Duke University Health System

Consent To Participate In A Research Study

A Prospective Observational Study to Evaluate the Safety of COVID-19 Vaccination in Pregnant Women

CONCISE SUMMARY

The purpose of this study is to learn more about the safety of COVID-19 vaccine in pregnant women and their babies. Pregnant women who plan to receive the COVID-19 vaccine (either the first dose of the primary COVID-19 vaccine series or booster dose) during their current pregnancy will be offered participation. The study may also look at how much antibody (proteins in the blood that protect against the COVID-19 infection) the body makes after receipt of the COVID-19 vaccine. What we learn from this study may help doctors better understand if there is a difference in side effects or health outcomes following the different COVID-19 vaccines during pregnancy.

Through the course of the study you will have up to four in-person study visits and up to four phone/email/text visits. Participation is complete once you have delivered your baby and the study team has reviewed both you and your baby's charts for any medical occurrences approximately 90 days after birth.

Risks include that of having blood drawn.

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

You are being asked to take part in this study because you are pregnant, at least 18 years old, and you are planning to receive the COVID-19 vaccine (either the first dose of the primary COVID-19 vaccine series or booster dose) based on federal and local vaccination campaign distribution plans. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask her to explain any words or information that you do not clearly understand. We encourage you to talk with your healthcare provider, family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are explained below.

Please tell the study doctor or study staff if you are taking part in another research study.

Through a contract from the Centers for Disease Control and Prevention (CDC), the CDC will support this research study. The CDC will pay a portion of Dr. Geeta Swamy and her research team's salaries to conduct the study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Geeta Swamy will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

COVID-19 was first detected in December 2019 and rapidly spread to become a pandemic affecting the entire world. Pregnant women have not been spared and, according to the CDC, they represent one of the groups at high-risk for severe COVID illness as well as death from COVID-related complications.

This study will enroll pregnant women who plan to receive the COVID-19 vaccine (either the first dose of the primary COVID-19 vaccine series or booster dose) during their current pregnancy according to the guidelines created by the US Food & Drug Administration (FDA), the CDC and local public health agencies.

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Vaccines work by causing the body to make proteins called antibodies that fight infection. Vaccination is the most effective way to prevent infections like COVID-19. The Advisory Committee on Immunization Practices (ACIP) and the American College of Obstetricians and Gynecologists (ACOG) currently recommend that the COVID-19 vaccines that are licensed or under FDA Emergency Use Authorizations (EUAs) should be made available to pregnant women in conjunction with federal and local vaccination campaign distribution plans. Along with those guidelines, pregnant women are encouraged to discuss with their provider to decide if getting the COVID-19 vaccine would be appropriate.

A number of studies show that COVID-19 vaccines are safe to give to non-pregnant women. Although there were no studies before COVID-19 vaccines were authorized by FDA that looked to see if this is also the case in pregnant women, information collected by the CDC's registry that tracks pregnancies after COVID-19 vaccine has not shown any concerning effects.

The purpose of this study is to learn more about the safety of the COVID-19 vaccine in pregnant women and their babies. The study will look at whether or not antibody to COVID-19 is present at the study start and may also look at how much antibody the body makes after receipt of the COVID-19 vaccine.

What we learn from this study may help doctors better understand if there are any side effects or health outcomes from the COVID-19 vaccine during pregnancy.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 350 pregnant women will be enrolled in this study overall, with approximately 170 pregnant women to take part at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to participate, you will be asked to sign and date this consent form. We ask that you:

- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor or study staff.
- Record your health information for the first 7 days after vaccination(s).
- Tell study staff about any changes in your health or the way you feel, especially any colds or respiratory (lung) infections.
- Sign a medical release to permit us to review medical records for you and your baby, if needed for the hospital where you are planning to deliver.

Screening visit (clinic or virtual visit by phone/video) (either 1-dose, 2-dose or booster vaccination groups):
Study staff will review this consent form with you as well as the study criteria to make sure you qualify. Additionally, study staff will ask you about your health and any medicines you are taking. If you agree to participate, you will be asked to sign and date this consent form.

Visit 1 (clinic visit) (either 1-dose, 2-dose or booster vaccination groups): You will get your COVID-19 vaccine through a vaccination appointment or clinic visit that you have scheduled based upon national and local guidelines. The COVID-19 vaccination is not a study procedure. On this appointment day, the study staff will review the study criteria with you and ask about your health and any medicines you are taking to make sure that you still qualify for the study.

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Within the first day of receiving your COVID-19 vaccination, you will be given a Memory Aid form, ruler and thermometer, and shown how to use them for the study. You will be asked to write down your temperature and any symptoms that you have daily from the evening of the day you got the vaccine through seven days after you receive the vaccine. You should also write down any new medicines you take during this time, even over-the-counter medicines like acetaminophen (Tylenol). You will also be asked to measure (with the ruler) the spot where you received your vaccine if the area gets red or swollen.

You have the choice of filling out the Memory Aid either on paper, or online, using the study's web-based system, "REDCap." If you choose to complete the Memory Aid online, you can also choose to receive email or text reminders with the link to the online system.

The study team will ask that you present to the study site to complete the remaining portions of the visit on the same day as your COVID-19 vaccination or up to 3 days afterwards. During this in-person portion of the visit, study staff will take your vital signs (temperature, blood pressure, respiratory rate, and heart rate) and a blood sample of 12 mL (~3 teaspoons) will be taken to test for COVID-19 antibody levels. We will measure these COVID-19 antibody levels using a test that is allowed under the FDA's Emergency Use Authorization during the pandemic. We will test for antibodies at a later time during the study and share them with you as permitted by the FDA, CDC, and local regulations.

You should contact the study staff if you have any severe reactions (explained on the Memory Aid form you will receive) in the week after the vaccine.

Visit 2 (phone call/email/Text follow-up) (either 1-dose, 2-dose, or booster vaccination groups): This visit will occur approximately 7 days after Visit 1. If you chose to use the paper Memory aid, a member of the study staff will contact you to review your symptoms and medications. If you choose to enter your Memory aid information in the web-based system (that is REDCap), study staff will review your entries online. If the study team sees that you have not entered any information, the study team will contact you by phone, email, or text to get this information from you. The study team may also contact you if more information is needed regarding the details you entered in REDCap.

If you have a severe reaction to the vaccine, you will be encouraged to follow up with your obstetrician or primary care provider. You may be asked to return to clinic for an unscheduled visit where you will have an evaluation by the study doctor.

Visit 3 (clinic visit) (either 1-dose, 2-dose, or booster vaccination groups): About 21 to 29 days after Visit 1 (-2 + 0 days before second dose) you will return to the clinic for another in-person visit. You will be asked about any changes to your health and any medicines you are taking. A blood sample of 12 mL (~3 teaspoons) will be taken to test for COVID-19 antibody levels.

If you received a one-dose regimen or a booster dose of the COVID-19 vaccine, you will not need to do an additional Memory Aid.

If you received a second dose of the COVID-19 vaccine, you will be given a Memory Aid form, ruler and thermometer. You will be asked to complete the form daily from the evening of the day you got the second dose of the vaccine through seven days after you receive the vaccine. You should write down any new medicines you

take during this time, even over-the-counter medicines like acetaminophen. You will also be asked to measure (with the ruler) the spot where you received your vaccine if the area gets red or swollen.

Again, you will have the choice of filling out the Memory Aid either on paper, or online, using the study's web-based system, "REDCap." If you choose to complete the Memory Aid online, you can also choose to receive email or text reminders with the link to the online system.

Visit 4 (phone call/email/Text follow-up) (2-dose vaccine group only): Depending on the vaccine received, you may or may not have this visit. If you received a vaccine that requires a second dose this visit will occur 9 to 12 days after the second dose. If you chose to use the paper Memory Aid, a member of the study staff will contact you to review your symptoms and medications. If you choose to enter your Memory Aid information in the web-based system (that is REDCap), study staff will review your entries online. If the study team sees that you have not entered any information, the study team will contact you by phone, email, or text to get this information from you. The study team may also contact you if more information is needed regarding the details you entered in REDCap.

If you have a severe reaction to the vaccine, you will be encouraged to follow up with your obstetrician or primary care provider. You may be asked to return to clinic for an unscheduled visit where you will have an evaluation by the study doctor.

Visit 5 (clinic visit) (2-dose vaccine group only): Depending on the vaccine received, you may or may not have this visit. If you received a vaccine that requires a second dose this visit will occur about 28 to 35 days after the second dose.

You will be asked about any changes to your health and any medicines you are taking. A blood sample of 12 mL (~3 teaspoons) will be taken to test for COVID-19 antibody levels.

Post-vaccination Visit (phone call/email/Text follow-up) (either 1-dose, 2-dose, or booster vaccination groups): About 6 weeks after receiving the last dose of any COVID-19 vaccine you will be contacted. You will be asked about any changes to your health and any medicines you are taking.

Visit 6 (hospital visit/chart review) (both 1-dose and 2-dose vaccination groups): During your admission for the birth of your baby, a blood sample of 12 mL (3 teaspoons) will be taken from you to test for COVID-19 antibody levels. The study team will work with your care providers to have this drawn when you are having other blood drawn for part of your care (for example when your IV is placed). If this is not possible, a member of the study team will draw your blood for the study before you go home from the hospital.

After the birth of your baby, the study team or your care providers will collect approximately 12 mL (3 teaspoons) of umbilical cord blood (the blood that remains in the placenta after delivery), if feasible, in order to evaluate your antibody levels. This blood sample will be collected after the umbilical cord is cut so that there is no risk for the baby. Also, this will not affect your ability to donate the remaining umbilical cord blood if you so wish.

Study staff will review your and your baby's medical records until your baby is 90 days old in order to complete research questions. After you deliver, study staff will review your labor and delivery medical records to collect additional information on the delivery and the health of you and your baby during your hospital stay. If you do

not deliver at Duke University Medical Center, study staff will obtain records from these health care providers (after you have signed a medical record release form for you and your baby). Study staff will review your medical record up to 90 days after the birth of your baby to see if you develop any new or worsening medical problems.

Visit 7 (phone call/email/Text follow-up) Postnatal Day 90 (either 1-dose, 2-dose, or booster vaccination groups): Study staff will contact you to record any unexpected medical events that occurred in you or your baby. Information will also be collected on hospital admissions; emergency room visits and unanticipated visits to the primary care pediatrician or a specialist. This information will be verified by reviewing medical records.

Unscheduled Visit (either 1-dose,2-dose, or booster vaccination groups): Unscheduled visits may occur at any time during the study. If you experience a severe reaction to the vaccine, the study team will recommend that you follow up with your healthcare provider. Should you come in for an unscheduled visit, the study team will take your vital signs (just like in Visit 1) and you will be asked about any changes in your health or medications you are taking. Depending on the severity of the reaction, the study doctor may refer you to your primary care or pregnancy doctors for assessment and possible treatment as well as report the event to Vaccine Adverse Events Reporting System (VAERS), a national vaccine safety surveillance program run by the CDC and FDA.

If you received the 2-dose regimen of COVID vaccine, a total of up to 48mL (~3 tablespoons) of your blood will be drawn over the course of the study. If you received the 1-dose or booster dose regimen of the COVID-19 vaccine, a total of up to 36mL (~2.5 tablespoons) of your blood will be drawn over the course of the study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for 2 to 7 months, depending on how far along you are in your pregnancy when you enroll and when you deliver. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

Blood draws

Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely. Staff will apply direct pressure to the blood draw site to reduce any bruising. Sterile techniques will be used to prevent infection at the site where blood will be drawn.

Other potential risks

Because e-mail and text messaging do not provide a completely secure and confidential means of communication, please let us know if you would prefer the study team to only communicate with you through regular channels like the telephone.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Health System (DUHS) in the event that you are injured as a result of your participation in this research study. However, there is no commitment by DUHS or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Swamy at 919-681-5220 during regular business hours and at 919-970-6606 (pager) after hours and on weekends and holidays.

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ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There are no direct benefits to you or your baby for participating in this study. Information learned from this study may help doctors better understand about the health effects of COVID-19 vaccine in other pregnant women and their babies.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

This study is supported by the CDC. Because of this support, your study information is protected by a Certificate of Confidentiality.

With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the FDA.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Your records may be reviewed in order to meet federal or state regulations or local regulations. Reviewers may include representatives from the DUHS Institutional Review Board, as well as the CDC and its affiliates, and the FDA as appropriate. If one of these groups reviews your research record, they may also need to review your entire medical record. This information may be further disclosed by the sponsor of this study, the CDC. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your and your baby's private information with anyone not involved in the study, the federal law designed

to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The study results will be retained in your research record for at least six years after the end of the study. At the end of this retention period, either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at Duke. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

A description of this clinical study will be available on http://www.ClinicalTrials.gov. 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.

WHAT ARE THE COSTS?
There are no additional costs to you associated with this study. However, you or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. If your phone data plan includes charges for text messaging that you do not want to pay, discuss this with study staff.

WHAT ABOUT COMPENSATION?
All study participants will be compensated $50 after completing each blood draw visit, $25 for completing each study phone call, $25 after completing the Memory Aid, with a total of up to $225 to $325 for all completed study visits and depending on whether you received a 2-dose regimen vaccine (e.g., Pfizer or Moderna) or a 1-dose or booster dose regimen (e.g., Johnson & Johnson (Janssen) or Pfizer or Moderna booster dose) vaccine. Subjects will only be compensated for successful completion of each study visit.

If an unscheduled visit is needed to assess any adverse reactions to the vaccine(s), you will receive an additional $50 for completion of that visit.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

If you do decide to withdraw, we ask that you contact Dr. Swamy in writing and let her know that you are withdrawing from the study. Her mailing address is 2608 Erwin Road Suite 210, Durham, NC 27705. Once you withdraw consent, you can no longer take part in the study. You may also contact the study team to notify them of your decision to withdraw from the study by calling 919-613-9630 during regular business hours. However, the study doctor may continue to use and share your health information that was collected before you stopped your consent.

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Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at DUHS including receiving the COVID-19 vaccine outside of the study. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.
The study doctor may decide to take you off this study if he/she determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include changes in medical practice, or problems with the study. If this occurs, you will be notified.

CONSENT FOR STORAGE OF BLOOD AND FUTURE TESTING
Your blood samples will be stored and labeled only by a unique study subject number and will not be labeled with any identifying information such as your name or initials. Samples will be kept confidential to the best of our ability within state and federal law. After all study tests are done, we would like to keep any remaining samples to use in possible future research studies. These studies may test for antibodies against other bacteria or viruses, markers of inflammation, or used in research on the health of mothers and infants. No human genetic tests will be performed on your samples. Your coded samples will be linked to the information (including personally identifiable information) that you have provided to this study.

You will not receive results of any future testing that is done on these samples. Your decision regarding future research will not affect your participation in this study.

If you agree to allow your blood to be kept for future research, you are free to change your mind at any time. We ask that you contact Dr. Swamy in writing and let her know you are withdrawing your permission for your blood to be used for future research. Her mailing address is 2608 Erwin Road Suite 210, Durham, NC 27705. You may also choose to contact the study team at 919-613-9630 to inform them of your decision to withdraw your permission for your blood to be used for future research. At that time, we will ask you to indicate in writing if you want the unused blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

PLEASE INITIAL your decision about permission for us to use your leftover samples for future research (indicate only ONE option):

_____YES, I agree to allow my ***coded*** samples to be stored and tested in the future. My samples may be used in new or different laboratory tests, or for further research into vaccines. If I decide later to cancel my consent to storage and future testing, I will write a letter to the study doctor at the address listed on page 8 of this form.

_____ No, I DO NOT agree to allow my samples to be stored and tested in the future. My decision will not affect my ability to participate in the study. My samples collected for this study will be destroyed at the end of this study.

CONTACT FOR FUTURE STUDIES
We may want to contact you in the future to ask if you or your child would like to participate in other studies. If you agree, we would like to keep your name, address, phone number and email address on file. This information will be kept confidential and will not be shared with other research groups. If you agree to be contacted for a future study, you will be asked to sign a separate consent form for that study. Your decision regarding future research contact will not affect your participation in this study.

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PLEASE INITIAL your decision about permission for us to contact you for future research studies (indicate only ONE option):

_____ YES, I agree to be contacted for possible participation in future research studies.

_____ No, I DO NOT agree to be contacted for possible participation in future research studies.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or if you have problems, concerns or suggestions about the research, contact Dr. Swamy at 919-681-5220 during regular business hours and at 919-970-6606 (pager) after hours and on weekends and holidays. The study team can also be reached by calling 919-613-9630 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the DUHS Institutional Review Board (IRB) Office at 919-668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____
Signature of Subject Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time