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香港心腦血管健康工程研究中心

Hong Kong Center for Cerebro-cardiovascular Health Engineering

**Informed Consent Form**

We invite you to participate in our “Voluntary Data Collection Day" in Hong Kong Centre for Cerebro-Cardiovascular Health Engineering (COCHE).

This Informed Consent Form has two parts:

• Information Sheet (to share information about the research with you and your information with the researcher)

• Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

\*English Version shall prevail.

**PART I: Information Sheet**

**Purpose**

In this Voluntary Data Collection Day, we have selected several spin-off startups and their research prototypes to collect data for our COCHE Database. The researchers will collect your data in the following experiments:

E.1. Blood Glucose

* 1. Preparation of the subject: Fast overnight such that there is no food intake for at least six hours.
  2. Invasive requirement: Perform blood glucose test by puncture of the right-hand index fingertip.
  3. After the blood glucose test, heart rate and PPG are tested by SpO2 sensor and Analog Devices.
  4. Drink 440mL Lucozade drink within 5 minutes.
  5. After 30 minutes, repeat steps b. to c..
  6. **Risk of the experiment:** (1) Pain on pricking of fingertip (2) Infection: There is a risk of infection each time the skin is broken for a blood sample.

Contact email: Mr. Victor Fu (zfu@hkcoche.org)

E.2. Pulse Sensor

* 1. Rest 5 minuets for a resting blood pressure to be obtained.
  2. Measurement of Pulse Sensor, PPG, and continuous BP will be obtained on right or left arm for 5minutes.

Contact email: Dr. Iyappan Gunasekaran (igunasekaran@hkcoche.org)

E.3. Multichannel PPG Sensor

* 1. Rest for 5 minutes for a resting blood pressure to be obtained.
  2. Mercury blood pressure measurement is obtained.
  3. Measurement of multichannel PPG will be obtained on right or left arm for 3 minutes.

Contact person and email: Ms. Julee Liu (zjliu@hkcoche.org)

E.4. EIT

* 1. An eligibility questionnaire is to be filled.
  2. The circumference of waist is recorded.
  3. A waist belt is worn within a private space.
  4. A scan is done for 5 minutes.
  5. Steps n. to o. are repeated 1-2 times, if necessary.

Contact person and email: Dr. Eddie Wong (ecswong@hkcoche.org)

E.5. Portable Ultrasound

* 1. Ultrasound gel is applied on the neck area.
  2. Ultrasound probe is arranged on the neck, under the chin.
  3. The probe is moved from the middle to both sides of the neck.
  4. A scan will be made for around 3-5 minutes.

Contact email: Dr. Liang Sun (lsun@hkcoche.org)

**Voluntary participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating in the middle of the experiment even if you agreed earlier.

**What are the risks and adverse effects of my participation in this study?**

For E.1., possible side effects from a blood draw include fainting (rare) and pain, swelling, bruising, or bleeding where the needle is inserted. In very rare occasion, infection might occur where the needle is inserted. Please note that all the procedures followed the safety guideline from the human ethics approval. Otherwise, no other adverse reactions are expected to occur during the study. If there are questions about your participation in the research, you can contact the research team.

Other parts of the experiments are non-invasive.

**What benefits can I gain from this research?**

There are no direct benefits to you for participating in this study, however, the information provided in this study will help diagnose and treat other patients with similar conditions.

**Will I be paid for this study?**

You will not be paid for participating in this study.

**Confidentiality**

All the identifiable information will be kept in a separate file protected with double passwords. Unless the participant’s prior permission is obtained or it is required by law, the identifiable information or identity of the participant will remain confidential and will not be disclosed. Only authorized personnel can access this information. Anonymized data will be used for research, stored in a database and presented as group data in journals, conference presentation and related scientific activities.

By consenting to participate in this event, you expressly authorize the access to, the use of, and the retention of your personal and experimental data by the investigators and members of his/her research team, and COCHE for the purposes and in the manner described in this informed consent. For any query, you should consult the COCHE office (Email: general@hkcoche.org) and the research team as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

**Contact for further information**

If you have any problems, concerns, questions, or complaints about this clinical study, you should preferably contact COCHE (Email: general@hkcoche.org) for further information.

**Part II: Patient Informed Consent Form**

**Voluntary Data Collection Day**

**Thank you for your time to read this information sheet and consider taking part in this clinical investigation. If you agree to take part in this clinical investigation, please date and sign two of these documents on the last page together with a witness. One signed document is for you, the other one will remain at COCHE.**

**PATICIPANT STATEMENT**

1. I understand that my participation is voluntary.
2. I understand that I am free to refuse to participate in the proposed investigation, without giving any reason and without my medical care or legal rights being affected.
3. I understand that I am free to withdraw from the proposed investigation at any time, without giving any reason, without my medical care or legal rights being affected.
4. I agree to have my personal information collected during the investigation, used by researchers, and kept confidential and safely protected in the database. However, without my consent, researchers cannot give my personal information to third parties.
5. I agree to have my experimental anonymized data collected during the investigation prior to the withdrawal, used in the analysis and communicated in research findings and publications.
6. I confirm that I have read and understood the information presented for the investigation and have had the opportunity to ask questions, which were answered to my satisfaction.

6. I have decided to take part in this data collection. I understand I will get a signed and dated copy of this document. I agree to comply with the procedures related to it.

**I am willing to participate in the following experiments: (please add “✔” in the box provided)**

☐ **1.** **Blood Glucose (by Mr. Victor Fu, Ms. Han Zhu & Ms Emerald Sy)**

☐ **2. Pulse Sensor (by Dr. Iyappan Gunasekaran)**

☐ **3. Multichannel PPG Sensor (by Ms. Julee Liu)**

☐ **4. EIT (by Dr. Eddie Wong)**

☐ **5. Portable Ultrasound (by Dr. Liang Sun)**

**2 copies of this Participant Information Sheet and Consent Form must be signed and dated by you and the researcher. You will receive one copy of the participant information sheet and the participant informed consent form and one copy is for the witness/researcher to be filed in COCHE.**

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| --- | --- | --- |
| **Print name of Participant** | **Participant Signature** | **Date** |
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| **Print name of Witness/Researcher (if applicable)** | **Witness/Researcher Signature** | **Date** |
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