

 Federal Ministry  
Republic of Austria  
Education, Science  
and Research

## Information on participation and declaration of consent for school pupils and their parents for the gargle study (to determine the frequency of the novel coronavirus<sup>1</sup> among school pupils and teachers in the 2020/21 school year)

(Study to determine the prevalence<sup>2</sup> and development of the prevalence of active SARS-CoV-2 infections (COVID-19)<sup>3</sup>)

Dear school pupil, dear parents,

We would like to invite you to take part in the above study. You can also find information about this study in the folder ([https://www.bmbwf.gv.at/dam/jcr:184df324-bfb5-4a88-bbe8-9831a5994bb3/gs\\_folder.pdf](https://www.bmbwf.gv.at/dam/jcr:184df324-bfb5-4a88-bbe8-9831a5994bb3/gs_folder.pdf).) (in German).

Additional information for your parents: You can also find information about this study online at <https://www.bmbwf.gv.at/Themen/schule/beratung/corona/gs.html> (in German).

**Your participation in this study is voluntary. You can withdraw from the study at any time without giving a reason. If you decide not to take part or if you leave the study early, there will be no negative consequences for you.**

An ethics committee (a group of independent experts that examines medical research projects) has reviewed and approved the study and this information on participation and declaration of consent.

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<sup>1</sup> Coronaviruses are viruses that can cause respiratory and other infections, and include the novel coronavirus SARS-CoV-2

<sup>2</sup> Prevalence: frequency of a disease in a particular group at a particular time

<sup>3</sup> SARS-CoV-2 and COVID-19: SARS-Coronavirus-2, also referred to as COVID-19, is the name of the novel coronavirus which emerged in 2019 and the illness caused by this virus.

## **1. What is the purpose of this study?**

The aim of this study is to determine the frequency of the novel (new) coronavirus among school pupils and teachers in the 2020/21 school year.

The time frame for the research project is the 2020/21 school year.

Samples are collected by asking study participants to gargle with a harmless liquid, a very gentle way of detecting whether someone is infected with the novel coronavirus SARS-CoV-2. The gargle samples obtained are tested for the novel coronavirus using RT-qPCR (this is a very accurate laboratory method). Leftover material from the samples is kept for further special virus tests.

## **2. How will the research project be conducted?**

This study will be carried out at your school and at other schools all over Austria throughout the 2020/21 school year. Overall, about 12,000-14,000 school pupils and around 1,200 teachers will take part in each round of tests. Testing will be carried out at intervals of three to five weeks and is scheduled to be conducted 10 times over the entire study period.

The study involves the following activities:

You will be tested a total of 10 times at intervals of three to five weeks. The test requires you to gargle with a small amount (10 ml, about two teaspoons) of salt water solution. On the test days, you should not have eaten, cleaned your teeth or gargled (for practice) for at least one hour before the test. You should gargle for one minute and then spit everything into a sample tube. This will be supervised by the school doctor or study staff and will preferably take place outdoors or in a well-ventilated room at a distance from other people. The gargle sample and your data will be used in such a way that only the study team, following a specific procedure approved by the ethics committee, can link you to the gargle sample. Samples must be evaluated in this way in order to protect your personal data while at the same time enabling samples to be linked to individuals if the novel coronavirus is detected in the gargle sample. The test will require about five minutes of your time on the test days and around two hours overall for the group of study participants at your school. The samples will be taken in the first two hours of school. As soon as you have gargled, you may have something to eat.

Additional information for your parents: The gargle sample and data will be evaluated in a way that only allows your child to be identified indirectly (“pseudonymised”). This means that only the study team, following a specific procedure approved by the ethics committee, can link data

and individuals to the gargle sample. In accordance with the Epidemics Act, any gargle sample that tests positive for SARS-CoV-2 must be linked to personal data.

### **3. What happens if a test is positive, in other words if a gargle sample indicates that I am infected with the coronavirus?**

If your gargle sample indicates that you are infected with the novel coronavirus, the local health authorities will be notified due to the requirements of the Epidemics Act. Furthermore, your parents, you yourself and also your school will be notified of this result. These notifications will be sent automatically to the contact details provided by you or your parents (email and/or text message). Further measures will be determined by the local health authorities.

You and your parents will of course also be notified if your test is negative.

### **4. What are the benefits of taking part in the observational study?**

The test can indicate that you are infected with the novel coronavirus (SARS-CoV-2) even if you do not yet have any symptoms. This has the advantage that school pupils and also teachers infected with the novel coronavirus are notified and can self-isolate at home to protect others while they are infectious. This can benefit other pupils at the school and also teachers. All other school pupils and teachers in Austria and ultimately also worldwide may potentially benefit from the findings of the study.

In addition, the study will provide an up-to-date overview of infections at Austrian schools, allowing the role of children in the spread of the novel coronavirus to be better understood. Moreover, these findings can provide policy-makers with knowledge to help them adapt the protective measures at schools according to current infection levels.

Additional information for your parents: There are no costs associated with taking part in this study. Conversely, your child will not receive any payment for participating in the study.

### **5. Are there any risks, complications or side effects?**

No. Since gargling is generally a harmless activity, there are no risks. However, you should be aware that if you test positive, the local health authorities must be notified. They will then decide what action to take.

The method of obtaining gargle samples used in the study has already been tested on thousands of school pupils and many adults, and has proven to be reliable and safe. Nevertheless, it is possible that a test may be negative even though someone is infected with the novel coronavirus (e.g. in the first few days after becoming infected). You must therefore continue to comply with social distancing and hygiene measures even if the gargle test did not show that you have the virus.

## **6. How will the data collected in this observational study be used?**

Your data is protected by detailed safeguards (the General Data Protection Regulation (GDPR)).

Your school enters your personal data (name, date of birth, gender, social insurance number, address, email address, phone number) in a computer form (online form), which is set up by Novid20 (a company that will process your data in accordance with special protective measures), and confirms that your parents have signed this declaration of consent and privacy statement.

The data is stored on a computer (server) at the Austrian Federal Computing Center (BRZ), where the security of your data is guaranteed.

Novid20 uses an electronic number for you and links it to your personal sample via an appropriate computer program (software). During the test, the school doctor enters the reference number for your personal sample into Novid20's online form by means of a tablet specially used for these tests and a hand-held scanner.

The sample tube containing your gargle sample is put in a safety container and sent to a laboratory at one of the universities – in Vienna, Graz, Innsbruck or Linz – by a specialist company. At the university, your sample is analysed in a partially automated test line.

The laboratory sends an automatic report to the Novid20 database, in which all test results are stored. From there, the data is forwarded automatically to the health authority if necessary.

At the same time, your parents and you yourself will be notified by text message and/or email if you test positive. Negative test results are also sent electronically.

Your school will also be notified about positive tests.

As soon as Novid20 has forwarded the test results, the data is automatically deleted from the database.

The Federal Ministry (BMBWF) will receive evaluated data without any personal reference so that it can react to changes in the infection rate at an early stage. It will set up a dashboard on which the status of new coronavirus infections (COVID-19 infections) in Austrian schools is displayed and made public.

## **7. Opportunity to discuss further questions**

If you have any further questions about this study, the study doctor and his/her colleagues at your school will be happy to answer them.

## **8. Data protection, controller and data protection officers**

Additional information for your parents: Data about your child will be collected and processed as part of this clinical study. During the study, pseudonymised personal data will be collected; this is data in which all information that can be directly traced to a specific person is either removed, replaced by a code (e.g. a number) or made unrecognisable (in the case of images, for example). However, despite compliance with these measures it cannot be completely ruled out that individuals may be re-identified unlawfully.

The school, study doctor and other study centre staff have access to the data that can be used to directly identify your child (name, date of birth, etc.). In addition, authorised individuals at the participating universities and the BMBWF, who are sworn to secrecy, representatives of health authorities in Austria and/or abroad, and the competent ethics committees may inspect this data provided that this is necessary and/or stipulated in order to check that the clinical study is being properly conducted. Everyone who has access to this data will be subject to the applicable national data protection regulations and/or the EU General Data Protection Regulation (GDPR) when handling the data.

The code that enables the pseudonymised data to be attributed to your child will be kept only at the study centre.

Only the pseudonymised or anonymised data will be used for any publications.

Your consent provides the legal basis for the processing of personal data. You can withdraw your consent to the collection and processing of your child's data at any time without giving a reason. After you have withdrawn your consent, no further data about your child will be collected. However, the data that was collected before your consent was withdrawn may continue to be processed during this clinical study.

Under the GDPR, you are generally entitled to the rights of access, rectification, erasure, restriction of processing, data portability and objection provided that this does not make impossible or seriously impair the objectives of the clinical study and provided that it does not conflict with other legal regulations.

The clinical study is expected to take about one year. The length of time for which your child's data will be stored beyond the end or termination of the clinical study is regulated by legislation.

If you have any questions about the handling of your child's data in this clinical study, please contact your school, which will be able to help you.

The controller responsible for processing personal data under the GDPR in connection with the implementation of this study is the **Federal Minister for Education, Science and Research**.

**Contact:**

Federal Ministry of Education, Science and Research  
Minoritenplatz 5  
1010 Vienna  
T +43 1 53120 0  
F +43 1 53120 3099

The **data protection officers** at the Central Office of the Federal Ministry of Education, Science and Research are:

- Thomas Menzel (education)
- Lothar Hahn (science and research).

A list of the data protection officers is available here (in German):

[https://www.bmbwf.gv.at/Themen/schule/schulrecht/ds/kontakt\\_dsb\\_schule.html](https://www.bmbwf.gv.at/Themen/schule/schulrecht/ds/kontakt_dsb_schule.html)

Data protection officers at the universities participating in the study:

dsba@univie.ac.at (Vienna), datenschutzbeauftragter@i-med.ac.at (Innsbruck),  
datenschutz@kepleruniklinikum.at (Linz), datenschutz@medunigraz.at (Graz)

## 9. Insurance

Additional information for your parents: As a participant in this clinical study, your child is covered by no-fault insurance. Insurance has been taken out for your child with Wiener Städtische (WIENER STÄDTISCHE Versicherung AG Vienna Insurance Group, Schottenring 30,

1010 Vienna) under policy number 08-N811.957. The insurance documents are available for you to inspect upon request. In the event of a claim, you can contact the insurer directly and pursue your claim yourself. The insurance contract is governed by Austrian law; the insurance claims are enforceable in Austria. For further assistance, you can also contact the patient advocacy service (Patientenanwaltschaft), patient representative body (Patientenvertretung) or patient and care ombudsman (PatientInnen- und Pflegeombudsschaft) in your particular federal state.

## **10. Withdrawal of consent and complaints procedure**

You can end your participation in the study without giving a reason.

Additional information for your parents: If you wish to withdraw your consent or request information, please contact the headteacher's office at the school. Withdrawal of consent does not affect the legality of any data processing that took place on the basis of consent given prior to its withdrawal.

You also have the right to lodge a complaint with the data protection supervisory authority. In Austria, this is the Austrian Data Protection Authority ([www.data-protection-authority.gv.at](http://www.data-protection-authority.gv.at)).

## 11. Declaration of consent

Participant's first and last name(s) in capital letters:

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Date of birth: .....

I have read and understood this information sheet, which comprises eight pages.

All my questions have been answered and I do not currently have any further questions.

Additional information for your parents: By signing and personally dating this form, I hereby freely give my consent to my child's data being recorded and forwarded to the above-named institutions as specified above. I am aware that authorised individuals at the competent authorities and participating universities may view personal data that is relevant to the study in order to check the data and verify its accuracy.

I know that I can withdraw this consent at any time and without giving a reason.

I expressly agree to the data being processed in the manner described in the "Data protection" section of this document.

I have received a copy of this information on participation and declaration of consent.

Pupil's name in capital letters:

.....

.....

Place, date and signature of child's legal guardian

*(The participant will receive a signed copy of the information on participation and declaration of consent; the original will remain at the school.)*