Participant Information Sheet and Consent Form for Participation in Research of the Vaccine "Stamaril" against Yellow Fever

Research Title: Clinical Research to Collect Safety Information Obtained Following Vaccination with "Stamaril"

This brochure consists of participant information sheet and consent form to request participation in clinical research using the vaccine "Stamaril" against yellow fever. With funds and the vaccine provided by Sanofi Pasteur SA in France, this research will be conducted at domestic institutions designated by the Ministry of Health, Labour and Welfare where certificates of vaccination against yellow fever can be issued. This research is approved by the administrator of each institution.

The contents of this research will be registered at jRCT (https://jrct.niph.go.jp/) based on the Clinical Research Act. However, information that may identify you as an individual will not be disclosed. You can search on this website at any time.

1. Introduction

This participant information sheet is provided to help you accurately understand the contents of this research and judge whether or not to participate in the research based on your own free will. Please decide if you would like to participate in the research after you read the participant information sheet, received an explanation from the doctor in charge, and sufficiently considered it. If your decision changed after you gave consent to participate, you have the right to withdraw your consent and quit participating in the research. In such cases that you decided not to give consent or chose to withdraw your consent for research participation, you will not be treated unfavourably. If there is anything you do not understand or if you have any concern about this research, feel free to ask whatever it is. If you would participate in the research, please sign and date the consent form and give the form to the doctor in charge. If you would like to withdraw your consent, please sign and date the consent withdrawal form and provide the form to the doctor in charge.

2. What is Specified Clinical Research?

The study which is conducted on people to elucidate the cause of disease or improvement of prevention, diagnosis, and treatment is called "Clinical Research".

This research is distinctively called "Specified Clinical Research" as it involves domestically unapproved vaccine with fund from a pharmaceutical company. It will be conducted following the Japanese regulation called the Clinical Research Act. This research is not a clinical study (clinical trial) intended to obtain approval for manufacture and market pharmaceuticals from the Ministry of Health, Labour and Welfare.

3. About Yellow Fever

Yellow fever is a systemic viral disease which is transmitted by mosquitos (particularly Aedes aegypti). When transmission of the disease occurs, symptoms such as fever, headache, muscle pain, and queasiness would appear after an incubation period of 3 to 6 days. It is said that most of these symptoms resolve and improve in 3 to 4 days, but when is becomes severe, symptoms such as bleedings from nose, gum and other various organs and jaundice will appear and 50% of the severe cases will lead to death. There is no special treatment for the disease, so symptomatic therapies to diminish symptoms will be performed. Human-to-human transmission will not occur with Yellow fever.

Yellow fever is prevalent in the tropical areas of Africa and Latin America. Since 2015, yellow fever has been prevalent in the Republic of Angola and the Federative Republic of Brazil. In Brazil, at the beginning of 2018, the number of patients definitively diagnosed with yellow fever increased three-fold in several weeks. Also, there have been reports that travelers who stayed in Angola or Brazil without prophylactic vaccination had developed yellow fever after returning home.

The most important prophylactic measure against yellow fever is prophylactic vaccination. Once if sufficient immunity against yellow fever is acquired by a single dose of vaccine, lifelong immunity may be maintained.

4. Purpose of and Background of This Research

"Yellow Fever Vaccine" distributed by Sanofi K.K. is the only vaccine against yellow fever which is approved by the Ministry of Health, Labour and Welfare and marketed in Japan. The "Yellow Fever Vaccine" is currently temporarily unavailable due to switching manufacturing equipment to a new facility in the United States where this vaccine is manufactured. This means that it could cause a big impact on travellers entering the epidemic area since they could not get vaccinated with the yellow fever vaccine in Japan. Such being the situation, we would like you to get vaccinated with the vaccine "Stamaril" against yellow fever which is manufactured by Sanofi Pasteur SA in France, as an alternative, and participate in this research to confirm its safety. Sanofi K.K. in Japan and Sanofi Pasteur SA in France are both the members of the Sanofi Group.

5. About the Vaccine "Stamaril"

"Stamaril" and "Yellow Fever Vaccine" are both made from the same viral strain and by using almost the same method. The intended population for vaccination, the method of vaccination, and the amount of vaccination are also similar to each other. The only difference is that "Stamaril" does not contain gelatine as an additive agent (stabilizer). For this reason, "Stamaril" can be injected safely to people who are allergic to gelatine. "Stamaril" is a vaccine approved in advance by the World Health Organization (WHO). It has been approved as a product in more than 70

countries and regions since 1986, and to date, more than 400 million doses of the vaccine have been shipped. Countries that approve “Stamaril” includes Asian countries such as Korea and Hong Kong.

6. Other Options

If you participate in this research, you will be vaccinated with “Stamaril” and will receive a certificate (yellow card). “Yellow Fever Vaccine” is approved in the United States and Canada, other than Japan. “Yellow Fever Vaccine” will also be temporarily unavailable in these two countries; therefore, there is no way to obtain a certificate (yellow card) by “Yellow Fever Vaccine” injection, both domestically and internationally.

If you do not wish to participate but need to obtain the certificate, you could receive it overseas. As “Stamaril” is approved in many developed countries such as European countries, you will be able to receive certificate abroad by injecting the same vaccine as being used in this research. Some developing countries approve other vaccines that are unique to their country.

For those who cannot receive injection due to the mismatch to participation criteria, can request a certificate of exemption to prove that you are not eligible for immunization. Other options are to postpone, cancel or abort your travel to the risk area.

7. The Scheduled Period of Research and Scheduled Number of Participants

We will start the research from around November 2018, and in about 7 months, approximately 10,000 persons will be participating in this research. We expect the enrollment period to last till May 2019.

8. Research Methods

<u>Eligibility Criteria for Participation</u>

First, your doctor will check if you meet the criteria to participate in this research.

The criteria for participation are as follows:

1) Person who may be exposed to the risk of yellow fever.
2) Person aged 9 months or older on the day of vaccination with “Stamaril”.
3) Person who gave written consent to get vaccinated with “Stamaril” which is unapproved in Japan, as an alternative to “Yellow Fever Vaccine”.
   *Note: For persons aged 16 to less than 20 years, written consent from their legal representative is also needed in addition to written consent from the participant.
   *Note: For persons aged less than 16 years, written consent from their legal representative is needed.
4) For persons aged 6 months to less than 9 months, persons who are or are possibly pregnant, persons aged 60 years or older, and persons infected with asymptomatic human immunodeficiency virus not associated with immune dysfunction, their doctor

should judge that the expected benefits of vaccination outweigh the risks.
*Note: The doctor will give the final decision for vaccination eligibility, considering the area, length, and purpose of the travel.

Persons meeting any of the following criteria cannot participate in the research:

1) Person with hypersensitivity to any of the additives contained in “Stamaril”, chicken eggs, or chicken meat proteins
   *Note: Additives contained in “Stamaril” are: lactose; sorbitol E420; L-histidine monohydrochloride; L-alanine; sodium chloride; potassium chloride; disodium phosphate, anhydrous; potassium dihydrogen phosphate; calcium chloride; and magnesium sulphate. These additives generally do not cause any allergic problems. However, if you have any concern, for example, if you have previous experience of adverse reaction, please consult the doctor beforehand.
2) Person with congenital or acquired immunodeficiency, such as those receiving immunosuppressive therapy with chemotherapy, systemic administration of corticosteroids, etc.
3) Person with a history of thymic dysfunction (including myasthenia gravis, thymoma, and thymectomy)
4) Person infected with symptomatic human immunodeficiency virus
5) Person infected with asymptomatic human immunodeficiency virus associated with immune dysfunction
6) Person with fever (≥37.5°C)
7) Person who is judged by the doctor to have severe acute disease
8) Breastfeeding women who cannot suspend breastfeeding for at least 14 days after vaccination with “Stamaril”
9) Other persons who are judged by their doctor to be not appropriate for getting vaccinated prophylactically

Research Procedures

If you gave written consent to participate in this research and met all of the conditions necessary for participation, you will receive 0.5 mL of “Stamaril” subcutaneously after a medical interview by a doctor.

After that, you will be asked to stay in the vaccination facility for about 30 minutes so that appropriate measures can be taken immediately if any acute adverse reaction has occured, and to check the safety of “Stamaril”.

You will need to pay attention to changes in your physical condition for about 30 days after vaccination.If you feel any problem, you should visit a medical institution as needed, and undergo a medical examination by a doctor after telling that you got vaccinated with “Stamaril”. Also,

contact the facility where you got vaccinated with "Stamaril." In this regard, you will be asked about things such as the time of occurrence or detailed description of your condition and the treatment you received when you visited the medical institution.

Other Things You Need to Report

If you found to be pregnant within 30 days after "Stamaril" vaccination or if you breastfed within 14 days after "Stamaril" vaccination, please contact the facility where you got vaccinated.

If New Information is acquired

If new information, which may affect your will regarding this research participation, is acquired, we will provide it to you.

Discontinuation of Research

If you wish to withdraw consent to participate in this research, or if the doctor in charge judges that participation in the study is not appropriate due to a change in the condition, etc. after you signed this consent form, or if this research itself is aborted, your participation in research will be discontinued.

9. Expected Benefits and Disadvantages

Expected Benefits

There is no special treatment for yellow fever, so if you contract the disease, symptomatic therapies will be given. It is said that 20% of the patients infected and 50% of the severe cases will result in death. By participating in this research, you will get vaccinated against yellow fever, obtain a certificate of vaccination, and may acquire lifelong immunity against yellow fever. Also, you may be able to avoid the risk of mortality by protecting yourself from the disease.

Expected Disadvantages

When a person gets vaccinated with "Stamaril," it is known that he/she will acquire protective immunity against yellow fever for a long period, but alike "Yellow Fever Vaccine," it is not certain that "Stamaril" injection will 100% protect people from yellow fever.

Like other vaccines, adverse reactions may occur due to vaccination with "Stamaril." Frequently reported adverse reactions are headache, muscle pain, fatigue or weakness, and injection-site pain. Children who get vaccinated with it may react to a slight stimulus, may not stop crying even when someone is trying to soothe them or may develop anorexia or sleepiness. Other common adverse reactions are fever, queasiness, rash, and injection-site redness or swelling. Many of these adverse reactions occur within 3 days after vaccination (fever often occur in 4 to 14 days after vaccination), but these symptoms usually subside within 3 days.

In addition, like other vaccines, allergic reactions may occur due to vaccination with "Stamaril." Symptoms include itchy skin, urticaria, rash, swelling of the lips, face, or throat, tachycardia, sweating, fear, respiratory discomfort, and dizziness or light-headed feeling due to blood pressure decrease. These allergic reactions are usually seen almost immediately after vaccination.

After vaccination with vaccines against yellow fever including "Stamaril," serious adverse reactions may occur. There have been reports of yellow fever vaccine-associated neurotropic disease (YEL-AND) which affects the cranial nerves, and yellow fever vaccine-associated viscerotropic disease (YEL-AVD) which causes symptoms similar to those of infection with yellow fever and rapidly affects multiple organs.

- Yellow fever vaccine-associated neurotropic disease (YEL-AND) is reported to occur usually within 30 days after vaccination. There may be symptoms such as high fever associated with a headache, confusion, convulsion, and immobility or numbness of a part of the body or the whole body. Almost all the persons who were affected by this disease recovered.
- Yellow fever vaccine-associated viscerotropic disease (YEL-AVD) is reported to occur usually within 10 days after vaccination. There may be symptoms such as fever, muscle pain, fatigue, headache, and hypotension, and subsequently, severe liver disorder with yellowing of the skin or eyes, muscle disorder, internal bleeding, haemorrhage, and abnormal function of the respiratory apparatus or kidneys. About a half of people who were affected by this disease had died, and the other half had recovered.

Although these adverse reactions occur very rarely, it may lead to death in some cases. Persons aged 60 years or older, infants aged less than 9 months exposed to the vaccine against yellow fever via breastfeeding, persons with congenital or acquired immunodeficiency, and persons with thymic dysfunction are known to be at high risk of these adverse reactions.

Regarding the incidences and types of adverse reactions, please see the list on page 8.

<u>About Pregnancy</u>

From the previous experience of the use of "Stamaril," it has been suggested that "Stamaril" has no harmful influence on the health of pregnant women or unborn or newborn babies. However, the data providing evidence for it are limited, and therefore, pregnant or possibly pregnant women should avoid vaccination in principle. This shall not apply when traveling cannot be avoided and when their doctors judged it as necessary to get vaccinated. If you are found to be pregnant within 30 days after vaccination with "Stamaril," please contact the facility where you got vaccinated. You will be contacted until the end of pregnancy to check the health status of you and your baby.

<u>About Breastfeeding</u>

The vaccine virus may move to the infant by breastfeeding, and therefore you should avoid breastfeeding for at least 14 days after vaccination with “Stamaril.” If you breastfed within 14 days after vaccination with “Stamaril” by mistake, please contact the facility where you got vaccinated with the vaccine. You will be contacted for 30 days to check the health status of you and your baby.

List of Adverse Reactions

Type	Incidence of Adverse Reactions					
	≥10%	1% to <10%	0.1% to <1%	0.01% to <0.1%	<0.01%	Incidence unknown*3
Infections				Rhinitis	yellow fever vaccine-associated viscerotropic disease (YEL-AVD)	
Lymphatic system disorders						Lymphadenopathy
Immune system disorders						Anaphylactoid reaction (including angioedema)
Metabolic and nutritional disorders	Loss of appetite*1					
Nervous system disorders	Headache, drowsiness *1		Dizziness		Yellow fever vaccine-associated neurotropic disease (YEL-AND)	Paresthesia
Gastrointestinal disorders	Vomiting*2	Nausea	Abdominal pain	Diarrhea		
Skin disorders		Rash	Pruritus			Urticaria
Musculoskeletal disorders	Muscle pain	Joint pain				
General and inoculation-site reactions	Irritability *1, crying*1, pyrexia*2, asthenia, injection-site pain/tenderness	Injection-site erythema/redness, injection-site hematoma, injection-site induration, injection-site edema/swelling	Injection-site papule			Influenza-like illness

*1: Adverse reactions particularly frequently seen in children.
*2: Adverse reactions seen in 10% or more of children and 1% to <10% of the general population.
*3: It is not possible to estimate the incidence from the data obtained to date.

10. Rules We Want You to Follow

- Please stay in the vaccination facility for about 30 minutes after vaccination with “Stamaril.”
- Please pay attention to changes in your physical condition for about 30 days after vaccination. If you feel any problem, you should visit a medical institution as necessary and receive medical examination by a doctor. In this regard, please tell the doctor that you got vaccinated with “Stamaril.”
- If you notice any change to your physical condition within about 30 days after vaccination, please report the details via internet, facsimile or phone call. Please access the designated website and report details in the form or send a survey sheet via facsimile. If you would like to report by phone call, please contact the facility where you got vaccinated.
- If you are female and found to be pregnant within 30 days after vaccination or if you breastfed by mistake within 14 days after vaccination, please contact the facility where you got vaccinated.
- Please follow other instructions written in this participant information sheet.

11. Action and Compensation in case Health Injury Occurs

If you feel any abnormality in your body or have any concern due to participation in this research, you should visit medical institution as necessary and receive medical examination by a doctor. In this regard, please tell the doctor that you got vaccinated with “Stamaril.” Also, contact the institution where you got vaccinated. If your case meets compensation standards, medical expenses which were considered necessary for the treatment will be paid by the insurance company. However, if the doctor judged that the abnormality has no causal relationship to this research or if the abnormality occurred due to your non-compliance to this participant information sheet or doctor’s instruction, the insurance will not cover this (See the attached compensation summary sheet for details).

12. Access to Records & Protection of Personal Information

If you wish to see materials pertaining to this research, please make a request, and we will enable you to access those materials to the possible extent.

During and at the end of this research, your age, gender, information on safety, etc. will be provided to the domestic and overseas regulatory authorities, the authorized institutional review board, and the company providing the vaccine “Stamaril,” but your name will be all replaced with a control number so that the personal information including your name and address will not be provided at all.

In addition, examination will take place to confirm if this research had been conducted accurately and your medical records may be accessed by parties concerned, such as the person designated by the research representative, the authorized institutional review board, and persons in charge at the Ministry of Health, Labour and Welfare. These parties concerned are obliged to

keep secrets by law, so that your personal information will not be disclosed. Your agreement to participate in the research means that you also permit these parties to access to your medical records.

13. About the Burden of Expenses

The vaccine "Stamaril" used in this research, will be provided free of charge by Sanofi Pasteur SA in France. Therefore, your expenses will be the medical interview fee, consultation fee, and the fee for issuance of the certificate, excluding vaccination expenses.

14. Research expenses and conflicts of interest

Conflict of interest (COI) in research is the state in which there is a risk of distorting the research results. For example, if the person in charge of a research was an employee of the pharmaceutical company manufacturing the drug being used for the research, research data could be falsified or the results will be falsely interpreted, so that research will not be disadvantageous to the pharmaceutical company.

This research is conducted based on research agreement (contract) between Sanofi Pasteur SA and Research Institute National Center for Global Health and Medicine, and the fund will be provided by Sanofi Pasteur SA. Sanofi Pasteur SA is a company manufacturing the vaccine "Stamaril®", and "Stamaril®" will be provided pro bono by the manufacturer. We will declare conflicts of interest in advance, along with the COI management plan to the review board noted in item #15. Then we will appropriately manage and publicize the COI according to the management plan approved by the board. In addition, Sanofi Pasteur SA will not analyze research data so that the research results are not distorted.

15. Authorized Institutional Review Board

The following institutional review board is authorized by the Ministry of Health, Labour and Welfare, and had reviewed that the contents of the research plan are scientifically and ethically reasonable in consideration of human rights and safety, and had approved the research plan. The research plan was also submitted to the Minister of Health, Labour and Welfare.

Name of the authorized institutional review board: Institutional Review Board, Research Institute National Center for Global Health and Medicine

Address of the authorized institutional review board: 1-21-1 Toyama, Shinjuku-ku, Tokyo

Authorization No. and authorization date: CRB3180021, March 30, 2018

Contact: 03-3202-7181, Secretariat, Institutional Review Board

16. Research Representative & Doctor in Charge of Research

This research will be conducted at hospitals and quarantine stations authorized by the Ministry

of Health, Labour and Welfare where certificates of vaccination against yellow fever can be issued. The research representative, Dr. Norio Ohmagari is the director of the Disease Control and Prevention Center, Research Institute National Center for Global Health and Medicine. Regarding the research representative and doctor in charge of research at your vaccination facility, please see the attached list of research sites.

17. Contact for Consultation

If you want to know more information or have any concern about this research or your rights, etc., please contact the vaccination facility. Regarding your vaccination facility and contact information, please see the attached list of research sites.

If you could not reach your vaccination facility in case of an urgency, please contact National Center for Global Health and Medicine, which is listed on top.

If you could not reach anyone at your vaccination facility in case of an urgency, please contact #01 “National Center for Global Health and Medicine” and tell the operator to connect to “Disease Control and Prevention Center”.

	Facilities	The principle investigator in each facility	The title of the principle investigator	Address	Phone No.
01	Research Institute National Center for Global Health and Medicine (NCGM)	Norio Ohmagari（The research representative）	The director of the Disease Control and Prevention Center	1-21-1 Toyama, Shinjuku-ku, Tokyo	03-3202-7181
02	Tokyo Medical University Hospital	Atsuo Hamada	The professor in Traveller’s Medical Center	6-7-1 Nishishinjuku, Shinjuku-ku, Tokyo	03-5339-3726
03	Japanese Quarantine Association	Kiyoshi Tanaka	The director of Japanese Quarantine Association	Yaesuguchi Kaikan 3F 1-7-20 Yaesu, Chuo-ku, Tokyo	03-3527-9136
04	Otaru Quarantine Station ‘ Examination Room	Nobumasa Tsujimura	The chief of Otaru Quarantine Station	Otaru Harbor Government Bldg. 1F 5-2 Minato-machi, Otaru, Hokkaido	0134-23-4162
05	Otaru Quarantine Station Chitose Airport Quarantine branch office‘ Vaccination Room	Tomoko Nishiura	The section chief (environmental quarantine) of Otaru Quarantine Station	New Chitose Airport Bldg. (Government Bldg.) 2F Bibi, Chitose, Hokkaido	0123-45-7007
06	Sendai Quarantine Station ‘ Examination Room (National Hospital Organization Morioka National Hospital, Sendai Medical Center)	Hidemaro Ono	The chief of Sendai Quarantine Station	Minamihara, Shimomasuda, Natori, Miyagi	022-367-8101
07	Niigata Quarantine Station’ Examination Room	Katayama Yuko	The chief of Niigata Quarantine Station	Niigata Harbor Government Bldg. 2F 1-5-4 Ryugashima, Chuo-ku, Niigata, Niigata	025-275-4615

08	Tokyo Quarantine Station' Examination Room	Yasuko Homma	The chief of Tokyo Qua0tine Station	Tokyo Harbor Government Bldg. 8F 2-7-11 Aomi, Koto-ku, Tokyo	03-3599-1515
09	Yokohama Quarantine Station' Examination Room	Jun Kitazawa	The chief of Yokohama Quarantine Station	Yokohama Second Harbor Government Bldg. 4F 1-1 Kaigan, Naka-ku, Yokohama, Kanagawa	045-201-4456
10	Nagoya Quarantine Station Chubu Airport Quarantine branch office' Examination Room	Norihiko Yoda	The chief of Nagoya Quarantine Station	CIQ Bldg. 4F 1-1 Centrair, Tokoname, Aichi	0569-38-8205
11	Osaka Quarantine Station' Examination Room (Osaka City General Hospital)	Etsuro Kashiwagi	The chief of Osaka Quarantine Station	Osaka Harbor Government Bldg. 5F 4-10-3Chikko, Minato-ku, Osaka	06-6571-3522
12	Kansai Airport Quarantine Station' Examination Room	Mie Kasamatsu	The chief of Kansai Airport Quarantine Station	1 Senshu-kuko-naka, Tajiri-cho, Sennan-gun, Osaka	072-455-1283
13	Kobe Quarantine Station' Examination Room	Masami Kato	The chief of Kobe Quarantine Station	1-1 Toyahama-cho, Hyogo-ku, Kobe, Hyogo	078-672-9653
14	Hiroshima Quarantine Station' Examination Room	Koji Haga	The chief of Hiroshima Quarantine Station	Hiroshima Harbor Government Bldg. 3F 3-10-17 Ujinakaigan, Minami-ku, Hiroshima, Hiroshima	082-251-2927
15	Fukuoka Quarantine Station Moji Quarantine branch office' Vaccination Room	Koichi Ohtsubo	The chief of Moji Quarantine branch office	Moji Harbor Government Bldg. 1-3-10 Nishikaigan, Moji-ku, Kitakyushu, Fukuoka	093-321-3056
16	Fukuoka Quarantine Station' Examination Room	Takeshi Azuma	The chief of Fukuoka Quarantine Station	Fukuoka Harbor Government Bldg. 8-1 Okihama-cho, Hakata-ku, Fukuoka, Fukuoka	092-291-3585
17	Fukuoka Quarantine Station	Shoko Tanaka	The section chief (environmental	Nagasaki Customs 2F	095-826-8081

	Nagasaki Quarantine branch office' Vaccination Room		quarantine) of Fukuoka Quarantine Station	1-36 Dejima-machi, Nagasaki, Nagasaki	
18	Fukuoka Quarantine Station Kagoshima Quarantine branch office' Vaccination Room	Naoko Yuda	The quarantine medical officer of Fukuoka Airport Quarantine branch office	Kagoshima Harbor Government Bldg. 18-2-31 Izumi-cho, Kagoshima, Kagoshima	099-222-8670
19	Naha Airport Quarantine branch office' Examination Room	Kazuhiro Kakimoto	The chief of Naha Quarantine Station	Naha Airport International Flights Terminal Bldg. 3F 280 Kagamimizu, Naha, Okinawa	098-857-0057

Outline of the Health Compensation Scheme

for Participants of Clinical Research

(STA00014)

1. Introduction

・This clinical research will be conducted with meticulous attention, however, if any health injuries (such as an adverse reaction) might occur due to vaccination or research participation, our health compensation scheme will be applied to you.

・This document summarizes the terms and conditions of the health compensation. Please keep this document along with the "Participant Information sheet and Consent form" with care.

・If you notice any health injuries and thought it was caused by participating in the research, do not hesitate to inform your doctor, vaccination institution, or the National Center for Global Health and Medicine (NCGM). If the doctor judges that the health injury had occurred due to the research, you may be able to receive compensation according to the compensation protocol adopted by NCGM.

・ If you are to be compensated, you need to notify us with your name, address, description of your health injury, bank account number, and your identity verification documents to the vaccination institution or NCGM. Then, your information will be kept strictly confidential and will never be used for other purposes.

2. Compensation by the vaccination institution

(1) General rules

① Compensation will be given based on the Clinical Trials Act to cover for your loss appropriately. Even if there is no legal liability nor negligence of the institution, if any health injuries occur to you, it will cover your damage.

② If you request to receive compensation for the health injury occurred after participating in this research, NCGM will make compensation according to the compensation protocol.

③ Compensation will only be given to the health injury occurred after you signed the consent form and was caused by the research (caused by the study vaccine, study method, and/or procedures). Technically, this is known as having a causal relationship between the health injury and the research. Unless the doctor determines that the research did not cause the health injury, it will be treated as having causality to the research.

④ Even after you received compensation, if you noticed any legal liability to the vaccination institution, your doctor, or any other third party, you have the right to claim for the compensation for damages (which means to claim for pain and/or suffering, treatment costs, lost profits, etc.).

(2) Cases which will not be covered

If there is no causal relationship between your health injury and the research, NCGM will not compensate for the injury. For example:

① On your way to the vaccination institution, if you were hit by a car due to the driver's carelessness and got injured, as there is no causal relationship to the research, the injury will not be compensated.

② If the legal liability of the health injury was on the vaccination institution, your doctor, or any other third party, the compensation will not cover your injury. Instead, person or party who is responsible to the injury will pay for the damage.

③ In case that the study vaccine did not work, generally, this is also non-eligible for the compensation.

④ If it was proven that you are responsible for the health injury, you may either unable to receive compensation, or receive the reduced compensation. Those instances are such as your disobedience on the instructions given on the informed consent form or the doctor's instruction.

(3) Limitation

If there was an obvious cause of the health injury and the causality of the research could obviously be denied, you will not be eligible for the compensation.

(4) Compensation Details

Medical expenses, medical allowance, and indemnity will be given if you were eligible.

① Medical Expenses:

We will first ask you to pay for the medical expenses (expenses for medicine, examination, treatment, and/or hospitalization) required to treat the health injury due to the research. NCGM will then pay the amount equivalent to your payment according to the compensation protocol[*1].

If medical expenses exceed the self-pay limit based on the High Medical Care Cost System[*2], please apply for the limit application standard certificate or the high medical care cost system. After application, NCGM will pay your self-payment amount, deducting the refund.

② Medical Allowances:

If the health injury required hospitalization based on doctor's decision (including outpatient visit under injury equivalent to hospitalization), medical allowances will also be covered by NCGM, according to the compensation protocol[*4] and in line with the Relief System for Sufferers from Adverse Drug Reactions[*3].

③ Indemnity:

a. Permanent Disability Indemnity

If you meet the conditions of disability grade on the Industrial Accident Compensation Insurance, NCGM will pay the disability indemnity[*5], in line with the Relief System for Sufferers from Adverse Drug Reactions.

However, the eligible disabilities are those occurred within 18 months (including onset day) after the injury onset.

b. Death Indemnity

In case of death, indemnity for bereaved family[*6] will be paid to one representative of the family who was in the same living, according to the

compensation protocol and in line with the Relief System for Sufferers from Adverse Drug Reactions.

④ Note

Temporary disability compensation (salary loss due to work absence) will not be paid. Additionally, in case if there is a special reason such as emergency or life-saving purpose, amenity bed expenses will not be paid.

(5) Decision on Causality

① Your doctor is responsible for making the decision on the causal relationship or disability grade. You do not need to prove the causality between the research and health injury yourself. Doctors of vaccination institution will judge the causality rationally, and if the causality could not be denied, you will be eligible.

② It may take some time to judge causality. Before the decisions are made, as it is inappropriate to suspend the payment of medical expenses, thus, the payment will be initiated before the decision. After the judgment was made, we will contact you again. If the causality were denied at the judgment, the payment of medical expenses would be terminated. However, you do not need to return the medical expenses which are already paid to you.

③ Generally, medical expenses will be transferred to your declared bank account in 2-3 months. Please note that in advance.

(6) Compensation Application Procedures

① If you noticed any health injury such as an adverse reaction after the research participation and thought it was caused by the research, please consult your doctor or NCGM personnel.

② If you wish to receive compensation, please inform your doctor. The doctor will contact NCGM for compensation application. Then, doctors at the vaccination institution will investigate the causality between the health injury and the research. The personnel at the vaccination institution will contact you whether the health injury was eligible for the compensation.