The Quality Management System set up at CeRBiM enables all the processes presented in the process map to be controlled, so as to guarantee the quality of human biological resources and collections built up and used for research purposes.

11. PREMISES AND EQUIPMENT

They are dedicated to collections management activities and used for the research work of certain CHUM host teams.
Access to CeRBiM's conservation facilities is restricted to authorized personnel (access badge). The equipment and its maintenance meet the objectives of quality and safety for collections and staff.

The equipment required for CeRBiM's activities is selected and maintained in line with quality requirements.

The temperature of the refrigerated chambers and freezer rooms is monitored 24 hours a day by the centralized technical management system, enabling rapid intervention in the event of a technical fault. Temperature monitoring software continuously records the temperature of +4°C refrigerated chambers, -20°C, -80°C and -150°C freezers and technical rooms.

Refrigerated chambers and emergency freezers are kept empty to enable rapid sample transfer in the event of prolonged failure of one of the storage chambers.

12. SYSTEM COMPUTING FROM CRB AND TRACABILITY DATA TRACEABILITY

CeRBiM has a specific CRB database hosted, managed and backed up by CHUM's IT department.

An online service provided by the application supplier ensures after-sales support.

This database is protected in accordance with current safety and security standards (including servers and computers in a closed room, database access code, daily data backup).

The IT department defines a policy for the flow of medical data, and grants access authorizations to certain software (including DIAMIC). Access rules are set out in the IT charter.

The information collected on this database, was the subject of a CNIL declaration on 03/07/2009, under number 1368484, number kept to comply with the General Data Protection Regulation (RGPD) at CeRBiM.

Bodies - * Exceptional meetings can be scheduled to deal with an event or an issue.

	Composition	Frequency	Traceability	Roles and missions
Service meeting	• All Service personnel	Depending of on service de requirements	Minutes with list of attendees	It is used to disseminate useful information to all team members simultaneously and/or to deal collectively with issues of interest to participants, or with projects or developments impacting on CeRBiM's operations.
Quality meeting	• Quality Manager • Quality referent □ +/- Technical staff • Guest(s)	Depending of on service de requirements	Minutes with list of attendees	• Draft or revise the Quality documents required for CeRBiM's operations, in accordance with current standards. • Propose indicators f o r evaluating CeRBiM to the Quality Committee • Monitor the QMS
magazine fro m Managem ent (RDD)	• General Management represented by the Director of Research • CeRBiM Coordinator • CeRBiM Quality Manager • CeRBiM quality referent • Vice-President Research CHUM • Head of Laboratories • CHUM DQR representative • Representative of the Anatomy and Cytology Pathology Laboratory □ +/- Guest(s)	Annual	Report Attendance list	• Validate and enforce CeRBiM's Quality Policy • Provide the resources needed to deploy the quality policy • Liaise with the legal entity to ensure consistency of strategy with the supervisory authority • Monitoring the ethical rules applied at CeRBiM • Review the Quality Management System (QMS) • Ensure that the QMS is relevant, adequate and effective • Evaluate opportunities for improvement and modification of the QMS • Validate indicators • Validate investment choices
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□ **Board scientific**	• Non-fixed composition, Expert(s) in the field studied : •	According to fro m needs fro m requests	Report Attendance list	Guides and advises on visit questions order scientific, technique and/o r administrative and other.

13. MANAGEMENT OF BIOLOGICAL RESOURCES AND COLLECTIONS

Participation in the development of the research project

CeRBiM participates in the implementation of research projects: thanks to its technical expertise, it can make proposals and study the feasibility of collections and other services required. The collection of human biological samples is carried out by CeRBiM after transmission and acceptance of a "collection" dossier. Other services are provided after submission and acceptance of a "service" file.
In both cases, contracts can be drawn up with the help of CHUM Clinical Research staff, stipulating the requirements and commitments of the parties involved.

Collection

CeRBiM can organize the logistical handling of your samples by collecting them from the laboratory sorting center or from the Pierre Zobda Quitman Hospital, in compliance with pre-analytical conditions.

Receiving samples

All samples arriving at CeRBiM are processed in accordance with the procedure.

On receipt, samples are checked to ensure compliance with the predefined requirements for each study. CeRBiM will notify you of any "non-conformities" found.

All samples are accompanied by a document containing all the information required to process the sample (date and time of sampling, sampling location, etc.).
In order not to compromise the quality of the biological resource, the BRC authorizes the receipt and preparation of the sample, right up to its conservation, despite the absence of informed consent. However, the biological resource created will be clearly identified in the BRC's sample management software as not having consent at the time of conservation. Under no circumstances will this biological resource be made available to a user, whatever the request, until consent has been signed.
Once informed consent has been received, the biological resource will be "requalified" in the sample management software as a biological resource with informed consent. In the event of non-consent by the patient, the resource will be destroyed.

Sample preparation

The preparation of biological samples collected by CeRBiM is organized according to preparation procedures specifically established in collaboration with the project sponsor.
If not specifically requested, samples are prepared in such a way as to meet the objectives of maintaining their quality over the long term, and packaged in such a way as to optimize their subsequent use.

Conservation of biological resources

Samples are stored in accordance with the predefined requirements for each type of protocol, and as a *minimum, in* such a way as to guarantee as far as possible the quality of the samples over the long term, to enable optimized use of the collections.

Collections are kept for at least the duration of the collection reservation period. Collections may only be retained after the research project has been completed if donors have consented to the banking of their duly anonymized biological samples and to their requalification for use in other research purposes.

Provision of biological resources or collections

Biological samples are made available by CeRBiM after submission and acceptance of a "collection availability" file.

The signature of the "biological collection release" file and the biological resource transfer contract, if applicable, are essential for the release.

In view of a request to make available a collection managed by CeRBiM :

- □Le CeRBiM requests authorization to make samples available from the Initiator of the collection and/or the person(s) competent in the field of expertise (scientific council). (only if the User is an individual other than the Initiator).
  This authorization takes the form of a written agreement or a provision agreement.
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- After a positive response to t h e previous step, CeRBiM transmits, under the same conditions compatible with their use, the samples and associated data it holds from the User, after ensuring that the donor's consent is appropriate for the intended use.

Tracking availability

CeRBiM collects the satisfaction of collection creators and users in order to improve the quality of its services. The value of collection management work is enhanced by monitoring the use of the biological resources made available and by bibliographic watch.

Publication acknowledgements

CeRBiM customers **undertake to** cite CeRBiM in all scientific publications arising from results obtained from biological material made available (transfers or services), as follows:

- In the "Materials and Methods" paragraph, it should be written that the samples were provided by the Centre de Ressources Biologiques de la Martinique (CeRBiM) CHU Martinique or
  "Human samples were obtained from the processing of biological samples by the Centre de Ressources Biologiques of Martinique *(CeRBiM), CHU Martinique, France*. BRIF number: **BB-0033-00099.**
- In the acknowledgements, the authors thank the Centre de Ressources Biologiques de Martinique (CeRBiM), CHU Martinique, for managing and making available the study patients' samples" or "*The authors acknowledge the Centre de Ressources Biologiques de Martinique (CeRBiM) CHU Martinique, France) for the managing of patients' samples".*
  BRIF number: **BB-0033-00099**.

Destruction of biological resources

At any time, at the request of the depositor or patient, a biological resource and/or collection may be destroyed.

14. OTHER SERVICES

Depending on the request and its capacity, CeRBiM can provide biology services (extraction and assay of nucleic acids, etc.) or services (loan of premises, equipment, etc.).