

Institutional Review Board
Informed Consent Document for Research
MASTER CONSENT

Study Title: Observational, Prospective Cohort Study of the Immunogenicity and Safety of SARS-CoV-2 Vaccines Administered during Pregnancy or Postpartum and Evaluation of Antibody Transfer and Durability in Infants
Version: V2.0, May 21, 2021

Part 1 of 2: MASTER CONSENT – Pregnant Participants and their Infants

You are being invited to take part in a research study about the disease caused by SARS-CoV-2 virus called COVID-19. This study is a multi-site study, meaning it will take place at several different study locations. This consent form includes two parts. Part 1 is the Master Consent and includes information that applies to all study sites. Part 2 is the Study Site Information and includes information specific to the study site where you are being asked to enroll. Both parts together are the consent form and must be provided to you.

KEY INFORMATION:

You are being asked to take part in a research study. Participation is voluntary. This section will give you key information to help you decide whether to participate. Detailed information can be found after this section. Ask the research team any questions you have about the study. This study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) Division of Microbiology and Infectious Diseases (DMID).

Approximately 1,000 pregnant and postpartum participants and 1,000 infants will be in this study. This observational study is designed to collect clinical information, and blood and breast milk (optional) samples to determine how much protection is available to the mother and their babies after receiving a COVID-19 vaccine during pregnancy. The study will also collect COVID-19 vaccine safety information.

You are being asked to take part in this study because you are pregnant, and you have received or are scheduled to receive, a COVID-19 vaccine. **COVID-19 vaccines are NOT given as part of this study.** If you agree to take part in this study, your baby(ies) will become a study participant when born.

You will have up to 6 study visits (initial screening/enrollment visit, delivery visit, 3-4 follow-up clinic visits and a follow-up contact). Your baby(ies) will have 4 study visits (delivery visit and 3 follow-up clinic visits). You and your baby's follow-up visits will be scheduled together whenever possible; participation in this study will last up to 12 months after delivery. You may withdraw from the study at any time if you choose.

Study visits may include:

- Mother
 - Questions about your recent medical history, obstetric history, and medications, history of respiratory illnesses, and pregnancy outcome
 - Brief physical exam, if needed
 - Recording the date(s) of your COVID-19 vaccination, type of vaccine received, and any reactions to the vaccine
 - Blood samples
 - Optional breast milk samples if you plan to breastfeed and agree

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- Infant(s)
 - Questions about your baby's medical history, medications and vaccinations, history of respiratory illnesses, and delivery information
 - Baby's growth measurements
 - Brief physical exam, if needed
 - Blood samples, including cord blood at delivery

Others may benefit in the future from information learned from the study.

The possible risks of participating in this study include those associated with having samples collected and the possibility of a breach of confidentiality.

BACKGROUND:

You are being asked to take part in this study because you are pregnant, and you have received or are scheduled to receive a vaccination series of any licensed or Emergency Use Authorization (EUA) COVID-19 vaccine. **The COVID-19 vaccine is not given as part of this study.**

While COVID-19 vaccines are being administered to women during pregnancy and post-partum, there is a need to understand the effect of maternal vaccination on the infant, including the possibility that infants could be protected from COVID-19. This study will help better understand how vaccination in pregnancy and in the post-partum period could benefit mothers and their infants.

By signing this consent, you are agreeing to your participation and participation of your infant(s) once born. Medical information about you and your infant(s) are important to the study, so you will be asked to sign a release of medical records authorization form (this is what is on next page) for you and your infant(s) to allow study staff to obtain necessary medical and delivery information.

RISKS OF THIS STUDY:

Blood draws: Pain, redness, or bruising at the site of the needle stick; rarely an infection. If you feel faint while having your blood drawn, you should lie down to avoid falling. Your infant(s) may cry while blood is collected.

Breast milk collection (optional for breastfeeding mothers): Mild irritation from the cup on the breast pump or tenderness from milk expression.

Breach of confidentiality: The risk of breach of confidentiality related to your participation in this study is very low. Precautions are taken to protect the privacy of your personal information, including removing information that could be used to identify you. However as with any study, there is a potential risk of loss of confidentiality of your information.

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POTENTIAL BENEFITS:

You may receive results of the blood and breast milk tests done as part of this study by the time the study ends. Also, the knowledge gained from this study may be used to inform future policy recommendations and personal decision-making about the use of approved COVID-19 vaccines in pregnant and lactating individuals. There is potential benefit to society resulting from insights gained from participation in this study due to the ongoing threat of the COVID-19 outbreak.

You do not have to be in this research study. You may choose not to be in this study without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

STUDY PROCEDURES:

Screening/Enrollment Visit (approximately 2 hours):

If you agree to be in the study, we will:

- Ask you to sign a release of medical records authorization form
- Get your contact information
- Ask you questions to see if you can be in the study
- Ask you about your medical, medication, obstetrics and respiratory illness history, including COVID-19 infections and vaccination
- Record or calculate your BMI
- Perform a brief physical exam, if needed
- Draw about 2 teaspoons of blood
- Schedule your next visit. If you:
 - Already received a COVID-19 vaccine: next study visit will be when you deliver your baby(ies)
 - Have an upcoming COVID-19 vaccine: next study visit will be 28 days after your last shot and will be approximately one hour. At that visit, we will:
 - Ask you about your medical, medication, obstetrics and respiratory illness history, including COVID-19 infections and vaccination
 - Perform a brief physical exam, if needed
 - Draw about 2 teaspoons of blood

Optional for breastfeeding participants: If you are planning to breastfeed and agree to collect breast milk for this study, we will advise you on how to collect and store samples at follow-up visits. We will give you sample collection bags and a collection log to record the date when samples were collected.

Hospital Delivery Visit:

During your delivery, we will:

- Confirm you agree for you and your baby(ies) to continue in the study

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- Draw about 2 teaspoons of blood from you (preferably at the time of admission for delivery)
- Obtain blood from the remaining umbilical cord after your baby(ies) is delivered. If cord blood is not obtained, we may collect a sample of blood (about 1 teaspoon) from your baby(ies) by heel stick or from a vein.
- Review you and your baby's medical records
- Ask for your baby's name, sex, and date of birth
- Ask you about your baby's plans for pediatric care and ask you to provide authorization for release of pediatric medical records
- Schedule you and your baby(ies) for follow-up visits at 2, 6, and 12 months after delivery

2 Weeks Postpartum Follow-up Contact (approximately 15 minutes):

We will contact you by your preferred method of contact (phone call, email, text message, etc.). We will:

- Ask you about any medical problems you or your baby(ies) have experienced
- Ask you about your and your baby's history of respiratory illness and COVID-19
- Perform a brief physical exam, if needed and you choose to return to the clinic to provide breastmilk samples
- Remind you about you and your baby's 2-month visit

If you breastfeed and agree to provide breastmilk samples (optional):

- You can choose to return to the study clinic for this visit to provide a sample of breast milk (about 2-4 teaspoons). Alternatively, you can collect the sample at home, freeze it, and bring it to your next scheduled visit. We will provide supplies and detailed instructions on how to collect and store the sample.

2, 6, and 12 Months Postpartum Follow-up Visits (approximately one hour):

At these visits, we will repeat the following at each visit:

- Mother
 - Ask you to update your medical and respiratory illness history, including COVID-19
 - Perform a brief physical exam, if needed
 - Draw about 2 teaspoons of blood
 - Collect a sample of breast milk (about 2-4 teaspoons) if you are breastfeeding (optional)
- Infant(s)
 - Ask you about your baby's medical, medication, vaccination, respiratory history including COVID-19
 - Measure your baby's growth
 - Perform a brief physical exam, if needed
 - Obtain about 1 teaspoon of blood from a vein (preferred) or by heel stick (months 2 and 6 visits)

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Unscheduled visits may take place as needed (for example if a sample is missed or there is an issue with processing a sample).

REASONS FOR INVESTIGATOR WITHDRAWAL:

You may be removed from the study if:

- the study would present a health risk to you
- you fail to follow the study requirements
- the study stops or
- you are no longer eligible for the study.

PARTICIPANT WITHDRAWAL:

Your participation in this study is completely voluntary. You can stop at any time. There is no penalty or loss of any benefits to which you are otherwise entitled if you choose not to enroll, stop, or change your mind. Always tell the study staff if you wish to stop. They will discuss any concerns about your safety, and whether you need any follow up or medical care.

SOURCE OF FUNDING:

This study is being funded by the NIH, NIAID, Division of Microbiology and Infectious Diseases. The research investigator is not being paid directly by the Sponsor. A payment will be made to the study center to cover the costs of the study procedures and the services provided by the research investigator and the study staff.

LABORATORY TESTING OF BLOOD AND BREAST MILK SAMPLES:

Research tests will be done on blood samples collected from you and your baby(ies) and in breast milk to measure immune response to COVID-19 vaccines. This means that we will measure your and your baby's antibodies, which are proteins that the body uses to fight off the virus. We will also look at how different cells of you and your baby's immune system help to fight the virus. The results of these tests are useful only for research purposes. No genetic testing will be done.

Blood and breast milk samples for these research tests may be sent to a central storage facility then sent to the research testing laboratories. The samples will not be labeled with your name or initials, or any other information that could readily identify you. The samples will be labeled only with a barcode and a unique tracking number (ID code) to help protect your confidentiality. Staff at the central storage facility and research testing laboratories will not know your identity, or even the study identifier you were assigned.

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The clinical study staff will keep a list in a secure area with your name, contact information and the ID code (called a code key) that can link the samples to you, if needed. Access to the code key is limited to study staff working at the research site where your blood samples were collected.

STUDY RESULTS:

Individual research results may be provided to participants by the end of the study, but they will not be made available to your regular doctor and will not be placed in your medical record. Results from this study may be published while the study is ongoing and at the end of the study. Your individual identity will not be used in any reports or publications resulting from this study.

SECONDARY RESEARCH:

What happens to the blood and breast milk samples after testing?

After all tests required for this study are done, we will save you and your baby's leftover blood and your breast milk samples, as applicable, at a central storage facility for possible secondary research. These samples may be shared for secondary research with investigators at the site, or with researchers at other sites or other institutions. Secondary research is research that is not part of this study and is not planned yet. There is no time limit on how long these samples will be stored.

Importantly, the samples and the information we collect about you and your baby(ies) will not be labeled with personal identifiers; they will only have an ID code on them. Reports from secondary research will not be kept in your health records or shared with you, unless required by law.

You do not have to agree to let us to save your samples for secondary research. If you choose not to let us to save these samples for secondary research, they will be destroyed when the study is over. Your medical care at this clinic will not be affected if you do not let us to save your samples for secondary research.

If you decide at any time that you do not want the samples stored for secondary research, you must contact study staff in writing who will then notify the laboratory/storage facility. They will mark your samples with a "Destroy" label and destroy them at the end of this study, or laboratory staff will take the samples out of storage and destroy them as soon as possible.

MATERNAL SAMPLES (blood and breastmilk, if provided) FOR SECONDARY RESEARCH

Please **INITIAL** whether or not **your samples** may be kept for use in secondary research:

_____ YES, my samples may be kept for secondary research.

_____ NO, my samples may not be kept for secondary research.

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INFANT(S) SAMPLES FOR SECONDARY RESEARCH

Please **INITIAL** whether or not **your baby's samples** may be kept for use in secondary research:

_____ YES, my baby's samples may be kept for secondary research.

_____ NO, my baby's samples may not be kept for secondary research.

BREASTMILK SAMPLES

Breastmilk samples will be collected from lactating individuals who agree to provide samples as detailed above. You do not have to agree to give breast milk samples to participate in the study. Your medical care at the clinic where you were enrolled will not be affected if you decide not to give breast milk samples. Please **INITIAL** whether or not you agree to give breast milk samples as part of this study.

_____ YES, I agree to give breast milk samples.

_____ NO, I do not agree to give breast milk samples.

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