Date: November 06, 2026

《Research Title》
“Immunological Evaluation of a Universal Influenza Vaccine in Healthy Adults”

《Research Participants》
Among the participants in the “A Single Center, Randomized, Double-blind, Placebo-controlled, First-in-human Phase 1 Study to Assess the Safety, Tolerability and Immunogenicity of the Adjuvanted Universal Influenza Vaccine “fH1/DSP-0546LP” After Intramuscular (IM) Administrations in Healthy Adults” (Approval No. R2411201), conducted by Sumitomo Pharma Co., Ltd. (hereinafter, the “Phase 1 Study”), those who consented to the use of residual samples, including blood samples collected during the study, for future vaccine- or disease-related research.

Request for Cooperation in Research

The National Institutes of Biomedical Innovation, Health and Nutrition (NIBN) will conduct the study identified by the research title above. This study will use residual samples, including blood samples (serum and peripheral blood mononuclear cells [PBMCs]), collected from eligible individuals during the Phase 1 Study, as well as information such as test results collected in the Phase 1 Study. The purpose and methods of the study are described below. Eligible individuals will not be contacted individually to receive an explanation of the study or to provide additional consent for the use of their samples and information. Instead, information about this study is being made available through this public notice. We ask eligible individuals to review the information below.

If you do not wish to provide your samples or information for this study, or if you have any questions about the study, please contact the inquiry point listed in Section (7) below.

（1）Overview of the Study
《Research Title》
“Immunological Evaluation of a Universal Influenza Vaccine in Healthy Adults”

《Research Period》
From the date of approval by the President through March 31, 2029

《 Principal Investigator》
National Institutes of Biomedical Innovation, Health and Nutrition
Precision Immunology Project, Project Leader
Takuya Yamamoto

《Significance》

Seasonal influenza vaccines may not provide sufficient protection when the viruses that actually circulate differ from the viruses targeted by the vaccine. Therefore, there is a need to develop vaccines that are expected to be effective against a broad range of influenza viruses.

fH1/DSP-0546LP is a vaccine that targets regions of the influenza virus that are relatively conserved across different virus types. This study will examine how antibodies and immune cells respond to the vaccine and whether the immune response induced by the vaccine may also act against different types of influenza virus. The findings are expected to contribute to the development of vaccines that can address a broad range of influenza viruses, the evaluation of more appropriate vaccination regimens, and preparedness for a future global influenza pandemic.

《Objective》

The objective of this study is to investigate in detail the immune responses that occur in the body after vaccination with fH1/DSP-0546LP. Specifically, we will examine the amount of antibodies that bind to influenza viruses, the ability of antibodies to prevent viral infection, and their ability to work with immune cells to eliminate virus-infected cells. We will also examine whether the antibodies induced by the vaccine act against different influenza virus subtypes, and how cells that regulate immune responses and cells that attack virus-infected cells respond. Through these analyses, we will characterize the immune responses induced by fH1/DSP-0546LP in antibodies and immune cells.

（２）Research Methods

《Study Details》

This is a multicenter collaborative study led by NIBN, with the cooperation of Sumitomo Pharma Co., Ltd.

Using residual specimens and related information collected in the Phase 1 Study of fH1/DSP-0546LP conducted by Sumitomo Pharma Co., Ltd. and retained after completion of the study, NIBN will conduct exploratory analyses of immune responses induced by vaccination.

Using serum, NIBN will examine the amount of antibodies that bind to influenza viruses, the ability of antibodies to prevent viral infection, and their ability to work with immune cells to eliminate virus-infected cells. NIBN will also evaluate whether antibodies induced by the vaccine act against different influenza virus subtypes.

In addition, using peripheral blood mononuclear cells (PBMCs), which are immune cells found in blood, NIBN will examine the types and numbers of cells that regulate immune responses and cells that attack virus-infected cells, the extent to which these cells are activated, and their ability to produce substances involved in immune responses.

We will analyze these results together with the vaccine administered, the timing of blood collection, and relevant information obtained in the Phase 1 Study to characterize the antibodies and cellular immune responses induced by vaccination with fH1/DSP-0546LP.

This study will not use names, addresses, telephone numbers, or other information that can directly identify research participants. Participants will not be asked to provide any new specimens, undergo examinations or tests, or make additional visits for this study.

《Samples and Information to Be Used or Provided》

The samples and information to be used in this study or provided to collaborating research institutions are as follows:

- Samples: serum and peripheral blood mononuclear cells (PBMCs)
- Basic information: age, sex, height, weight, and medical history
- Information relating to the Phase 1 Study and test and analysis results obtained in the Phase 1 Study
- Analysis results obtained in this study

When the study results are presented at scientific meetings or published in academic journals, no information that could identify individuals will be disclosed.

《Planned Date for Commencement of Use or Provision》

December 1, 2026

① 《Method of Obtaining the Samples and Information to Be Provided》

Sumitomo Pharma Co., Ltd. will provide residual samples (serum and PBMCs) and clinical information managed by subject ID only for individuals who consented to the use of their samples and information for future research in the Phase 1 Study.

② 《Method of Providing Samples and Information》

Residual samples (PBMCs and serum) labeled with subject ID numbers will be transported to NIBN while maintained in a frozen state. Clinical information will contain no information that directly identifies research participants and will be provided as data labeled with subject ID numbers, using access-restricted electronic media or encrypted electronic methods.

③ 《Names of the Institutions Providing, Receiving, and Using Samples and Information, and Their Principal Investigators, etc》

《Scope of Persons Who Will Use the Samples and Information》 ※Excluding contracted service providers

Name of Research Institution	Principal Investigator (◎ indicates the Lead Principal Investigator)	Name of Head of the Providing Institution	Provides (Source)	Provides (Source)	Uses
			Circle the applicable item		
National Institutes of Biomedical Innovation, Health and Nutrition	**◎Takuya Yamamoto**	Yusuke Nakamura	N.A.	○	○

Sumitomo Pharma Co., Ltd.	Akihisa Fukushima	Toru Kimura	○	N.A.	○

N.A.：Not applicable

《Person Responsible for the Management of Samples and Information》
National Institutes of Biomedical Innovation, Health and Nutrition
Precision Immunology Project, Project Leader
Takuya Yamamoto

（３）Handling of Personal Information

The clinical information relating to medical care and the clinical trial used in this study includes medical history, test results, and other information and therefore constitutes “special care-required personal information” under the Act on the Protection of Personal Information. NIBN will not obtain names, addresses, telephone numbers, email addresses, or other information that can directly identify research participants, and will use only information managed using a research identification number assigned to each participant. The correspondence table linking each research identification number to the relevant participant will be securely managed at the clinical trial site and will not be provided to the researchers conducting this study. Accordingly, the study researchers will not be able to identify participants from their research identification numbers. The clinical information and research data received will be handled only by authorized research personnel under the supervision of the Principal Investigator. Electronic data will be stored on devices or servers protected by access controls, passwords, and similar safeguards. If paper records are used, they will be managed in a lockable storage location. This information will be used only within the scope of the research purpose, and no information that could identify an individual will be included when the study findings are published.

（４）Publication of Study Results

The results of this study will be made public through presentations at scientific conferences, publications in academic journals, and databases. Care will be taken to ensure that individuals cannot be identified when the results are made public.

（５）Obtaining or Reviewing the Research Protocol and Related Documents

Eligible individuals or their representatives may, upon request, obtain or review the research protocol and other documents relating to this study, to the extent that doing so does not interfere with the protection of the personal information of other research participants or with intellectual property rights. To make a request, please contact the inquiry point listed in Section (7) below.

（６）Discontinuation of the Use of Samples and Information

At the request of an eligible individual or their representative, we will stop using that

individual’s samples and information in this study or providing them for other research. To make such a request, please contact the inquiry point listed in Section (7) below.

（７）Contact for Inquiries About This Study

Contact: National Institutes of Biomedical Innovation, Health and Nutrition,
Precision Immunology Project, Project Leader
Takuya Yamamoto
Address: 7-6-8 Saito-Asagi, Ibaraki, Osaka 567-0085, Japan
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