



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: 01.42.17.74.63 / 01.42.17.75.06
Mobile: 06.60.32.08.36 - Fax: 01.42.17.74.59
E-Mail: 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 treatment for people with neuromuscular diseases.

To help researchers and advance knowledge, the AFM created a non-profit **Research Tissue Bank (RTB) - MYOBANK-AFM**. This bank is a service of the Institute of Myology (medico-scientific centre of expertise dedicated to muscle) intended 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 distribution of tissue samples 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 set up within the Biological Resources Common Platform located on the site of the **Pitié-Salpêtrière Hospital in a partnership between patient organisations and l'Assistance publique – Hôpitaux de Paris (public hospital system of the city of Paris and its suburbs)**.

ORGANISATION

I. MYOBANK-AFM ORGANISATION

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

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

- Authorisation to conserve and prepare human tissues for scientific and medical research: the MYOBANK-AFM tissue bank obtained this authorisation in May 2014 for five years, from the Ministry of Higher Education and Research after approval by the Committee for the Protection of Persons of Pitié-Salpêtrière Hospital.
- Authorisation for automated file management: to ensure full traceability of biosamples and management of collaborations, MYOBANK-AFM has developed software specific to the activities of a biological resource centre. Use of this software was authorised after approval by the Commission nationale de l'informatique et des libertés (CNIL)¹ (National Commission for Information Technology and Civil Liberties), particularly for the management of donor consent.
- Authorisation for import and export of human tissues: because the MYOBANK-AFM is involved in international networks, permission was granted by the Ministry of Health in 1997 to import and export human tissues and cells for scientific purposes². This authorisation was renewed in 2002, 2008 and 2013 for a period of 5 years.



- MYOBANK-AFM is certified according to the standard NF S 96-900 of biological resources centers since August 2012.

Because of its specific activity, MYOBANK-AFM is now a service organised for the collection, storage and distribution of surgical waste for scientific research.

Its organisation enables MYOBANK-AFM to engage in numerous collaborations with practitioners to obtain the best quantity and quality of tissue needed for each research subject. This centralised collection and the ability to store biosamples in optimal conditions allow to respond appropriately 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.

¹Law 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

²Article L 1245-5 of the Public Health Code.

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 biosamples

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

- temperature safety
- fire safety
- protection against malicious acts
- data security

1. Validation of research projects

MYOBANK-AFM never scientifically evaluates research projects that are submitted for collection. Projects are evaluated in advance by one of the following procedures:

- either the project has been examined by an independent scientific council, whose members are well-known (the AFM's scientific council or other association),
- or the project has not yet been submitted to a scientific council, it is thus submitted for review to MYOBANK-AFM's scientific council.

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. Centralisation 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, its collaborations with the rest of the country are also important, thanks particularly to the presence of specialised consultations for neuromuscular diseases.

This national network, as well as quality collaborations with international networks, allows each researcher to benefit from a significant potential for collaborations. Each biosample request can thus be treated in the best conditions 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 can be notified of its activities: members and AFM networks via VLM³ and healthcare professionals through the Myoline⁴ 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. These regular contacts also allow to better meet their demands, to anticipate their needs, or to promote medico-scientific collaborations.

MYOBANK-AFM informs practitioners of the results obtained, thanks to their collaboration. This information to practitioners can be 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 to a scientific study.

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

⁴Myoline : the AFM's bimonthly bulletin on medical information about neuromuscular diseases

4. Valuation Policy

Research programs that require the use of biological samples collected by MYOBANK-AFM can be 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 biosamples 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 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 Myology's board of directors.

II. SERVICES PROVIDED BY THE TISSUE BANK - MYOBANK-AFM

1. Collection: collaborations with practitioners

All biosamples are obtained in compliance with the donor and according to the rules of medical ethics requirements, as well as the requirements of current legislation (primacy of the individual, inviolability of the human body, consent, free access of the act, no advertising ...).

To collect biosamples requested by researchers, several possibilities are possible according to the requirements in terms of tissues and desired conditions:

- collection of surgical exeresis intended for incineration (surgical waste)
- Use of excess biopsies made under diagnosis.

To obtain biosamples, MYOBANK-AFM works with national and international networks of collaborations with the various practitioners. Each of these collaborations is organised so that the team collecting the biosamples does so under the best conditions. The patient is informed and the doctor makes him sign an **informed consent**. Experience shows that the informed patient is highly motivated to participate actively in research concerning his disease.

For each biosample, an information sheet is completed by the doctor; these anonymous data allow to identify the characteristics of the tissue sample (age and sex of the donor, pathology, tissue type, serological tests...), essential for its proper use. For each biosample, the

medical team must have appropriate protocols and any packaging materials required (sterile flasks, transport medium, nitrogen, dry ice...), all supplied by MYOBANK-AFM.

Once the biosamples have been obtained, they are quickly sent either directly to the research laboratory, or MYOBANK-AFM.

The **transport** and packaging of these biosamples, considered as potentially infectious materials, are conducted according to European standards of Transportation Regulations for Dangerous Goods⁵. MYOBANK-AFM personnel assure transportation in Ile-de-France; other shipments are made by a company specialised in rapid transit and authorised 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 tissues 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, biosample preparation, conditions of accommodation, reservation and distribution of the collection). The collection is reserved for a priority period defined in the agreement.

⁵ADR 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 biosamples

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

- “preparation”⁶ of the tissues,
- standardisation of their volumes,
- packaging of biosamples 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[®])
- preparation in a specific medium for electron microscopy,
- cryopreservation in a specific medium for future cell culture
- transport at 4°C in a specific medium for cell culture.

Myoblast and fibroblast **cell cultures** can be carried out in collaboration with partners of MYOBANK-AFM, notably Genethon.

4. Storage of biosamples

MYOBANK-AFM is equipped with two storerooms: one grouping **nitrogen** tanks to store biosamples 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 biosamples 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 to quickly distribute to researchers at a later date, the tissue 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 tissue samples or **duplications** of collections in optimal safety conditions, pending their use for a research project.

⁶ In diseases involving muscle atrophy, muscle is often replaced by fat and connective tissue. A muscle biosample 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 biosamples.

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 biosamples”, “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 biosamples: collaborations with researchers

Distribution is free of charge or made against payment, the conditions being 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 human tissues in relation to their research theme. In addition to the nature of the tissue 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 biosample type, the distribution of tissues is based on a rotating waiting list or according to the priorities given by the scientific committee.

Each biosample is shipped with an information sheet called “**distribution sheet**” indicating the elements necessary to identify the biosample (age and sex of the patient, diagnosis, exact nature of the biosample, 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 this. It also informs each Principal Investigator of **potentially infectious** biosamples. The document “Information on the risk of infection - Some Health and Safety tips and recommendations”⁷ for

handling equipment with a non-zero risk of containing infectious agents, is offered to all research teams that obtain tissues via MYOBANK-AFM.

⁷ 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:

- comply with current legislation for the use of human biological samples as part of scientific research,
- use tissues only for scientific research outlined in his application
- not lend or distribute to a third party the biosamples obtained by MYOBANK-AFM for any purposes other than for research, as outlined in his application,
- not use tissues or their derivatives at a profit
- notify MYOBANK-AFM when the research project ends
- identify MYOBANK-AFM Institute of Myology with **the number BB-0033-0012**, 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.

6.3 Distribution against payment

Some biosamples may be distributed against payment for scientific research.

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

- comply with current legislation for the use of human biological samples as part of scientific research,
- use tissues only for scientific research outlined in his application
- not lend or distribute to a third party the biosamples obtained by MYOBANK-AFM for any purposes other than for research, as outlined in his application,
- reimburse the costs incurred by MYOBANK-AFM and if necessary, pay the price of services carried out on the biosamples.
- notify MYOBANK-AFM when the research project ends
- identify MYOBANK-AFM Institute of Myology with **the number BB-0033-0012**, 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.