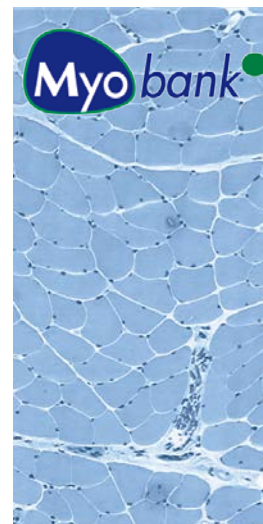




## **MYOBANK-AFM Institute of Myology**



# **CHARTER**

### **MYOBANK-AFM**

#### **Institute of Myology**

Common platform for biological resources

Pitié-Salpêtrière Hospital

47-83 Bd de l'Hôpital, 75013 PARIS

Tel: +331.42.17.74.63 / +331.42.17.75.06

Mobile: +3316.60.32.08.36 - Fax: 01.42.17.74.59

E-Mail: [myobank-afm@institut-myologie.org](mailto:myobank-afm@institut-myologie.org)

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## INTRODUCTION

The main objective of the French Association against Myopathies (AFM) is to promote the development and implementation of treatments for people with neuromuscular diseases.

To help researchers and advance knowledge, the AFM created a non-profit **Biological Resource Centre entitled MYOBANK-AFM** Institute of Myology. This biological resources centre is a department of the Institute of Myology (medico-scientific centre of expertise dedicated to muscle) intended<sup>[AIM5]</sup> for the exclusive use of research, in compliance with fundamental human rights.

MYOBANK-AFM aims to facilitate research in the field of neuromuscular diseases through its mission of collection, preparation, storage and provision of biological resources from patients (surgical waste) affected by these diseases. Its operation and objectives correspond to the definition of Biological Resource Centres and in accordance with current legislation.

MYOBANK-AFM is located at the Common Platform of Biological Resources of the site of the Pitié-Salpêtrière Hospital, within the framework of a convention of accommodation and operation of the Platform of Biological Resources (PRB) University Hospital Group APHP.6.

## ORGANIZATION

### I. MYOBANK-AFM ORGANIZATION

MYOBANK-AFM aims to facilitate research in the field of neuromuscular diseases through its actions for the collection and distribution of biological resources.

In this context, MYOBANK-AFM has received the following authorisations:

- Authorisation to conserve and prepare human biological resources. For scientific and medical research: the MYOBANK-AFM tissue bank obtained the authorization in December 2019 for five years, from the Ministry of Higher Education and Research

Positive opinion from the Protection of Individuals Committee (CPP) of Tours delivered in February 2019, for a 10-year research project aimed at collecting biological fluids in the context of care for research into neuromuscular diseases (NMD Biobanking project).

- Authorization for automated file management: to ensure full traceability of biological resources and management of collaborations, MYOBANK-AFM has developed a software specific to the activities of a biological resource centre. Use of this software was authorized after approval No 997078 of 2 February 1999 and amended on 16 September 2002 by the Commission Nationale de l'Informatique et des Libertés (CNIL)<sup>1</sup> (National Commission for Information Technology and Civil Liberties), particularly for the management of donor consent.

- Authorization for import and export of human tissues: regarding MYOBANK-AFM's activities with international networks, permission was granted by the Ministry of Health in 1997 to import and export human tissues and cells for scientific purposes<sup>2</sup>. This authorization was renewed in 2002, 2008, 2013 and 2018 for a period of 5 years.



- - MYOBANK-AFM is certified according to the NF-S 96-900 standard of the Biological Resource Centres (BRC) since August 2012. The certification is awarded by the certifying body for 3 years with annual follow-up audits.

<sup>1</sup> Law No. 2004-801 of 6 August 2004 relative to the protection of individuals with regard to the processing of personal data and amending Law No. 78-17 of 6 January 1978 on information technology, data files and civil liberties

<sup>2</sup> Article L 1245-5 of the Public Health Code.

Because of its specific activity, MYOBANK-AFM is now a service organized for the collection, storage and distribution of biological resources for scientific research.

Its organization enables MYOBANK-AFM to engage in numerous collaborations with practitioners to obtain the best quantity and quality of biological resources needed for each research subject. This centralized collection and the ability to store biological resources in optimal conditions allow appropriate responses to the demands of each research team, reducing as much as possible waiting times.

MYOBANK-AFM makes every effort to ensure that its assigned missions are carried out under the best conditions.

MYOBANK-AFM has established appropriate procedures and security measures:

- compliance with Good Laboratory Practice regulations
- compliance with validated protocols and a methodology of quality
- qualified personnel
- equipped premises
- appropriate, qualified and secured equipment
- implementation of controls and security systems
- traceability of biological resources

MYOBANK-AFM guarantees the safeguard of biological materials entrusted to its care:

- temperature safety
- fire safety
- protection against malicious acts
- data security<sup>[AIM6]</sup>

## 1. Validation of research projects and services

All requests for collection, storage, accommodation, provision of biological resources and services must be made in writing. The Scientific Committee of MYOBANK-AFM is asked to issue an opinion before the implementation of requests and services. Requests and services are evaluated according to the availability of biological resources, technical feasibility and the research project.

A response is transmitted electronically. If the response is positive, it confirms the request and validates the letter of agreement.

For any research subject requiring specific official approval, a copy of the authorisation granted by the competent official authorities is required (for example Committee for the Protection of Persons engaged in Biomedical Research or Ethics Committee).

## **2. Centralization of collaborations and participation in professional networks**

MYOBANK-AFM has a large number of collaborations within local hospitals in Ile-de-France (the district that includes Paris and Greater Paris), skilled in the treatment of neuromuscular diseases.

In addition, MYOBANK –AFM collaborates with the rest of the country. Those collaborations are essential thanks particularly to the presence of specialized neuromuscular diseases consultations.

Through this national network, and close collaborations with international networks, each researcher has access to a large biological resources collection, which facilitates potential collaborations. Each biological resources request can thus be treated in the best conditions in terms of quality and deadlines.

## **3. Scientific information**

Information about the Research Tissue Bank - MYOBANK-AFM, its objectives, its actions and its operation is distributed in different ways.

Thus, as a patients' association, the AFM, is in direct contact with patients, their families and doctors. Furthermore, because of its research actions, MYOBANK-AFM is in constant contact with researchers. These relationships are strengthened through meetings or seminars organised within the Institute of Myology.

In addition, the AFM has communication tools via which all MYOBANK-AFM partners are notified of its activities: members and AFM networks through VLM<sup>3</sup> and healthcare professionals through the Myoline<sup>4</sup> bulletin. Information about MYOBANK-AFM is also available on the following websites:

- The AFM (<http://www.afm-telethon.fr>),
- The Institute of Myology (<http://www.institut-myologie.org>),
- French network of Biological Resource Centres (<http://www.crbfrance.fr/>),
- European network of tissue banks (<http://www.eurobiobank.org>)

MYOBANK-AFM keeps abreast of the results obtained by researchers. It is in fact an obligation for researchers who have benefited from the support of the bank. Those regular contacts allow a better understanding of their demands, anticipation of their needs, or promotion of medico-scientific collaborations.

MYOBANK-AFM informs practitioners of the results obtained, thanks to their collaboration. This information to practitioners is done periodically by sending the most outstanding scientific publications or through the Institute of Myology's activity reports.

However, the rule of donor anonymity will never be broken, as the publications never associate a name with a scientific study.

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<sup>3</sup> VLM (Vaincre les Myopathies): the AFM's bimonthly journal for its members and networks.

<sup>4</sup> Myoline : the AFM's bimonthly bulletin on medical information about neuromuscular diseases

#### **4. Valorization Policy**

Research programs that require the use of biological resources collected by MYOBANK-AFM are carried out in partnership with or by public or private research laboratories. The results of these research programs can lead to publications in scientific journals or give rise to patent registrations.

It is also possible that biological resources lead to the development of biotechnology products, which may be distributed against payment, for scientific purposes, to public or private research teams. If financial benefits were generated by the the Association Institute of Myology through the use of these results, they would be entirely reinvested in funding for other research programs or be used to finance an association that promotes research, under the control of the Institute of Association Institute of Myology board of directors.

## **II. SERVICES PROVIDED BY THE MYOBANK-AFM OF THE INSTITUTE OF MYOLOGY**

### **1. Collection: collaborations with practitioners**

All biological resources are obtained with respect of the donor's rights and in accordance with the rules of medical ethics, as well as the current legislation (primacy of the individual, inviolability of the human body, consent, free access of the act, no advertising with the provisions of the GDPR...).

Several options are possible to collect the biological resources requested by the researchers. Those options must comply with the current legislation regarding biological resources and meet the desired quality:

- Collection of surgical exeresis intended for incineration (surgical waste)
- Use of excess biopsies made under diagnosis.
- Collection of biological fluid from samples previously of routine medical care

To obtain biological resources, MYOBANK-AFM collaborates with national and international networks with various practitioners. Each of these collaborations is organised so that the team collecting the biological resources does so under the best conditions. The patient is informed and signs an **informed consent** provided by the doctor. Experience shows that aninformed patient is highly motivated in participating actively in a research concerning his disease.

For each biological resources, a doctor completes an information sheet; these anonymous data allow the identification of the characteristics of the biological resource (age

and sex of the donor, pathology, tissue type, serological tests...), essential for its proper use. For each biological resource, the medical team must have appropriate protocols and MYOBANK-AFM supplies any packaging materials required (sterile flasks, transport medium, nitrogen, dry ice...).

Once the biological resources are obtained, they are quickly sent either directly to the research laboratory, or to MYOBANK-AFM.

The **transport** and packaging of these biological resources, considered as potentially infectious materials, are conducted according to European standards of Transportation Regulations for Dangerous Goods<sup>5</sup>. MYOBANK-AFM personnel assures transportation in Ile-de-France; other shipments are made by a company specialized in rapid transit and authorized to transport dangerous goods, according to the instructions of MYOBANK-AFM.

For its part, MYOBANK-AFM commits to collaborating practitioners:

- to respect their medical activity without interfering in their practice or the relations with their patients,
- to stop the collaboration upon request.

## **2. Establishment of a collection**

For research purposes, a special agreement may be established between MYOBANK-AFM and one or more of its partners, to develop a collection of biological resources from patients with a given rare disease. The collection of DNA can be made in conjunction with Genethon's DNA and cell bank.

The agreement will describe the details of the collection (partnership, implemented funding, logistics, biological resources preparation, conditions of accommodation, reservation and distribution of the collection). The collection is reserved for a priority period defined in the agreement.

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<sup>5</sup> ADR 1999: European Agreement concerning the International Carriage of Dangerous Goods by Road, decree of 17 December 1998 amended by decree of 25 April 2000.  
Decree of 29 May 2009 on the transport of dangerous goods by road



### 3. Preparation of biological resources

The obtained biological resources are prepared in a L2 laboratory within the BRP (Biological Resources Platform) to meet several objectives:

- “preparation”<sup>6</sup> of the biological resources,
- standardisation of their volumes,
- packaging of biological resources for conservation according to the wishes of the researchers.

Certain preparations or packaging are provided by:

- freezing in isopentane for morphological studies,
- direct freezing with liquid nitrogen for biochemical studies,
- slow-freezing
- preparation in a specific medium for the study of RNA (RNA Later<sup>®</sup>)
- preparation in a specific medium for electron microscopy,
- Specific centrifugation for serum-plasma fluids
- cryopreservation in a specific medium for future cell culture
- transport at 4°C in a specific medium for cell culture.

In addition, cell cultures of **myoblasts** and **fibroblasts** m be made in collaboration with MYOBANK-AFM partners, notably **Genethon** and the **Myoline** platform of the Center of research in Myology.

### 4. Storage of biological resources

MYOBANK-AFM is equipped with two storerooms: one grouping **nitrogen** tanks to store biological resources either in liquid nitrogen or in nitrogen vapour; the other contains **-80°C** freezers. Each storage apparatus is secured by an automated system connected 24/7 to a telephone alarm that monitors the temperature and nitrogen levels. An on-call system operates continuously and allows, if necessary, to correct detected errors.

All biological resources that are not immediately used by researchers are stored at MYOBANK-AFM. This storage activity allows the preservation of rare, unwanted, tissues. It also allows a quick distribution to researchers at a later date of the biological resources that they desire, under conditions that are as close to ideal as possible (same age range of the patient, same muscle...).

### 5. Accommodation of a collection

Due to its equipment and implemented procedures, MYOBANK-AFM can, under certain conditions specified in an agreement, accommodate **collections** of biological resources samples or **duplications** of collections in optimal safety conditions, pending their use for a research project.

<sup>6</sup>In diseases involving muscle atrophy, muscle is often replaced by fat and connective tissue. A muscle biological resources can thus contain more than 50% of non-muscle tissue, which introduces a significant contaminating factor in experiments. A preparation that eliminates unwanted tissue can therefore significantly increase the quality of the biological resources.

This potential service is conditioned by the technical possibility of carrying it out, especially in terms of storage volumes.

The contributor authorises MYOBANK-AFM to post on a website the existence of the collection (only the items “pathology”, “number of biological resources”, “head contact” are mentioned).

MYOBANK-AFM commits to reserve these collections on behalf of the contributor who requests accommodation for a priority period defined by the agreement. During this priority period, the contributor has exclusive access to the collection that gives him the right to oppose any third party access. If a third party asks to access the collection, MYOBANK-AFM agrees to inform the contributor and to refuse this request during the priority period, unless expressly authorised by the contributor.

## **6. Distribution of biological resources: collaborations with researchers**

Distribution is free of charge or made against payment, the conditions are governed by common and specific provisions.

### **6.1 Common provisions**

To benefit from the services of MYOBANK-AFM, research teams make a written request (“**application**”) explaining the need for biological resources in relation to their research theme. In addition to the nature of the biological resources requested, the storage and transport conditions required by the researcher and his team must also be mentioned.

Consideration of the demand and its priority are determined by the research theme, with those supported by the AFM being priority. If several teams need the same biological resource type, the distribution of tissues is based on a rotating waiting list or according to the priorities given by the scientific committee.

Each biological resource is shipped with an information sheet called “**distribution sheet**” indicating the elements necessary to identify the biological resource (age and sex of the patient, diagnosis, exact nature of the biological resources, packaging...). But no information identifying the patient is transferred.

To prevent any accident due to an infectious agent, MYOBANK-AFM endeavours to obtain, if possible, the results of screening tests for major infectious diseases, but cannot guarantee it. MYOBANK-AFM also informs each Principal Investigator of **potentially infectious** biological resources. The document “Information on the risk of infection - Some Health and Safety tips and recommendations”<sup>7</sup> for handling equipment with a non-zero risk of containing

infectious agents, is offered to all research teams that obtain biological resources via MYOBANK-AFM.

<sup>7</sup> This guide summarises the official texts on laboratory biosafety.

## 6.2 Free distribution

This distribution request is accompanied by a **signed agreement** by the researcher who agrees to:

- To respect the legislation applicable to the use of biological resources in the context of scientific research carried out,
- to use biological resources only for the scientific research outlined in my application,
- not to lend or transfer for the benefit of a third party the samples obtained by the MYOBANK-AFM of the Institute of Myology except with the agreement of MYOBANK-AFM,
- not to use the biological resources obtained or their derivatives for profit,
- to notify MYOBANK-AFM of the termination of the research project, organize the return of biological resources or their destruction at the request of MYOBANK-AFM,
- to inform MYOBANK-AFM of all publications made thanks to the use of biological resources made available and/or ceded by MYOBANK-AFM to mention MYOBANK-AFM of the Institute of Myology and the service providers involved if necessary in the acknowledgements of publications presenting results obtained thanks to the use of biological resources made available and/or ceded by MYOBANK-AFM of the Institute of Myology

## 6.3 Distribution against payment

Some biological resources may be distributed against payment for scientific research.

In this case, the biological resources distribution request is accompanied by an agreement binding the recipient notably to:

- Comply with the current legislation for the use of human biological samples as part of scientific research,
- use biological resources only for scientific research outlined in his application
- not lend or distribute to a third party the biological resources obtained by MYOBANK-AFM for any purposes other than for research, as outlined in the application,
- reimburse the costs incurred by MYOBANK-AFM and if necessary, pay the price of services carried out on the biological resources.
- notify MYOBANK-AFM when the research project ends
- identify MYOBANK-AFM Institute of Myology , in the acknowledgments of publications that present results obtained through the use of tissues distributed by MYOBANK-AFM and systematically inform MYOBANK-AFM of publications.