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Study information booklet

Developing a vaccine to prevent RSV, a cause of serious respiratory infections in infants

The Oxford Vaccine Group would like to invite your child to take part in a study to understand the safety of a new respiratory syncytial virus (RSV) vaccine.

This study is being run by the Oxford Vaccine Group in collaboration with Janssen, a pharmaceutical company of Johnson & Johnson who make vaccines. The overall aim is to develop a vaccine that prevents RSV disease.

The Oxford Vaccine Group is part of the University of Oxford and is an independent research team of doctors, nurses and play assistants. We carry out research studies of new and improved vaccines for babies, young children, teenagers and adults and teach doctors and nurses about immunisations. In the past 5 years alone, over 7000 participants in the Thames Valley area have taken part in our research studies.

Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information, please contact the study team.

Thank you for reading this. You will be given a copy of this information to keep.

Summary

- We are researching a new vaccine against respiratory syncytial virus (RSV), a highly infectious respiratory (lung) illness which is a common cause of infection in infants and can cause serious acute illness, hospitalisation and in some cases death. Despite the high disease burden, no licensed vaccine is currently available for RSV.
- **What do we want to know?** – This study is researching a new vaccine called Ad26.RSV.preF. The main purpose of this study is to check that the vaccine is safe. We will also measure how your child's immune system responds to the study vaccine.
- **How are we going to do it?** – Across the study twelve healthy adults and 36 healthy children aged 12 to 24 months will take part. They will receive either the new vaccine Ad26.RSV.preF or placebo (a salt water injection). Participants will receive the study vaccine on 2 occasions, with 9 routine visits from a nurse or doctor, four blood tests and phone calls every 14 to 30 days over 1 year.
- Vaccines will be given at your home, and you will be provided with 24 hour contact details for a study doctor
- A description of this clinical trial (research study) will be available at http://www.ClinicalTrials.gov as required by laws governing our studies. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the study results. You can search this Web site at any time.

Why has my child been invited to take part?

You have been approached because your child is 12-24 months old and you live in an area where the study is being carried out. This booklet may have been posted to you by an NHS database Please note that unless you have previously been in contact with us about this study, the Oxford Vaccine Group has not been given your child's name and address. Taking part in this study is voluntary and if you do not want your child to participate you do not have to reply to this invitation.

What is respiratory syncytial virus (RSV)?

Respiratory syncytial virus (RSV) is a highly infectious respiratory virus (germ) that infects the lungs and breathing passages. In children RSV infection typically occurs at least once a year and in adults every 3-5 years during the winter season. RSV is considered to be one of the most important causes of serious acute respiratory illness in infants and children under 5 years of age. Children usually experience mild to moderate cold-like symptoms and recover in a few days to a week. However, some infants require hospital admission and sometimes need a ventilator to help with breathing. In a small number of these cases, RSV can result in death. RSV disease is also associated with persistent coughing and recurrent wheeze. Despite the high disease burden, no licensed vaccine is available for RSV.

What are we studying?

In this study, we are interested in learning more about an investigational vaccine designed to protect against RSV disease. Investigational means that the study vaccine is not yet licensed for use in the UK or elsewhere.

Vaccines stimulate our immune system to help protect against infections. If a child or an adult comes into contact with an infectious disease against which they have been vaccinated (or "immunised"), their body will be able to recognise and fight the disease. This is known as an **immune response.** Without vaccines, people are at increased risk of catching many serious diseases.

We are interested in studying a new vaccine, Ad26.RSV.preF. The main purpose of this study is to see if the study vaccine is safe (if it causes any side effects) and how people feel after the vaccine ('tolerability'). We will also measure your child's body's immune response to the study vaccine. In this study, some participants (adults and toddlers) will receive placebo instead of the study vaccine. Placebo given in this study will consist of sterile saline for injection, with no vaccine in it.

The **Ad26.RSV.preF vaccine** is made from a virus called Adenovirus. This virus is common in everyday life and can cause colds and respiratory infections. However, the adenovirus used in this study vaccine has been weakened so that it cannot multiply and cause a respiratory infection and therefore is expected to be harmless to humans. The vaccine includes certain parts of the DNA from the RSV virus. DNA is a natural substance found in all living things, including people and viruses. When the study vaccine is injected, the vaccine will tell the body to make small amounts of a protein normally made by RSV. We will then see if your child's body develops an immune responses to these RSV proteins using blood tests. The Ad26.RSV.preF vaccine has been given to both children and adults in completed and ongoing studies. These studies raised no safety concerns.

In the 1960s different vaccines in which the whole RSV virus was chemically inactivated were developed. These induced an inappropriate immune response in infants without pre-existing immune antibodies (seronegative) and increased the severity of the RSV respiratory disease in these infants instead of protecting them. This was not observed with vaccines based on live, but weakened, -versions of the RSV virus, suggesting this problem is not seen with all RSV vaccines. The data in animals immunised with the Ad26.RSV.preF vaccine being used in this study showed an appropriate immune response and protection against disease. As part of this study your child will be closely monitored for respiratory infections**.**

Who can take part in the study?

The study will take place over three sites in the UK (Oxford, Manchester and Southampton). A total of 36 healthy children and 12 adults will be enrolled.

We want to recruit children who:

- Are 12-24 months of age
- were not born premature (before 37 weeks gestation) or below 2.5kg
- Have received their routine vaccinations
- Are in good health without any significant medical illness
- Have previously had an RSV infection (e.g. a cough, cold or bronchiolitis). This will be most children aged 12 to 24 months, but will be confirmed by a fingerprick blood sample checking whether your child is RSV 'seropositive'.
    - If your child has already had a blood test taken for the study VAC18194RSV2002 (another study evaluating Ad26.RSV.preF) and the result shows that your child is RSV seropositive, the blood test will not need to be repeated in this study.

What happens in the study?

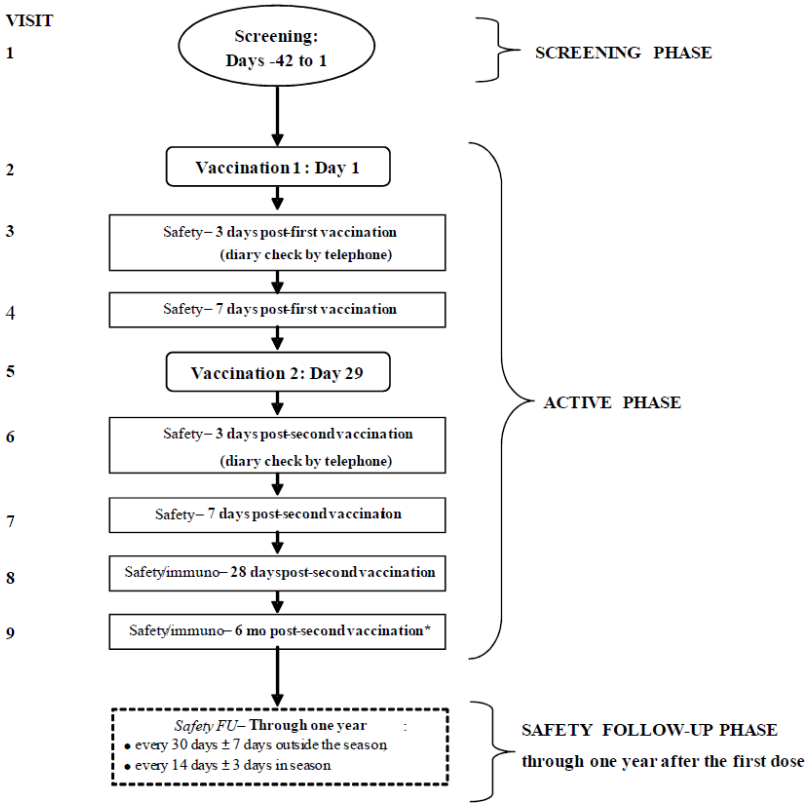
The study consists of:

- Vaccination with 2 doses of Ad26.RSV.preF or placebo 1 month apart
- Blood tests and nose swabs
- Completion of a symptom diary for 7 days following vaccination
- 7-9 visits at home over a 36 week period, and regular phone calls
- We will also ask your permission to access information about your child's vaccinations through medical notes.

In this study, your child would be randomly allocated to receive either Ad26.RSV.preF or placebo by chance (like flipping a coin). This is a double-blind study which means that neither you nor the Study Doctors and clinical staff (apart from those who administer the study vaccine) will know whether your child has received the study vaccine or placebo. In an emergency your study doctor will be able to find out which treatment your child has received.

You or the study team would not be able to influence which vaccine your child is given and you would not be told what your child had received until after the end of the study.

The study design is shown below.



*If Visit 9 occurs during the RSV season, an additional visit will be made by telephone at the end of the RSV season to collect safety information

	Group	Day 1	Day 29/Week 4
12 Adults	Group 1	Ad26.RSV.preF ($1x10^{11}$ vp*)	Ad26.RSV.preF ($1x10^{11}$ vp*)
	Group 2	Placebo**	Placebo**
36 Children	Group 3	Ad26.RSV.preF ($5x10^{10}$ vp)	Ad26.RSV.preF ($5x10^{10}$ vp*)
	Group 4	Placebo**	Placebo**

*viral particles **Placebo is normal saline

Other things that will happen during the study are listed below:

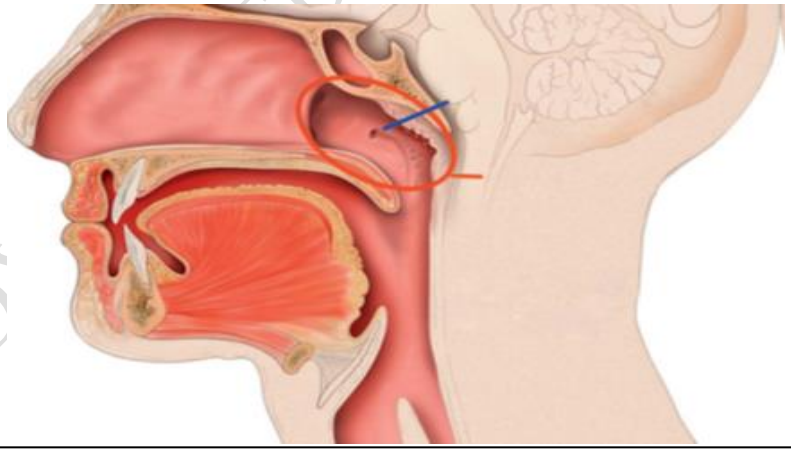
Information
Collection of information about your child such as medical history and details of any medications they are currently taking or have taken in the past.

Vital signs
The study doctor will measure your child's height, body weight, heart rate, breathing rate and body temperature. The study doctor will also conduct a physical examination and general health check during the study.

Blood tests
In order to understand the effect of the vaccines, your child will have 4 blood tests through the study. The first blood test will be to assess your child's antibodies against RSV (serostatus), if not already available from study VAC18194RSV2002, and subsequent tests will be to determine your child's response to the vaccine. We will take up to 5.5ml (a teaspoon) of blood.

In order to minimize any distress caused by the procedure we will:
-Use anaesthetic cream to help numb the skin (provided before visits with explanation of use). This will not be used for 'fingerprick' blood tests.
-Provide a play assistant to be present at all blood test visits to help distract your child
-Only have a maximum of 2 attempts at obtaining the blood, and you would have final decision to proceed with 2nd attempt if 1st attempt was unsuccessful.

Nasal swab
If your child experiences respiratory symptoms, we will do a nose swab to test for the RSV virus. The swab will look like a cotton bud on a flexible wire. We will tilt your child's head back and then pass the swab towards the back of the nose and rotate it gently (area indicated on diagram below). This feels a bit tickly in the nose but will only take a few seconds.



Picture modified from: Shak, J.R., Vidal, J.E., & Klugman, K.P. 2013. Influence of bacterial interactions on pneumococcal colonization of the nasopharynx. Trends in Micro. 21:3 pp 129-135

Diary
Following vaccination we will ask you to complete a diary for 7 days in order to record any reactions following vaccination.

Review of study eligibility
Based upon your child's medical history and tests done during screening the study doctor will decide if your child can participate on the study. Should there be any abnormalities found during the screening

process, these would be discussed with you and a recommendation to follow up with your child's GP would be made. With your agreement, we would also contact the GP to report any findings.

Medications
At each visit the study doctor/nurse will review your child's medications (if they are taking any) with you and ask you about any side effects.

Telephone Calls
At least monthly for 1 year after the first injection, you will need to be available for phone calls to confirm that your child is well.

How will your child receive the study vaccine?

If you decide for your child to take part in this study, you also agree that they receive the study vaccine as directed by the study staff.

The study vaccine is given via an injection. The needle is put into a muscle of their leg. This will be done 2 times during the study.

What are the side effects of any treatment received when taking part?

Potential Discomforts, Side Effects, and Risks Associated with Ad26.RSV.PreF Vaccine

The Ad26.RSV.PreF Vaccine has been studied in animals and in human volunteers. The active vaccine component of Ad26.RSV.preF vaccine has been administered to both children and adults in completed and ongoing clinical trials.

In a recently completed clinical trial, the Ad26.RSV.preF vaccine was given alone or together with a flu vaccine to 180 healthy volunteers aged 60 years and older. The most common reported local symptom was injection site pain/tenderness (mild to moderate). The reported body symptoms were mostly mild to moderate; the most frequently seen were fatigue, muscle pain, headache, chills and joint pain. Although there were no significant safety concerns, some older adults experienced body symptoms (such as headache, fatigue and chills) that interfered with their daily activities, but these symptoms were short-lived and resolved within days. Results from this study show that the vaccine had acceptable tolerability.

In ongoing clinical trials, the Ad26.RSV.preF vaccine has been given to more than 335 volunteers aged 60 years and older, 39 volunteers aged 18 to 50 years and more than 20 children. No safety concerns have been identified from those ongoing studies.

Vaccines similar to the Ad26.RSV.PreF Vaccine have been administered to more than 900 of human volunteers in completed clinical trials of vaccines designed to prevent RSV and other diseases including HIV (Human Immunodeficiency Virus infections), Ebola and Malaria. These vaccines have been shown to be generally safe and well tolerated.

All vaccines can cause side effects. Problems that are not expected may arise and they may be life-threatening. If your child has any side effects or problems during your participation in this study, you

should let your child's study doctor know right away. There may be risks with the use of Ad26.RSV.PreF vaccine that are not yet known. Sometimes during a study the sponsor may learn new facts about the study vaccine. It is possible that this information might make you change your mind about having your child in the study. If new information is discovered, your child's study doctor will tell you about it right away.

What are the possible benefits, disadvantages and risks of taking part?

Benefits

There is no known medical benefit to your child from being in the study. By taking part in the study your child may help future patients to prevent severe RSV.

Risks and possible side effects related with vaccination in general

General Risks Associated with Vaccination: There may be arm discomfort, pain or soreness around the injection, bruising, swelling or redness at the site of injection. These reactions may occur with all types of injections. It is also possible that your child will get a fever, chills, rash, aches and pains, muscle pain, nausea, headache, and fatigue (feeling tired). The side effects usually last 48 to 72 hours. Rarely, people may experience more severe side effects that limit their normal activities or make them go to the doctor.

It is rare, but your child could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing, itching, and swelling of lips, tongue or face. **Allergic reactions can be life-threatening**; therefore, the study staff will watch your child for at least 30 minutes after each injection. You should tell your study doctor if your child has ever had a bad reaction to any injection or vaccine. The medically qualified research doctors and nurses carry all necessary medication to treat serious allergic reactions. If you think your child is having a severe allergic reaction after your doctor or nurse leaves, contact the emergency number and seek medical attention immediately.

Side effects from tests:

Blood tests: Taking blood may cause bruising at the place where the needle goes into the skin. Fainting, and in rare cases infection, may occur.

Nasal swab: Your child may experience some slight discomfort or tickling in the nose while this procedure is being done.

Before participating you should consider if this will affect any insurance you have for your child (e.g. travel insurance, private medical insurance) and seek advice if necessary.

Will I be compensated for travel and inconvenience?

You will not be paid to participate in the study. However for where home visits are not possible we will reimburse travel costs and inconvenience up to a maximum of £45.00 per visit.

If you wish to take part

If you are interested in your child taking part, a member of the study team will discuss the study with you in more detail via the telephone. We will then arrange an appointment to meet you at your home, at your convenience, to answer any further questions that you may have, check your child's health and complete the consent form if you wish to proceed with the study. The first appointment should last around one and a half hours, and all following appointments between 30-45 minutes.

You will also have 24hr telephone access to a study doctor should you have concerns relating to the study. We will let your GP, health visitor and child health department know that your child is taking part in the study.

What are the alternatives to taking part in this study?

Taking part in this research is completely voluntary and if you decide to say no it will not affect your child's regular care in any way. Your child does not have to be in this research study. You are also free to change your mind and withdraw your child at any time without giving an explanation. It will not affect your child from getting all the care, medicine, and equipment they should be getting.

What will happen to any samples my child gives?

Samples are any fluid (e.g., blood, nasal secretions) collected from your child in this study. The samples we take for this study will be labelled with a study number and tested anonymously in certified laboratories. Your child's samples may also be shared with research partners for scientific research purposes. Before sharing with research partners, your child's samples will be labeled with a code number that is different from your study number. Your child's samples will not contain any personal identifiers. Some or all of your child's samples may also be kept and used for up to 15 years. This will allow for the scientific research described above to be done in the future as new discoveries are made. Samples may be transferred outside of the UK and EU for tests from labs with specific experience. The sponsor will ensure that your samples are kept securely. Your child's samples will be destroyed no later than 15 years. You will not be informed when they are destroyed.

You can withdraw your permission for your child's samples to be used for future research. In this case your child's samples will be destroyed only after they are no longer needed for the main study. You would need to tell your child's study doctor that you are withdrawing your consent for your child's samples to be used for future research. This can be done at any time, for any reason.

Your child will not be paid for any use of the samples, results, or inventions made from research on them. You are providing your child's samples for use by the sponsor. The sponsor (and research partners, where applicable) plan(s) to own the use of the results, treatments, or inventions that can be made from this research.

What happens when the study stops or if my child stops the study early?

Once all participants within the study have completed their relevant visits the study will continue for several months for the analysis and interpretation of the findings. Once complete, a publication will be written and published. Following this, we will notify you of the results and provide a link to the published paper. This whole process can take anywhere from one to three years after completion of all study visits. All publications arising from our studies are listed on the Oxford Vaccine Group website.

Your child's study doctor has the right to take your child out of the study at any time with or without your agreement. The sponsor has the right to direct your child's study doctor to take your child out of the study at any time with or without your agreement. These decisions will be made if:

- It is in your child's best medical interest to stop their participation
- Your child needs treatment not allowed in this study
- Instructions are not being followed for your child's participation in the study
- The study is cancelled

If your child stops the study early, we would ask to arrange a visit as soon as possible to have final tests done. Blood samples for safety laboratory and immune response testing may be collected. Also, a nasal turbinate for immune testing may be collected as well if the early exit is within 14 days of the previous vaccination.

If your child stops the study early and/or you withdraw your consent at any time, we would use your child's study information collected up to the point of the end-of-study visit. The Sponsor will not collect any new information from your child for any parts of the study from which your child has withdrawn. Your child's collected samples will continue to be analysed as described in this form unless you specifically ask for your child's samples to be destroyed. This is to protect the quality of the study.

The sponsor will not collect any new information from your child.

What if relevant new information becomes available?

Sometimes we get new information about the study vaccine that might be relevant to this study. There may be risks with the use of Ad26.RSV.PreF Vaccine that are not yet known. If that happens or if the study is stopped for any reason, we will discuss it with you as soon as possible as this information might make you change your mind about your child being in the study. We will write to your GP with information about you and your child's continuing care. If your child stops the study early, you agree not to limit our use of your child's study information.

What if there is a problem?

If you feel that your child has been injured or has become ill as a result of your child's participation in the study, immediately contact your child's study doctor. If your child needs treatment for a medical event or injury that happened as a result of study drug(s) or procedures, medical care will continue to be provided to your child by the NHS.

The Sponsor will provide compensation for injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that the Sponsor should compensate your child without you having to prove that it is their fault or go to court.

The Sponsor will pay compensation where the injury is serious and persistent and probably resulted from:

- A drug being tested or administered as part of the study protocol;
- Any test or procedure your child received as part of the study that your child would not have undergone but for taking part in the study.

The Sponsor has agreed to be bound by the ABPI guidelines. (Please ask if you wish more information on this or go to the ABPI website at www.abpi.org.uk)

The Sponsor will not pay the costs to test or treat a condition or injury that is not related to the study drug, or study procedure, or for expenses related to the normal progression of a pre-existing medical condition or an underlying disease. In no event will the Sponsor pay for treatment for injury or illness that is not a result of the study.

The Sponsor will maintain insurance for clinical research as required by local law and regulations.

To help avoid injury, it is very important to follow all study directions.
The above statements do not limit your child's legal rights.

What if I wish to complain?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or email the head of CTRG, Heather House ctrg@admin.ox.ac.uk.

Will my child's taking part in this study be kept confidential?

General information on the use of personal data in research
Health and care research should serve the public interest, which means that the Sponsor has to demonstrate that the research serves the interests of society as a whole by following the UK Policy Framework for Health and Social Care Research.

The Sponsor uses personally-identifiable information to conduct research to improve health and care. As a pharmaceutical company, the Sponsor has a legitimate interest in using information relating to your child's health and care for research studies, when you agree to your child taking part in a research study. This means that the Sponsor will use your child's data, collected in the course of the research study, in the ways needed to conduct and analyse the research study.

How will my child's data be used?

The Sponsor of this study is based in Europe and will use information from your child and your child's medical records in order to undertake this study and will act as the data controller for this study. This means that the Sponsor is responsible for looking after your child's information and using it properly.

How will my child's personal data be protected?
Your child's personal data will be labelled with the study number and your child's subject number ("Your child's Coded Data") before it is reported to the Sponsor. No personal identifiers such as name, initials, date of birth or NHS number are included in your child's coded data.

Your child's coded data will be used to learn more about RSV, the drug and similar drugs, any related devices, diagnostic products or other therapies. In addition, your child's coded data may be used:

For submissions to regulatory authorities;
To help with the design of future studies;
For research, which is compatible with research related to this study including statistical purposes.

What personal data will the study staff collect?
The Research Site will collect information from your child and your child's medical record for this research study in accordance with the Sponsor's instructions.

The Research Site will keep your child's name, date of birth, NHS number and contact details confidential and will not pass this information to the Sponsor. The Research Site will use this information as needed, to contact you and your child about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Certain individuals from, or authorised by, the NHS, Sponsor and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study.

The Sponsor will only receive information without any identifying information. The people who analyse the information will not be able to identify your child and will not be able to find out your child's name, date of birth, NHS number or contact details.

How long will my child's personal data be stored?
The Research Site will keep identifiable information about your child from this study for a minimum of 15 years after the study has finished on behalf of the Sponsor. In addition, the Sponsor will retain your child's coded data in accordance with the regulations for research.

How will my child's coded data be shared and transferred?
The Sponsor may share your child's coded data with its affiliates and regulatory authorities as well as with business partners with whom it is working to jointly conduct scientific research in other countries. The data protection laws in these countries may be less protective than data protection laws in the EU. With regards to transfers from the EU to other countries, including the U.S., the Sponsor has put in place adequate measures to protect your child's information and to permit the compliant cross-border transfer of your child's coded data. You may contact your child's study doctor to request a copy of these measures.

What rights do I have concerning my child's personal data?
Your rights to access, change or move your child's information are limited, as the Sponsor needs to manage your child's information in specific ways in order for the research to be reliable and accurate. If your child withdraws from the study, the Sponsor will keep the information about your child that has already been obtained. To safeguard your child's rights, the Sponsor will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsor uses your child's information by contacting the Sponsor via your child's study doctor or by using the email address for the Data Protection Officer given below.

If you wish to raise a complaint on how the Sponsor has handled your child's personal data, you can contact the Sponsor's Data Protection Officer who will investigate the matter. If you are not satisfied with the response or believe the Sponsor is processing your child's personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

You can contact the Sponsor's Data Protection Officer via your child's study doctor or by email at emeaprivacy@its.jnj.com.

Involvement of the General Practitioner/Family Doctor (GP)

We would like your permission to contact the doctors your child sees regularly (GP) to let them know that your child is taking part in this study. It is important for all your child's doctors to know that your child may be receiving an investigational vaccine. We may also need to contact your child's GP to request their vaccination history and medical history to check if they meet our inclusion/exclusion criteria for the study.

Who is funding the research?

Janssen Vaccines & Prevention B.V, a pharmaceutical company Represented by in the UK by Global Clinical Operations UK, Janssen Research & Development
50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4DP

A pharmaceutical company that makes vaccines are funding the Oxford Vaccine Group to undertake this research. The study investigators do not have financial conflicts of interests with the study funder.

Who has reviewed this study?

All clinical research is looked at by an independent group of people, called a Research Ethics Committee to protect your child's safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Central Berkshire Research Ethics Committee.

What do I do now?

You do not need to make a final decision straight away. Please contact us by:

Tel: 01865 611400
Email: info@ovg.ox.ac.uk

Members of the research team will be happy to discuss the study with you and answer any questions you may have. Alternatively, you can complete the reply slip and return it in the pre-paid envelope provided. You are welcome to tick the 'No' box below and provide feedback if you wish.

A postcard reminder would be posted to you in two weeks' time. If we do not hear from you after this, we will assume that you do not want to take part in the study. If you do not wish to receive invitations of this kind in the future, please contact the NIHR CRN: Thames Valley and South Midlands – Primary Care team on:
Email: optout.tvsm@nihr.ac.uk, Phone: 01865 223295
Address:
Optout TVSM
NIHR Clinical Research Network: Thames Valley & South Midlands
TVCN Offices, Block-8
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford OX3 7HE

Please provide your child's full name, date of birth and postcode, if you do not provide all data it is difficult to ensure you are removed from future mail outs. Postcard reminders are sent two weeks after the initial invitation. There is a possibility that your response and the postcard reminder may cross in the post. We apologise if this is the case.

Contact

Oxford Vaccine Group
Centre for Clinical Vaccinology and Tropical Medicine (CCVTM)
Churchill Hospital Oxford OX3 7LE
Tel: 01865 611400
Email: 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/Legal Guardian Consent Form

Short Title: Developing a vaccine to prevent RSV, a cause of serious respiratory infections in infants

Study Title: A Randomized, Double-blind, Phase 1/2a Study to Evaluate the Safety, Tolerability and Immunogenicity of Ad26.RSV.preF in Adults 18 to 50 Years of Age and RSV-Seropositive Toddlers 12 to 24 Months of Age

Principal Investigator: Associate Professor Matthew Snape

Child's name:		**CRF ID:**	
Parent/Legal Guardian's name:			

	Please read the following statements and put your initials in the box to show that you have read and understood them and that you agree with them.	**Please initial each box**
1	I confirm that I have read and understand the information sheet dated 07-Jun-2019 for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	
2	I understand that my child's involvement is voluntary and that I am free to withdraw my child at any time, without giving any reason and without my child's medical care or legal rights being affected.	
3	I understand that relevant sections of any of my child's medical notes and data collected during the study may be looked at by responsible individuals from the Sponsor or authorised by the Sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.	
4	I agree to my child's GP being informed of my child's participation in the study. *(Your child may still be able to take part in this study even if you do not agree to this.)*	
	OPTIONAL: I agree that my child's samples can be used for future research.	
	OPTIONAL: I agree to being contacted by the Oxford Vaccine Group about studies in the future that are related to this study and I understand that I would be under no obligation to take part in these future studies	

To be filled in by the parent/legal guardian

I agree for my child to take part in the above research study

Your name	**Date** (Day/Month/Year) (e.g. 01 Jan 2016)	**Signature**

To be filled in by the person obtaining consent (investigator)

I confirm that I have explained the nature, purposes and possible effects of the research study to the person whose name is printed above. They have agreed for their child to take part by signing and dating above.

Name of Investigator (or person obtaining consent if different from Investigator)	**Date** (Day/Month/Year) (e.g. 01 Jan 2016)	**Signature**

Instructions to Study Staff

If the study doctor signing this form is not the Principal Investigator, they must be authorised to take consent on the Site Signature (Delegation) Log.

Filing instructions:

- 1 (copy) for parent/legal guardian
- 1 (copy) for medical notes
- 1 (original) to be filed in the Trial Centre File