Informed Consent Form for Vaccination of SARS-CoV-2 Vaccine (Vero Cell), Inactivated

(phase I, medium dosage, emergency immunization procedure, healthy volunteers aged 18-59)

You are invited to participate in a clinical trial, which is to evaluate the safety, tolerability, and preliminary immunogenicity of SARS-CoV-2 Vaccine (Vero Cell), Inactivated, by administered to adults under different immunization procedures in different doses. This form describes the details, risks, benefits and duties of the study. Before agreeing to participate in this study, please read the following information carefully. You can ask the investigator if you have any questions. This study has been approved by the National Medical Products Administration and the Ethics Committee of Jiangsu Provincial Center for Disease Prevention and Control.

Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

This informed consent consists of two parts: the information disclosure part about the study and the signature part that certifies your agreement to participate in the study.

1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. . Most patients have a good prognosis, while few of them are in a critical condition. Patient were elderlyor with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is inactivated SARS-CoV-2 virus.The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml

In this study, the placebo composed of aluminum hydroxide diluent , is used as the control, which is produced by Sinovac Research & Development Co., Ltd..

1.3 Objective

To evaluate the safety, tolerance and preliminary immunogenicity of different vaccine administered at different immunization in adults.

1.4 Subjects

It is planned to enrol 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high- dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).

You are invited to participate in the medium- dosage group (phase I), will be vaccinated in the emergency immunization procedure (0, 14 days). You have a 2/3 chance of getting a medium dosage of the investigational vaccine, and a 1/3 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; collecting peripheral venous blood and urine for blood biochemistry, blood routine and urine routine tests before enrollment, measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood and urine sample will be collected during the trial which need your cooperation. For blood sample, 13ml will be collected from you before vaccination, 8ml for 3 days post-vaccination and 5ml for 7 days post-vaccination for each dose. In addition, 5-10ml urine sample will be collected from you before vaccination and 3 days post-vaccination for each dose to evaluate the safety of the vaccine.15ml blood sample will be collected from you before vaccination, 5ml for 7 days post-vaccination for each dose. Beside, 15ml blood sample for 14 days post-vaccination, 5ml for both 28 and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate to complete 10 times of blood sample collection and 4 times of urine sample collection, totaling about 117 ml of peripheral venous blood and 20-40 ml of urine. For all female subjects, 5-10 ml of urine were also required to be collected for urine pregnancy test before each dose.
- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse

events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.

- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.
- We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, there common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time if an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risk of blood collection is pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co., Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a compensation of RMB 800 for each visit.

1.9 Rights and obligations

Your participation in this study is entirely voluntary. You can get any information related to this study at any time during the study. We will inform you the information in time that may affect your willingness in this study. You will also be able to withdraw your participation any time during the study, without showing any cause. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits or attention. If you decide not to participate in this study or to withdraw at any time, please contact us. We can suspend or terminate your participation without your consent in the following cases: you are unable to comply with the requirements of the study protocol, or you are not in a healthy condition to continue , or the study is suspended or terminated ahead of schedule. If you agree to participate in this study, you are obligated to cooperate with us during the study.

1.10 Confidentiality agreement

All of your personal information and test results will be kept strictly confidential. All of your source materials will be kept by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institue of Jiangsu Province). And can be consulted only by National Medical Products Administration, the Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention and the auditors or inspectors entrusted by Sinovac Research & Development Co., Ltd. in accordance with the regulations.

You are not allowed to provide any information related to this study, including the progress of the study, without the signature of the investigators.

1.11 Others

All data collected in this study will be used for this study only. The specimens used for blood routine test, blood biochemical test, urine routine test, inflammatory factor test and T cell reaction test shall be disposed as medical waste by the testing institution after the test. The backup serum shall be temporarily kept by the institution of the study site until the immunogenicity test report is issued by National Institute for Food and Drug Control and verified to be correct. After the end

of the project, the backup serum can be stored or processed by the sponsor, and its use requires the approval of the ethics committee and the consent of the subjects.

1.12 Contacts

If you have any questions or need help, please contact the following individual or institution:

_____County/city-level Center for Disease Control and Prevention

Contact: _____ 24-hour Tel: _____

For rights and interests related to the study, please contact:

Ethics committee of Jiangsu Provincial Center for Disease Control and Prevention

Tel: 025-83759406 (8:30-17:30)

2. Signing of the Informed Consent

If you sign this informed consent form, it indicates that the investigator has explained to you all the relevant contents of this study and answered all your questions about this study; you have fully understood all the contents and implications of this informed consent; you have given full consideration and voluntarily agreed to participate in this study.

2.1 Signature of the Volunteer

Name of Participant: _____ (to be completed by the Investigator)

Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minute, day month year

2.2Statement of theWitness

Because the participant were unable to read and fill in the form correctly, the investigator has informed the participant on-site of all the contents. The participant have understood all the contents of the informed consent and agreed to participate in this study. As a third-party witness, I witnessed the whole process of informed consent.

Name of Witness: _____ (to be completed by the Investigator)

Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

hour minute day month year

2.3 Statement of the Investigator

I promise that I have fully introduced all the relevant information of this study to the volunteers, and have fully communicated with them, and obtained all the above information with the volunteers' voluntary assistance.

Signature of Investigator:_____

Date: _____ : _____, _____/_____/_____ (to be completed by the Investigator)

hour minute day month year

Informed Consent Form for Vaccination of SARS-CoV-2 Vaccine (Vero Cell), Inactivated

(phase I, high dosage, emergency immunization procedure, healthy volunteers aged 18-59)

You are invited to participate in a clinical trial, which is to evaluate the safety, tolerability, and preliminary immunogenicity of SARS-CoV-2 Vaccine (Vero Cell), Inactivated, by administered to adults under different immunization procedures in different doses. This form describes the details, risks, benefits and duties of the study. Before agreeing to participate in this study, please read the following information carefully. You can ask the investigator if you have any questions. This study has been approved by the National Medical Products Administration and the Ethics Committee of Jiangsu Provincial Center for Disease Prevention and Control.

Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

This informed consent consists of two parts: the information disclosure part about the study and the signature part that certifies your agreement to participate in the study.

1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. Most patients have a good prognosis, while few of them are in a critical condition. Patient were elderly or with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is inactivated SARS-CoV-2 virus. The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml
In this study, the placebo composed of aluminum hydroxide diluent, is used as the control, which is produced by Sinovac Research & Development Co., Ltd.

1.3 Objective

To evaluate the safety, tolerance and preliminary immunogenicity of different vaccine administered at different immunization in adults.

1.4 Subjects

It is planned to enroll 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high-dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).

You are invited to participate in the high-dosage group (phase I), will be vaccinated in the emergency immunization procedure (0, 14 days). You have a 2/3 chance of getting a high dosage of the investigational vaccine, and a 1/3 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; collecting peripheral venous blood and urine for blood biochemistry, blood routine and urine routine tests before enrollment, measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood and urine sample will be collected during the trial which need your cooperation. For blood sample, 13ml will be collected from you before vaccination, 8ml for 3 days post-vaccination and 5ml for 7 days post-vaccination for each dose. In addition, 5-10ml urine sample will be collected from you before vaccination and 3 days post-vaccination for each dose to evaluate the safety of the vaccine.15ml blood sample will be collected from you before vaccination, 5ml for 7 days post-vaccination for each dose. Beside, 15ml blood sample for 14 days post-vaccination, 5ml for both 28 and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate to complete 10 times of blood sample collection and 4 times of urine sample collection, totaling about 117 ml of peripheral venous blood and 20-40 ml of urine. For all female subjects, 5-10 ml of urine were also required to be collected for urine pregnancy test before each dose.
- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in

the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.

- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.
- We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, there common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time if an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risks from blood collection are pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co., Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a compensation of RMB 800 for each visit.

1.9 Rights and obligations

Your participation in this study is entirely voluntary. You can get any information related to this study at any time during the study. We will inform you the information in time that may affect your willingness in this study. You will also be able to withdraw your participation any time during the study, without showing any cause. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits or attention. If you decide not to participate in this study or to withdraw at any time, please contact us. We can suspend or terminate your participation without your consent in the following cases: you are unable to comply with the requirements of the study protocol, or you are not in a healthy condition to continue , or the study is suspended or terminated ahead of schedule. If you agree to participate in this study, you are obligated to cooperate with us during the study.

1.10 Confidentiality agreement

All of your personal information and test results will be kept strictly confidential. All of your source materials will be kept by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institue of Jiangsu Province). And can be consulted only by National Medical Products Administration, the Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention and the auditors or inspectors entrusted by Sinovac Research & Development Co., Ltd. in accordance with the regulations.

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committee and the consent of the subjects.

1.12 Contacts

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Tel: 025-83759406 (8:30-17:30)

2. Signing of the Informed Consent

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2.1 Signature of the Volunteer

Name of Participant: _____ (to be completed by the Investigator)

Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minut, day month year

2.2Statement of theWitness

Because the participant were unable to read and fill in the form correctly, the investigator has informed the participant on-site of all the contents. The participant have understood all the contents of the informed consent and agreed to participate in this study. As a third-party witness, I witnessed the whole process of informed consent.

Name of Witness: _____ (to be completed by the Investigator)

Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

hour minute day month year

2.3 Statement of the Investigator

I promise that I have fully introduced all the relevant information of this study to the volunteers, and have fully communicated with them, and obtained all the above information with the volunteers' voluntary assistance.

Signature of Investigator:_____

Date: _____ : _____, _____/_____/_____ (to be completed by the Investigator)

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(phase I, medium dosage, routine immunization procedure, healthy volunteers aged 18-59)

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Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

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1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. . Most patients have a good prognosis, while few of them are in a critical condition. Patient were elderly or with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is

inactivated SARS-CoV-2 virus.The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml
In this study, the placebo composed of aluminum hydroxide diluent , is used as the control, which is produced by Sinovac Research & Development Co., Ltd..

1.3 Objective

To evaluate the safety, tolerance and preliminary immunogenicity of different dosage vaccine administered at different immunization schedules in adults.

1.4 Subjects

It is planned to enrol 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high-dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).
You are invited to participate in the medium-dosage group (phase I), will be vaccinated in the routine immunization procedure (0, 28 days). You have a 2/3 chance of getting a medium dosage of the investigational vaccine, and a 1/3 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; collecting peripheral venous blood and urine for blood biochemistry, blood routine and urine routine tests before enrollment, measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood and urine sample will be collected during the trial which need your cooperation. For blood sample, 13ml will be collected from you before vaccination, 8ml for 3 days post-vaccination and 5ml for 7 days post-vaccination for each dose. In addition, 5-10ml urine sample will be collected from you before vaccination and 3 days post-vaccination for each dose to evaluate the safety of the vaccine.15ml blood sample will be collected from you before vaccination, 5ml for 7 days post-vaccination , 15ml blood sample for 14 days post-vaccination, 5ml for both 28 and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate to complete 10 times of blood sample collection and 4 times of urine sample collection, totaling about 112 ml of

peripheral venous blood and 20-40 ml of urine. For all female subjects, 5-10 ml of urine is also required to be collected for urine pregnancy test before each dose.

- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.
- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.
- We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time once an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risk of blood collection is pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co., Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a compensation of RMB 800 for each visit.

1.9 Rights and obligations

Your participation in this study is entirely voluntary. You can get any information related to this study at any time during the study. We will inform you the information in time that may affect your willingness in this study. You will also be able to withdraw your participation any time during the study, without showing any cause. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits or attention. If you decide not to participate in this study or to withdraw at any time, please contact us. We can suspend or terminate your participation without your consent in the following cases: you are unable to comply with the requirements of the study protocol, or you are not in a healthy condition to continue , or the study is suspended or terminated ahead of schedule. If you agree to participate in this study, you are obligated to cooperate with us during the study.

1.10 Confidentiality agreement

All of your personal information and test results will be kept strictly confidential. All of your source materials will be kept by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institue of Jiangsu Province). And can be consulted only by National Medical Products Administration, the Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention and the auditors or inspectors entrusted by Sinovac Research & Development Co., Ltd. in accordance with the regulations.

You are not allowed to provide any information related to this study, including the progress of the study, without the signature of the investigators.

1.11 Others

All data collected in this study will be used for this study only. The specimens used for blood routine test, blood biochemical test, urine routine test, inflammatory factor test and T cell reaction test shall be disposed as medical waste by the testing institution after the test. The backup serum shall be temporarily kept by the institution of the study site until the immunogenicity test report is issued by National Institute for Food and Drug Control and verified to be correct. After the end

of the project, the backup serum can be stored or processed by the sponsor, and its use requires the approval of the ethics committee and the consent of the subjects.

1.12 Contacts

If you have any questions or need help, please contact the following individual or institution:

_____County/city-level Center for Disease Control and Prevention

Contact: _____ 24-hour Tel: _____

For rights and interests related to the study, please contact:

Ethics committee of Jiangsu Provincial Center for Disease Control and Prevention

Tel: 025-83759406 (8:30-17:30)

2. Signing of the Informed Consent

If you sign this informed consent form, it indicates that the investigator has explained to you all the relevant contents of this study and answered all your questions about this study; you have fully understood all the contents and implications of this informed consent; you have given full consideration and voluntarily agreed to participate in this study.

2.1 Signature of the Volunteer

Name of Participant: _____ (to be completed by the Investigator)

Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minute, day month year

2.2Statement of theWitness

Because the participant were unable to read and fill in the form correctly, the investigator has informed the participant on-site of all the contents. The participant have understood all the contents of the informed consent and agreed to participate in this study. As a third-party witness, I witnessed the whole process of informed consent.

Name of Witness: _____ (to be completed by the Investigator)

Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

hour minute day month year

2.3 Statement of the Investigator

I promise that I have fully introduced all the relevant information of this study to the volunteers, and have fully communicated with them, and obtained all the above information with the volunteers' voluntary assistance.

Signature of Investigator:_____

Date: _____ : _____, _____/_____/_____ (to be completed by the Investigator)

hour minute day month year

Informed Consent Form for Vaccination of SARS-CoV-2 Vaccine (Vero Cell), Inactivated

(phase I, high dosage, routine immunization procedure, healthy volunteers aged 18-59)

You are invited to participate in a clinical trial, which is to evaluate the safety, tolerability, and preliminary immunogenicity of SARS-CoV-2 Vaccine (Vero Cell), Inactivated, by administered to adults under different immunization procedures in different doses. This form describes the details, risks, benefits and duties of the study. Before agreeing to participate in this study, please read the following information carefully. You can ask the investigator if you have any questions. This study has been approved by the National Medical Products Administration and the Ethics Committee of Jiangsu Provincial Center for Disease Prevention and Control.

Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

This informed consent consists of two parts: the information disclosure part about the study and the signature part that certifies your agreement to participate in the study.

1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. . Most patients have a good prognosis, while few of them are in a critical condition. Patient were elderlyor with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as

investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is inactivated SARS-CoV-2 virus.The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml
In this study, the placebo composed of aluminum hydroxide diluent , is used as the control, which is produced by Sinovac Research & Development Co., Ltd..

1.3 Objective

To evaluate the safety, tolerance and preliminary immunogenicity of different dosage vaccine administered at different immunization schedules in adults.

1.4 Subjects

It is planned to enrol 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high-dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).

You are invited to participate in the high-dosage group (phase I), will be vaccinated in the routine immunization procedure (0, 28 days). You have a 2/3 chance of getting a high dosage of the investigational vaccine, and a 1/3 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; collecting peripheral venous blood and urine for blood biochemistry, blood routine and urine routine tests before enrollment, measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood and urine sample will be collected during the trial which need your cooperation. For blood sample, 13ml will be collected from you before vaccination, 8ml for 3 days post-vaccination and 5ml for 7 days post-vaccination for each dose. In addition, 5-10ml urine sample will be collected from you before vaccination and 3 days post-vaccination for each dose to evaluate the safety of the vaccine.15ml blood sample will be collected from you before vaccination, 5ml for 7 days post-vaccination , 15ml blood sample for 14 days post-vaccination, 5ml for both 28 and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate

to complete 10 times of blood sample collection and 4 times of urine sample collection, totaling about 112 ml of peripheral venous blood and 20-40 ml of urine. For all female subjects, 5-10 ml of urine is also required to be collected for urine pregnancy test before each dose.

- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.
- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.
- We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time once an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risk of blood collection is pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the

newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co., Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a compensation of RMB 800 for each visit.

1.9 Rights and obligations

Your participation in this study is entirely voluntary. You can get any information related to this study at any time during the study. We will inform you the information in time that may affect your willingness in this study. You will also be able to withdraw your participation any time during the study, without showing any cause. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits or attention. If you decide not to participate in this study or to withdraw at any time, please contact us. We can suspend or terminate your participation without your consent in the following cases: you are unable to comply with the requirements of the study protocol, or you are not in a healthy condition to continue , or the study is suspended or terminated ahead of schedule. If you agree to participate in this study, you are obligated to cooperate with us during the study.

1.10 Confidentiality agreement

All of your personal information and test results will be kept strictly confidential. All of your source materials will be kept by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institue of Jiangsu Province). And can be consulted only by National Medical Products Administration, the Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention and the auditors or inspectors entrusted by Sinovac Research & Development Co., Ltd. in accordance with the regulations.

You are not allowed to provide any information related to this study, including the progress of the study, without the signature of the investigators.

1.11 Others

All data collected in this study will be used for this study only. The specimens used for blood routine test, blood biochemical test, urine routine test, inflammatory factor test and T cell reaction test shall be disposed as medical waste by the testing institution after the test. The backup serum shall be temporarily kept by the institution of the study site until the

immunogenicity test report is issued by National Institute for Food and Drug Control and verified to be correct. After the end of the project, the backup serum can be stored or processed by the sponsor, and its use requires the approval of the ethics committee and the consent of the subjects.

1.12 Contacts

If you have any questions or need help, please contact the following individual or institution:

_____County/city-level Center for Disease Control and Prevention

Contact: _____ 24-hour Tel: _____

For rights and interests related to the study, please contact:

Ethics committee of Jiangsu Provincial Center for Disease Control and Prevention

Tel: 025-83759406 (8:30-17:30)

2. Signing of the Informed Consent

If you sign this informed consent form, it indicates that the investigator has explained to you all the relevant contents of this study and answered all your questions about this study; you have fully understood all the contents and implications of this informed consent; you have given full consideration and voluntarily agreed to participate in this study.

2.1 Signature of the Volunteer

Name of Participant: _____ (to be completed by the Investigator)

Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minute, day month year

2.2Statement of theWitness

Because the participant were unable to read and fill in the form correctly, the investigator has informed the participant on-site of all the contents. The participant have understood all the contents of the informed consent and agreed to participate in this study. As a third-party witness, I witnessed the whole process of informed consent.

Name of Witness: _____ (to be completed by the Investigator)

Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

hour minute day month year

2.3 Statement of the Investigator

I promise that I have fully introduced all the relevant information of this study to the volunteers, and have fully communicated with them, and obtained all the above information with the volunteers' voluntary assistance.

Signature of Investigator:_____

Date: _____ : _____, _____/_____/_____ (to be completed by the Investigator)

hour minute day month year

Informed Consent Form for Vaccination of SARS-CoV-2 Vaccine (Vero Cell), Inactivated

(phase II, emergency immunization procedure, healthy volunteers aged 18-59)

You are invited to participate in a clinical trial, which is to evaluate the safety and preliminary immunogenicity of SARS-CoV-2 Vaccine (Vero Cell), Inactivated, by administered to adults under different immunization procedures in different dosage. This form describes the details, risks, benefits and duties of the study. Before agreeing to participate in this study, please read the following information carefully. You can ask the investigator if you have any questions. This study has been approved by the National Medical Products Administration and the Ethics Committee of Jiangsu Provincial Center for Disease Prevention and Control.

Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

This informed consent consists of two parts: the information disclosure part about the study and the signature part that certifies your agreement to participate in the study.

1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. Most patients have a good prognosis, while few of them are in a critical condition. Patients were elderly or with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is inactivated SARS-CoV-2 virus.The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml

In this study, the placebo composed of aluminum hydroxide diluent is used as the control, which is produced by Sinovac Research & Development Co., Ltd..

1.3 Objective

To evaluate the safety and immunogenicity of different dosage vaccine administered at different immunization schedules in adults so as to determine the appropriate dosage and immunization schedule for further clinical evaluation.

1.4 Subjects

It is planned to enrol 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high-dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).

You are invited to participate in phase II study, will be vaccinated in the emergency immunization procedure (0, 14 days). You have a 4/5 chance of getting the investigational vaccine, and a 1/5 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood sample will be collected during the trial which need your cooperation. 3ml will be collected from you before vaccination, 14days post-vaccination, 28days post-vaccination, and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate to complete 4 times of blood sample collection, totaling about 12 ml of peripheral venous blood. For all female subjects, 5-10 ml of urine is also required to be collected for urine pregnancy test before each dose.
- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.
- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.

— We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time once an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risk of blood collection is pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co.,

Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a RMB 200 equivalent gift for each blood collection or vaccination (4 times in total).

1.9 Rights and obligations

Your participation in this study is entirely voluntary. You can get any information related to this study at any time during the study. We will inform you the information in time that may affect your willingness in this study. You will also be able to withdraw your participation any time during the study, without showing any cause. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits or attention. If you decide not to participate in this study or to withdraw at any time, please contact us. We can suspend or terminate your participation without your consent in the following cases: you are unable to comply with the requirements of the study protocol, or you are not in a healthy condition to continue, or the study is suspended or terminated ahead of schedule. If you agree to participate in this study, you are obligated to cooperate with us during the study.

1.10 Confidentiality agreement

All of your personal information and test results will be kept strictly confidential. All of your source materials will be kept by Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institue of Jiangsu Province). And can be consulted only by National Medical Products Administration, the Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention and the auditors or inspectors entrusted by Sinovac Research & Development Co., Ltd. in accordance with the regulations.

You are not allowed to provide any information related to this study, including the progress of the study, without the signature of the investigators.

1.11 Others

All data collected in this study will be used for this study only. The specimens used for blood routine test, blood biochemical test, urine routine test, inflammatory factor test and T cell reaction test shall be disposed as medical waste by the testing institution after the test. The backup serum shall be temporarily kept by the institution of the study site until the immunogenicity test report is issued by National Institute for Food and Drug Control and verified to be correct. After the end of the project, the backup serum can be stored or processed by the sponsor, and its use requires the approval of the ethics committee and the consent of the subjects.

1.12 Contacts

If you have any questions or need help, please contact the following individual or institution:

_____County/city-level Center for Disease Control and Prevention

Contact: _____ 24-hour Tel: _____

For rights and interests related to the study, please contact:

Ethics committee of Jiangsu Provincial Center for Disease Control and Prevention

Tel: 025-83759406 (8:30-17:30)

2. Signing of the Informed Consent

If you sign this informed consent form, it indicates that the investigator has explained to you all the relevant contents of this study and answered all your questions about this study; you have fully understood all the contents and implications of this informed consent; you have given full consideration and voluntarily agreed to participate in this study.

2.1 Signature of the Volunteer

Name of Participant: _____ (to be completed by the Investigator)

Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minute, day month year

2.2Statement of theWitness

Because the participant were unable to read and fill in the form correctly, the investigator has informed the participant on-site of all the contents. The participant have understood all the contents of the informed consent and agreed to participate in this study. As a third-party witness, I witnessed the whole process of informed consent.

Name of Witness: _____ (to be completed by the Investigator)

Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

hour minute day month year

2.3 Statement of the Investigator

I promise that I have fully introduced all the relevant information of this study to the volunteers, and have fully communicated with them, and obtained all the above information with the volunteers' voluntary assistance.

Signature of Investigator:_____

Date: _____ : _____, _____/_____/_____ (to be completed by the Investigator)

hour minute day month year

Informed Consent Form for Vaccination of SARS-CoV-2 Vaccine (Vero Cell), Inactivated

(phase II, routine immunization procedure, healthy volunteers aged 18-59)

You are invited to participate in a clinical trial, which is to evaluate the safety and preliminary immunogenicity of SARS-CoV-2 Vaccine (Vero Cell), Inactivated, by administered to adults under different immunization procedures in different dosage. This form describes the details, risks, benefits and duties of the study. Before agreeing to participate in this study, please read the following information carefully. You can ask the investigator if you have any questions. This study has been approved by the National Medical Products Administration and the Ethics Committee of Jiangsu Provincial Center for Disease Prevention and Control.

Name of Sponsor: Sinovac Research & Development Co., Ltd.

Institution: Jiangsu Provincial Center for Disease Control and Prevention (Public Health Research Institute of Jiangsu Province)

Principal Investigator: Zhu Fengcai

This informed consent consists of two parts: the information disclosure part about the study and the signature part that certifies your agreement to participate in the study.

1. Information

1.1 Background

Since December 2019, several cases of unexplained pneumonia had been reported in Hubei province, China. A novel coronavirus has been identified from patients' throat swab sample on 7 January 2020. The World Health Organization (WHO) declared the official name of the disease caused by the virus was COVID-19. COVID-19 patients are the main source of infection, and asymptomatic patients may also be contagious. Respiratory secretions through droplets and intimate contact contributed to person-to-person transmission. As a new infectious disease, the whole population is generally susceptible. Based on the current epidemiological survey, the latent period of the COVID-19 is from 1 to 14 days, mostly 3 to 7 days. Fever, fatigue and cough are the main manifestations. A small number of patients with nasal obstruction, runny nose, sore throat, myalgia and diarrhoea. Severe patients arise with dyspnoea and/ or hypoxemia one week after the onset of the disease, among which could rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction. . Most patients have a good prognosis, while few of them are in a critical condition. Patients were elderly or with chronic diseases have poor prognosis. The clinical manifestations between pregnant women and non-pregnant were similar. The epidemic escalated rapidly. Such cases are reported in over 200 countries and territories, caused global COVID-19 pandemic. So far, no specific therapies or vaccines have been approved for COVID-19.

1.2 Investigational Vaccine

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Research & Development Co., Ltd..is used as investigational vaccine. The packaged is pre-filled syringe with an extractable volume of 0.5ml. The main ingredient is inactivated SARS-CoV-2 virus.The antigen content of medium and high dosage is 600SU/0.5ml, and 1200SU/0.5ml

In this study, the placebo composed of aluminum hydroxide diluent is used as the control, which is produced by Sinovac Research & Development Co., Ltd..

1.3 Objective

To evaluate the safety and immunogenicity of different dosage vaccine administered at different immunization schedules in adults so as to determine the appropriate dosage and immunization schedule for further clinical evaluation.

1.4 Subjects

It is planned to enrol 744 healthy adults aged 18-59 years in this study. All of them will be vaccinated in emergency immunization procedure (0, 14 days) or routine immunization procedure (0, 28 days). Each immunization procedure includes 372 subjects (72 for phase I, 300 for phase II). 144 subjects for phase I (48 for both medium- and high-dosage groups, 48 for placebo group) and 600 subjects for phase II (240 for both medium- and high-dosage groups, 120 for placebo group).

You are invited to participate in phase II study, will be vaccinated in the routine immunization procedure (0, 28 days). You have a 4/5 chance of getting the investigational vaccine, and a 1/5 chance of getting a placebo.

1.5 Procedures

We will visit you according to the following procedures after your agreement. Please cooperate with us to complete the following visits:

- Sign the Informed Consent Form. This Informed Consent is made in duplicate, and you will get a copy.
- Physical examination is necessary before your vaccination , including IgG/IgM screening of SARS-CoV-2 antibody, collecting throat swabs and anal swabs for nucleic acid testing to rule out SARS-CoV-2 infection; measurement of height, body weight and body temperature, urine pregnancy test of women of child-bearing age, inquiring about the history of vaccination, history of illness, etc.. If you are not qualified, you will be unable to participate in this study.
- If you are qualified after screening, a vaccine number to the participant will be assigned to identify your identity, and your information will be kept strictly confidential.
- You will be vaccinated with two doses of SARS-CoV-2 Vaccine (Vero Cell), Inactivated or the placebo in emergency immunization procedure (0, 14 days).
- You should stay on the site for 30 min observation and the possible immediate allergic reaction will be observed at the same time.
- Blood sample will be collected during the trial which need your cooperation. 3ml will be collected from you before vaccination, 28days post-vaccination, and 180 days post-vaccination for the last dose to evaluate the immunogenicity of the vaccine. To summarize, you need to cooperate to complete 3 times of blood sample collection , totaling about 9 ml of peripheral venous blood. For all female subjects, 5-10 ml of urine is also required to be collected for urine pregnancy test before each dose.
- We will conduct regular safety visits to you during the whole study process.
- After each dose, please record all your medical events in the diary card, including symptoms of adverse events, medical history, medication and other vaccine use. During the visits, we will guide you to fill in the diary card correctly, and solve the problems you encounter after vaccination. Please contact us in time if any serious disease or symptom happened.
- Your participation in this study is expected to be no more than 8 months, and after the full course of vaccination, we will also collect serious adverse events (diseases requiring hospitalization, injuries, disabilities, and life-threatening health events) that occurred in you 28 days to 6 months after the second dose of the vaccination.
- In order to maximize your safety, please take effective contraceptive measures (drugs or condoms) during the entire study period if you participate in this study. Please inform us in time if you get pregnant during the study.
- Please strictly abide by the requirements of the doctors and not participate in other clinical studies during this study.

— We may terminate your participation if you have serious adverse reactions during the study, or your health condition is not suitable to continue your participation, or you violate the requirements of the study protocol.

1.6 Potential Risks

Risks of the investigational vaccine: as a newly developed vaccine, there is no data from large-scale population safety evaluation, however previous animal studies shown that the vaccine is safe. We will pay close attention to the adverse reactions after your vaccination. You will not be infected with COVID-19 because of vaccination since the inactive vaccine contains no live viruses.

Potential risks of injection: according to experience of routine vaccination, common adverse reactions are pain, induration, swelling and redness at injection site. These adverse reactions are generally light and will be relieved or disappeared within 2-3 days without any special treatment. The possibility of infection at injection site caused by vaccination is very low. However, please contact us in time if any serious disease or symptom happened.

Risks of allergy: you may feel slight discomfort after vaccination, such as fever, general malaise and other reactions, which can disappear without any special treatment. You may have an acute allergic reaction, which is very rare but may be life-threatening. We will observe your health condition after your vaccination. We will provide appropriate treatment in time once an allergic reaction occurs.

Other possible risks after vaccination: You may also develop antibody dependence enhancement (ADE) or vaccine enhanced disease (VED) when reinfected with a SARS-CoV-2 or other viruses after vaccination. In case of the above, please contact us in time for guidance and assistance in your treatment.

Potential risks from blood collection: Drawing blood may include discomfort in your arm. The main risk of blood collection is pain and ecchymosis. Few subjects may syncope or get infection from the needle site.

Potential risks of pregnancy: As a novel vaccine, SARS-CoV-2 Vaccine (Vero Cell), Inactivated lacks evidence on pregnancy and fetuses. If you get pregnant during the study, please inform us in time. We will submit your pregnancy information to the sponsor and Ethics Committee of Jiangsu Provincial Center for Disease Control and Prevention. In addition, we will follow you up until the end of your pregnancy to obtain your pregnancy information, including details of delivery, neonatal assessment or termination of pregnancy. During pregnancy, please do routine pregnancy examinations. If you, the fetus or the newborn have any adverse events related to pregnancy, please contact us in time.

1.7 Selection of Other Preventive Measures

So far, there is no SARS-CoV-2 vaccine in sales neither in the Chinese market nor the international market. If you do not participate in this study, there are no other alternative vaccines available for vaccination. Please do common protection as required to avoid infection of SARS-CoV-2 during the study. If you are diagnosed as a suspected COVID-19 case during the study, we will follow the routine diagnosis and treatment process of COVID-19.

1.8 Benefit and compensation

We will help you understand the basic knowledge and preventive measures of SARS-CoV-2. You may benefit from the vaccine by getting the antibody against SARS-CoV-2., but there is no guarantee that you will definitely not be infected with SARS-CoV-2 after vaccination. If you are vaccinated with placebo, you cannot benefit directly from the vaccination but will be vaccinated for free after the marketing approval.

You will be treated in time if adverse event or serious adverse event occurs during the safety observation. The contingency plan for the damage and emergencies will be formulated in the study site as well as a green channel agreement with the local hospitals. If the adverse event is considered to be related to vaccination by the experts, Sinovac Research & Development Co.,

Ltd. will bear reasonable diagnosis and treatment costs and corresponding economic compensation.

There will be no cost to you for your participation in this study. The study vaccine, study-related procedures and study visits will be provided at no cost to you. You will be well served by the local health care institutions during the study and will receive a RMB 200 equivalent gift for each blood collection or vaccination (4 times in total).

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Signature of the Participant:_____ (to be completed by the Participant)

Date: _____ : _____, _____/_____/_____ (to be completed by the Participant)

hour minute, day month year

2.2Statement of theWitness

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Signature of the Witness:_____ (to be completed by the Witness)

Date: _____ : _____, _____/_____/_____ (to be completed by the Witness)

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