

GUIDELINES FOR WRITING THE INFORMATION SHEET FOR PARTICIPANTS AND THE INFORMED CONSENT FORM FOR RESEARCH INVOLVING INTERVENTIONS IN HUMAN SUBJECTS OR THE USE OF HUMAN SAMPLES OR DATA

INFORMATION SHEET FOR PARTICIPANTS

The information provided to study participants must comply with the requirements set forth in Spanish legislation on biomedical research and personal data protection:

- Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights.
- Law 41/2002 regulating patient autonomy and rights and obligations regarding clinical information and documentation.
- Law 14/2007 on biomedical research.

The information must be clear and understandable to the participant.

It should be given sufficiently in advance so that the person can reflect and decide freely, without feeling pressured.

The information sheet and informed consent must constitute a single document, with numbered pages.

CONTENT:

1. Identification of the principal researcher

- 1.1. Responsible
- 1.2. Centre
- 1.3. Department
- 1.4. Area of knowledge
- 1.5. Telephone number or contact details

2. Research data

- 2.1. Title
- 2.2. Location where the sample will be processed
- 2.3. Purpose of the research or line of research for which you consent
- 2.4. Expected benefits for participants
- 2.5. The study has received a favourable report from the Bioethics Committee of the University of Jaén.

3. Risks and Disadvantages for Participants

- 3.1. Brief description of the procedure for obtaining the sample or data.
- 3.2. Description of risks inherent in the process of obtaining the sample or data, if any.
- 3.3. Possible drawbacks associated with donating and obtaining the sample or data (if any), including the possibility of being contacted at a later date to collect new data or obtain new samples, for which you may be asked for information on how to do so. In any case, participants always have the right to refuse to participate in subsequent requests.
- 3.4. Scope and duration of proceedings

4. Participant rights in relation to the proposed research

- 4.1. Right to revoke consent and its effects, including the possibility of destroying or anonymising the sample, and that such effects shall not extend to data resulting from research that has already been carried out. In the case of students participating in an internship, they may also, for justified reasons, refuse to participate, in which case an alternative solution will be sought.
- 4.2. Possibility of contacting researchers in the event of an unexpected adverse effect.
- 4.3. Right to revoke consent at any time, without prejudice to your medical treatment.
- 4.4. Right to decide the fate of your samples and personal data should you decide to withdraw from the study.
- 4.5. Right to have your consent requested again if the sample or data is to be used in subsequent studies.
- 4.6. Insurance or other measures that exist to ensure adequate compensation in the event that the subject suffers any harm.
- 4.7. Guarantee of confidentiality of the information obtained, indicating the identity of the persons who will have access to the personal data of the source subject.
- 4.8. If the investigation involves genetic analysis: Right to know the purpose of the proposed tests.
 - 4.8.1. Right to know the confirmed individual and/or general genetic results obtained from the analysis of the donated samples and the known clinical implications thereof.
 - 4.8.2. Warning regarding the possibility that information relating to your health may be obtained from genetic analyses performed on your biological sample, as well as your right to take a position regarding its communication.
 - 4.8.3. Warning about the implications of the information that may be obtained for his family members and the advisability of him, where appropriate, passing on such information to them.
 - 4.8.4. Commitment to receive genetic counselling once the results of the analysis have been obtained and evaluated.

5. Information about the donated sample

- 5.1. Destination of the sample at the end of the investigation:
 - 5.1.1. Storage of samples/data: dissociation, anonymisation
 - 5.1.2. Destruction of the sample once the project is complete or incorporation into a sample collection or biobank for further research.
- 5.2. Use in other research or storage of the sample for possible future use (if these details are not known at the time, a commitment will be made to report on them as soon as they are known). In any case, this will also entail compliance with the requirements set out in Law 14/2007.

INFORMED CONSENT

Consent for the use of biological samples or data shall be given at the time of collection and specifically for a particular research project.

Specific consent may provide for the use of the sample or data for other lines of research related to the one initially proposed. If this is not the case, the source subject shall be asked to give new consent, if deemed appropriate.

Consent may be revoked, either completely or for specific purposes, at any time. When the revocation refers to any use of the sample, it shall be immediately destroyed, without prejudice to the preservation of the data resulting from research that has been carried out previously.

CONTENT:

Details of the study for which consent is being given

Principal researcher

Title of the project

Centre

Participant/patient details

Surname, First name and National Identity Card number

Person providing the information and consent form

Surname, First name, Date and Signature

1. I declare that I have read the Participant Information Sheet for the aforementioned study.
2. I have been given a copy of the Participant Information Sheet and a copy of this Informed Consent form, dated and signed. The characteristics and purpose of the study and the possible benefits and risks of the study have been explained to me.
3. I had the time and opportunity to ask questions and raise any concerns I had. All questions were answered to my complete satisfaction.
4. I have been assured that my data will remain confidential.
5. I give my consent voluntarily and understand that I am free to withdraw from the study at any time, for any reason, without this having any effect on my future medical treatment.

I GIVE
I DO NOT GIVE
My consent to participate in the proposed study

I GIVE
I DO NOT GIVE
My consent to the anonymisation of my samples

I GIVE
I DO NOT GIVE
My consent for the incorporation of samples into the Collection/Biobank (delete as appropriate).

.....
(specify the name of the responsible person or institution)

I sign in duplicate, keeping one copy for myself.

Date:

Signature of participant/patient

I hereby certify that I have explained the characteristics and purpose of the genetic study and its potential risks and benefits to the person whose name appears above. This person gives their consent by signing and dating this document.

Date

Signature of the researcher or person providing the information and consent form:

Before requesting a favourable report from the HREC at the University of Jaén, please note that:

1. The studies that require a favourable report from the Ethics Committee of the Province of Jaén, through the Andalusian Biomedical Research Ethics Portal, are as follows:

Studies conducted in public or private healthcare centres

Clinical trials with medicines

Clinical trials with medical devices

Other clinical trials

Observational studies with medicines

Observational studies with medical devices

If the research you are going to carry out is included in any of the above types, you must submit your application to: <https://www.juntadeandalucia.es/salud/portaldeetica/>

2. In the event that you are going to carry out research at the University of Jaén, but with patients from both public and private health centres, the request for a favourable report from this committee to endorse the procedures carried out at this University must be accompanied by the approval of the competent Ethics Committee in each case for the recruitment of participants at said health centre.