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PARTICIPANT INFORMATION SHEET AND CONSENT FORM - UK

NAME OF STUDY:	Phase III, randomized, observer-blind, placebo-controlled, multi-center, multinational study to evaluate the efficacy, immunogenicity, and safety of a Respiratory Syncytial Virus vaccine in infants and toddlers (PEARL)
SHORT TITLE:	TBC
STUDY NUMBER:	VAD00004
STUDY SPONSOR:	Sanofi Pasteur Inc. Discovery Drive, Swiftwater, PA 18370-0187, USA
STUDY DOCTOR (INVESTIGATOR):	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
RESEARCH ETHICS COMMITTEE (REC)	<REC Name>

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1 PART 1: INFORMATION ABOUT THE STUDY

1.1 INVITATION

We would like to invite your child to take part in a research study of an investigational vaccine. The vaccine has been made to protect against disease caused by respiratory syncytial virus (RSV disease). Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370-0187, USA, referred to as the Sponsor, is responsible for this study.

1.2 LETTING YOUR CHILD TAKE PART IN THIS STUDY IS YOUR CHOICE

You can choose whether your child will or will not take part in this study. You can also change your mind at any time about your child's participation in the study. Whatever choice you make, your child will not lose access to their medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It is important that you have as much information as you need and that all your questions are answered.

If you decide to let your child take part, your child can leave the study at any time if you change your mind. During the study, your study doctor will tell you about new information or changes in the study that may affect your child's health or your willingness to let your child continue in the study. Leaving the study will not affect your child's regular medical care.

1.3 WHAT IS THIS STUDY ABOUT?

The study is called VAD00004 (it is also referred to as PEARL), and it evaluates an experimental live vaccine named live-attenuated respiratory syncytial virus (RSV) vaccine (or RSVt vaccine). The study is being done to see if infants and toddlers who are given the RSVt vaccine are protected from RSV infection and acquiring RSV-related disease. The study will also look at the safety, side effects, and immune responses produced in response to the RSVt vaccine.

RSV is a virus (germ) that causes infections particularly during the winter months and throughout the year in some parts of the world. It is transmitted through droplets containing the virus when someone infected sneezes or coughs. In most infants, the RSV infection is a mild illness similar to a cold, with symptoms such as fever, runny nose, sore throat, ear infection, cough, and croup (barky cough with hoarseness). In some cases, RSV can cause serious lung illnesses such as pneumonia and bronchiolitis (an infection of small airways in the lung called bronchioles), which may lead to hospitalisation. At this time, there is no approved vaccine to prevent RSV illness in children. The only means of prevention against RSV is temporary protection with antibody (a type of protein that neutralises the virus) preparations and these are not yet widely available and do not target all ages impacted by the disease. In addition, there is no medicine to treat the disease.

The investigational RSVt vaccine in this study contains a live, weakened form of the virus and is given as a nasal spray. It is made to help a person's body respond in a way that will protect them from getting sick from the virus. This is called an "immune response". The vaccine has been tested in humans before, and other live RSV vaccines very similar to this one have also been tested in both adults and children. There were not many side effects (see Section 1.6), and the vaccine did produce an immune response.

This study will include over 6000 children who are 6 months to less than 22 months of age from several countries.

Your child will be in the study for about 24 months. Your child will receive 2 doses of either the RSVt vaccine or a placebo: the first administration will occur at the time of enrolment and the second administration will occur 56 days later.

The placebo used in this study looks the same as the liquid used in the RSVt vaccine. However, the placebo **does not contain RSV or any active ingredient** and it is considered to be safe for administration.

Both RSVt vaccine and the placebo will be administered in the nose using an investigational nasal spray device. Further details are provided in Section 1.5.

We will compare the results from children who got the placebo to the results from children who got the study vaccine to see if the study vaccine works to protect against infection with the virus and is safe.

Your child will be assigned by chance, like flipping a coin, to receive either the RSVt vaccine or the placebo. This means that **your child will have a 50% chance of getting the study vaccine or the placebo**.

Neither you nor your child nor the study doctor will know which product your child received until the study is over.

1.4 ARE THERE RULES I/MY CHILD NEED/S TO FOLLOW IF I DECIDE TO LET MY CHILD PARTICIPATE?

Participation in this study means that your child must follow certain study rules. Your child's safety and the ability of the study to produce reliable new knowledge depend on it. If you do not think you can follow these rules, it is better that your child does not participate. By agreeing to participate, you agree to:

- Provide information about your child's medical conditions and medications that your child has been taking or is taking now and allow the study doctor to review your child's previous medical records and records created during the study

- Tell the study doctor whether your child has gotten any RSV monoclonal antibody (a preventive strategy for RSV, such as nirsevimab or palivizumab) in the past or has been previously infected with RSV
- Tell the study doctor about the participant's biological mother's vaccination and medical history, including previous or planned vaccination with an investigational RSV vaccine during pregnancy or breastfeeding
- Attend and complete the scheduled visits, tests, and procedures as planned and follow the study doctor's instructions.
- Answer the planned phone calls
- Quickly inform the study doctor or study staff of any health problems, even if you think they are not caused by the vaccine.
- In case your child has any health issues or hospitalisation, provide additional information on your child's health or on your child's ongoing treatment if contacted by the study doctor or the study staff
- Take and record your child's body temperature with the thermometer provided at Visit 1
- Have blood samples and nasal swabs taken from your child as indicated in Section 1.5
- Complete your child's diary card / electronic diary card and memory aid regularly, as instructed by the study doctor
- Bring the diary card and/or memory aid to each visit

1.5 WHAT ARE THE REQUIRED STUDY TESTS AND PROCEDURES?

To conduct the study, the study doctor and his/her team will need to perform some tests and procedures, which are summarised in text and tables below:

For all participants:

- You will bring your child to the study clinic at least 3 times. We will arrange with you when to come in for your child's study visits, and they are shown in Table 1. During these visits, we will ask you about any changes to your child's health. During the first and third visits, we will collect a blood sample.
- You will use paper diary cards / an electronic diary card to record information about any health events your child has during the study. This includes any symptoms of RSV illness, which will be listed in the diary card.
- During the entire study, we will also contact you regularly to ask about your child's health and whether she/he has had any symptoms of RSV illness.
- Along with the visits and phone calls described above, we will ask you to contact the study team if your child has any symptoms of RSV illness or any other serious health events. If your child has any symptoms of RSV illness, we may also ask you to bring her/him in for a sick visit to collect swabs from the nose to test for RSV and other germs. Table 3 details the procedures for the follow-up of RSV illness.

In addition, we will randomly assign participants to a subgroup in order to collect information about the long-term immune response (immune response against RSV 3, 6, 12, and 18 months after Visit 2). If selected for this subgroup, your child will only join either Group 1 (G1) or Group 2 (G2) (as shown in Table 2).

For participants in the long-term immune response subgroup:

- You will bring your child to the study clinic at least 5 times. We will tell you when to come in for your study visits, and they are shown in Table 2 below. During these visits, we will ask you about any changes to your child's health and collect 4 blood samples.

All other procedures are as described above for all participants

Table 1: Schedule of Study Visits and Procedures for All Study Participants

Visit / Telephone Contact or Alternative Method	**Visit 1 (V1)**	☎	☎	**Visit 2**	☎	**Visit 3**	☎	☎	☎	☎	**Sick Visit***
Study calendar	**First day**	**3 weeks after V1**	**4 weeks after V1**	**8 weeks after V1**	**3 weeks after V2**	**4 weeks after V2**	**About 6 months after V2**	**About 12 months after V2**	**About 18 months after V2**	**About 24 months after V1**	
Interview with vaccine study staff, medical information collection, and paperwork	√										
Physical examination	√			√							√
Measurement of heart rate, respiratory rate, and temperature	√			√							√
Questionnaire about other medications and vaccinations	√			√							√
Collection of a blood sample (about 5 mL, 1 teaspoonful)											
Collection of a nasal swab											√
Study product administration											
30 minutes observation after study product administration	√			√							
Questionnaire about reactions, side effects, and illnesses following vaccination	√	√	√	√	√	√					
Questionnaire about any serious illness or health events	Throughout the study										
RSV illness monitoring	You will be contacted once a week during the entire study to find out whether your child has RSV illness and to remind you to contact the study staff if your child shows any symptoms or if your child has a positive RSV test from any other source than this study.										
*Additional nasal swabs will be collected in case of RSV illness.											

Table 2: Schedule of Study Visits and Procedures for the Subgroup of Study Participants

Visit /	Visit 1 (V1)			Visit 2 (V2)		Visit 3	Visit 4-A (G1)	Visit 4-B (G2)		Visit 5-A (G1)		Visit 5-B (G2)			Sick Visit*
Study calendar	**First day 1**	**3 weeks after V1**	**4 weeks after V1**	**8 weeks after V1**	**3 weeks after V2**	**4 weeks after V2**	**About 3 months after V2**	**About 6 months after V2**		**About 12 months after V2**		**About 18 months after V2**		**About 24 months after V1**	
Interview with vaccine study staff, medical information collection, and paperwork	√														
Physical examination	√			√											√
Measurement of heart rate, respiratory rate, and temperature	√			√											√
Questionnaire about other medications and vaccinations	√			√											√
Collection of a blood sample (about 5 mL, 1 teaspoonful)															
Collection of a nasal swab															√
Study product administration															
30 minutes observation after study product administration	√			√											
Questionnaire about reactions, side effects, and illnesses following vaccination	√	√	√	√	√	√									
Questionnaire about any serious illness or health events	Throughout the study														
RSV illness monitoring	You will be contacted once a week during the entire study to find out whether your child has RSV illness and to remind you to contact the study staff if your child shows any symptoms or if your child has a positive RSV test from any other source than this study.														
*Additional nasal swabs will be collected in case of RSV illness.															

Table 3: Schedule for Follow-up of RSV Illness

Days After Sick Visit / Contact type	Sick Visit[a]	Day 15 (+ 7 days)[b] ☎	Day 30 (+ 7 days)[b] ☎
Reminder to complete <To be adapted locally> the diary card / electronic diary card or memory aid	x	x	x
Physical examination and measurement of heart rate, respiratory rate, and temperature	x		
Questionnaire on RSV illness symptoms	x	x	x
Collection of a nasal swab	x	x	x
Questionnaire on health care information	x	x	x
Questionnaire about medications	x	x	x

a The study staff/doctor will verify information on RSV illness and schedule a visit for a nasal swab as soon as possible and preferably within 3 days and no later than 10 days of illness start date.

b If symptoms have not resolved at Day 30, a follow-up call will be performed every 30 days until resolution.

Additional visits may be required if the study doctor considers them necessary for your child's safety.

During the study, blood samples will be taken to test the effect of the vaccine on the natural defences of your child's body and for other related tests. **Genetic testing will never be performed on these samples without your consent.**

Access to your child's name and contact details is needed for some required services in this study. If you decide to let your child participate in the study, such personal information will be shared in a secured and confidential manner by the study doctor with the Service Provider. The Service Provider will use your child's name and contact details only for the purpose described below and will not keep such information for longer than necessary. If you do not want to share your child's name and contact details, you will not be able to participate in the study as these services are required for the conduct of the study.

- A service to complete the diary card electronically: The study doctor will provide your phone number and/or email address to Signant Health. The information shared with this Service Provider will only be used to complete your child's diary card before the next visit and will not be provided to the Sponsor of this study.
- A service to read and sign this informed consent form electronically: The study doctor will provide your phone number and/or email address to Signant Health. The information shared with this Service Provider will only be used to sign and share the electronic informed consent form with you and will not be provided to the Sponsor of this study.

1.6 WHAT ARE THE RISKS OF LETTING MY CHILD TAKE PART IN THE STUDY?

Foreseeable risks and discomforts from study products

As with any medicine or vaccine, side effects may occur with the use of this study vaccine. At this stage, some risks and side effects are still unknown. The majority of events reported in prior studies were mild in intensity and short in duration.

If your child does experience any side effects during the study, they will be recorded, so that scientists can learn from your child. In some cases, side effects can be serious, long-lasting, permanent, or life-threatening. The study doctor is trained to monitor for side effects and to take the appropriate measures to reduce risks and limit any discomforts your child may experience.

Discomforts and risks with receiving this vaccine or a similar vaccine observed in previous studies with people are listed below:

- If the vaccine is not weakened enough, it may cause a runny nose, nasal congestion, sore throat, cough, or other signs of a cold. It is also possible that it may cause a sinus infection, croup, ear infection, fever, wheezing, or pneumonia (infection of the lungs). In another study with a similar vaccine, mild respiratory illnesses were observed frequently in infants who received either vaccine or placebo. Runny nose occurred more often in infants who got the vaccine than those who got the placebo.

- There is no specific medicine to treat RSV illness. If any symptoms of RSV occur, such as runny nose, sore throat, cough, or difficulty breathing, your child should receive prompt medical care.

- One potential risk is called vaccine associated enhanced disease, which means that if a person who has never had the disease in the past gets the RSV vaccine, they may be at increased risk of getting sicker if they become infected with RSV in the future.
  This is a very low and theoretical risk, which means that it is possible, because it was associated with another type of RSV vaccine and with other vaccines but has not been seen with the type of vaccine used in this study.

This is not a complete list of possible side effects. Other side effects may also occur. The study doctor may provide further information about possible side effects.

It is very important that you tell the study doctor about any health problems your child experiences even if you think they were not caused by the vaccine. If a serious health problem occurs – for example, one that requires your child to go to the hospital – you or another person of your choice must tell the study doctor as soon as possible.

As with any vaccination, there is a possibility of an allergic reaction, such as a rash, swelling of the lips or face, or difficulty breathing. If such a reaction occurs, it is usually almost immediately after the vaccination. This is why we require that your child remains at the clinic/the site for

30 minutes so that we can provide immediate medical attention if needed. The study staff is fully trained and equipped to deal with this unlikely event.

Foreseeable risks and discomforts from study procedures

If your child has a sample taken from their nose, they may feel some discomfort from the swab during this procedure. Rarely, swabs can cause nosebleeds. The study staff is fully trained and equipped to deal with this unlikely event.

Your child may have pain, tenderness, or bruising at the place where blood was drawn. It sometimes takes more than 1 attempt to get blood from an infant or toddler although it is standard not to have more than 2 attempts at taking blood. Further attempts would not be carried out without discussion.

Your child can be given a local pain reliever to reduce any pain she/he may have after having a blood sample taken.

What if there is a problem?

Complaints
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions on **[contact number].** If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. We recommend that you obtain a copy of your hospitals complaints procedure or policy if you intend to make a complaint. (Insert site complaints team contact details).

Harm
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 trial protocol
- Any test or procedure you received as part of the trial

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 trial protocol
- The protocol was not followed.

Copies of these guidelines are available from your study doctor on request.

If you think you have an injury/illness that is related to the study, you should immediately tell the study doctor, or one of the site staff members working on the study. The study doctor and the site staff may be reached at **[*insert telephone number(s)*]**

Compensation and expenses

You will not be paid for your child's participation in this study, but you will receive **<sum>** to compensate for obligations related to the study, according to the applicable law. You will not have to pay for the study vaccine, or any expenses related to study procedures.

You will be reimbursed for reasonable expenses incurred as a result of taking part in this study (examples include but are not limited to travel expenses, meals/refreshments). You will need to provide receipts for those visits.

1.7 WHAT ARE THE POSSIBLE BENEFITS IF I LET MY CHILD TAKE PART TAKE PART IN THE STUDY?

There is evidence from other studies conducted in humans that being vaccinated with RSVt vaccine may provide protection against RSV disease. By participating in the study, it is possible that your child may get protection against RSV disease. However, given the experimental nature of the study, it is not certain that your child will directly benefit from participating. Children receiving placebo will not directly benefit from participating in this study. Even if your child does not directly benefit, this study will help us learn things that may help your child as well as other children in the future.

1.8 WHAT TYPE OF DATA ARE COLLECTED IN THE STUDY AND WHO IS RESPONSIBLE FOR PROTECTING MY CHILD'S DATA?

To conduct the study, the study doctor and the team at the study site will need to collect some of your child's personal and health data such as: your child's name and contact details (for example, address), your child's demographic information (for example, age), administrative information (for example, health insurance number), and information about your child's health. In addition, the study doctor will also need to collect biological samples (blood and nasal swab samples, refer to Section 1.5) from your child and the laboratory data that results from testing these samples. Finally, information from your child will be collected through diary cards / electronic diary card / memory aids and/or questionnaires. The above-mentioned data will be referred to as "your child's data" below.

The organisation responsible for the protection and confidentiality of your child's data is the Sponsor of the study, also referred to by data protection regulations as the "data controller". The data controller can be reached through its Data Protection Officer at the following address: Global Privacy Office, Sanofi, 46 Avenue de la Grande Armée, 75017 Paris, France or through the form available on this link https://www.sanofi.com/en/our-responsibility/sanofi-global-privacy-policy/contact.

1.9 WHAT ARE MY CHILD'S DATA AND BIOLOGICAL SAMPLES PROCESSED FOR?

The processing of your child's data and biological samples is needed to develop a vaccine against RSV disease; to comply with regulatory requirements; to market or to continue to market the vaccine. In this regard, your child's data may be processed to: understand how the study vaccine works and its effects in the body; understand the disease and its associated health problems; develop tests; modify the current study or plan new studies; improve scientific analysis methods; publish research results in scientific journals; and share scientific knowledge.

Under applicable data protection laws, the collection and use of your child's data are justified by the scientific research purpose detailed above, and the Sponsor's legitimate interest to conduct the study as per clinical trial regulations and is explained in Part 3 of this document.

1.10 WHO WILL HAVE ACCESS TO MY CHILD'S PERSONAL INFORMATION AND BIOLOGICAL SAMPLES AND HOW WILL MY CHILD'S PRIVACY BE PROTECTED?

Your child's privacy is very important to the Sponsor and researchers involved in this study and every effort to protect your child's privacy will be made.

The study doctor will collect the biological samples required for the study from your child for analysis. Biological samples will be identified by a unique code only and not by information that can directly reveal your child's identity (such as your child's name and contact details). Once coded, your child's biological samples may be transferred to affiliates of the Sponsor or to study Service Providers for analysis for the purpose of the study. Your child's biological samples will be securely stored.

To conduct the study, the study doctor will also need access to some of your child's personal and health information, including your child's name and contact details.

To protect your child's privacy, your child's name and contact details will be replaced by a unique code (a series of number and/or letters) before the study doctor shares your child's personal information with the Sponsor, its affiliates, and study Service Providers who do not need access to your child's name and contact details to provide the services. These individuals and organizations will therefore not know who your child is. The process of replacing your child's name and contact details with a code to protect your child's privacy is called "coding" and the dataset that results from this modification, and which will include this code associated with your child's health data, will be referred to as your child's "coded" data in the rest of this document.

In addition, the Service Providers listed in Section 1.5 will need access to your child's name and contact details so that they can provide your child with a specific study service. Refer to Section 1.5 for a description of each study service available in this study and the specific parts of your child's personal information that will be shared with each Service Provider if the service is used.

If authorised or required by law, the study doctor may grant study monitors, auditors, institutional review boards, ethics committees, and regulatory agencies access (if authorised, possibly

remotely) to your child's data, including potentially your child's name and contact details. These individuals and organisations ensure the protection of the people who take part in research, monitor the study's quality and verify that all requirements for research on human participants are followed. These individuals and organisations are required to keep your personal information private.

At the end of the study, the Sponsor may publish the study results in a scientific journal(s). As part of the review for publication, independent scientists may need to use "coded" data of all the study participants to independently verify the study's results. If research results are published, your child's name and other information that reveal your child's identity will not be made public.

Some of the above-mentioned individuals or organisations that may be granted access to your child's data could be located outside of your country. The countries where they are located may have different laws related to privacy and data protection rights compared to your country and may not ensure the same level of data protection as your country. For example, it is possible that a governmental and/or judicial authority in a country where your child's data are transferred requests, in accordance with their local laws, access to your child's data for public safety or national security reasons. If you do not want your child's data to be accessed by such authorities, your child should not participate in the study, and you should not sign this consent form.

Notwithstanding the above, Sanofi makes sure it complies with the recommendations of the Data Protection Authorities to maintain the protection of your child's data by implementing certain safeguards. Such safeguards will be defined in contracts between the Sponsor and the relevant persons or organisations involved in study conduct and may include the EU Standard Contractual Clauses. Such safeguards are also defined in Sanofi's Binding Corporate Rules. The Binding Corporate Rules are rules that the Sanofi Group follows to ensure the protection of your child's data. You may request a copy of the safeguards by contacting Sanofi's Data Protection Officer.

Finally, your child's data may be permanently modified by the Sponsor and its affiliates so that it will no longer be possible to identify your child by any means (for example, by destroying the code that has been assigned to your child and the link between this code and your child's health data). This process is called anonymisation. Your child's anonymised data could be shared with third parties and used for legitimate purposes, without informing you or obtaining your consent.

1.11 HOW LONG WILL MY CHILD'S "CODED" DATA AND BIOLOGICAL SAMPLES BE KEPT?

The Sponsor is required to keep all study data for 25 years after the end of the study or as per local regulations. Your child's "coded" data will then be deleted or anonymised.

Your child's biological samples (blood and nasal swab samples) will be stored for up to 25 years after the end of the study or as per local regulations. It can take many years for a vaccine to be developed and approved for use; therefore, your child's samples will continue to be needed to answer questions from health authorities and confirm the results of the study.

Any other biological samples collected to monitor your child's health during the study are dedicated for immediate use. If any of these biological samples are not completely used up, they will be destroyed at the latest at the end of the study or after the time requested by local law.

1.12 WHAT ARE MY CHILD'S RIGHTS WHEN IT COMES TO DATA COLLECTED ABOUT THEM?

You have the right to:

- Request access to your child's data
- Ask to have incorrect administrative data collected about your child corrected
- Restrict the use of your child's data
- Object to the use of your child' data. However, please note that this objection will result in you/your child having to leave the study, as the processing of your child's data is essential to the conduct of this study. The data already collected prior to your objection will not be deleted and will continue to be processed and stored for 25 years after the end of the study, as per applicable clinical regulation(s)

To ensure the scientific integrity of the study and comply with regulatory requirements, you may not be able to request the deletion of your child's coded data, nor exercise some of the above-mentioned rights until the study ends because in this study the doctor will not have access to some of the data until the study is finished, or neither you nor the study doctor will know if your child is receiving the RSVt vaccine or the placebo.

To exercise these rights, please contact the study doctor or any other healthcare professional from the study. If there are issues related to the use of your child's data, you can file a complaint to your local data protection authority and/or to the Information Commissioner's Office (ICO).

1.13 WHAT HAPPENS TO MY CHILD'S DATA AND BIOLOGICAL SAMPLES IF MY CHILD LEAVES THE STUDY?

If your child leaves the study, the study doctor will stop collecting data and biological samples from your child, but your child's previously collected data and biological samples will be kept and used to ensure the research remains scientifically valid and to comply with regulatory requirements. If you have allowed biological samples to be stored for Future Research Projects (see Part 2) but do not want those biological samples to be used after your child leaves the study, you must inform the study doctor. In such a case, your child's biological samples will be destroyed. The data collected prior to your child's withdrawal from the study will not be deleted and will continue to be processed and stored for 25 years after the end of the study, as per applicable clinical regulation(s).

1.14 HOW DO I OBTAIN ACCESS TO THE STUDY INFORMATION AND RESULTS?

A description of this study will be available on at least one of the following registries www.ClinicalTrials.gov, www.clinicaltrialsregister.eu. After the study ends, overall study results will also be available on at least one of these websites and/or Sanofi.com. As well, after this study ends, a simple summary of the overall results will be prepared for the public and made available at https://sanofi.trialsummaries.com.. These websites will not include information that can identify your child.

1.15 WHAT HAPPENS IN CASE OF ANY POTENTIAL NEW FINDINGS CONCERNING SAFETY OF STUDY PARTICIPANTS?

Once your child begins the study, you must immediately notify the study doctor if your child is hospitalised. The study doctor will keep you informed during the study of any changes or new information that could make you change your mind about your child's participation in the study and will provide you with any necessary instruction. In such a case, you will receive all available information allowing you to decide whether to let your child continue participation in the study.

1.16 WILL I BE GIVEN INFORMATION ABOUT MY CHILD'S VACCINATION STATUS WHEN THE STUDY ENDS?

At the end of the study, the study doctor will tell you which product your child received.

1.17 HOW WILL UNEXPECTED FINDINGS IMPORTANT TO MY CHILD'S HEALTH BE HANDLED DURING THE STUDY?

It is possible that some of the tests and procedures your child undergoes as part of this study will show an unexpected finding important to your child's health and medical care.

If this happens, efforts will be made to inform the study doctor and/or your child's physician, so that he/she can discuss further options with you related to the unexpected findings or refer your child to a specialist.

1.18 HAS THE STUDY RECEIVED MEDICAL OR ETHICAL APPROVAL?

All research in the NHS 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 the <insert name of committee> Research Ethics Committee.

1.19 INVOLVEMENT OF THE GENERAL PRACTITIONER/FAMILY DOCTOR (GP)

Your general practitioner (GP) or family doctor will be notified of your involvement in this study. They will be asked to pass relevant information about your health status and medication changes to the study doctor.

1.20 WHO CAN YOU CONTACT FOR MORE INFORMATION ABOUT THIS STUDY AND TO ASK ABOUT YOUR RIGHTS AS A STUDY PARTICIPANT?

While in this study, you will be under the care of Dr <insert study doctor name>. If at any time you feel that your symptoms are causing you problems or you have experienced a study-related injury, contact your study doctor. The telephone number to reach your study doctor or other study team members is:

<insert name>
<insert telephone number>
<must include after hours contact>

For any questions about your rights as a research participant, direct enquiries to:

[Insert Contact Information, such as the Patient Advise and Liaison Service (PALS) for sites in England or equivalent for sites in Wales, Scotland and Northern Ireland.]

2 PART 2: INFORMATION ABOUT FUTURE RESEARCH

The coded data and biological samples collected in this study could be very useful to future scientific medical research, referred to as Future Research Projects below. Allowing the reuse of your child's data and samples for Future Research Projects could allow researchers to make new discoveries which may benefit society and public health.

2.1 WHAT POSSIBLE FUTURE RESEARCH PROJECTS WILL MY CHILD'S CODED DATA BE USED FOR?

Today, it is not possible to anticipate and describe all future medical research questions where reuse of your child's coded data may be useful. However, the reuse of your child's coded data will be limited to future scientific research conducted under a research plan for the purpose of diagnosing, preventing, or treating diseases. Such Future Research Projects may help the development of new vaccines for your child or another disease. You will be provided with further information regarding Future Research Projects before your child's coded data are reused, unless the Sponsor or its affiliates have been granted a specific waiver from your data protection authority or ethics committee.

The following principles will apply to Future Research Projects:

- Future Research Projects will be conducted under the Sponsor's and/or its affiliates' control, acting alone or in collaboration with research partners such as universities, research institutions, or industrial partners with whom your child's coded data may be shared.
- Your child's coded data will be available only to the researchers involved in the specific Future Research Project and for a maximum period of 2 years after the end of such Future Research Project.
- If in the course of a Future Research Project your child's coded data are transferred to a country where the level of data protection is not the same as in your country, the Sponsor or its affiliates will ensure that the safeguards defined in Section 1.10 are followed.
- If results of Future Research Projects are published, your child's name and other personal information revealing your child's identity will not be publicly available. As part of the review for publication, independent scientists may need to use the "coded" data used for the Future Research Project to independently verify the findings to be published.
- All your rights (right to withdraw your consent, right to request access, right to correct your child's administrative data, right to restrict access to your child's data, right to file a complaint to your local data protection authority) under data protection laws will apply. To ensure the scientific integrity of the Future Research Project(s), you may not be able to request deletion of your child's data.

2.2 WHAT POSSIBLE FUTURE RESEARCH PROJECTS WILL MY CHILD'S LEFTOVER BIOLOGICAL SAMPLES BE USED FOR?

Today, it is not possible to anticipate and describe all the future medical research questions where use of what remains of your child's biological samples may be useful. If you consent to it, what remains of your child's biological samples after the conduct of the clinical study (ie, your child's "leftover samples"), if any, will be stored in a sustainable way and may be used, as long as their quality allows, only for Future Research Projects and will follow the same principles as those outlined in Section 2.1.

In some cases, the results of the analysis carried out on your child's "leftover samples" may need to be associated with some your child's "coded data" in order to answer the scientific research question.

Unless you consent to Genetic Testing in Part 3, the Future Research Projects conducted on your child's "leftover samples" will not include any Genetic Testing. Some research projects may require the analysis of your child's genetic information. You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body, but some words or letters may be different from 1 person to the other. Some of those differences have no effect on your health but others can influence the likelihood of developing a disease or affect how medicine to treat a disease will work. If genetic analyses are done in Future Research Projects, they may involve all or part of your child's genetic information.)

Your child's "leftover samples" will be stored for a maximum period of 25 years in a secure way by the Sponsor or a Service Provider acting on its behalf.

2.3 CAN MY CHILD'S DATA AND BIOLOGICAL SAMPLES BE USED FOR FUTURE RESEARCH PROJECTS WITHOUT MY PERMISSION?

No. The use of your child's coded data and biological samples for Future Research Projects requires your permission. This means that it is entirely up to you to decide whether you want, or not, your child's coded data and biological samples to be used for Future Research Projects.

If you agree to the use of your child's coded data and biological samples for Future Research Projects, your child's coded data and biological samples may be used to address various important medical research questions (see Section 2.1). The knowledge derived from these Future Research Projects may benefit society and public health by advancing scientific understanding and generating knowledge that could be generalisable and useful to others.

If you refuse the use of your child's coded data and biological samples for Future Research Projects, this choice will not affect your child's participation in this study, your child's medical care, legal rights, or benefits. Your child's coded data and biological samples will be handled in the manner described in Section 1.11.

You can withdraw your consent for the use of your child's coded data and biological samples for Future Research Projects at any time by contacting the study doctor or Sanofi's Data Protection Officer (see Section 1.8).

2.4 WILL I HAVE ACCESS TO MY CHILD'S INDIVIDUAL RESULTS?

Your child's individual results from Future Research Projects will not be sent to you because they are exploratory in nature. Furthermore, the study doctor will not have these results, as they will not be part of your child's medical record. However, if something important for your child's health is discovered, reasonable efforts will be made to inform your child's GP/doctor, so that he/she can contact and discuss these findings with you. In case you do not want to be informed about such findings, please indicate it in Part 3.

<To be completed by the study doctor>

CONTACT

STUDY DOCTOR: _____

ADDRESS: _____

PHONE: _____

E-MAIL ADDRESS: _____

THANK YOU

The Sponsor would like to thank you for considering letting your child take part in this study. We understand your time is valuable and appreciate your child's participation.

<Site headed paper>

CONSENT FORM

Principal Investigator: **Participant Initials:**

Participant Number:
Short Title: TBC

Statement of Consent	*Please initial box:*
I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and I am satisfied with the explanations provided	
I understand that my child's participation 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	
I agree to truthfully answer all questions about my child's medical condition and agree to the required study procedures and required services needed for the study and will follow all study rules listed in the document.	
What will happen to your data? I agree to: My child's name and contact details being collected during the study as described to me and accessible only to the authorised individuals and organisations listed in this document. My child's medical file being reviewed during or after the study and that, where allowed by local authorities, this may take place remotely. My child's "coded" data being used by the Sponsor or by people or companies acting on its behalf or working with the Sponsor for the purpose of conducting the study and that some of these individuals may be located in countries that do not have data protection rules equivalent to those of my country. I understand that the Sponsor will take all possible measures to protect my child's privacy. My child's biological samples being collected and analysed as described herein.	
I agree to my child's GP being informed of my participation in the study as described in this information sheet	
I understand that I will receive a copy of this signed and dated information sheet and consent form	
I voluntarily agree to take part in this study	

<Site headed paper>

CONSENT FORM- continued

PARTICPATING IN OPTIONAL FUTURE RESEARCH

Principal Investigator: **Participant Initials:**

Participant Number:
Short Title: TBC

Further understand that I can make a choice about the topics listed below and that by ticking "Yes", I give my consent to and that by ticking "No", I do not give my consent to:

Be informed of any unexpected finding important to my child's health and possibly that of my relatives	Yes ☐	No ☐
The storage and use of my child's coded data for future research, as described in "Part 2: Information About Future Research"	Yes ☐	No ☐
The use of my child's leftover biological samples and associated coded data for future research, as described in "Part 2: Information About Future Research"	Yes ☐	No ☐
The performance of future genetic analyses on my child's biological samples	Yes ☐	No ☐
Have the study doctor notify my child's physician of my child's participation in the study and share relevant medical information with him/her, if necessary, to manage my child's medical care	Yes ☐	No ☐

If you agree, please indicate the name and contact details of your child's GP here:

Dr _____ Telephone number _____
Address_____

_____
Name of participant (print)

_____ _____
Signature of participant Date

<Site headed paper>

CONSENT FORM- continued

PARTICPATING IN OPTIONAL FUTURE RESEARCH

Principal Investigator: **Participant Initials:**

Participant Number:
Short Title: TBC

_____
Printed name of authorised person obtaining informed consent

_____ _____
Signature of authorised person obtaining informed consent Date

_____
Printed name of witness or legally authorised representative (optional)

_____ _____
Signature of witness or legally authorised representative (optional) Date

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.