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

SHORT DECRIPTION 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, during the follow-up period of the 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. In addition, we will ask you to report if have symptoms daily.

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 you 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 kindergartens 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 hygiene measures. Understanding more about children's role in the spread of the virus is important for recommendations, measures and infection control in kindergartens and schools.

The project will investigate:

- How many people are infected with coronavirus at school / kindergartens, 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 people 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 at the kindergartens or primary school (grades 1-7) you work at. We ask you to participate in this study as you may be exposed at your work.

WHAT DOES IT MEAN TO PARTICIPATE IN THE STUDY?

All participants in the study participate 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 normal follow-up you receive from the health service.

If you agree to participate in the study, we will ask you to partake for up to 10 days (you will be informed about the precise duration). We will ask you to complete a short questionnaire on the first day (day 0) and again on the last day of the study. Here you will be asked to fill in some general information about yourself and your health, including any symptoms you had. The questionnaires take 5-10 minutes to answer. In addition, we will ask you to keep a daily symptom diary during the follow-up period (up to 10 days, <5 minutes daily). Data collection is preferably done electronically through a secure solution where you log in with BankID. 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 specific e-mail address for this study and get a quick answer.

You will be asked to provide a saliva sample at the beginning (as soon as possible) and the end of the study. The sample is taken at home by spitting in a tube 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 you are in quarantine. If you are not in quarantine, you can choose whether you want to deliver the sample at the kindergartens or school at a specific time or if you prefer it to be picked up at home.

In case of illness

If you become 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 you are infected with coronavirus, or not. If you are infected with coronavirus during the study period or later, you will receive the same treatment and follow-up as other patients, independent of this study.

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 by the municipal health service, and will not influence the measures recommended by the municipal health service.

By participating in this study, you will help 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?

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 you 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 your information will be treated confidentially and in accordance with applicable privacy laws.

Your 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 your test results in 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 your samples and information, 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 personal information. Researchers will only have access to deidentified data. The project manager is responsible for ensuring that your information 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.

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

You can complain about the processing of your 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 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 TO PARTICIPATE IN THE PROJECT AND THAT MY PERSONAL INFORMATION AND BIOLOGICAL MATERIAL CAN BE USED AS DESCRIBED ABOVE

Place and date	
Signature participant	
Name participant (block letters)	