*Annex 3: Patient Information Sheet and Informed Consent*

**PATIENT INFORMATION SHEET AND INFORMED CONSENT**

**PATIENT INFORMATION SHEET**

**TITLE OF THE STUDY: HEALTH NEEDS AND UNDERHOUSING IN SETTLEMENTS OF GRAN CANARIA.**

Dear Sir,

Your nurse has asked you to participate in this study, now and in compliance with Law 41/2002 of November 14 "Basic regulation of patient autonomy and rights and obligations in terms of information and clinical documentation" we reiterate the explanation given verbally, now, in writing in order.

Before deciding whether you want to take part, it is important that you understand why this study is being conducted and what it means if you agree to participate.

Please read the following information carefully and, if there is something that is not clear or you want more information, do not forget to consult it, you can request the extension of information to the main researcher or his collaborators, or to your responsible doctor. We will give you all the time you need to decide whether or not to participate.

**IDENTIFICATION AND DESCRIPTION OF THE STUDY**

The study consists of analyzing the data obtained through a self-administered questionnaire.

**OBJECTIVE EXPECTED TO BE ACHIEVED**

Like you, all study participants will be explained the purpose of the study and asked to sign the informed consent contained in this protocol.

The purpose of this study is to determine the self-perceived health needs of the inhabitants in substandard housing in settlements of Gran Canaria.

Participation is entirely voluntary. You are in no way required to participate and, if you choose to do so, you may change your mind at any time. All aspects of this study, including the results, will be treated strictly confidentially.

**WHY HAS HE BEEN CHOSEN?**

You have been chosen because your age, place of residence and time of use of the same match the profile that we have determined for obtaining the research data.

**CONFIDENTIALITY:**

The right to privacy and confidentiality of all data relating to your health is guaranteed, both those obtained during the investigation, and those contained in your medical record, in the terms established in Law 3/2018 on the Protection of Personal Data and guarantee of digital rights and law 41/2002, basic regulation of patient autonomy and rights and obligations in terms of information and clinical documentation. Both the surveys and the results obtained will be listed as anonymous.

For the stated purpose, you will be identified with a code and the personal information in your files will not be distributed or transferred to third parties without your prior written consent. In this sense, **you will not be personally identified** in written publications or seminars in which the results of this study could be presented.

Monitors, auditors, clinical ethics committee and competent authorities shall have direct access to the subject's original medical record for the verification of the procedures and/or data of the clinical study/trial, without violating the confidentiality of the subject, within the limits of the relevant standard and that, by signing the informed consent form, the subject or his/her legal representative is authorizing access to this data.

**ETHICAL CONSIDERATIONS:**

This study will be carried out following the rules of good clinical practice, and its sole purpose is to determine the self-perceived health needs of the inhabitants in substandard housing in settlements of Gran Canaria. This means that, by participating in this study, you will not undergo any unnecessary procedures, and you will not stop receiving the necessary attention to treat your disease if you decide not to participate.

**EXPECTED DURATION OF INCLUSION IN THE STUDY:**

The study will last around 8 months, but your participation will be restricted at the time of data collection which will last less than 1 hour if there is no inconvenience.

**APPROXIMATE NUMBER AND CHARACTERISTICS OF PARTICIPANTS EXPECTED TO BE INCLUDED IN THE STUDY:**

46 people between 18 and 75 years of age will be selected, who have as their main domicile a house located in one of the settlements that meets the predetermined conditions at the time of data collection.

In addition, it will be necessary that the participants have resided continuously for a period equal to or greater than three months in the settlement, that this period of 3 months is immediately prior to the time of data collection and that the participants reside in the settlement indefinitely.

**QUESTIONS YOU MAY HAVE DURING AND AFTER YOUR PARTICIPATION IN THE STUDY:**

If you ever need an answer to any questions about this study, you can contact: Héctor Santana Ramos: [hsanramz@gobiernodecanarias.org](mailto:hsanramz@gobiernodecanarias.org)

**FINANCIAL COMPENSATION:**

This study has NO financial compensation.

**PATIENT INFORMED CONSENT**

I have read and understood the Patient Information Sheet. I have had the opportunity to discuss the issues related to this information. My questions and doubts have been satisfactorily answered.

I understand that my participation is voluntary and that I am free to leave the study at any time and without this being detrimental to my legal rights.

I understand that the anonymized data in other documents can be used, leaving the personal data out of them and will be treated with due reservation and confidentiality.

I authorize my reports to be accessed without personal information being disclosed.

I agree that the information regarding my participation in this study should be communicated to my specialist and GP upon request.

I have read the above information and agree to participate in the study.

**PARTICIPANT**

Name and surname: ......................................................................................................

Signature: Date:

**LEGAL REPRESENTATIVE**

Name and surname: ......................................................................................................

Signature of father, mother or legal guardian: Date:

**RESEARCHER**

Name and surname: Héctor Santana Ramos, Ana Rivas Muro and Alejandro Castillo Manteiga.

Signature: Date:

**REVOCATION OF PATIENT INFORMED CONSENT**

D/DÑA: ...................................................................................... of........ years of age domiciled in ...................................................................................... and D.N.I. nº .......................................................................................................................   
**I REVOKE** the consent given on the date ...................................................................................................... and I request the deletion of all personal data and samples that remain stored without any harm or loss of the health benefits to which I am entitled. I understand that this deletion will not extend to data resulting from the consent given for research that has already been carried out.

In Las Palmas de Gran Canaria, a........de........................ of...............

**INFORMATION SHEET AND TRANSFER OF PERSONAL DATA**

In compliance with the provisions of article 5 of Organic Law 3/2018 on the Protection of Personal Data and guarantee of digital rights regulating the right to information in the collection of data, we inform you that the personal data provided in this form will be included and will be treated with confidentiality and security in files, responsibility of THE MANAGEMENT OF THE ......................................................................................

The recipient of the data is THE RESEARCH TEAM OF THE SERVICE, BEING RESPONSIBLE THE MAIN RESEARCHER (Héctor Santana Ramos, Alejandro Castillo Manteiga and Ana Rivas Muro), not having planned to make assignments to third parties other than those provided for by Law or, those expressly authorized by you or your legal representative. In the same way, the Collaborating Researchers will assume this responsibility:

The data provided must be true, accurate, complete and up-to-date. The interested party will be responsible for any damage, direct or indirect, as a result of the breach of such obligation.

In compliance with the principle of quality of your data, the MANAGEMENT DIRECTION OF THE ............................................................................ will keep the information entered for the purpose described. If you want to modify them, you will have to contact the principal investigator.

The interested party may exercise the rights of access, rectification, cancellation and opposition in the terms established in said Organic Law 3/2018 and concordant regulations before the MANAGEMENT DIRECTION ...................................................................

You may revoke the consent granted, without retroactive effect, through a written request to THE GENERAL REGISTRY of the ...................................................................................... located at ...................................................................[hsanramz@gobiernodecanarias.org](mailto:hsanramz@gobiernodecanarias.org)................

**PARTICIPANT**

Name and surname: ......................................................................................................

Signature: Date:

**LEGAL REPRESENTATIVE**

Name and surname: ......................................................................................................

Signature of father, mother or legal guardian: Date:

**RESEARCHER**

Name and surname: Héctor Santana Ramos, Ana Rivas Muro and Alejandro Castillo Manteiga.

Signature: Date: