INFORMED CONSENT FORM FOR STUDY PARTICIPATION AND PERSONAL DATA PROCESSING

Date: 01 September 2024

My name is Maria Beatriz Mourato, and I am a physician and researcher. Within the scope of the 2nd Edition of the PhD Program in Health Sciences and Technologies and Well-Being, of the National School of Public Health / NOVA Medical School / University of Évora, I am conducting a scientific study entitled:

“Multigene Germline Panel Test in Patients with Gastric Cancer in Portugal.”

This study will include patients who have or have had a diagnosis of gastric cancer and who have undergone a multigene germline panel test (MGPT). The MGPT is a test performed using a peripheral blood sample from a patient with a confirmed diagnosis of gastric cancer and allows simultaneous analysis of several genes to identify hereditary mutations included in the panel.

The main objective of this study is to quantify and characterize mutations associated with gastric cancer in the population of Alto Alentejo and relate them to clinical and prognostic factors, in order to improve knowledge of the disease and contribute to the development of new strategies aimed at improving gastric cancer prognosis.

The information required for this study will be collected through a data collection form completed by the principal investigator or your treating physician, as well as from your electronic medical records.

Participation in this study is voluntary and requires signing this Informed Consent Form.

Your data will be processed by the research team conducting the study, in compliance with the General Data Protection Regulation (GDPR) and Portuguese Law No. 58/2019 of August 8.

If you have any questions at any stage of the research process, you may contact the principal investigator, Beatriz Mourato, at +351 245301000 or via email at 2091@ulsaale.min-saude.pt.

After receiving oral information, the following written summary of the study characteristics is provided. Please read this information carefully. If you have any questions after reading, please contact the principal investigator using the contact details above.

1) Protocol and Description of the Process

Your participation will consist of providing responses to complete a questionnaire conducted by the principal investigator and authorizing the collection of selected data from your electronic medical records.

2) Objectives

The collected data will be used to analyze the prevalence and characteristics of hereditary mutations associated with gastric cancer in a Portuguese population with this condition and correlate them with clinical and prognostic factors.

3) Total Duration of Participation

Data will be collected retrospectively following performance of the multigene panel test. Your participation is considered ongoing until the completion of data analysis.

4) Benefits of Participation

You will not receive any direct benefit from participating in this study. However, this research may increase scientific knowledge about the genetic characteristics of gastric cancer and improve future clinical approaches.

5) Voluntary Participation

Your participation is entirely voluntary. Your decision to participate or not will not affect the medical care you receive. If you choose to participate, you may withdraw at any time without providing justification.

6) Compensation

Participation will not involve any costs for you. No monetary or other compensation will be provided.

7) Right to Refuse or Withdraw

Participation is entirely your choice. Whether you participate or not will not affect the quality of healthcare services you receive. If you choose to participate, you may withdraw at any time by informing the principal investigator.

8) Confidentiality and Personal Data Management

Your personal data will be processed by the research team. Authorized team members will have access to your digital medical record.

The personal data collected may include: age, sex, weight, height, comorbidities, date of diagnosis, histological type of gastric neoplasm, tumor location, stage at diagnosis and after each treatment phase, MGPT performance and results, surgical treatment (type and date), chemotherapy administration (regimens and cycles), presence of other neoplasms, family history of gastric and other cancers (including age at diagnosis), 12-month survival, and mortality.

Your personal data will be used for research purposes and may be made available for other scientifically relevant studies, subject to ethics committee approval.

Health data will be stored in an electronic database located on a hospital institutional server. All collected data will remain strictly confidential, stored in protected electronic systems, and pseudo-anonymized. The anonymization key will be kept in a restricted, password-protected database on the ULSAALE server.

Personal data will be retained for a maximum of 15 years.

As a data subject, you may request access to, rectification or deletion of your personal data, as well as restriction of or objection to data processing. You also have the right to lodge a complaint with the Portuguese Data Protection Authority (CNPD) if data protection is not ensured.

9) Contacts

For any future questions during or after the study, please contact the principal investigator:

Phone: +351 245301000

Email: 2091@ulsaale.min-saude.pt

Participant Declaration

☐ I received oral and written information about the objectives, procedures, and possible advantages and disadvantages of participating in this study.

☐ I have read and understood the informed consent.

☐ My questions have been fully answered.

☐ I received a copy of my signed informed consent.

☐ I had sufficient time to make my decision.

☐ I am aware of the conditions for processing my personal data.

I confirm, with my signature, that I agree to participate in this study.

Participant Name: _____

Signature: _____

Date: ___ / ___ / _____

Physician Declaration

☐ I provided the information contained in this consent form and ensured that the participant understood it.

☐ I gave the participant the opportunity to ask questions and answered them appropriately.

☐ The participant was not coerced and signed voluntarily.

☐ The participant received a signed copy of this consent form.

Physician Name: _____

Signature: _____