A Phase-1, Open-Label, Placebo-Controlled Evaluation of a Live, Recombinant Newcastle Disease Virus Expressing the Spike Protein of SARS-CoV-2 (NDV-HXP-S), an Investigational Product for Intranasal (IN) and/or Intramuscular (IM) Vaccination in Healthy Adults Previously Immunized Against COVID-19

PI: Sean Liu
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Icahn School of Medicine at Mount Sinai

Sponsor / Study Title:	**Icahn School of Medicine at Mount Sinai / "A Phase-1, Open-Label, Placebo-Controlled Evaluation of a Live, Recombinant Newcastle Disease Virus Expressing the Spike Protein of SARS-CoV-2 (NDV-HXP-S), an Investigational Product for Intranasal and/or Intramuscular Vaccination in Healthy Adults Previously Immunized Against COVID-19"**
Protocol Number:	**STUDY-21-01589**
Principal Investigator: (Study Doctor)	**Sean Liu, MD, PhD**
Telephone:	**212-824-7714 (Office)** **212-241-2724 (24-hour, Emergent / Urgent calls)**
Address:	**Icahn School of Medicine at Mount Sinai** **17 East 102nd Street, 8th Floor** **New York, NY 10029** **Icahn School of Medicine at Mount Sinai** **One Gustave L. Levy Place, Box 1090** **New York, NY 10029**

SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is assessing the safety and immune response of a new kind of investigational vaccine for COVID-19. COVID-19 continues to cause significant illness and death around the world. Several COVID-19 vaccines have recently been developed and are available in select countries. The Icahn School of Medicine at Mount Sinai has developed a new COVID-19 vaccine called NDV-HXP-S. NDV-HXP-S is a study vaccine (investigational product), which means that it has NOT BEEN APPROVED by the U.S. Food and Drug Administration (FDA).

To participate in this study, you must have received an FDA authorized or approved COVID-19 vaccine at least six months (180 days) before enrollment and be willing to postpone receiving any other COVID-19 vaccine booster dose for eight weeks (56 days) after receiving the study vaccine.

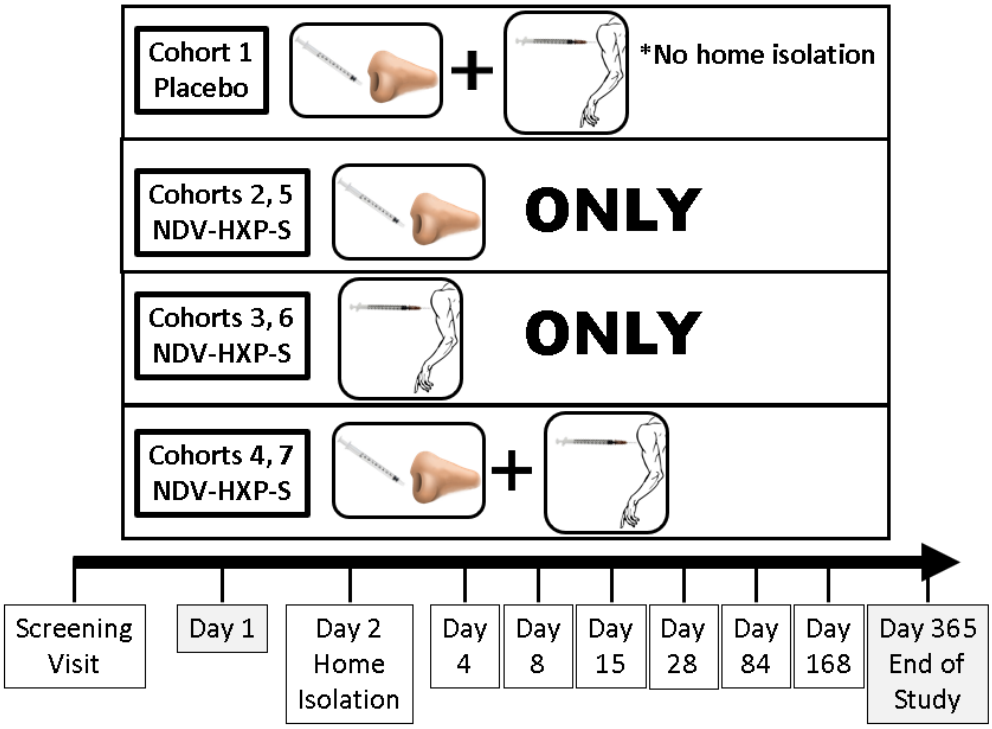
NDV-HXP-S contains a LIVE virus called Newcastle disease virus that contains the Spike protein of SARS-CoV-2. By introducing the Spike protein to your body, this study vaccine is designed to prepare your immune system to protect you from infection with SARS-CoV-2 which is the virus that causes COVID-19. You cannot get COVID-19 from this vaccine.

The LIVE virus in NDV-HXP-S is called Newcastle disease virus and it naturally targets birds for infection, very rarely infecting people. The few historical reports of Newcastle disease virus infections have involved people feeling temporary 'flu-like' symptoms (such as fevers, chills, headaches, and generally feeling of unwellness) and / or eye conjunctivitis (irritation or inflammation in the eye). Newcastle disease virus is NOT considered a harmful virus towards humans. NDV-HXP-S has undergone extensive animal testing and has been shown to be both safe and effective in animals. You will be participating in one of the first clinical studies to see if the NDV-HXP-S study vaccine will be safe for humans who have been previously immunized against COVID-19 by an authorized or approved COVID-19 vaccine. NDV-HXP-S has already been given as a study vaccine to several participants around the world who have not been previously vaccinated.

This NDV-HXP-S study vaccine has the potential to provide protection against COVID-19 by specifically promoting the immune responses on mucosal surfaces, like the inside of the nose and the mouth. Mucosal immunity is important as it may help prevent the transmission and spread of COVID-19. NDV-HXP-S has also been designed to be more easily manufactured, allowing for lower costs and greater distribution worldwide. Therefore, this NDV-HXP-S study vaccine may become a great opportunity for many countries to have access to a COVID-19 vaccine if these initial studies show safe and positive results.

If you choose to participate, you will be asked to receive ONE or TWO doses of the study vaccine or placebo (inactive substance). The first 15 participants enrolled will be randomly selected (like flipping a coin) to either participate in either Cohorts 1, 2, or 3 (SEE FIGURE BELOW). These participants will be made aware of their cohort assignment immediately following randomization. The next 20 enrolled participants will be assigned to a specific Cohort (2, 3, 4, 5, 6, or 7). Participants in Cohort 1 will not be given study vaccine and will be given placebo (an inactive substance) instead. Cohorts 2 to 7 will be given the study vaccine, NDV-HXP-S, and will require 4-hour monitoring post-study vaccination. After the enrollment, you will be monitored for ONE year and the remaining visits may be done either at home or at the research office.

Cohorts 2 to 7 will each vary in dose of the study vaccine or route of administration. Study vaccine or placebo may be given through your nose as nasal drops dripped into each nostril, or as a single injection into your arm, or as a combination of study vaccine in both the nose and arm.



Cohorts 2 to 7 will also require a period of HOME ISOLATION for about 5-7 days or more after receiving NDV-HXP-S. You will be asked to stay at home and remain isolated. During this time, our research team will collect daily specimens (blood, nasal swab, urine, and saliva) from you until we can confirm that you do not have any active infections from the LIVE Newcastle disease virus in the study vaccine. Because the NDV-HXP-S study vaccine is a live-virus vaccine, we will also monitor you very closely to look for any signs of infection (such as fevers, chills, runny nose, eye irritation, etc.) and ask that you keep a daily record of any symptoms that you experience for the two weeks following the study vaccination.

Participation in this study should not interfere or change your normal standard of medical care. This study vaccine is in its early stages of development and has not yet been shown to be effective against COVID-19. **After 56 days into the study**, you would still be eligible to receive any COVID-19 vaccines that have been authorized or approved by the federal government.

All human samples that are collected during this study will be de-identified and stored for further analysis.

There is no cost associated with participation with this study. You will be compensated for being in this study.

The main risks to you if you choose to participate are local reactions (such as pain at the administration site (nose or arm), redness, swelling, and runny nose) and systemic reactions (such as fever, chills, fatigue (tiredness), headache, eye inflammation / irritation, sore throat, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain).

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the currently available FDA authorized COVID-19 vaccines. The myocarditis and pericarditis may be related to the Spike protein of SARS-CoV-2 virus that is contained in the COVID-19 vaccines. Therefore, we will include screening at baseline and monitoring for this condition during this study. Myocarditis and pericarditis have been reported most often in males under the age of 40 years following a second dose of authorized mRNA vaccines.

Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart. Symptoms usually start within a few days following vaccination. The study doctor may perform blood tests or an electrocardiogram (ECG) or other heart imaging to check for myocarditis or pericarditis. Any participant who reports sudden chest pain, shortness of breath, palpitations, or any other symptom(s) that might be indicative of myocarditis or pericarditis should seek immediate medical attention and notify the study staff if any of these symptoms occur following vaccination. The chance of having this occur is very low. Any participant experiencing this condition will be referred to a cardiologist for further evaluation.

There is a THEORETICAL RISK for COVID-19 vaccine-associated enhanced respiratory disease (ERD). Animal studies investigating vaccines against OTHER coronaviruses (SARS-CoV and MERS-CoV) have raised concerns for inflammatory lung reactions following infection. This theoretical risk may occur with NDV-HXP-S, and all participants will be monitored for 365 days to see if any infection of COVID-19 is complicated by abnormal lung inflammation.

In addition, if you receive placebo, or if the active study vaccine is not effective, postponing receipt of an authorized or approved COVID-19 booster vaccine dose for 56 days after receiving study vaccine or placebo may place you at risk of acquiring COVID-19 if you are exposed during that time.

You may benefit from participating in this research if NDV-HXP-S is found to be effective against COVID-19. This study vaccine has been shown to provide a protective level of immunity against COVID-19 in animals. Therefore, this study vaccine may provide you with an immunity against COVID-19. However, there is no guarantee that you will benefit from participation.

Instead of participating in this research, you may choose to be vaccinated with other available booster doses of COVID-19 vaccines, as applicable.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the research team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are a healthy adult who has not been infected with COVID-19, and you received your last vaccination against COVID-19 over 6 months ago. We will measure antibody-levels against COVID-19. We are looking for participants with a LOW antibody level. Your levels will be confirmed during your initial screening via a blood test. You may also qualify because you are NOT a student, post-doctoral candidate, or trainee of Mount Sinai, nor are you a member of the research team.

Funds for conducting this research are provided by the Icahn School of Medicine at Mount Sinai.

A description of this clinical trial will be available on https://ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last one year. The number of people expected to take part in this research study at Mount Sinai Hospital is 35 to 40.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

- The research will be conducted at three locations. Office visits will occur on the 8th floor of 17 East 102nd Street at the Clinical and Translational Research Center (CTRC). At the CTRC you will interact with the COVID Clinical Trials Unit, consisting of study doctors, research nurses, and research coordinators, and you will receive your study vaccination. Several visits and the isolation period will occur at your home, and our Mount Sinai home health team will come to your home to collect specimens and data. You may also choose to have your follow up visits at the CTRC.

- As part of the study, we will collect your contact information as well as your medical history. We will physically examine you and collect blood, urine, saliva, and nasal samples from you. If your tests show that you are eligible to continue with the study, then you may be enrolled into either Cohorts 1 to 7 depending on when you enter the study.

- If you are one of the first 15 participants in the study, your group assignment will be chosen by chance, like flipping a coin. You will have an equal chance of being placed into Cohorts 1, 2, or 3. After you are randomized, you will be made aware of your group. Only Cohort 1 participants will receive placebo. If you are enrolled after the first 15 participants, then you will be assigned to a cohort sequentially and receive NDV-HXP-S. Neither you nor the study doctor will choose what experimental study group you join.

    - If you are assigned to Cohorts 2 and 5, you will receive NDV-HXP-S as droplets into the nose. These cohorts will be asked to lie down, while a registered research nurse drips a small amount of the NDV-HXP-S study vaccine into each nostril. Cohorts 3 and 6 will receive NDV-HXP-S as a single injection into the arm. Cohorts 4 and 7 will receive both the nasal droplets and the arm injection of NDV-HXP-S. After NDV-HXP-S has been given, each person will be monitored for 4 hours and then will be discharged to home.

- At home, we will ask you to keep online entries of your symptoms. Because this is a LIVE virus-vectored study vaccine, you may experience symptoms such as fevers, chills, runny nose, headaches, facial pains, gum tenderness, or potentially eye inflammation. You will remain isolated at home to avoid any potential spread of the LIVE-virus study vaccine to other members of your household. Because the LIVE virus in this study vaccine is naturally a bird virus and is not known to spread among people, we do NOT expect this virus to transmit from you to other members of your household. However, we will provide you with

detailed instructions to minimize any potential spread. Additionally, our home health team will arrive at your home on a daily basis to collect samples from you. Once we confirm that there is no detectable virus in your nasal swab specimens **for two consecutive days**, then you may be released from home isolation. We expect this isolation period to last from 5 to 7 days. You will need to continue to enter your symptoms online for a total of 14 days after the study vaccination. After this isolation period is complete, our home health team will visit you on nearly a weekly basis to collect information and specimens.

- We will follow up with you for a period of one year. During this time, we will collect samples from you at various timepoints to check for the safety of NDV-HXP-S and to measure your immune response to study vaccination. We will also record any medical events and changes in medications. These visits may be performed in the clinic or at home.

- Routine visits will require blood to be drawn. The volume will be about 20 milliliters (equal to about 1-2 tablespoons). There will be five visits when larger volumes of blood are drawn, about 80 milliliters (equal to about 5 to 6 tablespoons).

- Certain visits will require electrocardiograms (ECG). This will involve the placement of sensors across your chest and body to allow for monitoring of your heart. These visits will occur on Day 0, 8, and 84.

- Clinically relevant research results will be disclosed to you only if we discover any abnormalities in the 'routine safety labs'. Such labs would have been tested by the hospital's standard clinical laboratory. 'Exploratory labs' that involve measuring your immune system's response to the NDV-HXP-S will NOT be disclosed to you.

- Because this project involves the use of study drugs or a study device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

- To take part in this research project we will have to test your blood for evidence of HIV infection. HIV is the virus that causes AIDS. It can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV, and through contact with blood, as in sharing needles (piercing, tattooing, drug equipment including needles used to inject drugs). HIV-infected pregnant women can transmit to their infants during pregnancy or delivery or while breast feeding. There are treatments for HIV/AIDS that can help an individual stay healthy. Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.

- By law, positive test results are reported to the NYS Department of Health for epidemiological (the study of the factors determining or influencing the presence or absence of disease) and Partner Notification purposes. If you wish to be tested anonymously you will be referred to a public testing center, but you will not be able to be in this study. Please know that New York State law protects the confidentiality of HIV test results and other related information. The law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences. You are free to refuse this test, but if you refuse you will not be allowed to join or remain in this research project.

For Women:

Since you are participating in a research study that involves study drugs or experimental treatment with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. You should not participate if you are breastfeeding.

A urine pregnancy test will be done before you begin the study and will be repeated before each study vaccination and at the end of the study.

Practicing effective birth control is important. No individual birth control is 100% effective.

Recommended methods of birth control are:

- The consistent use of an approved hormonal birth control (pill/patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam),
- Sexual abstinence (no sexual intercourse) or
- Sterilization.

Hormonal birth control, implants, and injections are only considered effective if used properly and started at least one month before you begin the study and at least 90 days after the last study vaccination. You should ask your study doctor if you should continue birth control for longer than 90 days after the end of the study. If you are unsure whether the method of birth control you use is acceptable to use while participating in this study, you should ask your study doctor before you begin the study. If you are less than one year post-menopausal, there is the potential that you could become pregnant. If you or your partner become pregnant, or may be pregnant, at any time during the one year that you participate in this study, it is important that you tell your study doctor immediately. A referral may be made to an obstetrician or gynecologist for follow-up. If you plan to become pregnant in the year following the study, speak with your study doctor.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, its outcome, and the health of the child after birth even if you are withdrawn from the study and will share this information with the sponsor. Your written consent will be obtained separately in the case that this happens.

For Men:

Since you are participating in a study that involves study drugs or experimental treatment with potential risks to a developing fetus, it is recommended that you use a condom and not impregnate a woman or donate sperm for at least an additional 90 days after you receive the NDV-HXP-S study vaccination. This is because study vaccine may be present in the sperm and/or seminal fluid even after study vaccination. You are encouraged to tell your female partner(s) and/or their doctor(s) that you are participating in a clinical study.

USE OF YOUR DATA AND/OR SPECIMENS:

The researchers would like to ask your permission to keep the data and specimens (like blood, tissue, urine, saliva, cells, or any other body matter) collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

(1) Will you allow the researchers to store your information and/or specimens to use in future research studies? Please initial **ONE** choice:

Yes_____ No_____
If no, please stop here. If yes, please continue to the next question.

(2) The researchers can keep your information and/or specimens stored in one of two different ways: one way will store your information and/or specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information and/or specimens anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your information and/or specimens stored anonymously, you will not be able to change your mind to ask for your information and/or specimens to be destroyed at a future date.

How would you like your information and/or specimens stored? Please initial **ONE** choice:

I would like my information and/or specimens stored with a link to my identity _____

I would like my information and/or specimens stored anonymously _____

(3) Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information and/or specimens might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes_____ No_____

(4) Do you give the researchers permission to keep the information and/or specimens indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes_____ No_____

(5) Do you give the researchers permission to keep the information and/or specimens indefinitely and use them for future studies that are **not related** to the purpose of the current study (for example, a different area of research)? Please initial your choice:

Yes_____ No_____

(5.1) From time-to-time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. Do you give permission to use your information and/or specimens outside the fields of medicine and biological sciences? Please initial your choice:

Yes_____ No_____

(a) If the future research in a different area can be done without having to know that the information and/or specimens came from you personally, that will be done.
(b) If the future research in a different area requires that it is known specifically who the information and/or specimens came from, then one of the following will be done:

(i) If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use your information and/or specimens in that research project.

(ii) If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your identifiable data and specimens may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information and/or specimens linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the information and/or specimens will not be more than a minimal risk to you or your privacy. The Institutional Review Board (IRB) is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect the rights of people who participate in research.

(6) Do you give permission to have portions of the specimens and/or information given **to other researchers,** including those at Mount Sinai, other academic institutions and for-profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes_____ No_____

(7) Do you give permission to have portions of the specimens and/or data **deposited in large public repositories, (explained below)** for use in research with the limits you may have chosen above? Please initial your choice:

Yes_____ No_____

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by

Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section. This study will not include whole genome sequencing. We intend to perform exome sequencing which looks at which genes become activated after study vaccination. We will also sequence any virus specimens that are collected.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- Agreeing to the procedures instructed by the research team and attending all study visits.
- Specimen collections, including: blood, saliva, urine, nasal swabs.
- Study vaccination with NDV-HXP-S through the nose, as an injection in the arm, or a combination of both.
- Using birth control methods.
- Not receiving any other COVID-19 vaccines up to Day 56.
- Reporting any symptoms or side effects to the research team.
- Maintaining home isolation after receiving the first NDV-HXP-S study vaccine until two sequential laboratory confirmations provide your clearance.
- Avoid contact with birds (for example, pets) during the period of home isolation.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you $100 per routine visit, $800 per NDV-HXP-S administration, $500 per placebo administration, $1500 for the total duration of the home isolation, amounting to total of either $1300 if you receive placebo or $3100 if you receive NDV-HXP-S study vaccine for your time and effort. Payment will be given in the form of a rechargeable credit card (ClinCard), that will be recharged with the appropriate amount shortly after each visit. You will be paid following each completed visit.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

You should also know that it is possible that products may someday be developed with the help of your specimens and data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. However, possible benefits may be immunization and protection against COVID-19.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Risks of NDV-HXP-S:

- Physical risks, including: Local reactions (pain at the administration site, redness, swelling, runny nose) are occasionally expected and general reactions (fever, chills, fatigue (tiredness), headache, eye inflammation, sore throat, gum tenderness, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) are occasionally expected. These physical risks are expected to be reversible.
- Potential physical risks: Myocarditis and pericarditis, including inflammation of the heart and its surrounding tissue. Transmitting Newcastle disease virus to others is a possible risk, including spread to friends and family. This risk is rare and you will be kept in home isolation until we have confirmed that the Newcastle disease virus is not detectable.

Additional Risks:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.
- In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).
- If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant or impregnate a woman while on this research study. Please read the acceptable methods of birth control found under the Description of What's Involved section of this document.
- Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress,

anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

- Insurance Risks – There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers of over 15 people to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Theoretical Risk:

- There is a theoretical risk for COVID-19 vaccine-associated enhanced respiratory disease (ERD). Animal studies investigating vaccines against OTHER coronaviruses (SARS-CoV and MERS-CoV) have raised concerns for inflammatory lung reactions following infection. This theoretical risk may occur with NDV-HXP-S, and all participants will be monitored for 365 days to see if any infection of COVID-19 is complicated by abnormal lung inflammation.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

Instead of being in this research study, your choices may include:

- Vaccination with currently available FDA-authorized and / or approved COVID-19 vaccines.
- Enrollment in other COVID-19 vaccine studies.

The important risks and possible benefits of these alternatives are listed below:

- Benefits: The currently available authorized and / or approved COVID-19 vaccines are safe and effective at providing protection against COVID-19.
- Risks: These currently available COVID-19 vaccines each contain rare adverse effects. Details about these adverse effects are unique to each individual COVID-19 vaccine.
- Enrollment in other COVID-19 vaccine studies will have study-dependent risks and benefits.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the study doctor for more information.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a participant participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study vaccine, NDV-HXP-S used in this study. Participants using

NDV-HXP-S in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the study doctor or the research team. Our research team will help arrange with a withdrawal visit.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the research team and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the research team has will be withdrawn so that no future sharing of your samples and/or data will take place. If your samples have already been deposited in an external repository, the research team will request that your samples be removed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the study doctor believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

WHOM TO CONTACT ABOUT THIS STUDY:

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00058916.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The study vaccine utilized in this study was developed by faculty members at the Icahn School of Medicine at Mount Sinai. This vaccine technology has been licensed for commercial development to CastleVax, a Mount Sinai majority owned start-up company.

If this study is successful, both Mount Sinai and the faculty inventors could benefit financially.

The physicians leading this study, Dr. Sean Liu (Principal Investigator) and Dr. Judith Aberg (Co-Investigator) are not the faculty inventors of this vaccine and have no financial interests related to its development.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on our website at http://icahn.mssm.edu/.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail addresses, social security number, medical records number, health plan numbers, and emergency contact information.

The researchers will also get information from your medical record from either your existing medical record or your primary care physician.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

- Reviewing genetic tests

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human participants, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration.
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove

information with identifiers if necessary to complete their task. By signing and dating this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign and date this form, and you will not be allowed to volunteer in the research study. If you do not sign and date, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Signature Block for Capable Adult:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of participant	Date
Printed name of participant	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

I have carefully explained to the participant the nature and purpose of the above study. There has been an opportunity for the participant to ask questions about this research study and this form. I have been available to answer any questions that the participant has about this study and this form.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	Time