

NATIONAL DNA BANK. SPAIN

DONOR CONSENT FORM FOR ANONYMIZED SAMPLES

Last name:
First Name: Date:

VOLUNTARY DONATION OF PERIPHERAL BLOOD FOR BIOMEDICAL RESEARCH

Justification:

For the effective advancement of biomedical research, it is necessary to study blood samples from donors in order to know the genetic information (DNA) of the Spanish population.

The National DNA Bank is a non-profit biobank with the aim of storing and providing to researchers human biological samples (blood, DNA, cells, plasma, urine...) along with their associated data for biomedical research purposes.

The storage of these samples and data in the Spanish DNA Bank will allow scientists to use this information in order to investigate: 1) human evolution, 2) what genes influence development or protection against certain diseases in the human population, 3) what diseases are influenced by the environment where the person lives, and 4) what genes influence the effectiveness/resistance to specific treatments.

All samples and personal data compiled or generated in the study will be protected according to current legislation. To that aim, we will use the measures stated below.

Description of the process:

- The donor will receive information about the objectives of the research project and all his/her questions will be answered.
- The donor will fill in a health questionnaire which will be codified to protect donor's identity. In this questionnaire, the donor will be asked about heredity, medical history and the environment where he lives and works.
 - o The data of the questionnaire will be filled in voluntarily.
 - o Not to answer the questionnaire (all or any particular question) does not bear any consequence for the donor.
 - o The donor will not receive any money or other benefit from the information he has provided in the questionnaire, other than the fact that this participation will indirectly serve the Spanish population as a consequence of the research studies in which this data is used.
 - o The information of the questionnaire will be stored in the data files of the Spanish DNA Bank software, after which the questionnaire will be destroyed.
 - o Data stored in the Spanish DNA Bank data file can be processed statistically for the scientific research purposes described below.

- Anonymized data will be provided to third party researchers exclusively for the scientific research purposes for which the donor has given his consent.
 - The donor will always have access to the stored data he has provided, and he has the right to rectify, cancel or object to the later use of his data through a request to the Hospital or Health Center where he filled in the questionnaire.
- Once the questionnaire has been filled in, a relatively small volume of blood (3 x 10 ml tubes) will be taken from the vein of the arm in order to isolate the blood cells and extract the DNA. There is hardly any side effect resulting from the blood donation, the most frequent being the appearance of small bruises in the zone of the needle-prick which disappear after one or two days.
- Blood extraction and the filling in and verification of the questionnaire will be made at the Hospital or Health Center. Blood samples and the questionnaire will be sent to the Spanish DNA Bank.
- Blood cells will be isolated from the blood samples and the DNA will be extracted, and plasma will be obtained. In addition, blood cells will be cultured so that an inexhaustible source of DNA of each individual can be obtained without having to undergo further blood extraction. Phenotypic data obtained (i.e. cholesterol, immunoglobulin, hepatic enzymes...) from the plasma will be incorporated into the data file of the Spanish DNA Bank.
- The products obtained from the blood samples will be stored and maintained in the installations of the Spanish DNA Bank for a minimum period of five years.
- Both data from the questionnaire and the products obtained from the blood samples may be used subsequently for Biomedical Research studies performed by other national or international groups, only if: 1) the projects are considered scientifically important, and 2) they fulfill all the requirements established by the Scientific External Committee and the External Ethical Committee of the Spanish DNA Bank.
- The Spanish DNA Bank guarantees that all information and samples collected will be anonymized, codifying them with a random code previously to be sent to researchers. So that the identity of the donor will be hidden from external researchers.
- Although the donor may find out for which research studies his sample and personal data has been used, he will not receive any personal result obtained in these studies. However, the Spanish DNA Bank will have a summary of the information obtained in each research project that will be available through the web (<http://www.bancoadn.org>).
- Likewise, the Spanish DNA Bank undertakes never to commercialize the samples nor the personal data obtained from them. However, the information resulting from the research studies performed with the samples could be the source of commercial profit. In that case mechanisms will be implemented to ensure that the profit will benefit the general health of the population, though not the individual donor.
- The donor has the right to demand the National DNA Bank, through the Hospital or Health Center, at any time and without any obligation to specify the reason, destroy all their samples and any information gathered from them that in this moment will be stored in the DNA Bank.
- All issues not anticipated in this document will be subject to the current legislation about biomedical research (Spanish Biomedical Research Law 14/2007, 3 July), about personal data protection (Spanish law 15/1999, 13 December) and any other applicable legislation.

DECLARATIONS AND SIGNATURE

Please, read this information carefully and, if you agree, sign it.

Declaration by the donor:

- I have been informed by the health professional named below:
 - That my participation in this project is completely voluntary.
 - Of the advantages and the disadvantages of the project.
 - Of the place of reception, storage and processing that my personal data and my samples will undergo.
 - Of the purpose for which my samples and personal data will be used (genetic, public health or statistical studies that fulfill all the requirements that the law, the External Committee on Ethics and the Scientific External Committee of the Spanish DNA Bank requires).
 - That my samples and personal data will be provided anonymously/randomly coded? to the researchers that work with them.
 - That at any time I can revoke my consent and demand the destruction of my personal data and my samples stored in the Spanish DNA Bank.
 - That at any time I can request general information about the studies for which the products of my blood samples have been used.
 - That I have right of access and correction to my personal data stored in the Spanish DNA Bank
 - That I will not have access to the specific results of those studies.
 - That I have understood the information received and have been able to ask any questions I felt appropriate.

I agree that the Regional Transfusion Center / Blood Bank/ Hospital or Health Center can contact me in the future if it is appropriate to add new data to those requested in the questionnaire.

Yes
No

Full name: Signature:

Declaration of the health professional who has informed the donor:

Full name: Signature:

WITHDRAWAL OF CONSENT

I,....., withdraw my consent to participate in the study, signed above, with the date of.....

Date of withdrawal of consent

Signature:
