



## **INFORMATION FORM AND WRITTEN INFORMED CONSENT FORM**

### **ANDALUSIAN REGISTRY OF DONORS OF SAMPLES FOR BIOMEDICAL RESEARCH**

#### **DOCUMENT PROVIDING INFORMATION ABOUT JOINING THE ANDALUSIAN REGISTRY OF DONORS OF SAMPLES FOR BIOMEDICAL RESEARCH**

The purpose of this document is to give you the opportunity to grant your consent to form part of the Andalusian Registry of Donors of Samples for Biomedical Research (hereafter, the Registry), a body administered by the regional government Council with competencies in health matters. Your data will be stored in the Registry unless you request that they are removed. Joining the Registry means only that you agree to the storage of information about your health, lifestyle habits or disease/disorder, personal identification data, and contact information; it does not mean that you plan to donate biological samples at this time. If your cooperation is needed later because your data match the requirements of a request for biological samples for a specific project, you will be contacted and the nature of the research and the procedure for providing samples will be explained to you. At that time you will be able to decide whether to donate samples, and whether to grant your consent for samples to be obtained and for them to be used later for research purposes.

#### **WHAT IS THE REGISTRY?**

Approximately half of all biomedical research projects need biological samples, that is, any biological material of human origin that can be stored and that may contain information about the genetic make-up that characterizes a given person. Biological samples for research purposes are stored in biobanks and research collections. Donors provide their samples after providing their express consent, and the samples are provided to research projects that request them, as long as the project meets all scientific and ethical quality criteria. A biobank is a public, not-for-profit institution operating as a technical unit that meets appropriate criteria for quality, organization and purpose, and which hosts collections of biological samples so that they can be made available to biomedical research projects. The source of the samples is through voluntary donation by citizens. When samples are donated to a biobank, they are stored there and provided to research projects until the entire sample has been used. Human samples are an excellent tool for research in the prevention, course, and treatment of many diseases, or simply to improve citizens' quality of life.

The SSPA Biobank is an initiative of the Andalusian Regional Health Council (Consejería de Salud) as authorized under Decree 1/2013 of 8 January) (Decreto 1/2013, de 8 de enero). It was created as part of the strategy of the Andalusian Regional Government aimed at fulfilling its commitment to promote biomedical research, to protect the rights of citizens and donors of blood, tissues, or biological samples that are used for therapeutic procedures and in research, and to protect the rights of patients who may benefit thereby.

Although the Biobank is an excellent source of samples, it is still unable to meet approximately one third of all requests from projects that need human materials for research purposes. This is because the type of sample required by the investigator is not always available.

There exists an increasing need to respond effectively to the social desire to donate samples and data, as expressed by healthy individuals, those with diseases or disorders, patient advocacy associations, and volunteer associations, among others. Members of society wish to collaborate on a personal level with scientific advances, within the pertinent framework that ensures the protection



of the rights of individual donors. Accordingly, the regional government Council with competencies in health matters has established the Andalusian Registry of Donors of Samples for Biomedical Research. The creation of this Registry was promulgated through Order of 15 June 2015 (Orden de 15 de junio de 2015), establishing the creation, within the Council of Equality, Health, and Social Policy (Consejería de Igualdad, Salud y Políticas Sociales), of the registry of personal data designated “Donors of Samples for Biomedical Research in Andalusia”.

If you join the Registry, this means that you agree to the storage of information about your health, lifestyle habits, or disease or disorder. You will also be required to provide personal identification data and contact information, so that the Registry can contact you and so that authorized users of the Registry can access information stored in your Medical Record. This is the process that the Registry will follow any time a researcher requests samples and information about donors and their characteristics. If your characteristics match the requirements requested by the researcher, the Registry will contact you to ask you if you wish to donate your samples and data for research.

This Information Form is intended to give you information about what the Andalusian Registry of Donors of Samples for Biomedical Research is and how it operates, and to help you decide whether you wish to join the Registry. Please ask the staff member to explain anything that you do not understand. Take as much time as you need to decide whether you wish to join the Registry. If you have further questions or would like to receive additional information, please contact the Andalusian Registry of Donors of Samples for Biomedical Research by email at [registro.donantes.csalud@juntadeandalucia.es](mailto:registro.donantes.csalud@juntadeandalucia.es), by telephone at 958 894 672, or by postal mail at Andalusian Public Health System Biobank, Parque Tecnológico Ciencias de la Salud, Centro de Investigación Biomédica, Avda. del Conocimiento s/n, 18016 Granada, Spain.

If your collaboration is requested for a specific project, although the information obtained in the course of the research may not benefit you directly, you will have contributed to advances in knowledge about health and illness, and this will represent an indisputable benefit to society.

Joining the Registry and subsequently providing samples, if you choose to donate, are in themselves devoid of economic incentives, and no donations will be made for the purpose of obtaining profit.

Joining the Registry is a voluntary and disinterested act; in accordance with legislation and regulations currently in effect, you will have no rights whatsoever regarding the results that may arise from the research that may be carried out.

## **1. Possible subsequent contact**

When you join the Registry, the only data that will be stored are your identifying data and contact information, and a minimal set of data about your health status and lifestyle habits.

It may be necessary to contact you later in order to obtain or update some data. This is because in order to determine whether your samples and data may be useful for a specific research project, updated information is needed about your health or disease or disorder. If you consider it appropriate, you can update at any time the data you provided to us. When the Registry contacts you to check whether you meet all donor requirements in a researcher’s request, the data in your record will be updated.



Data may be needed about your health from the information systems of the Andalusian Public Health System (hereafter, SSPA). When you join the Registry, you authorize the staff member of the SSPA Biobank who is responsible for handling your record to obtain access to and consult these data. The SSPA Biobank will establish a system to ensure the oversight and traceability of access through previous authorization and access registries, under the responsibility of the Director of the network node through which access to your record is requested.

If you are identified as a candidate for sample donation for a research project on the basis of data available in the Registry, you will be contacted again to obtain your authorization to provide samples to the SSPA Biobank. You can accept or decline this invitation to provide samples, and your decision will not affect your status as a donor in the Registry. All biological samples and associated clinical or health data will be used in accordance with the contents of Law 14/2007 of 3 July, on Biomedical Research (Ley 14/2007, de 3 de julio, de Investigación biomédica).

### **1.1. Data protection and confidentiality of information**

Your identifying data and contact information, and your associated clinical or healthcare information, will remain confidential and will be used in compliance with the contents of EU General Data Protection Regulation 2016/679 (hereafter, GDPR), Organic Law 3/2018 of December 5, of Protection of Personal Data and guarantee of digital rights, and Law 14/2007 of 3 July, on Biomedical Research.

In compliance with the contents of articles 13 and 14 of the GDPR please be informed that:

- a) The personal data you provide to us will be used to manage the registry of sample donors, and will be stored for as long as necessary in order to comply with the stipulated legal obligations.
- b) The institution responsible for managing your personal data is the General Directorate for Research and Knowledge Management (Dirección General de Investigación y Gestión del Conocimiento) of the regional government Council with competencies in health matters, located at Avda. de la Innovación s/n, Edificio Arena 1, 41020 Seville, Spain.
- c) Your data will not be made available to third parties, unless there is a legal obligation to do so.
- d) The judicial basis for data handling policies is grounded on the consent you grant when you complete and sign this Informed Consent Form; without your express consent, compliance with the aims of the Registry as explained above would not be possible.
- e) You can contact the Delegate for Data Protection (Delegado de Protección de Datos) by email at: [dpd.csalud@juntadeandalucia.es](mailto:dpd.csalud@juntadeandalucia.es).

You can exercise your right to access, rectification, erasure, or portability of your data, and your right to restrict or deny permission for the processing of your data, via written request accompanied by a copy of your DNI or NIE, addressed to the General Secretary for Health Research, Development and Innovation (Secretaría General de Investigación, Desarrollo e Innovación en Salud) at Avda. de la Innovación s/n, Edificio Arena 1, 41020 Seville, Spain or by any of the means described in the following link (<https://www.sspa.juntadeandalucia.es/servicioandaluzdesalud/el-sas/protecciondedatos>), where you can expand the information on data protection.



## **1.2. Right to withdraw consent**

You may revoke or withdraw, at any time, the consent you granted. To do so, please contact the Registry to request that your data are removed.

## **1.3. Other considerations**

Once you have been informed about the points detailed above in the preceding sections of this document, if you decide to form part of the Andalusian Registry of Donors of Samples for Biomedical Research, you must sign the pertinent Informed Consent Form.



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**INFORMED CONSENT TO JOIN THE ANDALUSIAN REGISTRY OF DONORS OF SAMPLES FOR BIOMEDICAL RESEARCH**

DATA OF THE DONOR AND HIS/HER LEGAL REPRESENTATIVE (\*)

**Donor's surname(s) and first name:**

**DNI / NIE:** **NUHSA:**

**Legal representative's surname(s) and first name:**

**DNI / NIE:**

CONSENT GRANTED VIA ONLINE ACCESS TO THE REGISTRY WEBSITE  
 CONSENT GRANTED IN THE PRESENCE OF A STAFF MEMBER AUTHORIZED TO PROVIDE INFORMATION AND/OR REQUEST CONSENT  
 How did you find out about the Andalusian Registry of Donors of Research Samples?  
 Web page  Promotional events  External recommendations  Social networks / News  
 The following authorized staff member declares that information about the Andalusian Registry of Donors of Samples for Biomedical Research has been explained to the donor:  
**Surname(s) and first name:**  
**Date:** **Signature:**

As signatory (above) of this document, I solemnly declare that:

- I have read and understood the Information Form, and have been given a copy of this form.
  - I have received sufficient information about the Andalusian Registry of Donors of Samples for Biomedical Research.
  - I have had the opportunity to ask questions about the information provided to me, and to talk with the authorized staff member identified in this form, who has answered all my questions fully and satisfactorily.
  - I consent to the inclusion of my identifying data and contact information in the Andalusian Registry of Donors of Samples for Biomedical Research.
  - I consent to the inclusion of the set of data I have provided regarding my health status and disease or disorder in the Andalusian Registry of Donors of Samples for Biomedical Research.
  - I authorize the Registry to contact me at a later time, via the following contact information:  
 Phone  E-mail  Post mail  Any way
  - I consent to access to the clinical and health information contained in my Medical Record, for the purpose of determining whether I am eligible as a potential donor of samples for biomedical research.
  - I wish to set restrictions on the use of my data, as follows:
- 
- I am aware that I can revoke, at any time, my consent as granted in this document.

In _____, on _____ (date) _____ (month), _____ (year)	
DONOR	LEGAL REPRESENTATIVE (*)
Signature:	Signature:

(\*) Only in specific cases in which this signature is required. This applies to donors who are minors or who are incapacitated to grant consent, in accordance with applicable legal requirements and regulations currently in effect, e.g. Law 41/2002 of 14 November, Regulating Patient Autonomy, rights and obligations with regard to clinical information and documentation (Ley 41/2002 de Autonomía del Paciente, derechos y obligaciones en materia de información y documentación clínica)