Information form for donating biological samples and authorizing data access for a specific project managed by the Andalusian Public Health System Biobank, and for the subsequent use of surplus samples in other projects

1. Identification of the responsible investigator

The investigator responsible for this study is Dr. *(Provide given name and surnames)* _____ _____ *(Provide the researcher's affiliation, clinical unit and institution)*. If you need to contact the researcher, you may use this email address _____, this postal address _____, or this telephone number _____.

2. Information about the research

The samples that you are donating disinterestedly and without cost will be used in the project titled *(provide the title of the project, source of funding and call for applications if appropriate, and the duration of the project)*.

(Provide a brief description of the aims and characteristics of the project.)
_____
_____
_____
_____
_____
_____
_____
_____

The samples of *(Note the type of sample to be used, for example plasma, serum, etc.)* that you are donating voluntarily will be used to carry out this study. Below is a brief description of how each type of sample will be used:
_____
_____
_____
_____
_____
_____

This project will result in (*Describe the foreseen benefits*)
_____
_____
_____
_____

3. Risks and concerns for the participant

(Choose one or both options as appropriate.)

☐ The samples will be obtained during the procedure you will undergo or have undergone during your healthcare process, and in no case will interfere with your diagnosis and healthcare process, which will remain the first priority. In these cases there are no additional concerns arising from sample donation.

☐ The biological samples will be obtained expressly for this project.

(Note the possible risks or absence of risks arising from sample collection.)

4. Sample and/or data handling

The samples and/or data needed to achieve the aims of the project will be collected by the principal investigator, a member of the project team, or a staff member of the Andalusian Public Health System (Sistema Sanitario Público de Andalucía [SSPA]) Biobank who has been authorized by the principal investigator.

In compliance with the contents of EU General Data Protection Regulation 2016/679 and Organic Law 3/2018 on the Protection of Personal Data and Guarantees of Digital Rights (Ley Orgánica 3/2018 de Protección de Datos Personales y Garantías de los Derechos Digitales), please be aware that:

a) The person responsible for handling your data is the responsible investigator named in section 1 of this form.

b) Your signature on the informed consent form that accompanies this information form authorizes us to handle your personal data that is needed for the aims of the research project specified in section 2 of this form.

c) If you provide your authorization, access to your personal data will be provided to the Andalusian Public Health System Biobank.

d) You can exercise your right to access, correct, contest, or remove your data, and any other rights recognized by current regulations, and your right to withdraw your consent, by contacting the person responsible for your treatment.

You can obtain more information at http://www.juntadeandalucia.es/servicioandaluzdesalud/protecciondedatos, and can raise any questions regarding the protection of your personal data with the SSPA Delegate

for Data Protection (Delegado de Protección de Datos) at this email address: dpd.sspa@juntadeandalucia.es.

The security measures used to ensure your privacy and the confidentiality of your personal data, in accordance with the First Additional Provision of Organic Law 3/2018 (disposición adicional primera de la Ley Orgánica 3/2018), are those set forth in the National Security System (Esquema Nacional de Seguridad) or equivalent legislation.

In addition, the SSPA Biobank will record samples and their associated data in its information system in order to ensure full traceability and the quality of the samples and data for research purposes. The samples and/or data record will be coded (in which case they will be identified with a code designed to protect your identity) or anonymized (in which case any potentially identifying information will be permanently removed), in accordance with your preference as indicated in your informed consent form.

5. Participant's rights regarding the proposed research

You are providing your samples in a voluntary, disinterested manner at no cost. You will not receive, now or at any future time, any economic benefit from this donation, not even if this research eventually gives rise to possible commercial benefits derived from the discoveries that may result from this research.

Your participation is entirely voluntary, and you can refuse to allow your sample to be used in this project. Even if you confirm your participation, you can withdraw your consent at any time after you have provided it, without specifying your reasons.

Although you may not benefit directly from the information obtained in the course of research with your biological samples and associated information, you will have contributed to advances in medicine and knowledge about different diseases and disorders, and this will represent an indisputable benefit to society.

If your samples are not anonymized, you have the right to receive information relevant to your health that arises from the studies carried out for this project, if you indicate in your informed consent form that you wish to receive this information.

6. Handling of samples and data not used for the SSPA Biobank project

The SSPA Biobank is a public, not-for-profit body administered by the Health Council of the Andalusian Regional Government, which manages collections of biological samples and their associated information for the purposes of diagnosis, biomedical research, teaching, and quality assurance. These samples and data will be preserved in order to ensure their quality and traceability until your entire sample has been used, unless you request removal of your sample from the Biobank before that time.

Samples and data that are not used for this project may be transferred to other projects in the same research area or line of research as your disease or disorder, according to the classification used by the International Classification of Diseases (ICD-10):

_____ *(Note the appropriate chapter).*

In addition, because your samples may be useful for the study of other diseases and disorders, you can authorize the SSPA Biobank to transfer surplus samples and data to other projects in different research areas or lines of research. The areas or lines of research that you authorize will be specified in your informed consent form according to the classification used in the relevant chapter of the International Classification of Diseases (ICD-10) as detailed below:

- Certain infectious and parasitic diseases (A00-B99)
- Neoplasms (C00-D49)
- Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)
- Endocrine, nutritional and metabolic diseases (E00-E89)
- Mental, behavioral and neurodevelopmental disorders (F01-F99)
- Diseases of the nervous system (G00-G99)
- Diseases of the eye and adnexa (H00-H59)
- Diseases of the ear and mastoid process (H60-H95)
- Diseases of the circulatory system (I00-I99)
- Diseases of the respiratory system (J00-J99)
- Diseases of the digestive system (K00-K95)
- Diseases of the skin and subcutaneous tissue (L00-L99)
- Diseases of the musculoskeletal system and connective tissue (M00-M99)
- Diseases of the genitourinary system (N00-N99)
- Pregnancy, childbirth and the puerperium (O00-O9A)
- Certain conditions originating in the perinatal period (P00-P96)
- Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)
- Injury, poisoning and certain other consequences of external causes (S00-T88)

These projects will be accredited according to scientific criteria, will fulfil the legal requirements and ethical principals to which health research is subject, and will be authorized by the relevant bodies in compliance with current regulations. If your donated samples have not been anonymized, the Biobank will provide you with information about the research projects in which your samples are used.

In addition, you may authorize surplus samples to be used for teaching purposes (in health and biomedical training activities) or for evaluation and quality control activities (development and application of equipment and human resources, validation of new technologies and procedures intended to improve the health impacts of technologies). In these cases your samples will be anonymized before they are transferred and used for these purposes.

- **Possible subsequent contact**

It may be necessary to contact you again in order to obtain additional data or samples, or to give you information relevant for your health, unless you have requested anonymization of your samples.

- **Withdrawal of consent**

If your samples are not anonymized, you may at any time withdraw consent as granted in your signed informed consent form. Withdrawal may be complete or partial. For partial withdrawal, you may specify the cases for which you wish to withdraw your consent as detailed in section 2 of this form. In addition, you may request removal or anonymization of your biological samples. To do this, please contact the Biobank through the Andalusian Public Health System Network (Red del Sistema Sanitario Público de Andalucía). Address: Parque Tecnológico Ciencias de la Salud, Centro de Investigación Biomédica, Avda. del Conocimiento s/n, 18100 Armilla, Granada, Spain. Telephone: +34 958 894 672. Email: biobanco.sspa@juntadeandalucia.es.

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Informed consent for donating biological samples and/or authorizing data access for a specific project managed by the Andalusian Public Health System Biobank, and for the subsequent use of surplus samples in other projects

INFORMATION ABOUT THE DONOR AND (only in cases in which the donor is incapacitated) HIS OR HER LEGAL REPRESENTATIVE:

Donor's surname(s) and first name:

.....

DNI / NIE: .....

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

.....

DNI / NIE: .....

AUTHORIZED STAFF MEMBER RESPONSIBLE FOR PROVIDING INFORMATION AND/OR REQUESTING INFORMED CONSENT:

The following authorized staff member declares that information about donating biological samples has been explained to the donor:

Surname(s) and first name

.....

DNI / NIE: .....

CONSENT:

I, Mr/Mrs/Ms ..... declare that I have **read and understood the Information Form** provided with this Consent Form, and that I have been given a copy of the Information Form.

I have **received sufficient information** about the _____ (*title of the project*) study and about the Andalusian Public Health System Biobank, which is authorized to provide the samples and data for other related projects in the same line or area of research, ensuring full, constant compliance with legislation currently in effect.

(Indicate the line or area of research according to the appropriate ICD-10 chapter heading):

_____

I authorize the transfer of surplus samples and data for use in projects in the following lines or areas of research:

- ☐ Certain infectious and parasitic diseases (A00-B99)
- ☐ Neoplasms (C00-D49)
- ☐ Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)

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- ☐ Endocrine, nutritional and metabolic diseases (E00-E89)
- ☐ Mental, behavioral and neurodevelopmental disorders (F01-F99)
- ☐ Diseases of the nervous system (G00-G99)
- ☐ Diseases of the eye and adnexa (H00-H59)
- ☐ Diseases of the ear and mastoid process (H60-H95)
- ☐ Diseases of the circulatory system (I00-I99)
- ☐ Diseases of the respiratory system (J00-J99)
- ☐ Diseases of the digestive system (K00-K95)
- ☐ Diseases of the skin and subcutaneous tissue (L00-L99)
- ☐ Diseases of the musculoskeletal system and connective tissue (M00-M99)
- ☐ Diseases of the genitourinary system (N00-N99)
- ☐ Pregnancy, childbirth and the puerperium (O00-O9A)
- ☐ Certain conditions originating in the perinatal period (P00-P96)
- ☐ Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)
- ☐ Injury, poisoning and certain other consequences of external causes (S00-T88)

I also consent to the use of the samples for other purposes:

- ☐ Teaching
- ☐ Quality control

I have had the opportunity to ask questions about the information provided to me, and to talk with the authorized staff member identified in the Informed Consent Form, who has answered all my questions fully and satisfactorily.

I want my samples and their associated clinical data to be deposited in the Biobank in the following manner:

☐ **Coded** (They will be identified by a code that protects my identity, but will be traceable to me if necessary.)

or

☐ **Anonymized** (They will not be traceable to me because the digital information linking my identifying information to the samples and data will be permanently erased.)

I authorize the Biobank to **contact me later** (except if my samples have been anonymized):

☐ YES

☐ NO

If authorization is granted, I wish to be contacted by:

Telephone: (*indicate number*) .....

Email: (*indicate address*) .....

Other: (*indicate details*) .....

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I authorize the Biobank to send me information regarding genetic data and data relevant to my health. (I understand that if I have requested anonymization of my data, I will not be able to receive this information).

(*Indicate whether authorization is granted or not*):

☐ YES
☐ NO

I understand that I can withdraw from the study or withdraw my samples from the Andalusian Public Health Service Biobank:

- At any time
- Without specifying my reasons
- Without repercussions on my healthcare.

I am providing my consent freely to participate in the project specified above, and to permit my samples and data to be handled in accordance with the information provided to me.

In _____, on _____(date) _____(month), _____(year)

DONOR	LEGAL REPRESENTATIVE (only in cases in which the donor is incapacitated)
Signature:	Signature:

AUTHORIZED STAFF MEMBER
Signature:

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Junta de Andalucía
Consejería de Salud y Consumo
Biobanco del Sistema Sanitario Público de Andalucía

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Withdrawal or Modification of Consent for the use of biological samples and data in the research project or by the Andalusian Public Health System Biobank.

I, Mr/Mrs/Ms _____
hereby revoke informed consent granted in the document _____
(specify approximate date and/or procedure).

I request:

☐ **Anonymization of the biological samples and associated information:** Anonymization means I will not be able to receive any information relevant to my health that may arise from the research projects for which my samples are used.

☐ **Withdrawal of consent for the use of samples and data:** The samples and data (if they have not been used already) will not be eligible for use for the research project or by the Andalusian Public Health System Biobank.

☐ **Partial withdrawal of consent for use for teaching or quality control purposes if consent was previously granted:** This option allows continued use of the samples for research purposes, but not for future teaching or quality control purposes.

In _____, on _____ (date) _____ (month), _____ (year)

DONOR	LEGAL REPRESENTATIVE (only in cases in which the donor is incapacitated)
Signature:	Signature: