Notification of Clinical Study
Study Title: COVID-19 Registry

The National Center for Global Health and Medicine Hospital (NCGM) and Japanese Red Cross Narita Hospital are conducting the study described below. If you do not wish to participate in this study, you have the right to opt-out from the study. In order to make an opt-out request, please contact the hospital you were admitted to or make an inquiry to the study office described at the end of this notification. Please be assured that you will not be disadvantaged in any way by making this request. If the patient is a minor or lacks ability to make this request, your legal representative (family, relative, etc.) may make this request on behalf.

■ Objectives and Methods

Since December 2019, an outbreak of pneumonia caused by a new coronavirus was confirmed in Wuhan, China. This coronavirus infection (COVID-19) has spread throughout the world, and many cases are reported in Japan as well. Disease severity varies greatly from asymptomatic to severe, and cases are reported in pregnant women and children. Because it is a novel infection, information on effective treatment is limited, and much is still unknown, including the risk factors for developing into a severe condition.

In this study, by utilizing the clinical records, we will enroll the patients diagnosed as COVID-19, and study various outcomes, such as the characteristics and clinical course of those being severely ill, clinical course of those who were administered with certain pharmaceuticals, and more aspects of COVID-19.

■ Study duration and study target

Duration: From the day of approval by the director to March 31, 2026.

Target: Patients diagnosed as COVID-19 on and after January 1, 2020, who were admitted to hospitals in Japan

■ How you will be involved in the study

Medical information recorded during your stay at your designated hospitals will be utilized for the study. This information includes the following: age; sex; dates of onset, admission, and discharge; underlying diseases; records of hospital transfer; lifestyle; country of birth; race; epidemiologic information on COVID-19 (including occupational background and travel history); treatment and medication history; pregnancy and its course (applicable to women); height and weight; past COVID-19 contraction; vaccination history; admission signs, symptoms, and overall condition; treatment and medication for COVID-19; complications; outcome; results of pathogen testing (new coronavirus and other pathogens); findings from diagnostic image; etc. Upon utilization, we will strictly protect your personal information in accordance with the ethical guidelines set forth by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare. Results of the study will not include information that can identify an individual.

■ **Study participation**

If you do not wish your information to be utilized in the study, we will exclude your information for analyses. However, because COVID-19 is a novel infectious disease which is of great social and public health importance, all patient information will be kept in the database regardless of your participation in the study. In any case, information which enables to identify an individual will not be disclosed.

■ **Provision of Information to the Repository of Data and Biospecimen of Infectious Disease (REBIND)**

The information registered in this study will be provided to the Repository of Data and Biospecimen of Infectious Disease (REBIND). For further details, please refer to the appendix " Notice to patients who participated in the COVID-19 Registry ".

■ **Provision of samples and information to the outside world**

Study data will only be accessible to the specific parties involved. Patient identification key will be kept by the investigator at each hospital where patients were admitted and will not be shared with other parties. Study data may be shared with international research groups such as those of World Health Organization (WHO). In such cases, personally identifiable information will not be provided. In addition, data may be used by companies if the intended use was socially significant, after the use was approved in the data usage deliberation. In any of these cases, patient identification key will not be provided, and an individual will not be identified.

■ **Research Organization**

Principal Investigator: Dr. Norio Ohmagari, National Center for Global Health and Medicine

Information provider: All medical institutions in Japan where COVID-19 patients were admitted (Japanese Red Cross Narita Hospital is included)

■ **Conflict of Interests**

Conflict of interests (COI) are reported to the COI Management Committee at NCGM and will be managed according to their instructions. COI of personnel at other involved parties will be managed under the rules of each organization. There is no COI related to this study or investigators.

■ **How to obtain and view research protocols, etc.**

At your request, we can provide you with some study details including study methodology, as long as it does not violate privacy and the right of this study group. If you wish to view this information, please check our website from the URL below.

https://covid-registry.ncgm.go.jp/general/

■ **Procedures for disclosure of personal information**

You may view your information collected in this study in accordance with the regulation laid by each hospital. If you wish to apply for this service, please contact the hospital where you were admitted and treated for COVID-19.

■ **The lead investigator of the study**

Dr. Norio Ohmagari, Disease Control and Prevention Center, National Center for Global Health and Medicine.

■ **The Principal investigator of the study at Japanese Red Cross Narita Hospital**

Dr. Ryota Hase, Infectious Diseases Department, Japanese Red Cross Narita Hospital

■ **Contacts**

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