

Informed consent - Pharmacogenetics

1 Patient

Informed consent is required for genetic testing. The patient (or parent or guardian in the case of minors under the age of 18 or adults lacking legal capacity) must sign the attached consent form. If the samples are anonymous, we will accept a statement from the physician responsible for the patient indicating that an appropriate informed consent has been obtained (section "Statement of the existence of informed consent").

Patient's full name

2 Pharmacogenetic test

Pharmacogenetic test pharmaHIC

The purpose of this test is to analyze the most commonly found genetic factors that have been related to **changes in the response to drugs**. These changes may involve an increase or a decrease in the effects of certain drugs, as well as in the predisposition to drug-related adverse reactions.

3 Patient authorization

I hereby declare that I have been informed of, understand, and agree to the type of genetic study indicated above and in which I am voluntarily participating.

I hereby consent to the submission of my sample to **Health in Code S.L.**, a company whose data protection level complies with European regulations, or to the center/s it designates, to conduct the indicated pharmacogenetic test, complying with the ethical and regulatory considerations currently in force:

Yes No

I understand that:

- **Any change concerning drug treatments must be done by a licensed physician.** Physicians are the only healthcare professional authorized to modify medication prescriptions. Pharmacists can dispense medication and provide advice about its use and effects.
- In addition to genetic factors, **other factors can influence the effects of drugs** on the body (e.g. age, medical conditions, other treatments, etc.). All these must be assessed before prescribing medication.
- **A negative test result does not rule out the possibility of an altered response to some drugs** (given that some drug effects have multiple causes and testing for all of them is not possible).
- Occasionally, there may be **unusual alterations in the DNA structure** of certain individuals that may yield **results that are difficult to interpret**, making the diagnosis difficult and even making it impossible to obtain conclusive results.
- Although the methods used to perform this diagnostic testing are extremely sensitive and specific, there is always **a small chance of failure of the technique or of an interpretation error**. For this reason, repeating the test or performing additional ones may be necessary in some cases, which may or may not require obtaining new samples, particularly in those cases where quality of the biological sample is suboptimal.
- Given the complexity of DNA-based genetic studies and the important implications of the results of genetic testing, **I will be informed of said results by a physician, pharmacist, or genetic expert** always maintaining utmost confidentiality from both the medical and laboratory personnel.
- **I may change my mind at any time** and withdraw my hereby given consent to genetic testing, thereby revoking my decision to continue with the analysis.
- The only people who will have access to the test results will be the members of the Health in Code team and the healthcare professionals involved in patient care.
- **Unexpected information** may be obtained during the sample analysis process, which I hereby declare that I wish to be informed about:

Yes No

The personal data provided in this form are subject to the current data protection regulations, specifically to EU Regulation 2016/679 of the European Parliament and of the Council, of 27 April 2016, and to Law 14/2007, of 3 July, on Biomedical Research. The data you provide will be included in files whose responsible is Health in Code. The purpose is the analysis and diagnosis of genetic diseases. Likewise, the data categories are the ones reflected in this form, along with the results obtained. Your personal data will be processed exclusively for the aforementioned purposes. This data processing is made legitimate by the express consent provided by accepting these terms. Your data will be retained for the whole duration of the relationship established with the entity and while the data fulfil their purposes for this service or until you decide to exercise your cancellation or suppression rights. Said data will not be transferred to third parties without a corresponding prior consent, or in cases other than those expressly defined in data protection legislation. You are hereby informed that you may exercise your rights to access, rectification, cancellation, and objection, as well as to restriction of data processing and to data portability by contacting Health in Code through written communication addressed to Edificio O Fortín, As Xubias, s/n., Campus de Oza, 15006 A Coruña, España, with the subject: "Data Protection", including a copy of your national ID card or passport. You also have the right to file your claim to the Spanish Data Protection Agency (Agencia Española de Protección de Datos).

- **Information concerning relatives** of the sample donor may be obtained; in this case, we recommend that the donor (or his/her legal representative) should be the person who shares said information. In any event, each relative must consent to being informed.

Current legislation mandates that **Health in Code S.L.** must store all clinical information under the required conditions to ensure its proper management and security for purposes of due patient care for at least five years after the completion of the assistance process. I understand and **consent to the storage of an aliquot of my DNA sample in the laboratory** laboratory for subsequent tests and/or confirmations:

Yes No

Additionally, I authorize the company Health in Code S.L. to **to use my biological sample for research purposes** approved by the relevant ethical committee, always maintaining patient anonymity, once the test has been completed.

Yes No

In which case, you will be informed about:

- The purpose of the research related to the pathology whose diagnosis is intended and to other related lines of research.
- The expected benefits of the research, which will consist of a greater understanding of the pathologies studied, their development, and population-based analyses.
- The possibility that you will be contacted later for the purposes of collecting new data or samples.
- Your right to revoke this consent at any time and without any justification whatsoever and to decide to have the sample destroyed or anonymized.
- Health in Code's obligation to destroy or anonymize the sample once the research has been completed and after the legally mandated storage period, unless authorization for longer storage has been given.
- Your right to know the genetic data obtained from the analysis of your biological samples.
- The confidentiality of the information obtained, with solely members of the Health in Code, S.L. research team having access to personal data.

If applicable, I hereby authorize the extraction of biological samples and the genetic study of the dependent minor/s in my care to be used under the above stated terms and conditions for the genetic test for the aforementioned disease.

Name of patient or legal representative*

**In the case of minor or incapacitated patients*

National ID number of the patient or legal representative

Signature of the patient or legal representative

Date

4 Statement of the existence of informed consent

- I hereby declare that the patient identified on this requisition form is aware of the information on said request and has signed the Informed Consent form to permit this genetic study to be carried out and that this has been included in his/her clinical record

Physician's signature

Date

The personal data provided in this form are subject to the current data protection regulations, specifically to EU Regulation 2016/679 of the European Parliament and of the Council, of 27 April 2016, and to Law 14/2007, of 3 July, on Biomedical Research. The data you provide will be included in files whose responsible is Health in Code. The purpose is the analysis and diagnosis of genetic diseases. Likewise, the data categories are the ones reflected in this form, along with the results obtained. Your personal data will be processed exclusively for the aforementioned purposes. This data processing is made legitimate by the express consent provided by accepting these terms. Your data will be retained for the whole duration of the relationship established with the entity and while the data fulfil their purposes for this service or until you decide to exercise your cancellation or suppression rights. Said data will not be transferred to third parties without a corresponding prior consent, or in cases other than those expressly defined in data protection legislation. You are hereby informed that you may exercise your rights to access, rectification, cancellation, and objection, as well as to restriction of data processing and to data portability by contacting Health in Code through written communication addressed to Edificio O Fortín, As Xubias, s/n., Campus de Oza, 15006 A Coruña, España, with the subject: "Data Protection", including a copy of your national ID card or passport. You also have the right to file your claim to the Spanish Data Protection Agency (Agencia Española de Protección de Datos).