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Parent Information Sheet and Informed Consent Form

Study title:	Phase 1, Randomized, Observer-blind, Placebo-controlled, Age De-escalation Study of the Safety, Tolerability, and Immunogenicity of mRNA-1345 and mRNA-1365 in Participants Aged 5 months to < 24 months
Short study title:	A Safety, Tolerability, & Immunogenicity Study of mRNA-1345 & mRNA-1365 in Participants Aged 5M-24M
Protocol number:	mRNA-1365-P101
Sponsor:	ModernaTX, Inc.
IRAS ID:	1006997
Study doctor:	**Dr Simon Drysdale**
Phone number:	**0186511400**
Address:	**Oxford Vaccine Centre, CENTRE FOR CLINICAL VACCINOLOGY AND TROPICAL MEDICINE, CHURCHILL HOSPITAL, HEADINGTON, OXFORD, OX3 7LE**
Participant ID:	

Your child is being invited to take part in a clinical research study (also called a clinical trial) to learn about 2 study vaccines to prevent respiratory tract infections. This consent form asks for your permission as parent or guardian for your child to join the study.

This study is sponsored (funded and overseen) by the company ModernaTX, Inc. (called the "Sponsor" in this form). The study doctor or their institution is paid by the Sponsor to carry out all the tasks and activities related to this study.

What you should know about this consent form:

1. **Read this entire form carefully** to help you decide if you want your child to join this study**.** It gives you important information about the things you and your child will be asked to do before, during, and after the study, if your child joins.
2. **Ask the study team** any questions you may have before you sign this form.
3. **Discuss this study with your family or child's doctor** before you decide. You can take home an unsigned copy of this consent form to review prior to taking the decision to participate in the trial.
4. **Choose if you would like your child to join the study** – having your child join the study is voluntary. If your child joins, you can choose to have your child stop being in the study at any time. If you decide that you do not want your child to join the study or if you have your child stop being in the study, it will not affect your child's regular health care.

5. Sign and date the last pages of this form if you agree to have your child join the study. You will get a copy of the signed and dated form.

This form includes:

Why is this study being done?

This study will help researchers learn about the safety and effects of 2 Moderna TX, Inc. study vaccines in children. The study vaccines are designed to prevent respiratory tract infections caused by 2 common viruses. The study vaccines have not been approved by any health authority and can only be given to people in a study.

The main goals of this study are to learn:

- How safe the study vaccines are for children
- How children's immune systems respond to the study vaccines
- How well the study vaccines work to prevent 2 infections from 2 common viruses in children, Respiratory Syncytial Virus (RSV) and Human metapneumovirus (hMPV)

What are RSV and hMPV?

RSV is a common virus that infects the lungs and respiratory tract – the parts of the body related to breathing. It can cause a runny nose, sore throat, cough, and headache. RSV is the most common cause of lower respiratory tract infections in children around the world. RSV can lead to serious respiratory tract problems like pneumonia, especially in young children. In 2019, RSV was associated with over 100,000 deaths of children across the world.

hMPV is a common cause of upper and lower respiratory tract infections in children, with most being exposed by the age of 5 years. It causes symptoms similar to a cold. It can lead to more serious infections, such as pneumonia. Globally, an estimated 11.1 million acute lower respiratory infections, 502,000 hospital admissions, and 11,300 deaths were attributed to hMPV in 2018, with those under 12 months of age being particularly affected. There are no approved vaccines to prevent hMPV.

How many children will be in this study?

About 210 children will be in this study. All of the children will be between ages 5 months to less than 2 years old when they join.

This study will happen in 2 parts:

- **Part A** will include 90 children between ages 8 months to less than 2 years old
- **Part B** will include 120 children between ages 5 months to less than 8 months old

If the planned number of children join the study before your child starts in the study, the study site may stop your child from joining even if you have consented for them to take part in the study.

What vaccines are being studied?

The vaccines in this study are:

- **mRNA-1345**: A study vaccine designed to prevent infections caused by **RSV**. This vaccine has been given to over 15,000 adults, and to approximately 30 children aged 1 to 5 years in other studies.

Both mRNA-1345 and mRNA-1365 are **mRNA vaccines**, which give instructions to tell cells how to make a protein to start an immune system response (which is the way our bodies fight infection).

- **mRNA-1365**: A study vaccine designed to prevent both **RSV** and **hMPV.** The hMPV part of this vaccine has been given to approximately 100 adults and approximately 15 children aged 1 to 5 years in other studies of a vaccine to prevent both hMPV and parainfluenza (another virus). The RSV component of this vaccine is the same as mRNA-1345.

- **Placebo**: Looks like the study vaccine but has no active ingredient in it. Researchers compare the study vaccines to a placebo to learn if any effects are really due to the study vaccines.
    - One dose of placebo may be replaced with Nimenrix. Nimenrix is an approved vaccine to prevent infections caused by the bacteria meningococcus, such as meningitis (swelling of the covering of the brain and spinal cord) and sepsis (body's response to an infection) in children and young adults. Nimenrix is an approved, licensed vaccine that can be given to children from age 6 weeks and older.

The rest of this form uses "**study vaccine**" to refer to mRNA-1345, mRNA-1365, or placebo.

Which vaccine will my child get?

The study team will use a computer program to randomly assign your child to 1 of the 3 study vaccines (mRNA-1345, mRNA-1365, or placebo). Your child will have an equal chance of getting any of the 3 study vaccines:

- mRNA-1345
- mRNA-1365
- Placebo (which may include a dose of Nimenrix)

Neither you nor the study doctor will know which study vaccine your child gets. However, the study doctor will be able to find out if needed in an emergency.

How many doses will my child get?

Your child will get **3 doses** of their randomly assigned study vaccine. The study vaccine they get will depend on your child's age when they join in the study (Part A or B):

- **Part A (children ages 8 months to less than 2 years old):**
    - 30 children will get the **placebo** (the 3rd dose may be replaced with Nimenrix)
    - 30 children will get **mRNA-1345** at **30 micrograms (µg)**
    - 30 children will get **mRNA-1365** at **30 µg**
- **Part B (children ages 5 months to less than 8 months)**

- 40 children will get the **placebo** (the 3rd dose may be replaced with Nimenrix)
- 20 children will get **mRNA-1345** at **15 µg**
- 20 children will get **mRNA-1365** at **15 µg**
- 20 children will get **mRNA-1345** at **30 µg**
- 20 children will get **mRNA-1365** at **30 µg**

For safety reasons, the study team will give the study vaccines in this order:

1. First, they will give the study vaccine to children in Part A and review the safety
2. Then, they will give the 15 µg doses to children in Part B and review the safety again
3. Then, they will give the 30 µg doses to the rest of the children in Part B

As the vaccine is not yet approved for use in the UK, it will be available as part of this study only.

How is the study vaccine given?

Your child will get each dose of the study vaccine at an in-person study visit. They will get each dose as an injection (shot) in their upper arm or leg muscle. Study staff will watch your child for side effects for 30 minutes or longer after each study vaccine.

The study team may delay or not give your child a dose if:

- Your child has a current moderate to severe illness at the time
- Your child is taking another medicine that should not be taken at the same time as the study vaccine
- The study team decides your child's health prevents them from getting the study vaccine

Are there any other vaccine options to prevent RSV or hMPV?

No, there are no approved vaccines to prevent hMPV, and no active vaccines for children to provide lasting protection against RSV.

There are some options available in some countries to provide protection against RSV. These include:

- A preventive medication ('palivizumab') approved to be given to children who have a high chance (risk) of getting RSV. This protects against RSV for approximately 1 month and is given as an injection.

  - A newer version of this medicine ('nirsevimab') that has recently been approved for use in several countries including the Uk and the USA. This is designed to be given once to provide protection against RSV during their first or (for children at increased risk of RSV) their second RSV season. This is approved in the United Kingdom and is recommended for use.
  - A vaccine to be given to pregnant women to protect their baby against RSV has also recently been approved for use in several countries, including the UK and the USA, to provide protection against RSV during the first few months of life. This is approved in the UK and is recommended for use.

These options provide 'passive protection', meaning the child receives antibodies (either by an injection, or from their mother if she is immunized while pregnant). In contrast the mRNA-1345 investigational vaccine is designed to help babies make their own immune protection against RSV.

The study team will explain the risks and benefits of the different ways of preventing RSV before you decide if you want your child to join this study.

Your child will not be able to take part in this study if they have received any of the above measures to prevent RSV, or if you intend for your child to receive them while they are in the study.

What will happen to my child if they take part in this study?

Your child will be in the study for about 2 years and will have up to 27 planned study visits.

There will be 4 stages in this study. The table below explains what will happen at each stage:

Screening **(Up to 28 days before the 1st dose)**	**Study Vaccination** **(3 doses over 4 months)**	**Follow-up** **(Lasts 21 months)**	**End-of-study visit** **(At 2 years)**
You will sign this informed consent form. Then, the study team will check to see if your child meets the rules to be in this study. The Screening visit may be its own visit or on the same day as the 1st dose visit.	Your child will get their: • 1st dose after screening • 2nd dose about 2 months after the 1st dose • 3rd dose about 2 months after the 2nd dose After each dose: • Your child will have scheduled in-person and phone call visits • You will complete an eDiary	After your child's 3rd dose: • The study team will check your child's safety and health through in-person and phone call visits • You will also complete an eDiary	You will have 1 final visit.

In general, your child will need to visit the study site:

- For screening
- To get 3 doses of the study vaccine (the first dose may happen at the same time as the Screening visit)
- For follow-up activities, including to have their blood taken

Blood samples

The study team will collect blood samples from your child in this study. Your child's blood sample will be tested to check your child's immune system response to the study vaccine.

There will be a total of 4 blood samples collected (Days 1, 29, 85 and 141) if your child is enrolled in Part A of the study and at days 1, 85, 141 and 365 if your child is enrolled in Part B of the study. The actual amount of blood taken from your child for samples will depend on their age, at visits. The total amount of blood across all visits will be no more than 36 milliters (mL), which is about 7.3 teaspoons.

Age of child at visit	**Amount of blood taken at a visit**	**Part A study**	**Part B study**
5 months to 8 months	Up to 5 mL (up to 1 teaspoon)	**Samples taken at days 1, 29, 85, 141**	**Samples taken at days 1, 85, 141, 365**
8 months to 1 year	Up to 5 mL (up to 1 teaspoon)		

Age of child at visit	Amount of blood taken at a visit	Part A study	Part B study
Older than 1 year to 2 years	Up to 10 mL (up to 2 teaspoon)		
Older than 2 years	Up to 13 mL (up to 2.6 teaspoon)		

Where will study visits take place?

The study visits will include both in-person and phone visits with the study team. The study team will tell you which visits need to be in-person.

The study vaccine will be given at the study site. Other in-person visits will happen at the study site or at your home, depending on site arrangements.

The study staff will ask your permission before scheduling any home visits. If a home visit isn't possible, they may do a phone visit instead.

About the eDiary

You will complete an electronic diary (eDiary) to record information about your child's health throughout the study. The eDiary is a smartphone app. You will either download the app to your own phone or the study team will give you a phone to use. You will receive notifications and reminders when it is time to fill out the eDiary.

30 minutes after your child receives the study vaccine, you will be required to complete the eDiary once a day, preferably in the evening from the day of vaccination and for 6 days after vaccination. Any injection site reactions ongoing after Day 8, Day 64, and Day 120 must be reported to the Study Doctor.

- **Your child's body temperature**: Study staff will give you a thermometer to take home. Only take temperatures from in your child's armpit. Use the thermometer to take their temperature and enter it in the eDiary. If you take their temperature more than one time on a day, enter their highest temperature into the eDiary.
- **Side effects at the site where they got their study vaccine:** Look at your child's arm or leg where they got the study vaccine to see if there is any redness, swelling, or hardness. If so, use the ruler that study staff gave you to measure the area. Enter the measurement into the eDiary.
- **Swelling or tenderness under the arm or leg where they got their vaccine:** Check for any swelling or tenderness under the arm or leg where your child got the study vaccine and enter it in the eDiary.
- **Any medicine you gave your child:** Report if you gave your child any medicine to treat or prevent pain or fever.
- **Any other symptoms:** Describe any other symptoms or illness that you your child has.

If your child has any symptoms of a respiratory illness, fill out your eDiary and contact the study team right away.
Symptoms of a respiratory illness include:

- Cough
- Runny or stuffy nose
- Trouble breathing
- Wheezing (a whistling or rattling sound in your chest when breathing)

Phone visits

The study team will call you:

- There will be a total of 18 Safety calls (Part B) that will occur throughout the study: 3 times after your child gets each dose – about 1, 7, and 15 days after vaccination – and 9 more times throughout the study

During these calls, the study team will:

- Ask about any changes in your child's health since your last study visit, including possible reactions to the vaccine
- Talk about any medicines your child has taken, including other vaccines they got outside of this study
- Review your eDiary and remind you to complete it (as applicable)

RSV/hMPV Contact visits

- Throughout the study, the study team will contact you once a week during the RSV/hMPV season, and every month for the rest of the year
- They will ask if your child has had any symptoms of RSV and hMPV
- Review your eDiary and remind you to complete it. You will record any symptoms, along with start and end date
- Your eDiary will send you reminders during RSV and hMPV season to record any symptoms that may occur
- If your child has symptoms, the study team will ask you to come in for an unscheduled visit or request a home visit

Additional visits

Your child may have in-person visits that are not planned (and are not shown in the study visit table). These are called unscheduled visits. The visits will happen in-person at the study site, your home, or other location.

Your child may have an unscheduled visit anytime during the study when they have:

- Possible side effects of the study vaccine
- Breathing-relating symptoms that could be RSV or hMPV – **if your child has symptoms of a respiratory illness contact the study team right away. You will be asked to have an in-person visit within 5 days after their symptoms started.**

During unscheduled visits, the study team will:

- Ask about any changes in your child's health since your last visit, including side effects
- Talk about any medicines your child has taken, including other vaccines they got outside of this study
- Take your child's vital signs, such as temperature and heart rate
- Do a physical exam, including weight
- Collect a nasal swab sample to check for RSV, hMPV, and other viruses, if your child is having breathing-related symptoms:
    - In a **nasal swab**, the study team will insert a thin, long swab straight back into each side of your child's nostrils until it hits the back of their throat. Your child may have minor bleeding and may feel discomfort, but this should not be painful.

Study visit table

This table shows the tests and procedures your child will have during scheduled in-person visits.

What will happen at study visits	**Screening visit**	Day 1 **1st dose of study vaccine**	Month 1 **1 month after 1st dose**	Month 2 **2nd dose of study vaccine**	Month 3 **1 month after 2nd dose**	Month 4 **3rd dose of study vaccine**	Month 5 **1 month after 3rd dose**	Month 12 **1 year after 1st dose**	**End-of-study visit**
? Questions the study staff will ask you about									
Your child's age, race, sex, and ethnicity	✓								
Your child's medical history	✓								
Medicines your child has taken, including vaccines they've received	✓	✓	✓	✓	✓	✓	✓	✓	✓
Changes in your child's health since the last visit, including any possible reactions to the vaccine			✓	✓	✓	✓	✓	✓	✓

Study vaccine									
Your child will get a dose of their assigned study vaccine		✓		✓		✓			
Study staff will watch your child for side effects for 30 minutes after getting the study vaccine		✓		✓		✓			
Tests your child will have									
Physical exam, including weight, temperature, and heart rate	✓	✓	✓	✓	✓	✓	✓	✓	
Vital signs, such as temperature and heart rate	✓	✓		✓		✓			
Blood sample		✓	✓ (Part A only)		✓		✓	✓ (Part B only)	

Study eDiary									
Receive/Activate your eDiary		✓							
Check your eDiary		✓		✓		✓			

What happens to my child's samples?

Privacy
The study staff will label your child's blood and nasal fluid samples with a code and send your child's samples out of the UK to a laboratory. There will be many lab locations for this study including but not limited to the US, Belgium, and The Netherlands. Your child's samples will not be labelled with any information that could identify your child.

Storing the samples
ModernaTX, Inc. will manage and own your child's samples. ModernaTX, Inc. is responsible for storing the samples, no matter the location. If you would like to know the specific location of your child's samples, please ask the study team and they will give you this information.

Your child's samples will be stored for up to 25 years after the end of the study and may be used for future research purposes. The samples will remain the property of ModernaTX Inc. There are no plans to give you any results from the research with your child's samples unless specifically noted below. You are allowing ModernaTX Inc. to continue to use the information and samples in the research and development of the mRNA platform.

The use of your child's samples in future research is optional. You can decline and still take part in this study.

You have the right to decide what happens to your child's collected samples during and after the study. If you decide that you no longer want your child's blood samples tested or stored for this study, contact the study doctor to tell them your decision.

Leaving the study
If your child leaves the study early:
- The study team will not collect any new samples or data from your child for this study
- All the samples and data collected before your child left the study will still be used for study tests
- You can contact the Study Doctor if you want to have your child's samples destroyed and/or excluded from any study analysis

What will I have to do?

You should:	You should not:
Tell the study team correct and true information about your child's past health and current health, including: • Any reactions your child has to the study vaccine, such as fever, crying, sleepiness, or not wanting to eat • Other health problems your child has during the study	Do not have your child get any vaccine 14 days before a study vaccine injection and 7 days after a study vaccine injection

• Any new treatment, medicine, or vaccine your child takes before and during the study • Discuss with the study team your child's vaccine schedule	
Contact the study team right away if: • Your contact information changes • You no longer want your child to be in the study • Your child has symptoms of a respiratory illness	Do not have your child join other studies within 28 days before this study or during this study
Go to all of your scheduled study visits and answer study phone calls	Do not post or discuss the study on any social media or in public, including: • No blogging • No podcasting • No audio rooms such as Greenroom • No speaking to the media
Fill out the eDiary as the study team tells you, including to use the thermometers and rulers that the study staff gives you to check your child's body temperature and side effects at the site where they got the study vaccine	
You will be provided with an identification card which says that your child is taking part in this study. Please carry this card with you at all times and show it to any relevant doctors or nurses. Please return the card at the end of the study	
If your child needs emergency care or goes to the hospital, tell the doctor treating them that your child is taking part in this study	

When will this study end for my child?

The study will end for your child when any of these happens:

- **When your child has completed all study visits:** The study team will contact you when the study is close to the end to schedule your child's end-of-study visit.
    - If you wish to find out which study medication your child was on, your study doctor will be able to tell you after the study is over.
- **If you want your child to leave the study early:** At any time, you can change your mind and stop being in the study for any reason, including if your child has side effects that make you want to leave the study. If your child leaves the study early:
    - The study team will call you by phone to review any changes in your child's health and medicines for your child's own safety

- The study team may follow up with you either in person or over the phone if it was due to a health issue or a study-related reason to have you complete data about your child's health and safety. If you do not want to share this information about your child, tell the study team.

- **If the study team has your child leave the study early:** There are reasons that the study team may have your child leave the study early, including:
  - You did not follow instructions about what to do in the study
  - The study team could not reach you by phone
  - The Sponsor cancels the study

If the study team or Sponsor learn new facts during the study that might make you want to leave the study, they will tell you right away. You can then decide if you still want your child to be in the study.

What if I want my child to leave the study early and do not want their data to be used or shared?

If you decide to have your child leave the study early, data collected while your child was in the study may still be kept as part of the study. Normally, the study team will not collect any new data from you and your child unless you clearly agree to that.

What are the possible benefits of my child taking part?

Taking part in this study may or may not protect your child against respiratory infections caused by RSV and hMPV. We do not yet know how well the study vaccines work to prevent respiratory infections.

The data we get from your child and other children in this study may help researchers learn more about the study vaccines. This may help other children in the future.

What are the possible risks and disadvantages of taking part?

All vaccines can cause **side effects,** which are unwanted effects. If you choose to have your child join this study, your child is at risk for the side effects listed below. Talk about the side effects with the study team. The study staff will discuss the possible side effects with you and tell you what to do if your child has any side effects.

If your child has any of the side effects or symptoms below, tell the study team right away. If your child shows signs of serious illness, please contact emergency services first, prior to the study team. There may be other side effects that are not yet known.

Common side effects after getting a vaccine

The most common side effects after a vaccine in children are:

- Fever
- Crying or irritability
- Not feeling hungry

People who have gotten other Moderna TX, Inc study mRNA vaccines had these common side effects:

- Symptoms at the site where they got the vaccine, including:
  - Pain, redness, or swelling (hardness)
  - Large or painful lymph nodes in the armpit or underarm
- Feeling tired
- Chills

If you have any concerns about your child's health in the week following the study vaccination (for example a fever higher than 39.6 degrees Celsius), then please call the study team. This does not replace the need to seek help through your child's normal health care provider.

These side effects usually happen within 7 days of getting the study vaccine and go away over time without treatment.

Some people have had changes in lab test results after getting mRNA vaccines. The changes included higher levels of certain test results without any symptoms. The test results usually went back to normal levels and it is not known if the changes were significant.

Fainting before or after getting a vaccine

Fainting can happen before or after getting any vaccine. It is usually caused by pain or anxiety from the injection and is not related to the vaccine itself.

Rare side effects

- **Sudden, severe allergic reactions (anaphylaxis):** These can happen after any vaccine and are very rare. Based on an approved Moderna TX, Inc. mRNA COVID vaccine, the United States (US) Centers for Disease Control and Prevention (CDC) estimate the chance of severe allergic reactions right after a vaccine is very rare (less than 3 cases per 1 million vaccines given). Symptoms of anaphylaxis may include:
    - Trouble breathing
    - Swelling of the lips, tongue, and around the eyes
    - Light-headedness
    - Fast heartbeat
    - Sweating
    - Fainting
    - Rash
    - Vomiting

  The study team will watch your child for 30 minutes or longer after each dose of study vaccine. They will look for any of these symptoms and treat your child right away, if needed.

- **Myocarditis** (inflammation, or swelling, of the heart muscle) or **pericarditis** (inflammation around the heart): There have been very rare reports of people who have gotten mRNA COVID vaccines having myocarditis or pericarditis. Most of the reports have been in young adult and teenage males after the 2nd dose. There are very rare reports in children. Symptoms of myocarditis or pericarditis often start a few days after getting the vaccine and include:
    - Trouble breathing
    - A fast-beating, fluttering (irregular heartbeat), or pounding heart
    - Rapid breathing
    - Poor weight gain or not wanting to eat
    - Fever
    - Slow moving
    - Passing little urine (pee)
    - Pale, cool hands and feet

  If your child has any of the above symptoms of myocarditis or pericarditis, get medical care right away. Most of the time, people recover with treatment and rest.

Enhanced Respiratory Disease Risk:

Over 50 years ago a vaccine was developed by another company that was designed to prevent RSV in children. Unexpectedly, this vaccine caused a higher than normal chance of severe respiratory disease when they were infected with RSV the following winter.

That vaccine was made by a very different method than the RSV vaccines in this

Study. Experts believe that there is very little risk of this happening with the mRNA-1345 or mRNA-1365 vaccines in this Study, and there has been no evidence for this increased risk in the development of these vaccines to date. Nevertheless, children in this Study will be monitored closely to see if there is any sign of worse than usual RSV disease after vaccination.

Risk of loss of privacy with the eDiary

Information you record in the eDiary will be collected and shared with the researchers or people outside of the study. You can find a complete description of the data collection and sharing for the eDiary in the Terms of Use, End User License Agreement, or Privacy Policy for the app. If you would like to read these documents, ask the study doctor for a copy or how to get this information.

Your rights

While the Terms of Use, End User License Agreement, or Privacy Policy may limit your rights if you or your child are harmed as a result of using the eDiary app in this study, you do not release the study doctor, Sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a parent or legally authorized representative (LAR) of your child who is in this study.

The information collected in the eDiary is key to learn about the safety and effects of the study vaccines. Before you agree to have your child join this study, please carefully consider if you are willing and able to complete eDiary.

Who has reviewed the study?

An Internal Safety Team and a Data Safety Monitoring Board (groups of people who review study data to decide if it is safe to continue with the study) will watch over this study to protect the safety of children in the study.

All research in the United Kingdom is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Health and Social Care Research Ethics Committee B.

Expenses and payments

Your child's participation in this study will not cost you anything. You will not be charged for the study vaccine or any of the tests that are part of the study. The Sponsor will not pay you for doctor visits or other treatments or tests that are not part of this study as these are covered by the NHS.

The Sponsor of this study will pay the study site for including your child in this study

You will not be paid for your child taking part in this study. You may be reimbursed for meals and travel costs up to £43. Give the receipts for meals and travel costs to the study team for reimbursement.

What if there is a Problem?

If you have a concern about any aspect of this study, you should ask to speak to the study team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Study Team. Contact details are found in the "Further information and contact details" section."

The Sponsor will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

The Sponsor will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the study protocol;
- Any test or procedure you received as part of the study.

Any payment would be without legal commitment (please ask if you wish more information on this). The Sponsor would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the study protocol or where the protocol wasn't followed.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS Trust or Private Clinic, but you may have to pay your legal costs. The normal complaints mechanisms will still be available to you.

If you have private medical insurance, you are advised to inform your provider of your consideration to take part in a clinical research study as this may affect your cover.

It is important that you carefully follow all instructions given by the Study Team about this study.

By signing this form, you are not giving up your legal rights and are not releasing the Study Team or the Sponsor from their legal and professional responsibilities.

CONFIDENTIALITY

How will we use information about your child?

We will need to use information from you for this research project.

This information will include your child's

- name,
- contact details,
- gender,
- height and weight,
- racial origin,
- as well as information on your medical history,
- and clinical data collected about your participation in the study

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who you or your child are will not be able to see your name or contact details. Your child's data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be sent to USA. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data for up to 250 years so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your child's information is used?

- You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital or your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to datarequest@datarep.com, or
- by contacting the Sponsor's UK Data Protection Representative: datarequest@datarep.com or www.datarep.com/data-request

Involvement of the General Practitioner/Family Doctor (GP)

The study doctor will inform your child's GP/family doctor that your child is taking part in this study and may ask them to provide relevant medical information about you if necessary.

The following information about your participation in the study will be shared with your child's GP:

- Health records to verify that your child meets the eligibility criteria for this study;
- Monitoring, or notifying your child's GP of any adverse reactions to research treatments;
- Communicating any newly discovered health related findings about your child to his/her GP.

What Will Happen to the Results of this Research Study?

A description of this clinical study will be available on www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time.

After this study is over, the study results may also be shared with scientific journals and other researchers. Whenever the results of the study are shared or published, the results will not include information that could identify your child.

Please note, individual results will not be provided.

Further information and contact details

In case of a study-related injury or whenever you have questions about the study or your child's study medication, please contact:

Study Doctor Dr Simon Drysdale
Phone Number 0186511400

Study Nurse
Phone Number 0186511400

Address
Oxford Vaccine Centre, Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Headington, Oxford, OX3 7LE

If you need to report side effects or your child is feeling unwell, there is a 24 hour contact number:

Phone Number 07879631485

If you have questions about your child's rights as a research participant, or do not feel comfortable speaking with your child's study doctor please ask the study site for details or contact:

Patient Advice and Liaison Service (PALS) 01865611400 info@ovg.ox.ac.uk

Oxford Vaccine Group
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine,
Churchill Hospital, Headington, Oxford OX3 7LE
Telephone: 01865 611400 info@ovg.ox.ac.uk www.ovg.ox.ac.uk

Parent Information Sheet and Informed Consent Form

Title of Study:	Phase 1, Randomized, Observer blind, Placebo controlled, Age De escalation Study of the Safety, Tolerability, and Immunogenicity of mRNA 1345 and mRNA 1365 in Participants Aged 5 months to < 24 months
Short Study Title:	A Safety, Tolerability, & Immunogenicity Study of mRNA-1345 & mRNA-1365 in Participants Aged 5M-24M
Protocol Number:	mRNA-1365-P101
Sponsor:	ModernaTX, Inc.
IRAS ID:	1006997
Study Doctor:	**Dr Simon Drysdale**
Participant ID	

If you have any further questions, please ask the study doctor or one of the study staff, before signing this Participant Consent Form

	Please initial each box
• I confirm that I have read and understand the Parent Information Sheet and Informed Consent Form for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	
• I understand the relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the Sponsor or its representatives, or the regulatory authorities, where it is relevant to me taking part in this research. I give permission for these individuals to have access to my records.	
• I agree to the use of my child's blood and nasal swab samples as outlined in the Parent Information Sheet and Informed Consent Form.	
• I understand that my child's data will be collected, processed, reported and transferred within and outside the United Kingdom of my data for healthcare and/or medical research purposes where the data protection may not be as good.	

• I understand my child's data will be kept for 25 years	
• I agree to my child's GP being informed of his/her participation in this study and providing relevant medical information about him/her to the study doctor if necessary.	
• I understand I will receive a copy of this Parent Information Sheet and Informed Consent Form and signed Consent Form.	
I understand that my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, without my child's medical care or legal rights being affected.	
• I agree for my child to take part in the above study.	

Optional - For Use of Remaining Biological Samples for Future Research

☐ Yes, I agree to allow my child's samples to be stored and used for future research

☐ No, I do not agree to have my child's samples used for future research (this will not prevent you from participating in the current study)

_____

Printed Name of Child

_____

Printed Name of Parent/Legally Authorized Representative (LAR), in full

_____

Signature of Parent/LAR **Date (dd-mmm-yyyy)**

For study staff:

By signing this form, I agree that:

- I have explained the study and answered the participant's parent's/LAR's questions
- I will give the participant's parent/LAR a copy of this signed and dated informed consent form

_____

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

_____

Signature of Person Obtaining Consent **Date (dd-mmm-yyyy)**

Original copy for participant, 1 copy for researcher, 1 copy for medical records