PATIENT INFORMATION SHEET

(Version 3.0, October 28, 2021)

PROJECT TITLE:

Clinical validation study of a CAD system with artificial intelligence algorithms for the early non-invasive detection of cutaneous melanoma in vivo

RESPONSIBLE CLINICAL INVESTIGATORS:

HOSPITAL UNIVERSITARIO CRUCES: Dr. Jesús Gardeazabal García

HOSPITAL UNIVERSITARIO BASURTO: Dra. Rosa María Izu Belloso

INTRODUCTION

We are reaching out to inform you about a clinical study in which you are invited to participate. Our sole intention is to provide you with the correct and sufficient information so that you can evaluate and decide whether or not you wish to participate in this study. Please read this information sheet carefully, and we will clarify any doubts that may arise after the explanation. Additionally, you may consult with anyone you consider appropriate.

We inform you that this study has been reviewed and approved by the Ethics Committee for Research with Medicines of Euskadi.

VOLUNTARY PARTICIPATION

You should know that your participation in this study is voluntary and that you may decide not to participate or change your mind and withdraw your consent at any time, without needing to provide any explanation or justification. This will not affect your relationship with your doctor or have any negative consequences for your treatment. None of these circumstances will influence the medical care you receive in the future.

GENERAL DESCRIPTION OF THE STUDY

The Spanish Society of Medical Oncology (SEOM) has estimated that the number of new cancer cases diagnosed in Spain in 2019 will increase by 12% compared to 2015. Among the various types of cancer, cutaneous melanoma is the type of skin cancer that has been increasing significantly in frequency over the past decades.

Early identification of malignancy in skin lesions is crucial for making an early diagnosis and increasing the cure rate. Many times, these lesions are evaluated by healthcare professionals who may not have the same level of experience as dermatologists.

This study aims to validate a tool that, after analysing a photo of a lesion taken with a mobile device, can estimate the risk that the lesion may have a malignant component.

For this reason, we need your participation in this study. A photograph of your lesion will be taken to assess the accuracy of the tool being developed. This photo will not be stored anywhere outside the Osakidetza databases. Along with the photo, some clinical data will be collected. Once the photograph is taken, your medical care will proceed as usual, as if you were not participating in the study.

When you visit the dermatology consultation for the evaluation of your skin lesion, your dermatologist will ask if you would like to participate in this study. Participation involves allowing the analysis of images of your lesion using a mobile application. Additionally, some of your clinical data will be collected during the consultation. You will not need to make extra hospital visits for this study.

The results obtained from the mobile application's diagnosis will be compared with your biopsy results to determine the accuracy of the application's diagnosis.

BENEFITS AND RISKS OF PARTICIPATION IN THE STUDY

It is possible that you may not directly benefit from participating in this study. However, your participation will contribute to improving the quality of clinical care by increasing knowledge about the studied condition and helping develop new strategies and therapies applicable to patients.

CONFIDENTIALITY

Your data will be processed by Osakidetza – Basque Health Service. You are also asked to provide consent for this research project in compliance with the requirements of the European Regulation 2016/679 on Data Protection and the Spanish Organic Law 3/2018, of December 5, on Personal Data Protection and Digital Rights Guarantee. No data will be shared with third parties unless legally required.

You are informed that you have the right to access, rectify, delete your data, and limit or object to its processing. You can find additional information on data protection at the following website: http://www.osakidetza.euskadi.eus/protecciondatos.

Based on the information provided above, your consent is requested for the processing of your data for the specified purposes. If you have any concerns, you may address them with the principal investigator of the study.

The data collected for the study will be identified using a code, and only your study doctor and collaborators will be able to link the data to you and your medical history. Your identity will not be revealed to anyone except in cases of medical emergencies or legal requirements.

No data will include directly identifiable information such as your name, initials, address, or social security number. The study results may be published in specialized journals without ever identifying the patients included in the study.

Access to your personal information will be restricted to the study doctor/collaborators, health authorities (Spanish Agency of Medicines and Medical Devices), the Clinical Research Ethics Committee, and authorized personnel from the sponsor when necessary to verify study data and procedures. However, confidentiality will always be maintained following current legislation.

FINANCIAL COMPENSATION

Please note that you will not receive any financial compensation for participating in the study.

If you have any questions or require any additional information, please do not hesitate to contact the responsible investigators using the phone numbers provided at the top of this document.

CONTACT

Dr. Jesús Gardeazabal García – Principal Investigator

DERMATOLOGY DEPARTMENT Hospital Universitario Cruces

Telephone: 94 600 6000 (6145)

Dr. Rosa María Izu Belloso – Principal Investigator

DERMATOLOGY DEPARTMENT Hospital Universtiario Basurto

Telephone: 94 400 6063

INFORMED CONSENT

(Version 1.0, November 30, 2019)

PROJECT TITLE:

Clinical validation study of a CAD system with artificial intelligence algorithms for the early non-invasive detection of cutaneous melanoma in vivo

PRINCIPAL INVESTIGATOR: Dr. Jesús Gardeazabal García

I, (Patient's Name and Surname) ..... with ID ..... declare that I have read the Patient Information Sheet, of which I have been given a copy. I have been informed about the study's characteristics, my rights, and the provisions regarding data processing. I have received sufficient information about the study.

I understand that my identity will remain confidential and that the information will be handled in a coded manner.

I am free to revoke my consent at any time and for any reason, without explaining, and without any negative impact on my current or future medical treatment.

I give my consent for my data to be used as part of this study. I voluntarily agree to participate.

Date:……
Patient's Signature……

I confirm that I have explained the study's characteristics and the data storage conditions that will be applied.

Name of the Investigator or Designated Person Providing Information:

Date:……
Investigator's Signature:……..