INFORMED CONSENT FORM

Official Title of the study:

«Seroprevalence of Pertussis among Healthy Children and Adolescents in Kazakhstan: A Cross-Sectional Study»

Date of the document: **October 09, 2020**

NCT number: n\a

Internal Sanofi Pasteur Study Code: **PER00075**

Scientific organization: **Scientific and practical centre of sanitary and epidemiological expertise and monitoring, Almaty, Kazakhstan**

INFORMED CONSENT FORM

Dear Sir or Madam

Your child is being asked to volunteer to take part in the research study “Serosurveillance of Bordetella Pertussis among children and adolescents in Kazakhstan”. The Ethics Committee that approved this study is Ethics committee of Kazakh Medical University of Public Health on 17.10.2020, approval 03-05-282.

This document will provide you with the information needed to help you decide whether you wish your child to take part in this study. If you have any questions or want additional information, please do not hesitate to ask one of the study team members listed at the end of this document at any time.

What is pertussis?

Pertussis is an acute infectious disease caused by specific bacteria Bordetella pertussis. The disease is preferably caused long paroxysmal cough. The disease can be mild or asymptomatic in adolescents and adults. In infants, particularly unvaccinated, the disease is more severe and can cause complications and even death. Pertussis emerges after spread of the bacteria from infected respiratory drops of the sickened person. After the disease the patients usually have rather long immunity, which protect them against repeated disease. The effective method for protection against pertussis is vaccination. After the complete vaccination in the first years of life the immunity develops and the person is protected against pertussis during about several years. It is not clear for today the exact duration of protection after vaccination by different schedules against pertussis. Vaccinated persons have mostly mild forms of pertussis in case of the infection.

This study includes blood sample taking for detection the presence (or absence) of immunity against pertussis in your child’s blood.

What is the purpose of this study?

This study involves medical research. The purpose of this study is the detection of duration of protection after vaccination and groups for recommendations for booster vaccination against pertussis.

How will this study be done?

In case your child and you accept to participate in the study, one blood sample of approximately 3 ml will be taken. The samples will be used to test presence of immunity against pertussis in your child's blood.

What are the risks and possible unwanted effects of blood sampling?

Some pain, bruising or light headedness may occur following the drawing of blood. It is very important that you let the investigator know about any unwanted effects your child experience.

What are the possible benefits for your child?

There will be no direct benefit on your child health. However, you will gain the true information about your child's immunity against pertussis.

What will you have to do?

In case your child is hospitalized/ treated in diagnostic center you do not need any additional activity.

Who will see your medical and personal information?

Your child's name will be coded using his initials and study number. This is to protect your child'privacy when the information collected during the study is computerized and used the by the investigator. Your child's name and other information identifying him will not be forwarded to third parties. The computerized data may be accessed by the health authorities. You have the right to obtain updated information about what data are recorded as well as the right to require that errors be corrected.

In addition to the use of computerized information as described above, any personal records, including your child's medical records and health history, relating to this study may be inspected in the Investigator's offices by the health authorities or authorized representatives of ethics committee.

Absolute confidentiality of your child's records can therefore not be guaranteed.

The results of this study may be presented at meetings or in publications. Your child's identity will not be revealed in these presentations.

What happens if you refuse to let your child to take part in the study or change your mind after you agree?

Your child's participation in this study is entirely voluntary. If you do not want Your child to take part then you do not have to. Also, if you agree to take part but change your mind, you have the right to do so. Your child can withdraw from the study at any time. If Your child withdraw from the study, his (her) samples collected before withdrawal will be used unless if you specifically request otherwise.

Whatever your decision, Your child will continue to qualify for full medical care without any penalty or loss benefits to which Your child are otherwise entitled.

The Investigator may withdraw your child from this study for any reason at any time even without your consent.

What else do you need to know before agreeing to let your child to take part in this study?

Taking part in this research is entirely voluntary.

You will receive a signed copy of this Informed Consent Form. Please keep it safe and use it for information and reference during throughout the trial.

Do not sign this Informed Consent Form or participate in this study unless you are comfortable with the risks involved and you have had an opportunity to ask questions and feel you have received satisfactory answers.

What will happen to (blood) samples of your child?

As a part of this study, samples will be taken to test the immunity against pertussis in your child's body system. The tests will be done by microbiological laboratory of Institute Pasteur of St Petersburg.

What should you know about possible future use of the samples of your child for research?

The investigators also like to keep any unused part of your child's blood samples for use in other research in the future. The aim of any possible future research is unknown today, but may not be related to this particular study. It may be to either improve the knowledge about vaccines or infectious diseases or to improve laboratory methods. You will not be informed about the types of research that will be conducted or any of the results. Genetic tests will never be performed on these samples.

You have the right to agree to let your child to take part in the study proposed to you today and still refuse to allow keep any unused blood samples for future use. You will be asked to decide whether or not you permit this future use of your child's samples and indicate your decision on this consent form.

Should you allow keeping any unused blood samples of your child, they will be securely stored by the investigators until they are needed for testing.

Should you refuse to allow keeping any unused blood samples of your child then they will not be used for any testing other than for testing directly related to this study.

Who can you contact if you have questions?

If you have any questions about this study or if you want more information, please contact:

Informed consent statement for participating in the study

Subject's first and last Names: _____

Subject's study number: _____

Subject's initials: _____

By signing this form I certify to all of the following:

- I have read this entire Informed Consent Form and understood the study steps. I have had the opportunity to ask questions, I received satisfactory answers, and I understand that I may ask additional questions about this study at any time.
- I consent to make my child confidential personal information available for review by the any health authorities assigned this task, or if applicable, the Ethics Committee.
- I understand that my child is free to withdraw from the study at any time without justifying my decision to do so and without it affecting my child medical care and my child legal rights.

- I understand that I will be informed of any new information that may affect my willingness to continue participation in this study.
- I voluntarily consent to let my child take part in this study.
- I have been given a copy of this Informed Consent form to keep for my reference

Please indicate consent statement for the future use of your samples in research:

- I authorize the future use of my child’s blood samples for future research by the Investigator under the conditions described in this information sheet (see the paragraph called “What should you know about possible future use of your child’s samples for research.).

or

- I authorize the use of my child’s blood samples for doing tests related to this study BUT do NOT authorize the future use of my child’s samples for any other research.

Last and first name of parent/legally authorized representative

_____

Signature of parent/legally representative

Date_____ Investigator’s statement (or person performing the Informed Consent procedure)

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and reasonably foreseeable risks associated with participation in this research study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the trial, as described in the informed consent form, to the above volunteer on the date stated on this consent form.

Last and first name of Investigator

Signature of Investigator Date