Charter

Martinique **Biological** Resource Centre

CeRBiM

CeRBiM is certified by Euro Quality System

Standard NF S 96-900
- 12 April 2017: Initial cycle
- 19 March 2020: renewal

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

EURO-QUALITY SYSTEM
ISO 20387
ISO 9001

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Company name: Centre Hospitalier Universitaire de Martinique
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CHARTER MANAGEMENT RULES

Review: The entire document is reviewed and, if necessary, updated annually by the Quality Advisor, for example during the management review, but it may also be amended following significant changes to the organisation or the introduction of new activities, or following recommendations made after an audit.

The document is managed by the Quality Coordinator.

The CHUM communications department is responsible for disseminating information on the website.

Pagination subject to change following integration into the DMS

1. PREAMBLE

The charter presenting the Martinique Biological Resource Centre (CeRBiM) of the Martinique University Hospital governs the relationship between CeRBiM and the people who use its services.
This is done in compliance with the ethical principles concerning the collection of elements of the human body and the legal and regulatory provisions governing the collection, processing and storage of said elements and associated information.
It provides a guarantee of transparency and a commitment to continuous quality improvement by setting out the ways in which CeRBiM is organised and how its collections are managed.

It's a 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 specialised structure that could 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 Tumour Library, integrated into the Pathological Anatomy Department, joined the Biotheque in January 2018, giving rise to the Martinique Biological Resource Centre Platform.
Within the Platform, the two units remain distinct, each maintaining 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)

CeRBiM has been certified to ISO 9001 and ISO 20387 standards since 29 March 2023.

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

2. REFERENCES, ABBREVIATIONS AND DEFINITIONS

a. References

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

Catalogue: documentary tool used to list available biological resources.

Biological Resource Centre (BRC): an organisation 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 biological materials assembled according to common characteristics, taken from individuals for the purpose of scientific research.

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

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

Depositor : Organisation to which the natural person carrying out, or under whose responsibility, the sampling in order to constitute or participate in the constitution of a collection which will 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 field of application and scope of the quality management system adopted by CeRBiM.

The perimeter represents the places where the BRC's activities covered by the QMS are carried out.

Biological materials: for the purposes of the BRC, biological materials are defined as 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: Generic term for biological samples and the data associated with them.

Collection coordinator: This is the collection's clinical coordinator, 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 CeRBiM's quality policy to be implemented.

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 Ministry of Higher Education and Research, concerning the activity of conserving and preparing elements of the human body for scientific purposes.

CeRBiM holds an **authorisation** from the Ministry of Higher Education and Research for the conservation and preparation of elements of the human body with a view to their transfer for scientific use for the Tumour Library and the Biolibrary.

Updates and monitoring are regularly carried out by a DRCI employee dedicated to this activity.

5. CERBIM'S MISSION

CeRBiM's main mission is to provide assistance to researchers wishing to set up bio-collections as part of a research project. Its activities consist of helping to set up the logistics involved in collecting samples in order to build up, transform, preserve and make available the biological resources it houses, while guaranteeing the subject's consent and/or information, compliance with regulations, protection of individuals, as well as the quality and traceability of biological samples.
To fulfil its missions and comply with good practice in its activities, CeRBiM applies a rigorous quality approach, complying with the following standards:

- ISO 9001: Quality management system - Requirements
- ISO 20387: Biotechnology - Biobanking - Requirements for biobanking

The Tumour Library ensures the conservation of tumour and/or healthy tissues collected as part of medical care for re-use in research or collected specifically for research purposes.
The Biothèque stores biological fluids collected as part of 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 :

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

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

New projects accepted must therefore take account of this pricing system. 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 (General Management and Research)
- Reviewed at least once a year.

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

- Maintaining and improving the Quality Management System
- Improving the quality and efficiency of the management of Biological Resources
- Satisfy the needs and expectations of interested parties while complying with legal and regulatory requirements
- Improving organisation and work tools

8. DOCUMENTARY SYSTEM

To carry out its activities and its quality policy, CeRBiM relies on documentation to ensure the availability of the information needed to carry out its activities.

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

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

9. HOW CERBIM WORKS

CeRBiM is managed by the Biology and Pathology Laboratory division.
It is responsible for :
- strategy, with the support of General Management
- operational monitoring by the Medical and Scientific Coordinator

Director of Research

Its mission is to ensure :
- the administrative side
- the financial aspect
- the regulatory aspect
- the scientific part

The Medical and Scientific Coordinator

Its mission:
- Implementing the Research strategy
- Coordinating and organising CeRBiM's activities by organising meetings with staff
- Prepare and distribute the annual project and annual activity report
- Internal and external communications
- Deploying the quality policy
- Validate quality documents
- Comply with current legislation

Quality

From 2015 to April 2023, a Clinical Research Associate (CRA) from the Clinical Research and Innovation Department was in charge of Quality.
Since May 2023, CeRBiM's quality consultant, with support from the division's quality unit and the CHUM's Quality Department, has been responsible for this task.

Its mission:

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

Regulatory Activity

Is carried out by a DRCI agent

CeRBiM staff

CeRBiM staff are qualified and competent. Technical staff are only assigned to a research project once they have received specialised training (internal or external), have attained the appropriate level of training for the job and have been assessed (accredited) as competent.

Everyone's responsibilities are set out 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 Coordinator.
The training programme 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. ORGANISATION

The Quality Management System set up at CeRBiM enables all the processes presented in the process map to be controlled in order 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 are used for the research work of certain CHUM host teams.
Access to CeRBiM's conservation premises is restricted to authorised personnel (access badge).
The equipment and its maintenance meet quality and safety objectives 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 the freezer rooms are monitored 24 hours a day by the Centralised Technical Management system to enable rapid intervention in the event of a technical fault. The temperature monitoring software continuously records the temperature of the +4°C refrigerated chambers, the -20°C, -80°C and -150°C freezers and the technical rooms.

Refrigerated chambers and emergency freezers are kept empty to allow samples to be transferred quickly in the event of a prolonged breakdown in one of the storage chambers.

12. CRB COMPUTER SYSTEM AND DATA TRACEABILITY

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

An online service provided by the application's supplier provides after-sales support.

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

The IT Department defines a policy for the flow of medical data and grants access authorisations 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, a 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
Department meeting	• All Service staff	Depending on service 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, projects or developments that have an impact on the operation of CeRBiM.
Meeting Quality	• Quality Coordinator • CeRBiM operational team • Person(s) invited	Depending on service requirements	Minutes with list of attendees	• Drafting or revising the Quality documents required for the operation of CeRBiM, in accordance with the standards in force. • Proposing indicators for evaluating CeRBiM to the Quality Committee • Monitoring the QMS
Management Review (RDD)	• Executive Management represented by the Director of Research • Coordinator of CeRBiM • CeRBiM operational team • CeRBiM Quality Coordinator • Vice-President Research CHUM • Head of Laboratories • Representative of the CHUM DQR • Representative of the Anatomy and Cytology Pathology Laboratory • +/- Person(s) invited	Annual	Report Attendance list	• Validate and enforce CeRBiM's Quality Policy • Provide the resources needed to roll out the quality policy • Liaise with the legal entity to ensure consistency of strategy with the supervisory authority • Monitoring the ethical rules applied at CeRBiM • Reviewing the Quality Management System (QMS) • Ensure that the QMS is relevant, adequate and effective • Evaluate opportunities for improving and modifying the QMS • Validating indicators • Validating investment choices
⊗ ***Scientific Advisory Board**	• Medical and scientific coordinator of CeRBiM • General management or representative • Expert(s) in the field concerned	Depending on service requirements	Report Attendance list	Provides guidance and advice on scientific, technical, administrative and other issues.
***Consulting services**	• Coordinator of CeRBiM • Expert(s) in the field studied	Depending on demand	Report Attendance list	Advises on scientific and technical issues

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 collection and other services required. The collection of human biological samples is carried out by CeRBiM after submission and acceptance of a "collection" dossier. Other services are provided after submission and acceptance of a "service" dossier.
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 organise the logistical handling of your samples by collecting them from the laboratory sorting centre or the Pierre Zobda Quitman Hospital department, in compliance with pre-analytical conditions.

Receipt of samples

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

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

All samples are accompanied by a document containing the information needed to process the sample (date and time of sampling, location of sampling, etc.).
In order not to compromise the quality of the biological resource, the BRC authorises 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 the 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. If the patient does not consent, the resource will be destroyed.

Preparation of samples

The preparation of biological samples collected by CeRBiM is organised according to preparation procedures specifically established in collaboration with the project leader.
If not specifically requested, the 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 optimise 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, in order to optimise the use of the collections.

Collections are kept for at least the period during which they are reserved. Collections may only be kept after the research project has been completed if the donors have consented to their duly anonymised biological samples being kept in the bank and requalified for use for other research purposes.

Provision of biological resources or collections

Biological samples are made available by CeRBiM after a "collection availability" application has been submitted and accepted.

The signature of the "provision of biological collections" file and of the biological resource transfer contract, where applicable, are essential for the provision of biological resources.

With a view to a request to make available a collection managed by CeRBiM :

- CeRBiM requests authorisation to make the samples available from the Initiator of the collection and/or the competent person(s) in the field of expertise (scientific council). (Only if the User is an individual other than the Initiator).
  This authorisation takes the form of a written agreement or a loan agreement.

- After a positive response to the previous stage, CeRBiM sends the samples and associated data it holds to the User under conditions compatible with their use, after ensuring that the donor's consent is appropriate for the intended use.

Monitoring availability

CeRBiM is responsible for collecting the satisfaction of the originators and users of the collections in order to improve the quality of its services. The work of managing the collections is enhanced by monitoring the use of the biological resources made available and by bibliographic monitoring.

Acknowledgements on publication

CeRBiM's clients **undertake** to cite CeRBiM in all scientific publications resulting from the results obtained from the biological material made available (transfers or provision of services), in the following manner:

- In the "Materials and Methods" paragraph, it should be written that the samples were made available 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 the management and provision of patient 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 the patient, a biological resource and/or a 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.).