

INVITATION FOR YOUR CHILD TO PARTICIPATE IN A STUDY ABOUT CHILDREN'S ROLE IN TRANSMISSION OF CORONAVIRUS (SARS-COV-2) IN KINDERGARTEN AND PRIMARY SCHOOLS

SHORT DESCRIPTION ABOUT THE PROJECT

- This project will investigate the role of children in the spread of coronavirus in kindergartens and primary schools (grades 1-7). We will look at how many people are infected in kindergartens and primary schools, how many develop symptoms and what type of symptoms they get.
- This project will contribute knowledge to support recommendations and infection control measures in kindergartens and primary schools.
- The study will take up to 10 days
- The project involves taking two saliva samples from your child during the follow-up period of this study.
- The tests are analyzed as quickly as possible, and we will inform you about the results as soon as we receive them.
- We will also ask you to answer a short questionnaire at the beginning and end of the follow-up period on behalf of your child. In addition, we will ask you to report each day if your child has symptoms.

INFORMATION ABOUT THE PROJECT

A new coronavirus (SARS-CoV-2) that causes the disease COVID-19 has spread all over the world, including Norway. There still is a lot we do not know about the virus and the disease. We would like to invite your child to participate in a project carried out by the Norwegian Institute of Public Health. The project will investigate the role children play in the spread of coronavirus in kindergarten and primary schools (grades 1-7). Other studies have shown that infection from and between children occurs, but there is little evidence that children play a key role in the spread of the virus. In general, most children get no or mild symptoms and the ability of these children to transmit the infection further is uncertain. There is therefore a need for more knowledge in this field.

In Norway, all kindergartens and schools were closed on 13 March 2020 and from 20 April 2020, they gradually reopened under stricter infection control measures, including an increased distance between people and more hygiene measures. Understanding more about children's role in the spread of the virus is important for recommendations and infection control in kindergartens and schools.

The project will investigate:

- How many people are infected with coronavirus at school / kindergarten, after they have been in contact with a child diagnosed with coronavirus.
- What factors increase the risk of becoming infected with coronavirus.
- How many of those that are infected develop symptoms, what type of symptoms and how severe the illness is.
- If there is a difference in the spread of infection in kindergartens and primary schools with and without adults who are infected with coronavirus.
- Differences between viruses that are detected in primary schools and kindergartens.
- If it is possible to detect antibodies in saliva in children with coronavirus.

WHO CAN PARTICIPATE IN THIS STUDY?

The Norwegian Institute of Public Health has been informed by the district or municipal doctor that coronavirus has been detected in one or more children in your child's day care or elementary school (grades 1-7). We ask your child to participate in this study because he / she may be exposed to the coronavirus and thus is defined as a contact.

WHAT DOES IT MEAN TO PARTICIPATE IN THE STUDY?

All participants in the study are followed up in the same way, regardless of whether they have been diagnosed with coronavirus or not. It is important for the project that we get the same information from all participants and that everyone is tested for virus with the same method. The follow-up in this study is in addition to the follow-up the child will normally receive from the health service.

If you agree to your child participating in the study, we will follow him/her up for 10 days. We will ask you to complete a short questionnaire on the first day (day 0) and again on the last day of this period (day 10). Here you will be asked to fill in some general information and information about the child's general health and about any symptoms of infection. The questionnaires take 5-10 minutes to answer. In addition, we ask you to keep a daily symptom diary on behalf of the child during the follow-up period (10 days, <5 minutes daily). Data collection is preferably done electronically through a secure solution where you log in with BankID. You will receive an SMS with a link to log in. You can choose to answer the questions on paper if you wish.

You will be invited to an online meeting with the National Institute of Public Health when the study starts. Here you will have the opportunity to ask questions about the study and what participation includes. During the follow-up period, you can also ask questions to a separate e-mail address for this study and get a quick answer.

Your child will be asked to take a saliva test at the beginning (as soon as possible) and the end (day 10) of the follow-up period. The sample is taken at home by spitting in a glass and does not cause any discomfort. You will receive sample equipment and instruction on how to take the samples. A project employee will ensure that the samples are picked up at home if your child / you are in quarantine. If you are not in quarantine, you can choose if you want to deliver the sample at a specific time at the day care or school or that it is picked up at home where you live.

In case of illness

If your child becomes ill and you want to contact a doctor for assessment, it is important that you do this regardless of the study. Do not wait for the follow-up in this study.

POSSIBLE BENEFITS AND DISADVANTAGES

The tests are analyzed as quickly as possible, and we will inform you about the results as soon as we receive it. This means that you will be told early in a possible course of the disease whether your child is infected with coronavirus, or not.

The health service in the municipality is responsible for the follow-up around people with coronavirus infection and for deciding necessary measures. They define who are contacts, who will need to be in quarantine (contact tracing) and whether there is a need to inform others. Follow-up for this study will take place in parallel with the follow-up of your child by the municipal health service, and will not influence the measures recommended by the municipal health service.

By participating in this study, your child helps the National Institute of Public Health to gain better understanding of coronavirus and on children's role in the spread of this virus.

Participation does not involve any form of medical treatment or measures, apart from taking the saliva sample, and it does not entail discomfort, health risks or the need for special insurance.

WHAT HAPPENS TO THE SAMPLES AND INFORMATION COLLECTED FROM YOUR CHILD?

The information collected during this study will only be used for the specific purpose of this project as described above. Any extensions in use or storage period can only take place after approval from the Regional Ethics Committee and other relevant authorities. You have the right to access the information registered about your child and to correct any errors in the information registered. You also have the right to view the security measures used for processing the information.

All information about your child will be treated confidentially and in accordance with applicable privacy laws.

The child's name and birth number will be registered together with the result from the saliva tests. Only in the analysis of the saliva samples (virus detection) are these registered together (in the same way as if the sample is taken at a regular doctor's office), as coronavirus is a notifiable disease. We ask for permission to link the child's test results of this study with test results registered in the Infectious Diseases Notification System (MSIS). The purpose of the link is to ensure the quality of our research data. Such a connection is made using the personal identification number.

Upon further analyses of the samples and information about your child, identifying personal information (such as name and birth number) will be replaced with a code. This is called deidentification. There is a very limited number of project members who have access to the link between this code and your child's personal information. Researchers will only have access to deidentified data. The project manager is responsible for ensuring that information about your child is processed in a secure way. It will not be possible to identify any of the participants in the results of the study when data are published.

The samples taken from your child will be stored in a research biobank "Korona barn" at the National Institute of Public Health. The project manager at the National Institute of Public Health, Brita Askeland Winje, is responsible for the biobank.

The information about your child will be kept for five years after the end of the project for security reasons. The end of the project is set for 31 December 2025, but the project can be extended, given approval by the Regional Committee for Medical and Health Research Ethics (REK).

VOLUNTARY PARTICIPATION AND OPPORTUNITY TO WITHDRAW YOUR CONSENT

Participation of your child in this study is voluntary. You can withdraw your consent on behalf of your child at any time and without providing a reason. If you do not want to participate on behalf of your child or later choose to withdraw consent, it has no negative consequences for your child or his/her follow-up or treatment. If you withdraw your consent, no further research will be done on the child's information and the child's biological material will be destroyed. If you withdraw your consent, you can request to delete the collected test results and information about your child, unless they have already been included in analyses or used for a scientific publication. If you wish to withdraw the consent on behalf of your child or have questions about the study, you can contact the project manager via email or telephone.

You can complain about the processing of your child's information to the Norwegian Data Protection Authority and the Norwegian Institute of Public Health's privacy representative.

APPROVAL

The regional committee for medical and health research ethics (REK) has made a research ethics assessment and approved the project [REK Sørøst A, 151649].

According to the new Personal Data Act, the institution responsible for processing, the National Institute of Public Health, and project manager Brita Askeland Winje have an independent responsibility to ensure that the processing of your child's information has a legal basis. This project has a legal basis in the EU Privacy Regulation Article 6 (1a) and Article 9 (2a) and your consent.

We process the collected information based on your consent

DO YOU HAVE QUESTIONS ABOUT THE STUDY OR PARTICIPATION?

You can email any question to koronabarn@fhi.no

You will also find information about the study on the National Institute of Public Health's website: <https://www.fhi.no/studier/koronabarn>

If you have questions about privacy and data security, you can contact the data protection officer at the National Institute of Public Health by e-mail: personvernombud@fhi.no. The Norwegian Data Protection Authority can also be contacted by using the e-mail address postkasse@datatilsynet.no.

I AGREE THAT MY CHILD CAN PARTICIPATE IN THE PROJECT AND THAT MY CHILD'S PERSONAL INFORMATION AND BIOLOGICAL MATERIAL IS USED AS DESCRIBED ABOVE

As the guardian of _____ (Full name child), we agree that she/he can participate in the project.

Child's personal identification number (11 digits): _____

Both parents must consent for the child to be able to participate

Check if you have sole parental responsibility

Place and date	
Signature parent 1	
Name parent 1 (block letters)	

Place and date	
Signature parent 2	
Name parent 2 (block letters)	