

# INFORMED CONSENT FORM

**Research Institution:** Central South University

**Protocol Version Number and Date:** V1.0, June 12, 2024

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**Principal Investigator:** Liu Zhihan

**Unique Protocol Number:** 234083

## 1. Informed Section

Dear Sir/Madam,

We invite you to participate in a scientific research study that has been reviewed and approved by the Ethics Committee of Central South University. Your participation is entirely voluntary, and you are free to choose whether or not to participate. This informed consent document will introduce the purpose, background, process, risks, and benefits of the study. Please read it carefully and make an informed decision on whether to participate. You may ask questions at any time when the researcher explains and discusses this consent form with you, and they will clarify anything you do not understand. You may also discuss it with family and friends before making your decision. Please sign this consent form only after you fully understand the study.

### 1.1 Why is this research being conducted?

With the increasing aging population, elderly health has become a focus of societal concern. Effective management of elderly health and improvement of their quality of life have become significant social needs. In recent years, emerging information technologies such as artificial intelligence, the Internet of Things, big data, cloud computing, and 5G have been widely applied, making "smart healthcare and elderly care" a new breakthrough in the integrated healthcare and elderly care model. Community-based smart healthcare services, such as home care beds and home visits, ensure that elderly people with disabilities, dementia, chronic diseases, advanced age, or other critical conditions receive the necessary medical services at home. This model allows elderly people to live in a familiar home environment, maintain independence and dignity, and also alleviates the pressure on medical resources, enabling more resources to be allocated to emergency and highly specialized care. However, the smart healthcare and elderly care platform is still in the pilot phase, and more scientific evidence is needed to verify its actual impact on

elderly health. Through conducting a randomized controlled trial (RCT), high-quality scientific evidence can be obtained to verify whether the smart healthcare and elderly care platform can improve the health of elderly individuals and identify issues in the implementation process, which will help further improve the existing model.

## **1.2 How many people will participate in this study?**

A total of 64 participants are planned for recruitment in this study, with our center recruiting 64 participants.

## **1.3 What is the main process of this research?**

Participants will be randomly divided into an experimental group and a control group. The experimental group will use the "Hunan Province Integrated Healthcare and Elderly Care Smart Service Platform", while the control group will not. Health indicator data will be collected from the research group four times, at baseline, after 3 months, 6 months, and 12 months of intervention.

## **1.4 How long will this study last?**

This study will last for 12 months.

## **1.5 What are the benefits of participating in this study?**

By participating, you will have the opportunity to use the services provided by the "Hunan Province Integrated Healthcare and Elderly Care Smart Service Platform", such as home nursing, home care, and other services. These services will help elderly individuals detect health issues, manage chronic diseases, and prevent disease occurrence, thereby improving their overall health. Your participation will also help researchers collect reliable data, which will be beneficial for promoting and improving the smart healthcare and elderly care model in the future.

## **1.6 What are the risks of participating in this study?**

The study aims to improve participants' health, and there are no personal harms associated with participating in this research.

### **1.7 Is participation in this study mandatory?**

Your participation in this study is completely voluntary. If you do not wish to participate, you can decline, and this will not affect your current or future life in any way. Participation is voluntary, and even if you choose to withdraw from the study at any time, there will be no loss of rights or any penalties. Even if you agree to participate, you can change your mind at any time and tell the researcher that you wish to withdraw. Your withdrawal will not affect your access to normal services. After you withdraw, the researcher will securely store your data until it is destroyed, and it will not be used or disclosed. If any information arises during the study that may affect your decision to continue, we will inform you immediately.

### **1.8 Will participants receive any benefits?**

Participants will receive certain gifts after the study concludes.

### **1.9 Will my information be kept confidential?**

If you decide to participate in this study, your participation and personal information will be kept confidential. Personal data (such as birthdate, gender, ethnicity, and health information) will be collected during the study. This data will be encoded to protect your identity and will be legally protected under applicable laws. Your biological samples will be identified with a study code, not your name, and no identifying information will be disclosed to anyone outside of the research team without your permission. All research members and relevant parties will adhere to confidentiality rules. Your records will be stored in a locked file cabinet, accessible only to the research team. If necessary, government regulatory agencies or ethics committee members may review your personal data in accordance with regulations. The study results will be published without disclosing any personal identity information.

### **1.10 If I have any questions or concerns, who should I contact?**

If you have any questions regarding this study, please contact the researcher, Changchun Guyu, at 13572776221.

If you have concerns related to your rights, you may contact the Ethics Committee of Central South University.

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## **2. Consent Section**

**1.** I have read this informed consent form carefully and have had the opportunity to ask questions. The researchers have provided detailed explanations and answered all my questions. I understand that participation in this study is voluntary, and I can withdraw at any time without any impact on my medical or legal rights. I consent to the research team, researchers, ethics committee, and health monitoring departments reviewing my medical records. I understand that the research team will take all reasonable measures to protect my privacy. I agree to participate in this study.

**Participant's Signature (Handwritten):**

**Phone Number:**

**Date:** (Year/Month/Day)

**Participant's Guardian's Signature (Handwritten):**

**Phone Number:**

**Date:** (Year/Month/Day)

**Relationship to Participant:**

2. I, or the research personnel, have thoroughly explained the purpose, procedure, risks, and potential benefits of this study to the participant, and have satisfactorily answered all questions.

**Principal Investigator or Designated Researcher (Informed by):**

**Principal Investigator's Name (Printed):** Liu Zhihan

**Principal Investigator's Signature (Handwritten):**

**Phone Number:**

**Date:** (Year/Month/Day)

**Designated Researcher's Name (Printed):** Changchun Guyu

**Designated Researcher's Signature (Handwritten):**

**Phone Number:**

**Date:** (Year/Month/Day)