

CONSENT FORM (Randomization Phase)

Study Name: Using Biovitals® in Early Detection of Progression of Disease
in Patients Suspected with COVID-19

Version No.: COVID19_Biovitals_Consent_2_randomization_en (17/03/2020)

Protocol No: COVID19_Biovitals_Protocol_1

Study Site: Hospitals of the Hospital Authority, and
Quarantine Sites of Hong Kong SAR Government

Study Doctors: Prof HUNG Fan Ngai Ivan and Prof. SIU Chung Wah David

You are being invited to take part in a research study. Before you decide, it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask the study doctor or research staff any questions you may have before signing the attached consent form.

About This Study

The purpose of our study is to explore the potential of state-of-the-art wearable technology for remote monitoring of patients with suspected COVID-19 infection in order to achieve early diagnosis of the infection and prompt identification of complication to allow timely management.

Why have I been chosen?

You are considered high risk from having COVID-19, a condition associated with significant morbidity and mortality. Early diagnosis of the infection and prompt identification of complication would allow delivery of timely management, therefore you are invited into our study to undergo remote monitoring with wearable technology. We plan to recruit a total of 200 patients.

What will happen to me if I take part?

You will be randomized to receive standard of care or addition of Biovotion® armband with multiple sensors for telemonitoring of your health status. If clinicians detected abnormality from your measured parameters, further medical investigation or intervention might be arranged.

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What are the benefits of participating?

Taking part in this study may or may not make your health better. Information from this study will help doctors learn more about the value of using remote monitoring with wearable technology. This information will help patients in the future.

What if something goes wrong?

In the unlikely event of harm resulting directly from your participation in this study, medical treatment will be available. There are no special compensation arrangements provided to you. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal health service complaints mechanisms may be available to you. If you have any queries related to the insurance coverage from your own insurer(s) for your participation in the study, please discuss with your insurance consultant.

What are the alternatives for treatment?

Your participation in this study is voluntary. You may choose not to participate in this study. You may decline to participate by simply telling your doctor. If you decide not to participate in this study, your follow-up appointments will be scheduled and conducted as directed by your physician. Your decision will not in any way affect your medical care or treatment.

What if new information becomes available?

During the course of the study, if any new information becomes available that may relate to your willingness to continue to participate in this study, your research doctor will tell you about it and discuss with you. You also have the rights of access to personal data and known study results, if and when needed.

Will my participation in this study be kept confidential?

As a subject in this research study, all your information will be kept confidential. Your name or your personal identity will not be used for any public purpose, publication, or transmitted outside of the medical centre.

Under the laws of the Hong Kong Special Administrative Region and, in particular, the Personal Data (Privacy) Ordinance, Cap 486, you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the

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collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. By consenting to participate in this study, you expressly authorize the access to, the use of, and the retention of your personal data by the Investigator and members of his research team, and HKU/HA HKW IRB for the purposes and in the manner described in this informed consent process.

For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) 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.

Who should I contact if have questions?

If you have any questions regarding this study, you may contact Prof. SIU Chung Wah David or Prof FUNG Fan Ngai Ivan at XXXXXXXXX. If you have any queries regarding your rights in the study, you may contact the Secretary of Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster at 2255 4086.

By signing below, I agree that:

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

Title of the Project: Using Biovitals® in Early Detection of Progression of Disease
 in Patients Suspected with COVID-19

Patient Identification Number for this trial: _____

Participant’s Signature: _____

Participant’s Name: _____

Date: _____

Investigator’s Signature: _____

Investigator’s Name: _____

Date: _____

Witness’s Signature: _____

Witness’s Name: _____

Date: _____

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