Informed Consent Form
And
Authorization To Disclose Health Information

Study Treatment Stage 1 and Stage 2 Adult Informed Consent Form

Sponsor / Study Title:	**The National Institute of Allergy and Infectious Diseases (NIAID)/ "BOOSTER EFFECTS WITH AUTOIMMUNE TREATMENTS IN PATIENTS WITH POOR RESPONSE TO INITIAL COVID-19 VACCINE"**
Protocol Number:	**ACV01**
Principal Investigator: (Study Doctor)	**Judith James, MD**
Telephone:	**(405) 271-7805** **(405) 330-4471 (24 Hours)**
Address:	**Oklahoma Medical Research Foundation** **825 NE 13th Street** **Oklahoma City, OK 73104**

1. YOUR PARTICIPATION IS VOLUNTARY

We will explain this research study to you. You may ask questions.

- Taking part in this study is your decision.
- You may change your mind at any time.
- You will be given a copy of this consent form for your records

2. CONSENT KEY INFORMATION

This section is a summary of the research study to help you decide whether- or- not to participate. Detailed information is provided after the key information.

Why is this research being done?

The United States Food and Drug Administration (US FDA) has approved the use of the bivalent COVID-19 vaccines for adults. Both the Pfizer and Moderna COVID-19 vaccines used in this study and referenced below are the bivalent vaccines. The bivalent COVID-19 vaccines include a component of the original virus strain to provide broad protection against COVID-19 and a component of the Omicron variant to provide better protection against COVID-19 caused by the Omicron variant.

Some people with autoimmune diseases who take medications that weaken the immune system to control their disease have not had a good response to the COVID-19 vaccines. A positive response to the COVID-19 vaccine means that the immune system has made lots of antibodies against the COVID-19 virus. Antibodies are proteins made by the immune system that can attach to the COVID-19 virus and help to kill and remove it from the body. A strong antibody response to COVID-19 vaccine is needed to provide protection from COVID-19 infection. This research is being done to see if an additional shot of a COVID-19 vaccine will help these people develop a good response to the COVID-19 vaccines. The study is also being done to see if

temporarily stopping the medication you take for your autoimmune disease will help your immune system have a positive response to the additional COVID-19 vaccine.

What happens if you take part in this research study?
If you decide to join this study, you will receive an additional COVID-19 vaccination. This study will use COVID-19 vaccines that are authorized under an Emergency Use Authorization by the United States Food and Drug Administration (FDA) for initial vaccination and in some situations, they are authorized for an additional dose. This includes the Pfizer, Moderna COVID-19 vaccines. This study will also use a COVID -19 vaccine that is not currently authorized by the FDA. This is the Sanofi-GSK COVID-19 vaccine.

This study has two stages. In Study Treatment Stage 1, you will be asked to come to the clinic for up to 8 research visits over 13 months. If you move to Study Treatment Stage 2 because you do not respond to the additional dose given as part of Stage 1 and need a fourth vaccine dose (Moderna, Pfizer, Sanofi-GSK) you will be asked to come to the clinic for up to 8 additional research visits over 13 months. If you still do not develop antibodies (after your Stage 2 study vaccine shot), you may be eligible to receive another COVID-19 vaccine. If this happens you will start Stage 2 over and will come to the clinic for an additional 8 visits over 13 months. The Sanofi-GSK vaccine will only be used in Study Treatment Stage 2 as an option to those who have not responded to Moderna or Pfizer. At these research visits you will have the following procedures:

- Physical exam,
- Blood work,
- COVID-19 testing to see if you are currently infected, and
- Complete questionnaires and participate in assessments related to the autoimmune disease you have.

Is there any way being in this research can hurt me?
All procedures and vaccinations in this study have some level of risk. You may be asked to hold (temporarily stop taking) your autoimmune disease medication around the time you receive the COVID-19 vaccine. We do not know if stopping your medications will help your immune system develop a positive response to the COVID-19 vaccine. It is possible that stopping your medication could cause a flare of your autoimmune disease.

The most common risks associated with the COVID-19 vaccinations are:

- Pain at the injection site
- Fatigue (feeling tired)
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Redness or swelling at the injection site
- Axillary (armpit) swelling/tenderness
- Nausea/vomiting

Will being in this research study help me in any way?
There might be no direct medical benefit to you for being in this study. The information learned from this study may someday benefit people with autoimmune disorders.

What other choices do I have besides taking part in this research?
Before you decide to take part in this study, your study doctor will talk with you about other options available to you. Monoclonal antibody administration is available both to prevent COVID-19 infection either before or after exposure or as treatment for mild infection. Monoclonal antibody treatment is not a substitute for vaccination. There may be other research studies that you can choose to join.

Who is sponsoring this study?
This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is being conducted through the Autoimmunity Centers of Excellence (ACE) network.

DETAILED CONSENT INFORMATION
The rest of the consent document includes detailed information about this study.

3. INTRODUCTION

An autoimmune disease is a disease where the patient's immune system incorrectly attacks certain parts of their own body (for example, joints, nervous system, kidneys, or skin). There are many different types of autoimmune disease, including:

- Systemic Lupus Erythematosus (SLE),
- Rheumatoid Arthritis (RA)
- Multiple Sclerosis (MS)
- Systemic Sclerosis (SSc)
- Pemphigus

Approximately 1 in 12 Americans have an autoimmune disease. Minority populations are diagnosed with autoimmune disorders more frequently. These same populations are more severely impacted by the COVID-19 pandemic. People with autoimmune disease who become infected with SARS-CoV-2 (the virus that causes COVID-19) have worse symptoms and die more often than those without autoimmune disease. Early reports are indicating that some people with autoimmune disease are not responding to the COVID-19 vaccinations as well as expected. Doctors do not know if this is because of the disease itself or because of the medications used to treat autoimmune diseases. Doctors also do not know whether another dose of the same type of vaccine or another type of vaccine is needed to help these people with autoimmune disease respond better.

Some medications seem to have a greater ability to interfere with a proper immune response to the COVID-19 vaccine. This study will look at medications that may interfere with a good immune response (mycophenolate mofetil [MMF], mycophenolic acid [MPA], methotrexate [MTX], and B cell depleting medications like rituximab or ofatumumab).

This study will use two types of vaccines, mRNA (Moderna and Pfizer) and protein-based vaccines. mRNA vaccines teach our cells directly how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies to fight the COVID-19 infection. Protein-based vaccines include only the parts of a virus that best stimulate your immune system. This vaccine contains harmless viral proteins. Once your immune system recognizes the proteins, it creates antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies and cells will fight the virus. This

vaccine uses an adjuvant, a compound that helps stimulate an immune response. The adjuvant used in the Sanofi-GSK vaccine has been used before in certain influenza vaccines.

Why is this research being done?
The main reason this research study is being done is to see if additional COVID-19 vaccine doses will help people with autoimmune disease who are taking medications that weaken their immune system develop a better response to the vaccine. The study doctors also want to see if temporarily stopping some medications (such as mycophenolate mofetil, mycophenolic acid, and methotrexate) around the time of vaccination will help the immune system respond to the COVID-19 vaccination.

You are being asked to join this study because:

- You have one of the autoimmune diseases listed above,
- Your immune system did not develop COVID-19 antibodies (immune proteins that fight infection) after you received the COVID-19 vaccination,
- And you take one of the medications that doctors think may prevent a positive (effective) immune response (mycophenolate mofetil, mycophenolic acid, methotrexate, and B cell depleting medications like rituximab or ofatumumab).

4. STUDY COMPONENTS

Who is sponsoring this study?
This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is being conducted through the Autoimmunity Centers of Excellence (ACE) network.

How many people will be in the study? How many centers will conduct this study?
Up to about 2300 subjects (adults and children) could be in this study at about 30 centers in the United States.

How long will I be on this study?
Study Treatment Stage 1 can be up to 13 months. If you move to Study Treatment Stage 2, you will be on the study for a maximum of another 13 months. If you still do not develop antibodies after your Stage 2 study vaccine dose, you may be eligible to receive another COVID-19 vaccine. If this happens you will start Stage 2 over and will come to the clinic for an additional 8 visits over 13 months. Total study duration will depend on if and when you move from Study Treatment Stage 1 to Study Treatment Stage 2 and if you require an additional Study Treatment Stage 2 vaccine.

What am I being asked to do?
If you choose to take part in this study, you will need to sign and date this consent form before we do any study procedures.

Screening Phase
Once you have signed and dated this consent form, the screening phase of the study is started. The purpose of the screening phase is to find out whether you will be able to participate in the study. The screening phase can last for up to 21 days while we wait for the laboratory test results and review medical records if necessary.

The screening visit will include the following procedures:

Medical History and Physical Exam: During the screening visit, you will be asked about your medical history, your autoimmune disease history, any recent vaccines you have had, and any medication you may take. You will be given a full physical exam (including vital signs), urine and blood tests, and a test for pregnancy (if you are female and able to become pregnant). This includes testing your blood (and sometimes a skin test) for several infections, including HIV (the virus that causes AIDS), tuberculosis, hepatitis, and COVID-19. If you test positive for COVID-19, HIV, or hepatitis, we may have to report this information to the department of health. Approximately 2 tablespoons of blood will be needed for these tests.

Oklahoma law requires us to report positive HIV, hepatitis B, C and/or tuberculosis testing to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Oklahoma law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

Autoimmune Disease Evaluations: Based on the autoimmune disease that you have, you will have a set of evaluations and will be asked to complete questionnaires about your disease and its impact on your life.

After all screening tests are complete and you qualify for the study, you will move to the study treatment phase of the study.

This study has two study treatment stages. During the first stage you will receive the same type of vaccination that you received in the community. If at any point during Study Treatment Stage 1, the antibodies needed to fight COVID-19 infection drop below a certain level, you can move to Study Treatment Stage 2. In Study Treatment Stage 2 you will be able to receive an additional dose of vaccine. If antibodies still do not develop, one more vaccine dose may be available. Study Treatment Stage 1 and 2 and the vaccine dosing plan are described below in detail.

Study Treatment Stage 1

Randomization (Week -1): If you are taking mycophenolate mofetil, mycophenolic acid or methotrexate (immune suppression drugs), you will be assigned randomly (like flipping a coin, 50/50 chance) to either stop your immune suppression drug for a period of time around the booster vaccination or continue taking your medications as usual. If you are randomized to stop the immunosuppressive drug for a period of time around the time you receive the COVID-19 booster vaccination, the study doctor or coordinator will call you to tell you exactly how long the medication will be stopped and will give you detailed instructions on when to stop your medication. The medication is being stopped to see if this will allow your immune system to develop antibodies and thus be likely to have better immunity than you did in response to the primary vaccine series, once you receive the COVID-19 booster vaccine.

Baseline Visit (Week 0): The Baseline Visit includes the following evaluations:

- COVID-19 Testing (nasal swab): If this test is positive, you will not be allowed to receive the booster vaccination. We encourage you to take precautions to avoid COVID-19. Please see Information related to COVID-19 below.

- Brief Physical Exam: A brief physical exam will be conducted at each visit to monitor your general health and disease activity. During this exam you will be asked about any health events since the last visit, and you will review all the medication you are currently taking.
- Vital Signs: Weight, temperature, blood pressure, respiration rate, and pulse will be obtained at all visits.
- Clinical Labs: Clinical labs include blood work. The table below lists the total amount of blood to be collected at each visit for clinical labs. These tests are to monitor your general health and disease activity. If you are a woman of childbearing potential, urine will be collected for a pregnancy test at the week 0 visit. If the test is positive, you will not have the booster vaccination. You will be given the results of the clinical lab tests.
- Research Labs: The table below lists the total volume of blood to be collected at each visit for research testing. These research tests will help us learn more about your autoimmune disease, the immune system, and help us learn how your autoimmune disease responds to the COVID-19 vaccine. The research testing being conducted may look at large chunks of your DNA (whole exome testing) or all your DNA at once (whole genome testing). You will not be given the results of the research lab tests.
- Mycophenolate Mofetil or Methotrexate Drug Levels: If you take mycophenolate mofetil or methotrexate we will draw additional blood to determine what your current drug levels are. If you are taking mycophenolate mofetil, you will be asked to not take it the morning of the Baseline Visit.
- Autoimmune Disease Assessments: These are described above under Screening.
- Questionnaires: You will be asked to complete questionnaires related to how you feel physically and emotionally.
- COVID-19 Vaccination: You will receive a booster of the same vaccine as your original vaccine series (Moderna COVID-19 vaccine, Pfizer-BioNTech COVID-19 vaccine, or Janssen-J&J COVID-19 vaccine)
- Diary Completion Using electronic questionnaires: You will receive a link to MyOwnMed, where you will complete a daily diary on a mobile device (such as a desktop computer, tablet or smartphone) for seven days following your vaccination. There may be instances where your responses may trigger study staff to contact you to find out more information. For subjects who do not have internet access or a mobile device or do not wish to complete the questionnaires electronically, the study staff may provide paper versions of questionnaires to complete. Site personnel then will enter questionnaire responses into the system. If you would like reminders to complete the daily diary, you will need to provide your email address or your mobile phone number. This information will only be kept for the time you are completing the diary. Study staff will call you at the end of this week to review your diary entries.

Follow-Up Visits at Weeks 4, 12, 24, 36 and 48

The Follow-up Visits will last approximately 1 hour each and include the following evaluations:

- Brief Physical Exam: A brief physical exam will be conducted at each visit to monitor your general health and disease activity. During this exam you will be asked about any health events since the last visit, and you will review all the medication you are currently taking.

- Vital Signs: Weight, temperature, blood pressure, respiration rate, and pulse will be obtained at all visits.
- Clinical Labs: Clinical labs include blood work. The table below lists the total amount of blood to be collected at each visit for clinical labs. These tests are to monitor your general health and disease activity. If you are a woman of childbearing potential, urine will be collected for a pregnancy test at the week 0 visit. If the test is positive, you will not have the booster vaccination. We will also be testing your immune system's response to the study vaccination. You will be given the results of the clinical lab tests.
- Research Labs: The table below lists the total volume of blood to be collected at each visit for research testing. These research tests will help us learn more about your autoimmune disease, the immune system, and help us learn how your autoimmune disease responds to the COVID-19 vaccine. The research testing being conducted may look at large chunks of your DNA (whole exome testing) or all your DNA at once (whole genome testing). You will not be given the results of the research lab tests.
- Autoimmune Disease Assessments: These are described above under Screening.
- Questionnaires: You will be asked to complete questionnaires related to how you feel physically and emotionally.

Study Treatment Stage 1 Schedule of Study Procedures and Assessments
Below is a schedule of the procedures that you will have while in this study. A detailed explanation of each of these procedures is given above in the Screening Phase and Study Treatment Phase descriptions.

Study Week Number	**-1**	**0**	**4**	**12**	**24**	**36**	**48**	**Early Termination Visit**
Study Visit Number	**R***	**1**	**2**	**3**	**4**	**5**	**6**	**ET**
Randomization	**X**	**X**						
Brief Physical Exam		**X**	**X**	**X**	**X**	**X**	**X**	**X**
Vital Signs		**X**	**X**	**X**	**X**	**X**	**X**	**X**
Autoimmune Disease Assessment		**X**	**X**	**X**	**X**	**X**	**X**	**X**
Questionnaires		**X**	**X**	**X**	**X**	**X**	**X**	**X**
COVID-19 Vaccination and Diary Completion for 7 Days		**X**						
COVID-19 Testing		**X**						
Clinical Labs		**X**	**X**	**X**	**X**	**X**	**X**	**X**
Research Labs		**X**	**X**	**X**	**X**	**X**	**X**	**X**
Approximate Blood Volume for Clinical Labs (Tablespoons)		**1**	**1**	**1**	**1**	**1**	**1**	**1**
Approximate Blood Volume for Research Labs (Tablespoons)		**4**	**4**	**4**	**4**	**4**	**4**	**4**

***R=Randomization**

Study Treatment Stage 2

If at any point during Study Treatment Stage 1, the antibodies in your blood needed to fight COVID-19 infection drop below a certain level, you can move to Study Treatment Stage 2. In Study Treatment Stage 2 you will be able to receive an additional dose of study vaccine. If this dose of study vaccine does not work to create antibodies, one more study vaccine dose may be available. The table below explains what study vaccines would be available to you in Stage 2 based on the study vaccines you have already received.

Previous Vaccines Received	**Vaccine Option for Study Treatment Stage Two: First Dose**
3 doses of the same mRNA COVID-19 vaccine	A choice of an alternative mRNA COVID-19 vaccine ***OR*** Sanofi-GSK COVID-19 Vaccine
2 doses of Janssen COVID-19 vaccine	Moderna mRNA vaccine

Previous Vaccines Received	**Vaccine Option for Study Treatment Stage Two: Second Dose**
3 doses of Moderna mRNA COVID-19 vaccine followed by 1 dose of Pfizer mRNA COVID-19 vaccine	Sanofi-GSK COVID-19 Vaccine
3 doses of Pfizer mRNA COVID-19 vaccine followed by 1 dose of the Moderna mRNA COVID-19 vaccine	Sanofi-GSK COVID-19 Vaccine

Screening: The purpose of the Study Treatment Stage 2 screening phase is to make sure you are healthy enough to receive another vaccine dose. The screening phase can last for up to 28 days while we wait for the laboratory test results and review medical records if necessary. If you have had a recent study visit (within 4 weeks) you may not have to have all the laboratory tests completed.

Immune Suppression Drug Stopping: When you begin Study Treatment Stage 2, you will be asked to stop the mycophenolate mofetil, mycophenolic acid or methotrexate (if you are taking these) you take for a period around the time you receive the Study Treatment Stage 2 vaccine COVID-19 vaccination. The study doctor or study coordinator will call you to tell you exactly how long the medication will be stopped and will give you detailed instructions on when to stop and restart your immune suppressive medication. This medication is being stopped to see if this allows your immune system to develop antibodies and have better immunity than you did in response to the other vaccine doses.

Study Treatment Stage 2 Schedule of Study Procedures and Assessments
Below is a schedule of the procedures that you will have while in this study. A detailed explanation of each of these procedures is given above in the Screening Phase and Study Treatment Phase 1 descriptions.

If you receive a second Stage 2 study vaccine, you will start Stage 2 visits from the beginning and will come to the clinic for an additional 8 visits over 13 months.

Study Week Number	**Screening**	**S20**	**S2 4**	**S212**	**S224**	**S236**	**S248**	**Early Termination Visit**
Study Visit Number	**Screening**	**S21**	**S2 2**	**S23**	**S24**	**S25**	**S26**	**ET**
Brief Physical Exam	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Vital Signs	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Autoimmune Disease Assessment	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Questionnaires	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
COVID-19 Vaccination and Diary Completion for 7 Days	**X**	**X**						
COVID-19 Testing	**X**	**X**						
Clinical Labs	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Research Labs	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Approximate Blood Volume for Clinical Labs (Tablespoons)		**1**	**1**	**1**	**1**	**1**	**1**	**1**
Approximate Blood Volume for Research Labs (Tablespoons)		**4**	**4**	**4**	**4**	**4**	**4**	**4**

S2 = Study Treatment Stage 2

5. RISKS ASSOCIATED WITH PROCEDURES AND STUDY TREATMENTS

This study will use the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine, and the Janssen COVID-19 Vaccine (Commonly referred to as the Johnson & Johnson Covid-19 Vaccine).

RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your study vaccination provider may ask you to stay at the place where you received your study vaccine for monitoring after study vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer-BioNTech COVID-19 Vaccine, more commonly in adolescent males and adult males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart.

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the study vaccine
- Dizziness
- Irritability

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Not all adverse events (side effects) of the study vaccine are known and there may be effects of the vaccine on you or your unborn baby, including as yet unknown effects related to additional doses. Serious and unexpected side effects may occur. The possible side effects of the study vaccine are still being studied in clinical trials.

RISKS OF THE MODERNA COVID-19 VACCINE

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your study vaccination provider may ask you to stay at the place where you received your study vaccine for monitoring after study vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body

- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Moderna COVID-19 Vaccine, more commonly in adolescent males and adult males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection , swelling (hardness), and redness
- General side effects: fatigue (tiredness), headache, muscle pain, joint pain, chills, nausea and vomiting, fever, and rash.

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the study vaccine

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Not all adverse events (side effects) of the study vaccine are known and there may be effects of the vaccine on you or your unborn baby, including as yet unknown effects related to additional doses. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

<u>RISKS OF THE Sanofi-GSK COVID-19 VACCINE</u>

There is a remote chance that the Sanofi-GSK COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Sanofi-GSK COVID-19 Vaccine. If you have a known allergy to polysorbate, you cannot receive the Sanofi vaccine. For this reason, your study vaccination provider may ask you to stay at the place where you received your study vaccine for monitoring after study vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat

- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported in a clinical trial with the Sanofi-GSK COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue (tiredness), nausea, diarrhea, fever, headache, malaise (generally feeling unwell), myalgia (sore and achy muscles), arthralgia (joint pain), and chills
- Fainting in association with injection of the study vaccine may also occur.
- Narcolepsy is an illness that affects your brain and causes uncontrollable sleepiness. People with narcolepsy sometimes go limp or fall asleep suddenly, such as while talking or driving, and it can be a lifelong problem. Narcolepsy has been reported in people who received a flu vaccine containing the adjuvant (called Pandemrix) during the H1N1 pandemic in 2009-2010. A similar risk of narcolepsy was not seen with other vaccines that contain the adjuvant.
- No safety concerns have been seen with any of the Sanofi-GSK vaccine studies regarding blood clotting, myocarditis (inflammation of the heart muscle), or pericarditis (inflammation of the membrane around the heart). However, these side effects are included as possible risks from the Sanofi-GSK vaccine because they have been reported after getting COVID-19 vaccines from other manufacturers. You should seek medical attention right away if you have any of the following symptoms after receiving the Sanofi-GSK COVID-19 Vaccine:
- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

The adjuvanted vaccine formulations are not expected to give 100% protection against SARS-CoV-2 infection or COVID-19; therefore, SARS-CoV-2 infection or COVID-19 may occur even after the completion of the vaccination schedule.

These may not be all the possible side effects of the Sanofi-GSK COVID-19 Vaccine. Not all adverse events (side effects) of the study vaccine are known and there may be effects of the vaccine on you or your unborn baby, including as yet unknown effects related additional doses. Serious and unexpected side effects may occur. The Sanofi-GSK COVID-19 Vaccine is still being studied in clinical trials.

The risks associated with the study procedures in this study are described below.

Stopping Immune Suppression Drug: By temporarily stopping your immune suppression drugs you risk your autoimmune disease getting worse or flaring. If you notice any sign of this, please contact the study doctor right away. The time your medication will be stopped will be short to reduce the possibility of a flare. Your study doctor will tell you exactly how long your medication will be stopped. During this time, you should contact your doctor immediately if you begin to have a flare of your autoimmune disease.

Blood Draw: Having blood drawn can cause temporary pain and bruising in the area where the needle was put in your vein. Lightheadedness or rarely fainting due to temporary lowering of the blood pressure can occur.

COVID-19 Testing Nasal Swab: You may have some mild or moderate discomfort, and, in rare instances, nose bleeds can occur because of nasopharyngeal, nasal swab and/or other oronasal samples. You may also experience watery eyes and/or coughing, but only for the short duration of the swab.

Autoimmune Disease Assessments: There are no physical risks or discomforts involved with the autoimmune disease assessments. Completing testing may cause a feeling of stress or embarrassment. These assessments may make you think about unpleasant effects of your autoimmune disease on your life and may make you upset or anxious.

Questionnaires: You may find it inconvenient to participate in these surveys. Being asked to think about your health and healthcare related information could make you feel worried or anxious.

Study treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. Please ask your study doctor or the study staff to explain any procedures or risks that you do not understand.

Information related to COVID-19

- Measures to protect yourself and others from COVID-19 infection are outlined on the Centers for Disease Control website at the following link: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html. To decrease your risk of infection with SARS-CoV-2, we strongly recommend that you follow these recommendations, which include wearing a mask, practicing social distancing, and frequent handwashing/use of hand sanitizer.
- If you develop COVID-19 infection during your participation in the study or have a close contact exposure, notify the study doctor immediately.

6. POTENTIAL BENEFITS

If you agree to take part in this study, there may be no direct medical benefit to you.

Information learned from this study may someday benefit people in the future.

7. ALTERNATIVES TO PARTICIPATION

The study doctor and/or study staff will talk with you about this study and other options available to you. Monoclonal antibody administration may be available both to prevent COVID-19 infection either before or after exposure or as treatment for mild infection. Monoclonal antibody treatment is not a substitute for vaccination. There are also oral treatments available if you test positive for COVID-19. Your study doctor will be able to tell you about any additional COVID-19 prevention or treatments that become available during your study participation. You may choose not to be in this research study.

8. NEW FINDINGS

The study doctor will tell you about any new information that may affect your willingness to continue in this study.

9. VOLUNTARY WITHDRAWAL FROM STUDY

You may decide not to take part or to leave the study at any time. If you decide to leave the study, there is no penalty or loss of benefits in your routine medical care or any other benefit(s) that you would otherwise be entitled to receive. The study staff may ask you to return to the clinic for a final visit.

You should talk to your study doctor who will discuss future treatment and procedures for your continued care.

10. REASONS WHY YOU MAY BE TAKEN OFF STUDY WITHOUT YOUR CONSENT

You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to, the following:

- The study doctor feels it is not in your best interest to continue in this study.
- You are unable to complete required study treatments and examinations.
- The study is stopped by the Institution, the Sponsor(s), the Food and Drug Administration (FDA), or other health authorities.

If you are removed from the study, your study doctor will contact you to discuss stopping procedures and your future care.

11. PREGNANCIES, BREASTFEEDING AND BIRTH CONTROL

You cannot participate in this study if:

- You are currently pregnant or breast feeding
- You plan to get pregnant during the study

COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy has been growing. These data suggest that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy.

However, treatments for your underlying autoimmune disease and other procedures involved in this research study may involve risks to your unborn or nursing child. If you are female, a pregnancy test will be performed prior to your enrollment.

To prevent risk to the fetus, it is important that female subjects take care to avoid becoming pregnant during this study. Avoiding sexual activity is the only certain method to prevent pregnancy. However, if sexually active, female subjects of reproductive potential are encouraged to use reliable method(s) of contraception (birth control) unless you are unable to become pregnant because of prior surgical sterilization. Acceptable contraceptive methods should be used for the duration of the study.

If you should become pregnant while participating in this study, or if you suspect that you have become pregnant, you must contact the study doctor immediately. The study staff will collect information about the pregnancy, its outcome, and the health of the child after birth.

Because of the known pregnancy risks associated with MMF, the FDA created an education program, Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) to prevent unplanned pregnancies, reduce fetal exposure to MMF, collect information on pregnancies, and inform

patients about the risks of MMF. Your study doctor has enrolled, and we strongly encourage you to discuss the program with your doctor and to participate in the MMF REMS program as well. A description of this program is available at https://www.mycophenolaterems.com/PatientOverview.aspx.

12. COSTS TO YOU

The costs of all vaccinations, tests and procedures described above that are required by the study will be paid for by NIAID through the ACE. This study will not pay for your autoimmune disease standard of care medications. You will be responsible for any expenses related to your routine clinical care. Please ask your study doctor about any expected added costs that you may incur. Check with your health plan or insurance company to find out what they will pay for.

Taking part in this study may lead to added costs to you or your insurance company.

13. PAYMENTS (REIMBURSEMENT)

You will receive $50 for each study visit to cover travel and other expenses for taking part in this study for the following visits:

Screening
Baseline
Week 4
Week 12
Week 24
Week 36
Week 48
Early Term Visit (if necessary)

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid following each completed visit.

14. RESEARCH-RELATED INJURY

If you are injured or get sick while in this study, it is important to tell your study doctor listed on page one of this consent form.

Emergency medical treatment will be available to you. The study site will bill you or your insurance company in the normal way for the cost of such care. No payment or additional compensation is available to you for such injuries. There is no provision for free medical care or monetary compensation from the study sponsor, the NIAID, NIH. You do not lose any legal rights by signing and dating this form.

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 subject 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 vaccines, the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine, or the Janssen-J&J COVID-19 Vaccine used in this study. Subjects using the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine, or the Janssen-J&J COVID-19 Vaccine 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.

15. HIV POLICY

You will be tested for HIV as part of the screening visit before you start in the study. If you are found to be HIV positive, you will not be able to participate in the study. Your medical records will be kept confidential to the extent permitted by law. However, as mentioned earlier in this consent form, the study doctor may be required by law to report the result of this test to the local health authority.

16. CONFIDENTIALITY

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality.

You will be identified by a code, and personal information from your records will not be released without your written permission. A link will be created between your study information and the HIPAA compliant MyOwnMed web database. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible, and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

Your privacy is important to us and we will use safety measures to protect your privacy. Despite all the safety measures that we use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

As a NIH funded study, you are further protected through a policy that prevents the study doctor from releasing any sensitive information about you that may identify you. This does not prevent you or a family member from voluntarily releasing information about this research.

A description of this clinical trial will be available on http://www.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.

Organizations that may look at and/or copy your medical records for research, quality assurance and data analysis include:

- The National Institute of Allergy and Infectious Diseases, (NIAID) sponsor of the research,
- NIAID representatives, agents, employees, contractors, and other persons assisting in conducting, monitoring, or analyzing the study,
- The U.S. Food and Drug Administration,
- Other State and Local health authorities, and
- Pharmaceutical companies(s) and their commercial partners may review your medical and research records for regulatory purposes.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

17. 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 subjects. If you have any questions about your rights as a research subject, 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: Pro00055883.

18. FUTURE USE OF YOUR DATA/BIOLOGIC MATERIALS

Information about you, including your biospecimens, collected for this study may be shared with other researchers. It may also be used for other research studies. We will make sure that your identity cannot be linked to the information we share. We will not ask you for additional permission before sharing the information.

We are asking your permission to store samples of blood and urine collected during the study to be used in the future for tests that aren't yet planned.

Your stored samples will be used to obtain knowledge about genetic information in relation to the immune system. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body. Whole genome sequencing may be performed.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research and to share what is stored with other researchers. Collecting, storing, sharing information, and making it available for other studies may help people in the future. Coded information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases.

Samples will be stored at the ACV01 Central Repository. If you decide to allow storage, your samples and information may be stored for an unknown length of time.

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored

samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.

Please indicate your response below:
I agree to the storage and sharing of samples (urine, blood and/or tissue) for genetic tests not currently planned.

☐ Yes ☐ No

_____
Initials of Research Subject

I agree to the storage and sharing of samples (urine, blood and/or tissue) and information resulting from the analysis of my samples for other tests not currently planned.

☐ Yes ☐ No

_____
Initials of Research Subject

19. FUTURE CONTACT
May we contact you by phone to find out if you are interested in hearing about new research studies or to ask you about how current health is? Contact would be made by the study doctor or study staff. If you decide at any time that you no longer want to be contacted, please tell us, and we will stop calling you.

Would you like us to contact you about future research studies or to ask you about how current health is?

☐ Yes ☐ No _____
Initials of Research Subject

If you say “no” to this question, this will not affect your participation in this study.

20. SIGNATURE PAGE

Please sign and date below if you agree to take part in this study.

- You have read the informed consent and/or had it explained to you
- You were given the opportunity to ask questions about the information, and
- You voluntarily agree to take part in the study

_____	_____	_____
Research Subject's Name *(Typed or printed)*	Research Subject's Signature	Date

Signature and date of person explaining and obtaining the consent:

_____	_____	_____
Name and Title *(Typed or printed)*	Signature	Date

Signature and date of subject's legally authorized representative (if applicable):

_____	_____	_____
Name and Title *(Typed or printed)*	Signature	Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject

(NOTE: This consent form with the original signatures MUST be retained on file by the study doctor. A copy must be given to the research subject. A copy should be placed in the research subject's medical record, if applicable.)

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of the National Institute of Allergy and Infectious Diseases (NIAID).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.

- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law (HIPAA) and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____ _____
Printed Name of the Person Obtaining the Authorization Date

_____ _____
Signature of the Person Obtaining the Authorization Date

_____
Signature and date of subject's legally authorized representative (if applicable):

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject