INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID)/Infectious Diseases Clinical Research Consortium Leadership Group (IDCRC LG) / "A Prospective, Randomized, Open-label Phase 4 Study of the Immunology and Safety of Maternal RSV Vaccination (ABRYSVOTM), Infant Nirsevimab (BEYFORTUSTM) Immunization, or Both Products During the First Year of Life"**
Protocol Number:	**24-0003**
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
Address:	**University of Maryland, Baltimore, Center for Vaccine Development and Global Health (CVD)** [redacted]

KEY INFORMATION

Participating in this study is your choice. This form has important information to help you decide if you want to join. The first part gives you a brief summary of what the study is about. More details are in the next sections. Please read this form carefully and ask the research team any questions you have. The research team can explain words or information that you do not understand. If you decide to take part in this study, you are also choosing to allow your baby to take part in this study, starting at birth. The end of the form has a place for you to sign if you agree to enroll yourself and your baby.

The National Institute of Allergy and Infectious Diseases (NIAID) Division of Microbiology and Infectious Diseases (DMID) is paying for this study. Sanofi, the manufacturer of BEYFORTUS, is donating that product for use in this study.

The sponsor of this research study is the Division of Microbiology and Infectious Diseases (DMID) and Infectious Diseases Clinical Research Consortium Leadership Group (IDCRC LG). "Sponsor" includes any persons or companies that are working for or with the DMID and IDCRC LG and any companies that are owned by the DMID and IDCRC LG.

Why are you being asked to take part in this study? You are being asked to join this study because you are a person aged 18-45 years who is pregnant.

Do you have to take part in this study? Taking part in this study is your choice. If you agree to take part in this study, your baby will also take part in this study when born.

What is this study about? RSV (also called Respiratory Syncytial Virus) is a common virus that can make babies and small children very sick. There are two recently approved products that can help protect babies from RSV. One product is a vaccine called RSVpreF. It is given to pregnant people. The other product is a monoclonal antibody called nirsevimab. It is given to babies before or during their first RSV season. The difference between a vaccine and a monoclonal antibody is described later in this document. Both products are US Food and Drug Administration (FDA) approved and licensed and are recommended as part of standard care in the US. In most situations, *either* the pregnant person gets the vaccine, or their baby gets the antibody, but usually not both.

The purpose of this study is to better understand the safety and immune responses when both the vaccine and monoclonal antibodies are provided to a pregnant person and their baby, compared to using either study product alone. The results from this study could help pregnant people in the future make choices about how they want to protect their babies from getting RSV. If you choose not to take part in this study, you and your baby will still receive the standard of care from your doctors.

How many people will take part in this study? About 200 pregnant people and their babies will join this study. You and your baby will be randomized. Randomization is when people are put into groups by chance, like picking names out of a hat. Neither you nor the study team can choose which group you and your baby are in. This makes sure the study is fair.

There are 4 groups you and your baby could be placed in:

Group 1A	You receive the RSV vaccine and your baby does NOT receive the RSV monoclonal antibody
Group 1B	You receive the RSV vaccine AND your baby receives the RSV monoclonal antibody at birth
Group 1C	You receive the RSV vaccine AND your baby receives the RSV monoclonal antibody at 3 months of age
Group 2	You do NOT receive the RSV vaccine and your baby receives the RSV monoclonal antibody at birth.

If you want to pick which product you and your baby get, you should not join this study.

What will you have to do if you take part in this study? You will have about 7 in-person study visits (screening visit, enrollment visit, delivery visit, and 4 follow-up clinic visits). Your baby will have about 5 study visits (delivery visit and 4 follow-up clinic visits)through about 12 months after delivery. For babies who get the antibody, we will ask you to complete a short form about possible side effects, every day for about a week after the shot. There will also be a total of 2 scheduled phone calls from the study team: one when your baby is about 1 month old and a second phone call when your baby is about 4 months old. Your and your baby's follow-up visits will be scheduled together whenever possible; participation in this study will last from enrollment to about 12 months after delivery. You may decide to withdraw yourself and your baby from the study at any time.

What kinds of activities happen during study visits for you and your baby?

- Pregnant Person
    - Consent, either written or electronic: you will document your choice for you and your baby to join the study
    - Questions about your recent medical history, including your obstetric history, medications you take, vaccines you have received, and your history of respiratory illnesses
    - Brief physical exam, if needed
    - Blood draws
    - Breast milk collection if you plan to breastfeed.
    - Vaccination, for pregnant people assigned to some groups
- Baby
    - Questions about your baby's medical history, medications and vaccinations, history of respiratory illnesses, and delivery information
    - Baby's measurements
    - Brief physical exam, if needed
    - Blood collection, including collection from the umbilical cord at delivery and 3 blood draws
    - Receipt of the antibody shot, for some groups

BACKGROUND AND PURPOSE

RSV stands for Respiratory Syncytial Virus. RSV can cause infections in the lungs and breathing passages. It is very contagious, meaning it can spread easily from person to person. Most people get RSV at some point in their lives, and it is most common in young children. While it can cause mild symptoms like a cold in older children and adults, RSV can make babies and small children very sick. It is also a leading cause of hospitalization in babies in the US.

Until recently, there was no way to help prevent healthy babies from getting RSV. But in 2023, the FDA approved two products designed to prevent RSV lower respiratory tract disease in babies' lungs:

- An RSV vaccine based on what is called the pre-fusion F protein (referred to as RSVpreF or ABRYSVO and made by Pfizer) given during pregnancy
- A long-acting monoclonal antibody (referred to as nirsevimab or BEYFORTUS and made by AstraZeneca) given to babies at or closely after birth or at the start of their first RSV season.

The FDA is short for the Food and Drug Administration. It is a group of people who work for the government. They make sure that the food we eat, the medicine we take, and other products we use are safe. They also check to see if new medicines, including vaccines and monoclonal antibodies, work before they can be sold to people.

When pregnant people get the RSV vaccine, it helps protect their baby from getting sick with RSV. The vaccine works by teaching the pregnant person's body how to recognize and fight the RSV virus. This immune response can also help protect the baby from getting sick. This is because the pregnant person produces antibodies that are passed to the baby through the placenta and through breast milk. These antibodies help the baby's body fight off the virus if they encounter it.

Monoclonal antibodies are special proteins made in a lab. They are designed to help fight off specific germs or diseases. In this study, the monoclonal antibody is made to help protect babies from getting sick with RSV.

The CDC recommends that either product (but not both, in most cases) should be used to protect all babies from RSV in their first RSV season. The CDC is short for the Centers for Disease Control and Prevention. It is a part of the government that helps keep people healthy. They study diseases and how they spread. They also give advice on how to stop diseases from spreading and what to do if you get sick.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to better understand the safety and immune responses when both the vaccine and monoclonal antibodies are provided to a pregnant person and their baby, compared to using either study product alone. The results from this study may help pregnant people in the future decide how they want to protect their babies from RSV.

WHAT WILL HAPPEN DURING THE STUDY?
Your participation in this study will last approximately 14 months and will include up to 7 in-person study visits.

Screening Visit:
Screening will occur at 20 weeks gestational age or later during pregnancy and may be at the same time as your enrollment visit.

The following will be performed to determine if you qualify to take part in this study:

- Ask you questions to see if you can be in the study
- Ask you basic information about yourself
- Ask you about your medical and obstetrics history and about what medications you are taking
- At some sites, we may be able to complete this visit by telephone

Enrollment/Randomization Visit (Gestational Age 32 weeks 0 days through 36 weeks 6 days):

If enrollment does not take place the day you are screened, we will see if you still qualify to take part in this study. The following will happen:

You will be selected by chance to enroll into one the following four groups:

- Group 1A: You will receive the maternal RSV vaccine (RSVpreF) only
- Group 1B: You will receive the maternal RSV vaccine (RSVpreF) AND your baby will receive the RSV monoclonal antibody (nirsevimab) *at birth*
- Group 1C: You will receive the maternal RSV vaccine (RSVpreF) AND your baby will receive the RSV monoclonal antibody (nirsevimab) *at 3 months*
- Group 2: You will NOT receive the maternal RSV vaccine (RSVpreF), but your baby will receive the monoclonal antibody (nirsevimab) at birth only

The study staff will:

- Ask you about your demographics (like age and race), medical and obstetrics history and about what medications you are taking. At some sites, we may be able to collect some information from you, on this day, by telephone, before your in person visit.
- Draw about a teaspoon of blood. Your blood may be drawn by study staff or by clinical staff where you are getting your care. Give you a physical examination, if needed

Then, if you were selected to be in one of the groups where the pregnant person receives the maternal RSV vaccine, you will be given the RSV vaccine.

At this visit, you and your baby will also be randomized to have blood collected at either the 6-week or 3-month visit (but not both). This way, after delivery, you and your baby will have only 3 blood draws: (1) at 6 weeks OR 3 months, (2) at 6 months and (3) at 12 months.

Birth Visit:

For the mother

- Study staff will ask you to reconfirm that you want to continue taking part in this study.
- Study staff will ask about your medical and obstetrics history since the time you enrolled.
- About a teaspoon of blood will be drawn. If possible, this will be taken when you are having blood drawn as part of your routine care where you are delivering.
- Study staff will ask about whether you will be breastfeeding your baby.
- If you plan to breastfeed:
    - We will ask you, if possible, to provide about a tablespoon of breastmilk. If this is not possible right away, we may ask you to collect milk after you and your baby go home and return it to us.
    - Distribute at-home breast milk collection supplies for future visits.

For the baby

- Study staff will review your baby's eligibility criteria if you are in Group 1B or 2
- We will ask you to sign a release of medical records authorization form for your baby.
- We will collect medical and personal information about your baby.
- We will perform a physical examination or record the information about your baby's exam.
- Nirsevimab will be administered to babies in the groups assigned to get it at birth (Group 1B and Group 2).
- If your baby receives nirsevimab, we will instruct you how to complete a 7-day diary that tells us if your baby has any adverse effects from the shot.
- Collect baby cord blood. If we cannot collect blood from the cord, we will collect it directly from your baby.

1-Month Phone Call

For the mother

- Study staff will ask if you have had any health issues or medical problems since the time you gave birth to your baby.

For the baby

- Study staff will ask about medical history, medications, and vaccines and possible side effects from enrollment.
- If your baby received nirsevimab at their birth visit, study staff will review and discuss the 7-day diary that you filled out for your baby.

6-week visit

For the mother

- Collect about a teaspoon of blood (for about half of mothers).
- Ask you about your baby's breastfeeding status.

- If you have chosen to continue to breastfeed:
    - Collect about a tablespoon of breastmilk (either at home prior to the visit or in the clinic), and
    - Distribute additional at-home breastmilk collection supplies.

For the baby

- Collect medical history, medications, and vaccines.
- Collect up to a teaspoon of blood (for about half of babies).
- Perform a physical exam, if needed.

<u>3-month visit</u>

For the mother

- Collect about a teaspoon of blood (for about half of mothers).
- Ask you about your baby's breastfeeding status.
- If you have chosen to continue to breastfeed:
    - Collect about a tablespoon of breastmilk (either at home prior to the visit or in the clinic), and
    - Distribute additional at-home breastmilk collection supplies.

For the baby

- Collect information that includes medical history, and medications and vaccines received.
- Perform a physical exam, if needed.
- Collect about a teaspoon of blood (for about half of babies).
- For babies assigned to get the antibody shot (Group 1C), review eligibility and administer nirsevimab.
- If your baby receives nirsevimab, we will instruct you how to complete a 7-day diary that tells us if your baby has any adverse effects from the shot.

<u>4-Month Phone Call</u>

For the mother

Study staff will ask if you have had any health issues or medical problems since the time you gave birth to your baby.

For the baby

- Study staff will ask about medical history, medications and vaccines, and possible side effects from enrollment.
- If your baby received nirsevimab at their 3-month follow-up visit, study staff will review and discuss the 7-day diary that you filled out for your baby.

<u>6-month visit</u>

For the mother

- Collect about a teaspoon of blood.
- Ask you about baby breastfeeding status.

- If you have chosen to continue to breastfeed:
    - Collect about a tablespoon of breastmilk (either at home prior to the visit or in the clinic), and
    - Distribute additional at-home breastmilk collection supplies.

For the baby

- Collect information that includes medical history, and medications and vaccines received.
- Collect about a teaspoon of blood.
- Perform a physical exam, if needed.

<u>12-month visit</u>

For the mother

- Collect about a teaspoon of blood.
- Ask you about baby breastfeeding status.
- Collect about a tablespoon of breastmilk (either at home prior to the visit or in the clinic) if you have chosen to continue to breastfeed.

For the baby

- Collect medical history.
- Collect about a teaspoon of blood.
- Perform a physical exam, if needed.

<u>Unscheduled Visits</u>

You may be asked to come back to the study site at other times if needed, for example, if you or your baby have symptoms or an illness that should be evaluated before the next scheduled visit. The study doctor will decide what activities will be needed after reviewing any symptoms that you or your baby are having.

EXPECTATIONS

If you take part in this study, you will be expected to:

- Follow the instructions you are given.
- Come to the study site for all study visits (mother and baby).
- Tell us about any changes in your health or the way you feel or your baby's health.
- Tell us if you want to stop taking part in this study at any time (yourself or your baby).

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

There may be some risks to being in this study. You or your baby may experience one or more of the risks or side effects explained below. You should discuss these with the study doctor or study staff. Many side effects go away quickly, but in some cases, side effects can be serious, long lasting, or permanent.

RISKS OF STUDY PRODUCTS

The study products are the vaccine for pregnant people (RSVpreF vaccine) and the antibody for babies (nirsevimab). These study products are licensed, recommended, and part of standard medical care in the US. The risks after receipt of these study products are no different whether you get them as part of standard care from your doctor and your baby's doctor or because you choose to join the study. However, for groups where mother gets the vaccine AND baby gets the antibody, it is possible, but not likely, that the risks or side effects will be greater than either given alone. We are providing you with the standard information sheets for the vaccine and monoclonal antibody. These sheets explain the risks.

Potential side effects of the vaccine (RSVpreF) include:

- Short-term pain, redness, or swelling where you received your shot; feel tired; or have fever, headache, nausea, diarrhea, and muscle or joint pain.
- Feeling faint after receiving the shot.
- Some pregnant people reported preterm birth and high blood pressure, including pre-eclampsia, but it is not known if this was caused by the vaccine.
- Some older adults reported serious neurologic conditions, including Guillain-Barré syndrome (GBS- a rare neurological disorder in which a person's immune system mistakenly attacks part of their peripheral nervous system), after RSV vaccination in clinical studies of older adults, but it is unclear whether the vaccine caused these events.
- As with any drug, there is a very small chance that a vaccine including RSVpreF could cause a severe allergic reaction, other serious injury, or death.

Potential side effects of the monoclonal antibody (nirsevimab) include:

- Short-term pain, redness, or swelling where your infant received their injection, or a rash.
- Serious reactions including hives, shortness of breath, cyanosis (bluish or grayish skin or nails), and hypotonia (muscle weakness), have been reported following nirsevimab administration.
- As with any monoclonal antibody, there is a very small chance that nirsevimab could cause anaphylaxis (severe allergic reaction), other serious injury, or death.

<u>Allergic Reaction</u>

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

RISKS OF STUDY PROCEDURES

Blood draws: Blood will be collected from you and from your baby in the usual way, by inserting a needle into a vein or artery. You and your baby may have pain, redness, or bruising at the site of the needle stick; very rarely, it could lead to an infection. If you feel faint while having your blood drawn, you should lie down to avoid falling. At delivery, we will collect blood from the umbilical cord. This procedure does not cause you or your baby any pain and there are no significant risks. Typically, the leftover blood in the cord is discarded with the placenta. In exceptional circumstances, if cord blood is not collected at delivery, infant blood may be collected by venipuncture or arterial blood collection (in accordance with standard practices at the birth facility) within 72 hours after delivery.

Breast milk collection: If you have chosen to breast feed, we will ask you to give us breast milk for immune response analysis. You may collect it manually or with a breast pump. You could experience 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 and your baby's information, including removing information that could be used to identify you or your baby. However, as with any study, there is a potential risk of loss of confidentiality of that information.

UNFORESEEN RISKS

General: There may be risks and discomforts we do not know about right now. It is possible that we will learn new information on the risks and discomforts of being in this study. If this happens, the study doctor will tell you about them. Then you can decide if you want you and your baby to continue to be in this study or not.

Enrollment late in the season: RSV infections occur in most areas of the US primarily from November to March (the "RSV season"). If you join the study in February or March, your baby may be born after the end of this RSV season. Protection provided by maternal RSVpreF vaccine and/or infant nirsevimab as part of study participation is expected to wane after about 5 months. Therefore, your baby's protection may wane prior to the end of the next RSV season and they may be at risk of RSV. However, starting October 2025, your baby may be recommended to get nirsevimab as part of standard care. If your baby's pediatric provider recommends nirsevimab, your baby may then be receiving more than one dose of nirsevimab in the first year of life. Although we do not anticipate that there would be any additional risk for your baby, receiving a second dose is not within the current guidelines for most infants and there could be unforeseen risks. We can help you and your baby's provider decide what is best. There also may be the risk that your health insurance will not cover a dose of nirsevimab next season.

ALTERNATIVES TO PARTICIPATION
You and your baby do not have to be in this study**.** Your other options may include:

- Receiving either of the FDA-approved products designed to prevent RSV lower respiratory tract disease in all babies as standard of care.

Please talk to the study doctor and your providers about your options before you decide whether or not you will take part in this study.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You and your baby may not get direct benefit from being in this study. Since the study products have already been proven to reduce more severe RSV disease in babies, your baby will likely have lower risk of severe RSV infection than babies who do not receive nirsevimab or whose pregnant parents were not vaccinated. But, since these study products are standard of care, the same benefit would be expected if either product were given outside of the study. The knowledge gained from this study may be used to inform future policy recommendations and personal decision-making about the use of these products in pregnant people and in their babies.

COMPENSATION FOR PARTICIPATION
You will be paid up to a total of $[redacted] for Group 1A, $[redacted] for Group 1B, $[redacted] for Group 1C, or $[redacted] for Group 2 if you complete this study. You will be paid for the visits you and your baby complete according to the payment schedule provided to you.

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

Bus tokens and/or parking vouchers may also be provided for study-only visits.
You may need to report payments you receive for participating in the study as taxable income, which could affect your eligibility to receive certain government benefits (e.g., from the Maryland Supplemental Nutrition Assistance Program (SNAP) and the Maryland Temporary Cash Assistance program (TCA)). If you owe a debt to the State of Maryland or the federal government (e.g., child support, taxes), the amount you receive may be reduced.

CERTIFICATE OF CONFIDENTIALITY
To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) from the NIH. Study staff cannot provide to any person not connected with the research your name, or any materials that have identifiable, sensitive information about you, unless permitted by a legal exception, such as state and national laws that require reporting of some contagious

diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of your identifiable, sensitive information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission.

The study staff will use the Certificate to resist any demands for information that would identify you.

Your information protected by the Certificate may still be disclosed or used when the information:

1. Is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH; or
2. Is required to be disclosed by federal, state, or local laws, for example, when information must be disclosed to meet the legal requirements of the FDA. This does not include disclosure for use during legal proceedings as noted above;
3. Is necessary for your medical treatment and you have consented to this disclosure;
4. Is for other scientific research as allowed by applicable federal regulations;
5. Is disclosed with your consent.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing and dating below you consent to those disclosures. Reporting sexual abuse or assault of persons under 18 years of age is required by law and will become part of the person's medical record, but not their research record.

CONFIDENTIALITY

Efforts will be made to limit disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of the University of Maryland, Baltimore (UMB), or the study site.

Paper documents containing personal information about you and your baby will be kept in locked file cabinets. Computerized information will be kept in password-restricted files. Information from this study will be placed into a research database. A study number, rather than your and your baby's name, will be used on study records. Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access.

By signing and dating this consent form you are giving permission for representatives of the NIH, NIAID, the Office for Human Research Protections (OHRP), and the Advarra IRB (a group of people who review research studies to protect the rights and welfare of research participants), as well as the study doctor and other employees of the study site involved with this research study, to inspect sections of your and your baby's medical and research records related to this

study. Sanofi, the manufacturer of BEYFORTUS, has donated that product for use in this study. They will have access to results of the study, but not to your or your baby's personal information. While every effort will be made to protect the confidentiality of your and your baby's information, absolute confidentiality cannot be guaranteed.

The monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records for verification of the study procedures and date. By signing this document, you are authorizing this access.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted, and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

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.

COMPENSATION FOR INJURY

If you or your baby have an injury, promptly seek medical care from any healthcare provider. If you have an emergency, call 911 or go to the nearest emergency room. You should tell the healthcare provider that you and your baby have participated in a research study.

If you believe the injury is related to the study, notify the study doctor. UMB, if requested, will assist you to get medical care or referrals.

If you are injured as a result of being in this study, you or your insurance will be responsible for paying your medical expenses. Neither the hospital nor UMB has agreed to pay for the cost of medical care or other costs arising from an injury. However, you do not give up any of your legal rights by being in this study, and you may choose to pursue legal action if you are injured by being in the study.

If you or your baby become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you or your baby that you and your baby are taking part in this study. If you tell the study staff that you think you or your baby have been injured, then they will help you get the care you need. If you or your baby experience a research-related illness or injury, you and/or your and your baby's medical hospital insurance carrier will be responsible for the cost of treatment.

In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. By signing and dating this document, you and your baby will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS

There will be no fee to enroll in the study. However, you or your insurance will be billed, in accordance with applicable law and policy, for the costs of medical care that are required by the study. You or your insurance will also be billed for costs of medical care, including tests and procedures, that you would have needed or received if you were not in the study. These costs may include co-insurance, deductibles, and co-pays. You may also incur additional ancillary costs such as travel, lodging, parking, meals, etc.

The sponsor of the study will provide the study product. You or your insurance will not be billed for the study product, but you or your insurance may be billed for the cost of getting the study vaccine ready and administering it.

Talk to your insurance plan and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this research study. Also, find out if you need approval from your plan before your plan will agree to pay for any costs of this research study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you or your baby experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

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, for you or your baby, alert the treating physician that you or your baby are participating in this research study.

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

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  [redacted]
- or call **toll free**: [redacted]

- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: [redacted].

UNIVERSITY STATEMENT

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research study participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
[redacted]

Secondary Research

Secondary research means other research using data and/or samples collected in this study, for purposes that are not planned in this study. Data and samples may be coded or may be completely "de-identified" when used for secondary research. By "de-identified" we mean that they are not linked to the person they came from.

If you agree to secondary research, we will store and use leftover samples and data. If you do not agree to secondary research, we will destroy your and your baby's samples after the study is completed. It is your choice whether or not to let researchers share your data and samples for research in the future. If you say "yes," you can change your mind later by telling your study staff or putting it in writing. If you say "no," you can still fully participate in this study.

Secondary research that may be done with these data and samples includes studies on mother and baby infectious diseases and their immune responses. You will not be notified of any results from this secondary research. Data and samples will be labeled with a barcode or an ID (not identifiers such as you or your baby's name, initials, or any other information that could easily identify you or your baby). The research staff will maintain a link, called a code key, that

link the identifiers to the ID code or barcode for your or your baby's data or samples. The code key will be securely stored. This link is not shared with anyone outside this institution who receives the data or samples. Researchers cannot easily link your identifying information to the data and samples.

Leftover samples and data saved for secondary research will be stored indefinitely by IDCRC LG, or at the institution where they were collected.

The samples and data used for secondary research studies may be shared for secondary research with investigators at the participating site, with researchers at other sites or other institutions, or company-designated research laboratories without additional informed consent. When samples or coded data are used in the future, the results may be published. You will not be identified in such a publication.

There are no benefits to you or your baby in the storage, and secondary research use of your or your baby's samples and data. The results of any future research testing will be kept confidential in the same way as the results of other testing done for this study. The results of any future research will not be available to you or your or your baby's regular doctor and will not be placed in your or your baby's medical record.

You and your baby will not share in the commercial profit if your samples or data provided for this study and secondary research lead to a licensed product.

No human genetic testing will be done as part of this study.

You may change your mind about secondary research and withdraw consent for the storage and use of your or your baby's coded samples or data at any time. You will need to contact the study doctor using the contact information listed on page 1 of this form. Research that has already begun using your or your baby's samples or data cannot be withdrawn. For example, if some research with the samples and data has already been completed, the information from that research may still be used. Also, for example, if the samples and data have been shared already with other researchers, it might not be possible to withdraw the samples and data.

Please talk to the study staff if you have any questions about how your and your baby's samples and data may be used.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to take part in this study and to allow your baby to join is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your or your baby's future medical care. Whether or not you choose to take part in this study has no impact on the care you or your baby receive at this study site today or in the future. You can decide to stop your or your baby's study participation at any point. That said, we will continue to use any

information from your and your baby's participation in this study up to the point you withdraw from the study. If you do decide to stop your or your baby's study participation, we will ask you to please notify the study staff about this.

The study doctor or the sponsor can stop you or your baby's participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you or your baby.
- If you fail to follow directions for participating in the study.
- If it is discovered that you or your baby do not meet the study requirements.
- If the study is canceled; or
- For administrative reasons

The study doctor will tell you about this, and you will have the chance to ask questions if this happens.

If you or your baby leave the study for any reason, the study doctor may ask you or your baby to have some end-of-study tests for your safety.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as study data. You will be told of any significant new findings that develop during the study, which may affect your willingness to participate in the study.

Consent for Recontacting

We may want to contact you in the future to see if you/your baby would like to take part in another research study. Are you willing to be contacted about taking part in any future research studies? **Please initial one of the statements below, regarding consent for recontacting YOU in the future**:

_____Yes, I agree to allow you to contact me in the future about additional research for me or my baby.

_____ No, I do not agree to allow you to contact me in the future about additional research for me or my baby.

Consent for Secondary Research

Please initial one of the following statements below, regarding secondary use of research data and samples for YOU:

_____Yes, I agree for my **coded** samples and data to be stored, these may be used for secondary research.

_____No, I do not agree to any secondary research on my samples or data.

Please initial one of the following statements below, regarding secondary use of research data and samples for YOUR BABY:

_____Yes, I agree for both my baby's **coded** samples and data to be stored, these may be used for secondary research.

_____ No, I do not agree to any secondary research on my baby's samples or data.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I also agree that my baby will participate in this study when I deliver. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____
Participant's Printed Name

_____ _____ _____
Participant's Signature Date Time

_____ _____
Printed Name of the Person Conducting the Consent Discussion PID

_____ _____ _____
Signature of the Person Conducting the Consent Discussion Date Time

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____
_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: A Prospective, Randomized, Open-label Phase 4 Study of the Immunology and Safety of Maternal RSV Vaccination (ABRYSVO™), Infant Nirsevimab (BEYFORTUS™) Immunization, or Both Products During the First Year of Life.

UMB IRB APPROVAL NUMBER: [redacted]

RESEARCHER'S NAME: [redacted]

RESEARCHER'S CONTACT INFORMATION: [redacted]
University of Maryland, Baltimore, Center for Vaccine Development and Global Health (CVD)
[redacted]

This research study will use health information that identifies you/your child. If you/your child agrees to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Health-related information you have been asked to provide for the study during interviews and via questionnaires.*
- *Results of medical tests, laboratory tests, research procedures carried out for the purpose of the study.*
- *Medical records from another health care facility that may be needed to determine whether a side effect or other problem is related to the study.*
- *Billing and payment information and the medical information required to justify it.*

Federal laws require this researcher to protect the privacy of this health information. He will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. [redacted] and his research team including the nursing, laboratory, and regulatory affairs staff at the Center for Vaccine Development and Global Health (CVD), and contracted affiliates of the CVD.
- The reviewing IRB
- Government health agencies that approve and monitor trials like US FDA, MHRA, Health Canada, and their staff
- The sponsor of the study or its agents, such as data repositories or contract research organizations
- Contractors and consultants working for the sponsor of the study and for health authorities
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University of Maryland Faculty Physicians, Inc. (FPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS)
- Your health insurer to pay for covered treatments.

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you/your child. This researcher might not allow you/your child to continue in this study. He can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you/your child cannot participate in this study. This will not affect the care you/your child receives at:
    - University of Maryland Faculty Physicians, Inc. (FPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you/your child is otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, FPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your/your child's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your/your child's health information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from him.

My signature indicates that I authorize the use and sharing of my/my child's protected health information for the purposes described above. I also permit my doctors and other health care providers to share my/my child's protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official ([redacted]) with questions about your/your child's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.