Requirements of the Information Sheet to Participants to Consent for research involving the generation of Induced Pluripotent Cells (iPS)

This document is not a form. It provides guidelines for the drafting of the Participant Information Sheet (PIS) and informed consent (IC) for research projects involving the generation of induced pluripotent cells (iPS). After signing the patient should receive a copy.

**Information Sheet for participants in research**

The information to be transmitted participants in research must comply with the requirements referred to in the Spanish legislation in the field of biomedical research and the protection of personal data:

- Law 15/1999 on Protection of Personal Data.
- Law 41/2002 regulating patient autonomy and rights and obligations of clinical information and documentation.
- Law 14/2007 on biomedical research

The information must be clear and understandable to the participant subject. It must be given sufficiently in advance to enable the person to think and decide freely without feeling pressured.

The PIS and the IC should be a single document with numbered pages

**CONTENTS:**

1. **Identification of the researcher in charge**
   1.1. Person responsible.
   1.2. Position.
   1.3. Centre.
   1.4. Unit.
   1.5. Phone or form of contact.

2. **Research Project data**
   2.1. Project title.
   2.2. Place where the sample will be processed.
   2.3. Purpose of research or line of research for which the participant gives consent.
   2.4. Expected benefits for the participant.
   2.5. The project has been authorized and has the favourable report of the Guarantees Commission for the Donation and Use of Human Cells and Tissues.
   2.6. If stable cell lines are derived, such lines shall be deposited in the National Stem Cell Bank.
3. **Risks and inconveniences for the participant**

3.1. Succinct description of the procedure for obtaining the sample.

3.2. Description of risks inherent to the procedure for obtaining the sample, if there are any.

3.3. Possible inconveniences linked to the donation and procurement of the sample (if any), including the possibility of being contacted later to collect new data or obtain new samples, so the participant may be asked information on how to do so. In any case, the patient always has the right to refuse to participate in subsequent requirements.

4. **Specific aspects of research with induced pluripotent cells (iPS)**

4.1. Temporal framework of samples and lines generated

- Use of the sample and/or line for a specific project and its subsequent destruction.
- Indefinite maintenance of the line.

4.2. In the event that long term maintenance of the line is proposed it will be ENSURED that the donated material or its derivatives will NEVER be used in procedures unauthorized by the Spanish legislation (e.g. cloning techniques or the generation of viable embryos)

4.3. The donor should also be aware of the future possibility of generating gametes (both sperm cells and oocytes) from iPS cells

4.4. In case of long term maintenance of the line, it will be recommended to proceed to anonymize it, informing the participant of the possible difficulties in exercising their rights otherwise:

- Difficulty to maintain traceability to the donor indefinitely in the lineage of a supposedly immortal cell line, while these cells continue retaining relevant genetic information for the source subject, their close relatives and their present and future descendants.
- Difficulty to revoke consent once cell lines have been generated.

5. **Participant’s rights in relation with the proposed research**

5.1. Right to revoke consent and its effects, including the possibility of destruction or anonymization of the sample (and its derivatives) and that these effects will not extend to the data resulting from the research that has been already carried out.

5.2. Right to decide the destiny of the sample (and its derivatives) and personal data in case of withdrawing from the study.

5.3. Right to impose restrictions to the future use of the samples (and its derivatives) and data.

5.4. Right to being asked permission (if desired) to use the sample in subsequent studies.

5.5. Right to receive information of the insurance or other legally existing measures to guarantee an adequate compensation in case the subject suffers any harm or injury by participating.

5.6. Right to know the guarantees for maintaining the confidentiality of the information obtained, indicating the identity of the people who will have access to the source subject’s personal data.
5.7. In case the research includes genetic analysis: Right to know what the proposed tests are for.
5.7.1. Right to know the confirmed individual and/or genetic results obtained from the analysis of the donated samples and the known clinical repercussions it may involve.
5.7.2. Warning on the possibility to obtain information related to the participant’s health, derived from the genetic analysis carried out on their biological sample, as well as their right to take a stand regarding its publication/communication.
5.7.3. Warning of the implication of the information that could be obtained for the participant’s relatives and the convenience of the participant –or someone designated by him/her- transmits this information to them or manages it.
5.7.4. Compromise to receive genetic counselling –if appropriate– once obtained and evaluated the test results.

6. Information about other possible uses of the donated sample or derivatives.
6.1. Destination of the sample at the end of research: destruction or permanent deposit, either as a collection or in an authorized biobank.
6.2. Samples in a ‘collection’ can only be used by the investigator who requested them and cannot be transferred to third parties or used in research projects outside the particular research line foreseen in the consent. For other uses, it will be required a new consent.
6.3. Samples stored in an authorized biobank can be used in any research, with possible restrictions the donor may want to include, and can be transferred to third parties to be used in research projects, only in a non-identifiable format.
6.4. All collections and Biobanks must be registered in the National Registry of Biobanks.
6.5. Information about the centre or institution where the collection or biobank is housed; the address, contact details so that the donor can exercise their rights of access, opposition, rectification and deletion of data, as well as the right to information.
6.6. Possibilities for future identifiability (management of the link between sample and personal data): dissociation o anonymization.

The responsibility for monitoring compliance with all points associated with the use and research with iPS will correspond to the Guarantees Commission for the Donation and Use of Human Cells and Tissues, whose protection the donor may address when any inconvenience, reasonable doubt or disagreement arises about the use of biological material derived from their tissues.

Guarantees Commission for the Donation and Use of Human Cells and Tissues (Comisión de Garantías para la Donación y Utilización de Células y Tejidos Humanos)
Subdirección General de Terapia Celular y Medicina Regenerativa
Instituto de Salud Carlos III
Monforte de Lemos 5, 28029 Madrid
Informed Consent

Consent about use of the biological sample will be given either in the act of sample collection or later, specifically for a particular research. Specific consent may stipulate the use of the sample for other research lines related to the one initially proposed. If this is not the case, it must be asked to the source subject to give, if deemed appropriate, a new consent. Consent can be revoked, totally or for certain purposes, at any time. When the revocation concerns any use of the sample (or derivatives) it shall be destroyed immediately, notwithstanding the retention of data resulting from research that had been previously done.

In the event that participants were minors or persons unable to consent it would be necessary to meet the requirements established by the Law 14/2007.

CONTENTS:

Data from the study for which consent is given
Lead researcher
Project title
Centre
Details of the participant / patient
Name
Person providing the information and consent form
Name

1. I declare that I have read the Participant Information Sheet on the study cited.
2. I have been given a copy of the Participant Information Sheet and a copy of this Informed Consent dated and signed. I have been explained the main features and objectives of the study and the potential benefits and risks of it.
3. I have had time and opportunity to ask questions and raise any doubts I had. All questions were answered to my complete satisfaction.
4. I have been assured the confidentiality of my data will be maintained.
5. I have been guaranteed that the donated material or its derivatives will NEVER be used in procedures unauthorized by the Spanish legislation.
6. I grant consent voluntarily and know that I am free to withdraw from the study at any time thereof, for any reason and without it having any effect on my future medical treatment.

☐ I GIVE
☒ I DO NOT GIVE
My consent for participation in the proposed study.

☐ I GIVE
☒ I DO NOT GIVE
My consent for the anonymization of my samples.

☐ I GIVE.
☒ I DO NOT GIVE
My consent for storing my samples in a ☐ biobank ☐ collection
I authorize the Director, after consultation and specific authorization by the research ethics committee, to examine my medical records in the future, to collect only those data considered relevant to the development of the corresponding study, according to the scope of the authorization of the committee:

☐ YES  ☐ NO

Signed in duplicate, keeping one copy

Date: 
Signature of participant / patient

I certify that I have explained the main features and objectives of the study and its potential risks and benefits to the person whose name is written above. This person consents through his dated signature on this document.

Date 
Signature of the Researcher or the person providing the information and the consent form: