

GOOD PRACTICE GUIDE

Global citizenship

Multiculturalism in Biomedical Research Observatory

La Fe Biobank

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INTRODUCTION

La Fe Biobank and the Inter-University Institute for Local Development (IIDL¹) of the University of Valencia, through the VLC-BIOMED 2022 grant programme, are launching the Multiculturalism in Biomedical Research Observatory with the aim of responding to future demands in biomedical research by overcoming ideological and cultural barriers, promoting the collection of biological samples from different cultural and social groups.

The foundations of the Observatory are based on the results of the **COLUMBIA** research project (2021-2024), which established the need to generate appropriate communication mechanisms so that healthcare staff can propose the donation of biological material for biomedical and translational research purposes to the entire hospital population.

This **Good Practice Guide** is the result of a research analysis carried out by both working teams, who have developed, agreed and approved the contents of the Guide. The Guide is presented as a resource that reflects the relevance of the donation of biological samples and the need to approach cultural diversity from the perspective of respect for differences, as well as the common interest behind the cohesion between both fields of research: biomedicine and social work that truly consider cultural diversity.

This Guide is addressed to the global citizenry as a whole with the aim of facilitating the relationship between the hospital system and the immigrant population. It may also be of interest to other institutions and public and private administrations that share the desire to try to improve the principle of public health and biomedical research, as well as to other social organisations, whether from the tertiary sector or cultural associations whose action is aimed at the immigrant population and/or the general public.

REASON FOR THE INITIATIVE

In the 1980s, the World Health Organisation (WHO) began to recognise the importance of the study of culture, and the first projects on cultural diversity in the health-disease process were developed to provide health

¹ Representation of the IIDL has been taken on by a team of social workers specialised in cultural diversity and socio-sanitary intervention.

care to ethnic minorities with different cultures and languages. Health organisations must therefore develop protocols and programmes according to the communities they serve. Cultural difference cannot be an obstacle and it is necessary to explain, with a view to people's idiosyncrasies: (1) **what biomedical research consists of**, (2) **what biobanks are**, (3) **how to participate and**, (4) **what benefits society expects from this participation**.

Likewise, generating value and wealth from cultural diversity through its inclusion is a challenge facing all organisations, regardless of their field of action. Particularly in healthcare and research, due to the moral and ethical responsibility to offer a universal health service.

The challenge for biobanks in translational research is to translate research findings into clinical practice and to reduce the time to actual implementation. The search for biomarkers for clinical use in diagnostics is a very active field, but few are able to demonstrate their clinical utility, due to the lack of representativeness and the way in which samples are collected. Despite the increase in ethnically and culturally diverse resident citizenship in recent decades, there is no data on cosmogony, beliefs or important traits that may be barriers to potential donation. Currently, 99% of the samples managed by La Fe Biobank correspond to individuals of Spanish nationality and Caucasian race.

This Guide is a proposal that tries to tackle this challenge from an emancipatory perspective of intercultural competences, overcoming subaltern assimilation, racialisation of differences and functional interculturality; and recognising:

- the structural racism experienced by migrants,
- their rights and,
- resistance strategies.

COLUMBIA

The fieldwork has been carried out with an interdisciplinary, multidisciplinary and intersectoral approach, involving all the sectors concerned.

1.0. 2021-2022

The first year of the project and the preparatory action revealed the existing inequality with regard to the participation of the people coming to the Valencia-La Fe Health Department, specifically for the donation of biological samples for biomedical research purposes to La Fe Biobank. This aspect was determined through quantitative and qualitative analysis of attendees and their socio-health needs. Some of the most noteworthy results were:

- Of the total percentage of people belonging to the Valencia-La Fe Health Department, only 7.9% have donated samples to the biobank.
- There are several reasons that hinder the process of donating biological samples for biomedical research purposes, the one that is most mentioned by health personnel being cultural differences.
- There is a general lack of knowledge about the mechanisms for the donation of biological samples, whether voluntary or as diagnostic surplus.
- The causes that sometimes lead to disease, and how these should be addressed, have genetic components directly related to race and epigenetic components related to lifestyle and cultural habits.

The results highlighted the need to create a solid structure of care and public service aimed at different cultural, social and religious groups with a multidisciplinary and inter-institutional approach and with collaboration between social workers and biomedical professionals.

2.0 2023-2024

The second phase of the project consisted of the design and implementation of an Observatory as a unit of social and health cohesion that addresses the cultural diversity and heterogeneity of society, based on the characteristics and needs of the population-

The project integrates different perspectives, giving added value to the project, in what is known as the quadruple helix of social innovation, which in this case would include: the La Fe Biobank, the Inter-University Institute

for Local Development (IIDL) of the University of Valencia, the Hospital Social Work Units, the associations of migrants in the Province of Valencia and the consulates.

The results of the research have provided significant scientific evidence that has served as the basis for the design of the core of the COLUMBIA Observatory. Some of these results are:

- The greatest difficulty faced by organisations when it comes to relating to the immigrant population is the existence of cultural and religious barriers. Disinformation, different priorities and/or the digital divide also stand out.
- The organisations consider that biomedical research and diversity in the collection of biological samples are necessary for the advancement of society, global health and social justice.
- There is a general lack of knowledge about the field of biomedical research. There is a willingness on the part of the organisations to acquire information and disseminate it, as they believe that knowledge is an empowering tool for raising awareness and encouraging citizen participation.
- The majority of the immigrant population served by the entities shows a significant level of precariousness and vulnerability. They express difficulties and barriers in accessing public health care, which is limited to basic needs and immediate care; even so, they consider it to be positive. This does not take into account participation in more complex areas, such as prevention or research.
- Hospitals in Valencia do not have an explicit cultural mediation service. This situation is managed by the Social Work Units, and in some cases, they are supported by external translation professionals, associations and consulates.
- There is no Internal Logistical Protocol at La Fe Hospital that establishes a common methodology for all professionals involved in the collection of biological samples for research.
- Most entities recommended:
 - That the resources activated should be accessible, in simple language and accompanied by images and testimonials.
 - Conducting a dissemination campaign to improve impact.
 - Conduct training and face-to-face workshops on the subject.
 - Translating documentation into classical Arabic, English and French.

Part 1. Approach to the health and scientific context

This first part defines the basic aspects of biomedical research and the process of donating biological samples, with the aim of bringing the health and scientific context closer to everyone.

What is biomedical research?

Biomedical research in health sciences is one of the key aspects in the definition of a public health policy that aims to improve the quality of life of citizens.

In order to achieve quality research, it is essential to have properly managed collections of biological samples, calling for different organisational models, an already important aspect that became a necessity with Law 14/2007, of 3 July, on Biomedical Research, and Royal Decree 1716/2011, of 18 November.

This regulation aims to comply with article 44.2 of the Spanish Constitution, which entrusts the public authorities with the promotion of science and scientific and technical research for the benefit of the general interest. At the international level, the UNESCO Declarations on the Human Genome, Human Rights and Bioethics encourage the development of biomedical research, always taking into account the principle of health, interest and well-being of people. And finally, the Barcelona Declaration in 2003 established a Patients' Decalogue, indicating the need for plural and reliable quality information, provided in an intelligible language adapted to the patients' capacity for understanding.

What are biobanks?

In biomedical research, biobanks are responsible for bringing together ethical, legal and technical criteria and providing policies for responsible use of biological material.

The Biomedical Research Act 14/2007 of 3 July 2007 defines a biobank as "a public or private, non-profit establishment that houses collections of biological samples designed for diagnostic or biomedical research purposes and organised as a technical unit with criteria of quality, order and intended use".

They advocate the need to standardise and control the collection, treatment, storage and use of biological material under optimal conditions, so that current and future research personnel have samples that meet pre-defined analytical objectives.

Part 2. Approach to an emancipatory model of diversity management.

Based on the health and scientific context described above, this second part proposes a model for managing multiculturalism from an emancipatory perspective. To this end, some of the keys in the communication process between health personnel and immigrants are presented, as well as the importance of putting them into practice in order to improve the level of participation of the population in biomedical research issues, and consequently global health.

What does the process of social and health care look like?

The management of biological samples of blood, tissue, faeces, urine, biological fluids or other types of material is for biomedical research purposes. These may be used for biomedical and translational research projects previously approved by external ethical and scientific committees that the biobank is subject to, and which will be responsible for ensuring proper handling. The results of these research projects may lead to the discovery of new methods for the better diagnosis, prognosis and treatment of diseases and/or disorders.

1. The healthcare professional must be aware of the features that must be present for a patient's biological samples to be of interest in biomedical research. It is therefore a procedure that must be initiated by the healthcare and/or scientific team, which must inform

and explain to the patient the procedure for donation and management of the biological material.

It is at this stage of communication that the professional can make use of the resources that the COLUMBIA Observatory has developed. Specifically, the information leaflet (Annex 2) and the audiovisual pill, both in the language best understood by the patient.

If, even so, there are still doubts as to whether the procedure is correctly understood, the Hospital Social Work Unit can be contacted, which will activate its own resources for the care of the migrant population.

2. Make available the "INFORMED CONSENT" document in the language of the patient and in a manner that is appropriate to the context in which the sample(s) was/were obtained.

Previously translated (classical Arabic, French and English) documents prepared to ensure correct understanding will be sent to the donor.

3. Duly performed management of the biobank samples, consisting of:
 - i. Sending the biological material to the biobank's facilities for its appropriate processing by existing means (pneumatic tube, orderly service, etc.).
 - ii. Reception of biological material at the biobank facilities.
 - iii. Checklist validation of samples received and associated documentation.
 - iv. Identification and classification of biological material according to the collection using the minimum data questionnaires associated with the samples and designed in advance.

- v. Pseudonymisation process, in compliance with personal data protection regulations, through coding and labelling of all samples received.
- vi. Registration of the case and samples in the information management system designed for this purpose and available at the biobank.
- vii. Processing, handling and preservation of biological material.
- viii. Transfer of biological material in accordance with the precepts established in the Biomedical Research Act and Royal Decree 1716/2011.

What are the benefits of improving the level of participation?

Increasing the levels of citizen participation in the donation of biological samples will be a success for society as a whole, because it will mean:

- Improving accessibility and inclusion of the immigrant population in the public health system.
- Providing a case study of a model for managing cultural diversity that highlights its richness and opportunities.
- Having a diverse, meaningful and representative bank of biological samples available; improving availability.
- Being able to discover therapies, drugs, techniques, etc. that address the problems and/or risks facing all citizens, overcoming the borders between the countries of the North and the South.
- Jointly advancing human evolution by promoting biomedical research that improves global health.

ANNEX 1. DECLARATION

MANIFIESTO

PROYECTO COLUMBIA 2.0

La investigación biomédica es salud pública y el acceso a ella un derecho humano. La participación ciudadana como herramienta de transformación social. La diversidad cultural una oportunidad para la salud pública y la investigación.

Como sociedad se nos presenta el reto de crear y favorecer un sistema inclusivo en todas sus vertientes y contextos, debiendo conocer y reconocer los diferentes niveles de acceso y participación en la sanidad pública. La investigación científica, como parte inherente a ella, debe acercarse del mismo modo, y en la misma medida, a toda la ciudadanía, independiente de cualquier condición, contemplando la diversidad cultural. Solo así, seremos capaces de generar y avanzar en conocimientos presentes y futuros para la sociedad mundial.

La globalización alcanza al ámbito de la salud. Por ello, debemos trabajar en hacer una investigación biomédica global y de calidad, asumiendo las diferencias individuales y colectivas.

Aprovechando el contexto científico y las oportunidades de avance y progreso que nos brinda, MANIFESTAMOS que:

- *Las entidades implicadas creen en la necesidad social de disponer de muestras biológicas de calidad diversas y representativas de toda la población.*
- *La administración pública, empresas privadas y organizaciones sociales tienen un papel protagonista en la promoción de la participación de la población migrante y el equilibrio social.*
- *La educación y sensibilización son elementos fundamentales para fomentar el acceso y la participación de la ciudadanía en investigación.*
- *Difundir esta iniciativa genera valor y reconocimiento social.*



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APPENDIX 2. PATIENT LEAFLET

1. What is biomedical research?

Scientific research aimed at obtaining knowledge, innovating and proposing solutions for the health of society with the development of efficient treatments for pathologies and/or their prevention.

For more information:

[BOE-A-2007-12945 Law 14/2007, of 3 July, on Biomedical Research.](#)

[BOE-A-2011-18919 Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organisation of the National Register of Biobanks for biomedical research.](#)

2. What are biobanks?

Biobanks are the units that are responsible for and regulate the use of biological material for biomedical and translational research purposes.

They advocate the need to standardise and control the collection, treatment, storage and use of biological material under optimal conditions, so that current and future research personnel have samples that meet pre-defined analytical objectives.

3. What does voluntary donation of biological samples mean?

In order to achieve quality research where the results can be transferred to the public, it is essential to have properly managed collections of biological samples that are representative of the entire population. Thus, anyone can participate in research by donating samples obtained during a healthcare process.

Voluntary donation

This is a form of donation that involves, on the part of the persons who donate, a voluntary, anonymous gesture without expecting financial compensation or any other material benefit. Your samples or those of the person you represent will not be sold or distributed to third parties for commercial purposes.

Biological sample

"Any biological material of human origin that can be conserved and that may contain information on the characteristic genetic endowment of a person" (*Law 14/2007*).

4. What does it mean to be a donor of biological samples?

Being a donor of biological sample(s) is a free, voluntary and informed decision that is expressed through the informed consent document.

There are important benefits to participation:

- Collaborate in biomedical research projects or complete diagnostic tests.
- Collaborate in the discovery of new methods for the better diagnosis, prognosis and treatment of diseases and/or disorders.
- Help other people and the health of the global citizenry in the future.

Informed consent

"Manifestation of free and conscious will validly expressed by a capable person, or by his/her authorised representative, having previously received adequate information" (*Law 14/2007*). At any time, you can withdraw your consent, without giving any explanation and without any consequences for the treatment received from the care centre.

If you have any questions that you would like to resolve, please contact:

- biobanco_lafe@iislafe.es