THE BIOLOGICAL RESOURCES CENTER'S PLATEFORME OF REIMS GUIDELINE

(PF CRBs Reims)

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1. LEXICON ET DEFINITIONS

1.1. Lexicon

ANSM: National Agency for Medicines and Health Products Safety
CPP: Committee for the Protection of Persons
TCA: Champagne Ardenne Tumorothèque
CRB TCA: Biological Resources Center of Tumorothèque Champagne Ardenne of the CHU of Reims
CRB CHAR: Biological Resources Center of Champagne Ardenne
CRB *Toxoplasma*: Biological Resources Center *Toxoplasma*
PF CRBs Reims: Biological Resources Center's Platform of Reims
HAS: High Authority of Health
MTA: Material Transfer Agreement
OCDE: Organization for Economic Co-operation and Development
PI: Interested parties
PHRC: Hospital Clinical Research Project
BR: Biological Resources

1.2. Definitions

User: The User is the physical or legal entity whose research program requires the use of biological material stored at PF CRBs Reims. The User can be the Depositor, the physical person at the origin of the program or the scientific project requiring the constitution of a collection, or a different legal entity or physical person.

Collection: Collection of samples or biological materials with common characteristics and stored for a scientific research purpose.

Biological Resources (BR): Generic term for samples and associated data.

Interested Parties (IP): Term grouping together physical or legal persons having an interest in the functioning of PF CRBs Reims.

2. INTRODUCTION

The PF CRBs Reims administratively includes the 3 biobanks of the Territorial Biology Pole of the Reims University Hospital: the CRB TCA, the CRB CHAR and the CRB Toxoplasma.

CRB TCA history:

The collection of human tissue and cell samples began at the Anatomy and Pathological Cytology laboratory in Reims in 1976. A large number of samples were collected from then on, in frozen form or formalin fixed paraffin embedded blocks.

The creation of the Champagne Ardenne Tumorothèque (TCA) in 2005 structured a network; open to all health establishments in the Champagne Ardenne region.

The establishment of the CRB-TCA permitted to reach two objectives:

- Ensure the compliance of the collections with the CRB guideline and the HAS recommendations for the cryopreservation of human cells and tissues,
- Make available to research teams who present duly evaluated research projects, human biological resources whose quality and traceability were ensured according to the NF S96-900 standard.

CRB CHAR history:

The CRB CHAR was created to bring together, conserve and enhance the collections of biological samples, not yet included in a CRB, and thus provide support for scientific research. Its organization was based on a quality management system according to the NF S96-900 standard to ensure a continuous improvement process.

History CRB Toxoplasma:

The Toxoplasma Biological Resource Center (CRB) was created in 2002 to store strains of toxoplasma (Toxoplasma gondii) from human or animal toxoplasmosis under strict rules.
Its implementation benefited from a grant from the Ministry of Research following the call for proposals "Biological Resources Center 2002" launched jointly by the Ministry of Research, CNRS and IFREMER.
CRB Toxoplasma is certified according to standard NF S96-900.
The Toxoplasma CRB works thanks to a network of correspondents (ToxoBs) in France university hospitals, and is managed by the parasitology-mycology laboratory of Reims university hospital (Pr. I. Villena).

3. PURPOSE OF THE GUIDELINE

This guideline:

- Regulate the relationship between the PF CRBs Reims and its users.
- Recalls users the ethical principles, as well as the laws and regulations which govern the activities of the PF CRBs Reims.
- Inform on the functioning of the PF CRBs Reims, in particular on the provisions enabling users to access to the stored Biological Resources.

This document reflects the desire for transparency and continuous improvement of PF CRBs Reims in compliance with the regulations governing its activity.

4. PRESENTATION of the PF CRBs Reims

The PF CRBs Reims was created in 2020 by mutual agreement of the managers of the three biobanks of the Territorial Biology Pole of the Reims University Hospital (CRB TCA, CRB CHAR and CRB Toxoplasma). It is jointly managed by the scientific managers of the three CRBs.

The missions of PF CRBs Reims are:

- The reception, preparation and conservation of collections, resulting from treatment or research protocols, which can be used in biomedical and / or scientific research.
- The management of the data associated with the samples thereby creating exploitable biological resources for research purpose.
- The provision of biological resources for research projects duly accepted by the scientific board of the PF CRBs Reims.
- The promotion of biological resources by integrating national or international networks and by providing a catalog that can be consulted by users.

In order to guarantee a quality assurance process in accordance with good laboratory practices and bioethical laws, PF CRBs Reims meets the requirements of AFNOR ISO 9001 and ISO 20387 standards.

5. ETHICAL AND REGULATORY OBLIGATIONS OF THE PF CRBs Reims

The PF CRBs Reims ensures:

- Compliance with current laws, regulations and ethical rules regarding its activities
- That impartiality and integrity are an integral part of its quality management system and that the PF CRBs Reims is free from any commercial, financial and scientific influence.
- The anonymization of provided biological resources.
- Follows all relevant professional recommendations, especially those of Good Laboratory Practices.
- Compliance with the requirements of the ISO 9001 and ISO 20387 standards.

Similarly, the PF CRBs Reims asks Depositors and Users to comply with all legal obligations.

6. PROCEDURES

6.1. Establishment of a new collection / hosting of an existing collection

For establishing a new collection of biological samples, or to hosting an existing collection, a feasibility study is conducted by the PF CRBs Reims using the information provided by the depositor. This study takes into consideration the technical feasibility as well as the financial, human, regulatory and material resources to be implemented.

The scientific relevance of the request is evaluated by the scientific board of the PF CRBs Reims.
After obtaining the favorable opinion of the scientific board and completing the regulatory procedures (opinion of the CPP, necessary declarations and authorizations, etc.), a written agreement stipulating the rights and duties of each party is signed.

6.2. Conditions of acceptance of a Biological Resources in the PF CRBs Reims

To integrate an existing collection of the PF CRBs Reims, a BR must comply with the following conditions:

- Compliance with the relevant laws and regulations.
- Any depositor must have discussed his needs with the PF CRBs Reims and accepted the convention of the PF CRBs Reims.
- Presence of a consent form with patient agreement or at least a non-objection form from the patient for human BR.
- Absence of "major" non-compliance reported (a major NC means the NC significantly modifies the quality of the sample).
- Minimum data associated with samples.
- Signature of an agreement and / or a contract between the PF CRBs Reims and the CRB user.

6.3. Delivery of Biological Resources

Samples can only be delivered if:

- Human samples are associated with a consent form signed by the patient or at least a non-objection form from the patient.
- There are no major non-compliance reported on the BR.
- The project is approved by the majority of the scientific board members
- A material transfer agreement is established.

7. COMMITMENTS

The creation, deposit and delivery of a Biological Resource collection and / or the relative services are highly regulated.
Such activities can only be realized after a precise definition of the requirements, commitments, rights and duties of the interested parties which will be consigned in a contract. This guideline which is specifying these points may be appended to the contracts.

7.1. Biological resources user commitment

The depositor undertake to:

- Comply with the current legislation regarding the collection and use of biological samples for scientific research.
- Provide quality controlled Biological Resources, in terms of samples as well as associated data.
- Justify that the patients are duly informed by delivering to the PF CRBs Reims the informed consent form or at least a documented non-opposition.
- Inform the PF CRBs Reims in case of any withdrawal of refusal of patients to consent so samples already stored can be destroyed.
- Make all the useful elements in its possession available to the PF CRBs Reims which will enable it to collect, prepare, conserve and deliver the Biological Resources (samples and / or associated data) in the best conditions.

- Provide samples to PF CRBs Reims during its opening hours. Biological Resources arriving outside the opening hours can only be treated at the next reopening.
- Warn the PF CRBs Reims, in case the delivery of samples would be done in several stages, sufficiently in advance of the date of delivery. Likewise, he undertakes to inform PF CRBs Reims in advance of the sample withdrawal dates.
- Inform PF CRBs Reims in case of collection abandonment
- Mention the PF CRBs Reims in the "Materials and Methods" during any oral or written communication or in any other document recalling the use of Biological Resources provided by the PF CRBs Reims.
- Inform PF CRBs Reims of the results obtained and any publications resulting from the research undertaken.
- Respect contractual commitments, particularly financial commitments made with PF CRBs Reims.
- Not transfer secondarily the Biological Resources (samples and / or associated data) provided by the PF CRBs Reims, for any purpose other than the initial research as described in the Biological Resources request and validated by the scientific board.

7.2. PF CRBs Reims commitments

PF CRBs Reims agrees to:

- Respect the current legislation concerning management of biological resources and collections for scientific purposes. In particular, it undertakes to comply with ISO 9001 and ISO 20387 standards.
- Satisfy the requests of the interested parties.
- Collect BR under the best conditions of time and quality.
- Treat in confidence all information it obtains.
- Ensure each human sample, is linked to an informed consent form and is suitable for the intended use.
- Destroy any sample in the event of a patient's refusal or consent withdrawal.
- Notify any non-compliance occurring during the handling of Biological Resources.