**PARTICIPANT INFORMATION SHEET**

**VERSION & DATE:** Version 7, November 08, 2023
**STUDY TITLE:** K-HEALTHinAIR – Study 1: Follow-up of 200 outpatients for 2 years.
**PROMOTER:** Hospital Clínic de Barcelona - IDIBAPS
**PRINCIPAL INVESTIGATOR:** Josep Roca Torrent, Hospital Clínic-IDIBAPS (jroca@clinic.cat)
**CENTRE:** Hospital Clínic de Barcelona

## INTRODUCTION

We are writing to inform you about a research study in which you are invited to participate. The study has been approved by a research ethics committee (HCB/2023/0126), approved in Barcelona on 29 June 2023 by the CEIm of the Hospital Clínic, in accordance with current legislation (Biomedical Research Act 14/2007 of July 3).

Our intention is only that you receive correct and sufficient information so that you can evaluate and judge whether or not you wish to participate in this study. To do this, please read this information sheet carefully and we will clarify any doubts you may have. In addition, you can consult with the people you feel are appropriate.

## VOLUNTARY PARTICIPATION

You should be aware that your participation in this study is voluntary and that you can decide NOT to participate or change your decision and withdraw your consent at any time, without altering your relationship with your doctor or causing any harm to your treatment.

Participation in this study is free of charge. This means that you will have NO rights to the potential commercial benefits of discoveries derived from the results of biomedical research.

## OBJECTIVE OF THE STUDY

The project "*K-HEALTHinAIR - Knowledge for improving indoor AIR quality and HEALTH*" aims to assess the effects of indoor air quality on health. The study will be built on the basis of an extensive monitoring campaign of chemical and biological pollutants in indoor air, with the purpose of offering affordable and easy-to-implement measures to monitor and improve indoor air quality and consolidate guidelines for deploying real interventions.

## STUDY OVERVIEW

At present, the health effects of some pollutants remain unknown, because they can be harmful at very low concentrations, or because exposure is low and intermittent. The extent to which all the exposures to pollutants that an individual receives over the course of a lifetime and how these relate to health is especially relevant to understanding the development of chronic diseases. In addition, some pollutants are also likely to induce acute health effects, especially in some vulnerable groups.

In this regard, the project "*K-HEALTHinAIR - Knowledge for improving indoor AIR quality and HEALTH*" proposes multidisciplinary research to advance in the characterization of air quality in indoor spaces, for the identification of the main pollutants that affect people's health by correlating environmental data with the health data of the participants.

Conceived in 5 study pilots, developed in 6 European countries, the project will investigate the relationship between indoor air quality and health in a representative set of environments, such

as hospitals, metro stations, markets, canteens, nursing homes, student residences, schools and homes.

The project will provide structured knowledge on indoor air quality and associated health risks, generating guidelines to support public authorities and establish a future reference framework for research.

Specifically, you will participate in the 3-year follow-up study of 200 outpatients coordinated by the Hospital Clínic de Barcelona.

This study protocol proposes an innovative and integrative management of high-risk outpatients, which combines the use of an air quality monitoring tool at home with the follow-up of the patient's medical history, lung capacity, as well as monitoring of their vital signs. The study will be complemented with health data reported by the patient through periodically administered questionnaires and statistics from urban pollution records in their residential area.

**BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY**

By participating in this study, you will have daily physical activity monitoring data, relevant physiological data, information on sleep quality, and access, via chat, to a nurse case manager.

The combined action of the nurse case manager and the digital support will potentially create a synergistic and positive impact on their health, promoting the early detection of episodes of exacerbation of the disease, as well as an improvement in the management of their disease, increasing empowerment and potentially reducing the use of health resources.

No risk is foreseen in the study protocol.

**CONFIDENTIALITY**

Hospital Clínic de Barcelona, with CIF Q-0802070-C, as the data controller, informs you that the processing, communication and transfer of personal data of all participants will be in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of data and Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights.

Your identity will not be available to anyone else except for a medical emergency or legal requirement. Your personally identifiable information may be accessed by health authorities, the Research Ethics Committee, and personnel authorized by the study sponsor, when necessary to verify study data and procedures, but always maintaining confidentiality in accordance with current legislation.

Only the encrypted data will be transferred to third parties and other countries, which in no case must contain information that can directly identify the participant (such as name and surname, initials, address, Social Security number, etc). In the event that this transfer were to take place, it would be for the same purpose as the study described and guaranteeing confidentiality.

If encrypted data is transferred outside the EU, whether to entities related to the healthcare facility in which you participate, service providers or researchers collaborating with your doctor, your data will be protected by safeguards such as contracts or other mechanisms established by data protection authorities.

In addition to the rights already provided for in the previous legislation (access, modification, opposition and deletion of data, deletion in the new Regulation) you can now also limit the processing of incorrect data, request a copy or transfer to a third party (portability) the data you have provided for the study. To exercise these rights, or if you want to know more about

confidentiality, you must contact the principal investigator of the study or the Data Protection Officer of the Hospital Clínic de Barcelona through **protecciodades@clinic.cat.** You also have the right to contact the Data Protection Agency if you are not satisfied.

The investigator and sponsor are required to retain the data collected for the study for at least 5 years after completion. Subsequently, personal information will only be kept by the health care facility and by the sponsor for other scientific research purposes if the patient has given his or her consent to do so, and if permitted by applicable law and ethical requirements.

**DATA COLLECTION AND USE**

In order to encourage participation and ensure the inclusivity of the study, three complementary and freely chosen modalities of participation are offered, which are described below:

**Basic Modality (minimum requirement to participate in the study):**

Participation in the basic modality allows you to study the relationship between the air quality in your home and your health. This modality involves:

1. Home monitoring continues to use a smart device (MICA) installed at home by the nurse case manager. MICA has sensors for the detection of temperature, relative humidity, CO2, total volatile organic compounds, formaldehyde and suspended particles. Requires configuration with home WIFI. The installation does not involve any work in the home, it is only necessary to have it connected uninterruptedly to a power outlet.
2. Access by the clinical staff involved in the study to their medical records, and to data from the health registry of the health system of Catalonia.
3. A measurement at the beginning of the study and every six months of lung capacity using forced spirometry techniques and forced oscillation techniques. Technique performed by the nurse manager, with a duration of both tests of less than 45 minutes.
4. Administration of health questionnaires at baseline and every six months.

**Intermediate Modality:**

Participation in the intermediate modality, in addition to the commitments and benefits of the basic modality, allows the study of the identification of biomarkers that allow early detection of exacerbations of lung disease and adequate prevention.

In addition to the data collected in the basic modality, this modality involves:

5. Continuous monitoring of daily physical activity and heart rate using a smart bracelet (Beat One). This wristband must be linked to the mobile phone via Bluetooth to store the data. You will be asked for at least one connection every 30 days.

**Complete Modality:**

Participation in the full modality, in addition to the commitments and benefits of the intermediate modality, allows the integrated management of your disease through a digital application installed on your mobile phone, allowing detailed monitoring and a more direct and continuous interaction between health personnel.

In addition to the data collected in the intermediate modality, this modality involves:

6. Installation of the Health Circuit Surgifit™ App on your mobile phone as a means of communication with the nurse case manager and management of future appointments. You will be provided with a generic email address to access the App.
7. Administration every six months of health questionnaires administered through the Health Circuit Surgifit™ App.

If you have any issues with any of the devices or applications mentioned above, you will have the support of the nurse case manager to solve them. Do not hesitate to contact the research team.

The data collected by these studies will be collected only using a code, so no information to identify participants will be included. Only the study physician and his collaborators with a specific permit will be able to relate your data collected in the study to your medical record. The connection via WIFI or Bluetooth does not store other data from the patient's mobile phone or home.

If relevant information is obtained that could affect your health or that of your relatives, you will be notified. If it is necessary to contact you, the data contained in your medical record will be used. However, your right to decide not to be disclosed will be respected, for which you can tick the box found on the consent form.

**OTHER RELEVANT INFORMATION**

Any new information about the treatment used in the study that may affect your willingness to participate, which is discovered during your participation, will be communicated by your doctor as soon as possible.

If you choose to withdraw your consent to participate in this study, your data will not be added to the database and you may require the destruction of all previously retained identifiable samples to prevent further testing.

You should also be aware that you may be excluded from the study if the sponsor and/or study investigators deem it appropriate, either for safety reasons, because of any adverse events that occur and are deemed to be related to your participation in the study, or because they believe you are not complying with established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the enclosed consent form, you agree to comply with the study procedures that have been exposed to you.

At the end of your participation, you will receive the best treatment available and that your doctor considers the most appropriate for your condition.

**PARTICIPANT CONSENT FORM**

**STUDY TITLE:** k-HEALTHinAIR – Study 1: Follow-up of 200 outpatients for 2 years.

I, (participant's first and last name) .....

- I have read the information sheet provided to me about the study.
- I've been able to ask questions about the study.
- I have received enough information about the study.
- I've spoken to: (researcher's name) .....
- I understand that my participation is voluntary.
- I understand that I can withdraw from the study:
    - Whenever.
    - No explanations.
    - Without it affecting my medical care.
- In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and Organic Law 3/2018 of 5 December 2018 on the protection of personal data and the guarantee of digital rights, I declare that I have been informed of the existence of a file or processing of personal data, for the purpose of collecting data and recipients of the information.

Given this information that the data controller has given me, and having understood this:

1) I offer my consent for access to my medical records, both in the primary care setting (eCAP) and at the Hospital Clínic de Barcelona (SAP), by the nurse manager and the clinical team in charge of my follow-up during my participation in the study. As well as the processing of:

☐ My personal data to carry out the research project.
☐ My personal data to carry out research projects related to this or the same area of research.

2) I authorize my participation in the study through its modality (check only one box):

☐ Basic

☐ Intermediate

☐ Complete

3) I would like you to inform me of information derived from research that may be relevant to my health:

☐ YES or ☐ NO

Participant's signature
Date: _____/ _____/ _____

By the research group
Date: _____/ _____/ _____

*(indicate the name of the researcher)*