

## **“Analysis of the diagnostic utilities for novel coronavirus infection by using saliva specimens”**

Japan Self-Defense Forces Central Hospital conducts the research title of “Analysis of the diagnostic utilities for novel coronavirus infection by using saliva specimens”.

The purpose of research is that to clarify the diagnostic utilities for novel coronavirus (COVID-19) to use the clinical information and saliva specimens have taken from the patients infected with COVID-19. This research will contribute to the improvement of the clinical outcome, countermeasure for the COVID-19 in the future.

This research protocol, human rights, and safety were reviewed and approved by Institutional Review Boards of Self-Defense Forces Central Hospital and cooperating research institutes.

### **Contents**

- Approval number: xx-xxx
- The term of the clinical research: from the date on which approval was obtained to 31/ July /2020.
- Main researcher: Yasuyuki Kato (International University of Health and Welfare)
- Main researcher at Japan Self-Defense Forces Central Hospital: Kazuyasu Miyoshi
- Cooperating research institutes: International University of Health and Welfare, Rinku General Medical Center, Yokohama Municipal Citizen's Hospital, and Showa General Hospital

### **Introduction of COVID-19**

The outbreak of COVID-19 have been started from Wuhan, China, and some patients with infected with COVID-19 have been confirmed in all around the world. The best performance of diagnostic method for COVID-19 is still unknown. Therefore, the appropriate clinical diagnosis and countermeasure for COVID-19 is important to prevent the further outbreak. It is urgent needed for determination of best diagnostic method for COVID-

19. We conduct the collected and analysis of the clinical information, clinical specimens (saliva, nasopharyngeal swab and pharyngeal swab) to compare the several kinds of diagnostic methods, and report these results.

### **Voluntary participation**

Your participation in this research is completely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive will continue and nothing will change. You have the right to refuse or withdraw at any time. If you withdraw this study, your information and specimens will be deleted according to your wishes. However, this rule does not apply to all cases where the research article has already been published.

### **Type of research intervention**

The clinical findings have been recorded at the medical record and clinical specimens have been taken from the patients who diagnosed with COVID-19 are used for the study. Your information will be anonymizes to be not specified your private information. The term of the clinical research: from the date on 1/Jan/2020 to which approval was obtained.

### **Confidentiality**

The information we collect from this research project will remain private. Only the investigators will know what your information is and we will close that information with a padlock and a key. Your information will be anonymizes to be not specified your private information.

### **Information disclosure**

The research results will be published and reported as academic conference presentation, and application of extracorporeal diagnostic agents with the anonymization to prevent your and your family name being specified.

### **Cost**

You do not need to bear a cost, and will not be rewarded. There is no conflict of interest, which leads to disadvantage of participants or unfairly evaluation of research.

**Intellectual property rights**

The intellectual property rights which will be obtained from this research belong to the researcher and research institute, not participants.

**Who to contact**

If you have any questions, you can ask the responsible researcher.

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## **Document declaring the withdrawal of consent**

**“Analysis of the diagnostic utilities for novel coronavirus infection by  
using saliva specimens ”.**

To Self-defense Force Central Hospital

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I inform you the withdraw consent to this research.

I withdraw consent to following contents with marked.

☐ My clinical information is used of research

☐ My sample and specimen are used of research for detection of virus.

Name of the

participant\_\_\_\_\_

—

Participant's signature \_\_\_\_\_ Date

\_\_\_\_\_ Day /month / year \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_