Information brochure for participation in medical-scientific study

The 'Coronavirus' in children

Official title:
Clinical features of COVID-19 in Pediatric Patients (COPP-study).

Preface

Dear sir/madam,

We are asking your child to participate in medical-scientific research. You are receiving this invitation because your child is ill due to the Coronavirus (COVID-19). Participation is on a voluntary basis. To participate, your permission is required.

Before you decide whether your child can participate in this study, your attending physician will provide you with an explanation and with this information brochure. Please take your time to read this information.

Do you have any questions? You can ask the researcher. You can also ask questions to an independent expert. At the end of this letter (**Appendix A**) the name and contact information will be mentioned. You can also discuss it with your partner, friends or family. General information on participating in such research can be found on the website of the Dutch government: www.rijksoverheid.nl/mensenonderzoek.

1. General information

This study has been initialised by the LUMC and is conducted by doctors and researchers in several hospitals in The Netherlands. About 250 children and/or youth are participating. The Medical Ethical Committee, METC-LLD, has deemed this study as hardly causing any strain on your child. General information on the supervision of research can be found on the following website: https://www.kindenonderzoek.nl/voor- ouders/wetenschappelijk-onderzoek

2. Why this study?

The purpose of the study is to describe the disease that is caused by the Coronavirus in children. We want to know more about how the disease effects children, what the course of the disease is, and what treatments are given to battle it. We aim to understand how the immune system in children respond to an infection with the Coronavirus. Diseases can result in physical complaints relating to how you feel. For instance, emotional and social complaints caused by the disease. We call these psycho-social symptoms. In this study we also want to investigate what psycho-social effects the disease causes in children.

3. Background of the study

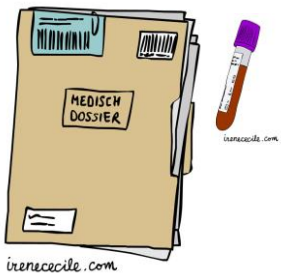
Since December 2019, a new virus has emerged, the Coronavirus, or SARS-CoV-2. This virus causes the disease COVID-19. Due to the spread of this virus, there was a large worldwide outbreak. Adults can become ill from it but so can children. It appears that children become ill less frequent and not as severe as adults. We do not yet understand why this is. We also do not yet know why some children become ill and others do not. With this study we hope to gain a better understanding of it.

4. What does it mean to participate?

Will your child participate? Participation will last for the duration of your child's stay in hospital and consists of three parts:

1. Your child will undergo the regular examinations and treatment by the hospital's physicians. We want to use information from your child's patient file for our study, such as the symptoms your child suffered from, blood levels and the medication your child received.

   Did your child reside in the Intensive Care Unit (ICU)? We will ask separate permission to retrieve the data from the check-up visits at the outpatient clinic. This would mean data about general health but also neuro-psychological tests. In other words: the working of your child's brain like intelligence and concentration.



2. During the time your child is/was admitted to hospital, blood may have been drawn. If there is any left over, we would like to utilize that as well. We will ask separate permission.

3. Finally, we ask separate permission for sending you a questionnaire. 6 weeks after the visit or admittance to the hospital we would like to send you and perhaps your child, a questionnaire. The questions are about how it went at home. And about how your child is doing (for example: happy/angry/quiet, sleep and contact with peers).

We will ask separate permission for participation in follow-up research. Do you consent? Then we may approach you to ask if your child would participate in follow- up research.

5. What is expected of your child?

We really want the study to go well. That is why we are making the following agreements with you:

- If you consent to participate in the study, we can collect the encoded data about the illness of your child
- If you consent to the filling out of a questionnaire, you agree to fill out the questionnaire we send you.

If you wish to retreat from the study, you will contact the researcher about this.

6. Possible inconveniences

Your child will experience no inconveniences during the collecting of data. No extra blood samples will be taken for this study. The filling out of the questionnaire which will be sent to your home, will take you or your child about 10-20 minutes, depending on your child's experiences.

7. Possible advantages and disadvantages

Consider the advantages and disadvantages carefully before you decide whether your child can participate in this study. Your child will have no benefit from participating in this research. Participation of your child can contribute to more knowledge about the disease COVID-19 and the treatment against it.

Possible disadvantages for participating in this study? It will cost you or your child about 10 to 20 minutes to fill out the questionnaire.

8. If you do not wish to participate or want to stop the participation in the study.

You yourself decide whether your child participates or not. Participation is voluntary. If you or your child decide not to participate, this will have no adverse consequences. The treatment of your child will continue as normal. You can always stop the participation of your child, also during the study. You do not need to give a reason why your child quits the study. You are required to inform the researcher right away. The data collected up to that point will be used in the study.

9. End of the study

Participation of your child in the study will stop when your child is discharged from the hospital and the data from questionnaires and potential follow- up research have been collected.

The study is completed if enough data has been collected about the Coronavirus and its effects on children. The study is also finished if not enough patients participate in the study (for example because there are too few new Coronavirus infections in the Netherlands). After processing all the data, the researcher will inform you about the most significant findings of the study. This will happen about a year after your child's participation.

10. Use and retaining of your data and your body material

For the benefit of this study, personal data and body material (left over blood samples) are collected from your child and are used and saved. It concerns personal data like gender, region, date of birth and information on the health of your child. All the data and the body material of your child are necessary to be able to answer the questions that are asked in this study and to be able to publish the results. We ask for your permission to use the personal data and the body material of your child.

Confidentiality of your personal data and body material

To protect the privacy of your child the personal data and body material will be coded. The name and other information that would directly identify your child are removed. Only with the key to the code can the information be traced back to your child. The key to the code is safely stored at the local research facility (LUMC). In reports and publications regarding the study, the information cannot be traced back to your child.

Access to your personal data for verification

A few people receive access to the personal data of your child at the research facility (LUMC). Also to the data which has not been coded. This is necessary for the purpose of verifying that the study has been conducted properly and is reliable. These following people can access the research results of your child for the purpose of verification of the study: An inspector who works for the LUMC. They keep the personal data of your child confidential. We ask for your permission for this.

Retention period personal data and body material.

The personal data of your child needs to be kept at the research location (LUMC) for 15 years. The body material from your child is not destroyed after use. We save it and keep it at the LUMC. It is kept for 15 years in order to, as the study advances, be able to make new determinations with it that pertain to this study. As soon as it is no longer needed, we will destroy the body material.

Retaining and use of personal data and body material for other research

The personal data of your child and the body material might be significant for other scientific research related to the Coronavirus and its effect on children. Do you agree with the use of it after this study? In that case the body material of your child will be retained for 15 years at the LUMC. Do you not agree? Then your child can still participate in the current study. You can express your preference on the consent form.

Revoke permission

You can revoke your permission at any time. The personal data of your child will not be used from that moment on. This is the case for this study and also for the retaining of data and its use in future research. The collected data up to the moment of the revoking of permission, will still be used in the study. The body material from your child will be disposed of upon the revoking of your permission. If the body material has already been utilised for measurements, this data will be used.

More information on your rights concerning the processing of personal data

You can find general information on your rights concerning the processing of personal data of you and your child on the following website: https://autoriteitpersoonsgegevens.nl/.

For questions regarding your rights, or a complaint about the processing of your personal data, you can contact the entity responsible for processing your personal data. In this case that is the LUMC. Do you have any questions or complaints about the processing of your personal data? Contact the research facility (LUMC). You can also contact the Data Protection Officer of the LUMC or the Authority Personal Data. In **appendix A** you can find all the contact information and the website of the LUMC.

Where can you find more information regarding this study?

Information regarding this study can be found at www.covidkids.nl. There is no personal data of your child on this website. On this website you can find a summary of the results of this study (in the dashboard).

11. No compensation for participation

There is no compensation for participating in this study.

12. Insurance for participants

Your child does not run any additional risks by participating in this study. Therefor there is no need for the researcher to provide an extra insurance.

13. Do you have any questions?

For questions, you can contact the researcher. For independent advice on participation in this study, you can contact the independent physician Dr Meijer. She knows a lot about the study but is not involved in it. Do you have any complaints about this study? You can discuss this with the researcher or your attending physician. Do you prefer not to? Then you can address the Complaints Officer of the LUMC. You can find all the information in **Appendix A**: contact information.

14. Signing the consent form.

After ample consideration time, you will be asked about your decision on participation of your child in the study. Children older than 16 can decide for themselves whether they want to participate. Children in the age of 12 to 15 years old, will decide together with the parents/guardians. For children under the age of 12, the parents or guardians will decide on behalf of the child.

Do you give permission? Then we ask you to fill out the accompanying consent form. With the permission you declare that you understood the information. You also consent to the participation of your child in the study. Both you and the researcher will receive a signed copy of this consent form.

Thank you for your attention.

15. Wish to learn more?

Do you wish to learn more about research in children in general? You can check www.kindenonderzoek.nl

On this website you can also find a comic for children called ‘Anne en de Groeneneuzengriep’ (Anna and the GreenNoseFlue”), about research.

Do you wish to learn more about the Coronavirus and this study? You can check www.covidkids.nl

Appendices to this information

A. Contact information

B. Consent form parents /guardians

C. Information form 12 to 15 years old

D. Information form 16 years and older

Bijlage A: contact information LUMC

Principal investigator :
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www.covidkids.nl

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Leiden University Medical Centre
c.r.meijer-boekel@lumc.nl
Phone number: +31-71-5262824

Complaints:
For complaints, please contact the Complaints Officer of the LUMC through e-mail: klachtenfunctionaris@lumc.nl. You can also call the Secretary of the Bureau of Quality and Patient Safety (071-5264646; during office hours). They will connect you with the acting Complaints Officer.

Privacy:
Data Protection Officer of the LUMC: If you have questions about the protection of your privacy you can contact the Data Protection Officer of the LUMC via infoavg@lumc.nl

More information about your rights:
Contact info LUMC
Albinusdreef 2 2333 ZA Leiden
Central phone number: (071) 526 91 11
For more information on your rights see the website of the LUMC: https://www.lumc.nl/12367/Deelnemers-wetenschappelijk-onderzoek

Appendix B: Consent form parents or guardians

The 'Coronavirus' in children

Official title: Clinical features of COVID-19 in Pediatric Patients (COPP-study).

I was asked to give permission for participation of the following person/my child to this medical scientific research:

Name participant (child): Date of birth: __ / __ / __

- I have read the information letter for the participant/parents or guardians. I was also able to ask questions. My questions were answered satisfactory. I had enough time to decide whether I want my child to participate.
- I understand that participation is voluntary. I also know that I can decide for my child not to participate, at any moment. I am not required to give a reason for that.
- I understand that for the purpose of verifying the study, a few people may receive access to all the personal data of my child. These people are mentioned in this information letter. I give my consent to allow access for these people.

I give permission to use data from the electronic patient file of my child for the benefit of this study (If you chose "No" your child won't be able to participate in this study)	☐ Yes ☐ No
I give permission to retain the personal data of my child for 15 years and to use it for future research concerning COVID-19	☐ Yes ☐ No
I give permission to retain body material of my child after this study for up to 15 years to use for follow-up study into COVID-19 as is stated in the information letter.	☐ Yes ☐ No
I give permission to retrieve information from the outpatient clinic after my child was admitted to the ICU, including the results of the neuro-psychological tests.	☐ Yes ☐ No ☐ N.A.
I give permission to send me, and perhaps my child, a questionnaire: this will happen 6 weeks after admittance /visit to the hospital	☐ Yes ☐ No
I give permission to approach my child again after this study for a follow- up study.	☐ Yes ☐ No

- My e-mail adres is: _____

Name parent/guardian**:
Signature: Date: __ / __ / __
Name parent/guardian**:

Signature: Date: __ / __ / __

I hereby declare to have fully informed the person(s) mentioned above, about the study concerned.

If, during the course of the study, information emerges that might impact the consent of the parent or guardian, I will inform him or her timely.

Name researcher (or their representative):
Signature: Date: __ / __ / __

<*if applicable*> Additional information was given by:
Name:
Function:
Signature: Date: __ / __ / __

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* Strike out what does not apply.
** If the child is younger than 16 years of age, either the parent with parental authority or the legal guardian will sign this form. Children between the ages of 12 and 15 years old who can make their own decisions (mentally competent), will also need to sign a form.

Appendix C: Information form

Information form 12 – to 15- year old

The 'Coronavirus' in children

Dear…….

Are you taking part in a medical study? Here you can read more about the study and your rights. Read this carefully because then you understand what you can decide on. It is fine to take your time to think about it before you make decision.

Your parents/guardians will also receive information about this study. You can discuss it with your parents/guardians. They will make a decision together with you.

Questions and contact

Do you have any questions? Talk about it with your parents/guardians. Or ask them to the researcher. You can write your questions down below.

You can also e-mail the researcher, Dr E.P. Buddingh, at copp@lumc.nl

Do you want to talk about the study with a Doctor who is not involved in this study? You can e-mail Dr Meijer: c.r.meijer-boekel@lumc.nl

Space to write down your questions:

Tip: take a picture of your questions, so you have them with you when you talk to the doctor/researcher

About the study

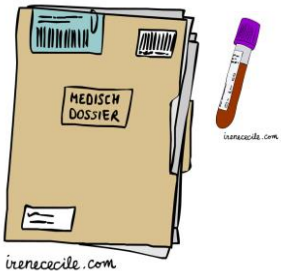
This is a study about the Coronavirus in children and is conducted by the LUMC, but also in other hospitals in The Netherlands. Around 250 children and/or youngsters are participating. The study has been verified by a special team, the Medical Ethical Committee of the LUMC (METC-LDD). They have determined that this study hardly causes any discomfort.

Why this study?

This study has been started to investigate the new illness caused by the 'Coronavirus'. This new virus

makes adults, as well as children, sick. We don't know exactly how the illness works yet. That's why we want to see how it affects you. For example, we want to know how long you are sick, what medication you get and how you got well. We also want to know how the illness effected your daily life.

How does participation work?



You don't have to do anything extra to participate in the study

Participation in the study consists of three parts:

1. The doctors will note all information about your illness in the computer. This is your digital 'patient file'. We will use the information in your patient file for our study.

   Were you admitted to the Intensive Care Unit (ICU)? Then we will ask separate permission to gain access to the information from the routine outpatient clinic visit after this ICU stay. That means the results from tests that doctors do to see how you are doing after having been admitted to the ICU. For example, your general health, ability to concentrate and an intelligence test.

2. During your stay in the hospital, maybe a blood sample has been taken. Is there any left over from that? Then we would like to use that. We will ask separate permission.

3. About 6 weeks after your visit or admittance to the hospital, we will send you and your parents a questionnaire. This is about whether you still have complaints after you got home and how you are doing in general (think mood, sleep and contact with friends).

About the treatment

It doesn't matter whether you participate in the study or not, you will receive the normal treatment.

Inconveniences

No extra blood samples will be taken for this study. The filling out of the questionnaire, which will be sent to your home, will take you about 10-20 minutes, depending on your experiences.

Important to know

The information we collect is "coded'. This means that your personal data is saved under a number and we won't know which number it is yours.

Advantages and disadvantages

1. An advantage of participating in this study is that you help to find out more about the new 'Coronavirus',
2. A disadvantage of participating is the time you need to fill out the questionnaire.

Compensation

There is no compensation for participating in this study.

Your rights

*Do you **have** to participate?*

No, it is **your choice** whether you want to participate or not. If you don't want to participate then you don't have to. Even if your parents/guardians would prefer you to participate. Do you want to participate? Then sign the consent form. You can **always quit** at a later stage if you wish to. Tell the researcher you wish to quit. You don't have to explain why you want to quit.

Revoking permission

If you wish to quit participating in the study, you inform the researcher. This is called: revoking your permission. The information that was already collected will still be used for the study.

Your personal data

For the study we need three things from you:

Personal data = information on who you are, for example your date of birth or whereabouts you live.	
Medical information = (also a sort of personal data) information about your health, for example if you are sick and if you use any medication.	
Your blood = what is left in the hospital. No extra blood sample will be taken.	

These **three things are necessary for the study**. You and your parents/guardians give permission so we can use these things. Do you want to know more about what we do exactly with your information? You can ask your parents/guardians, there is more explanation in the information letter. You can also ask the researcher.

Your decision

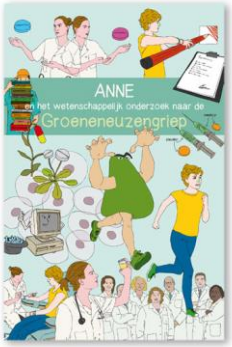
The form

Do you agree to participate? Then you sign the consent form. We also need a signature from your parents/guardians.

You can also decide if it is okay that we approach you for follow-up research. We will give you information about the new study later on. You can decide whether you want to participate or not at that time.

Find out more?

Do you want to find out more about medical research or your rights? Check www.kindenonderzoek.nl On this website you will also find the comic called ‘Anne en de Groeneneuzengriep’ (Anna and the GreenNoseFlue”) about research.



Do you wish to learn more about the Coronavirus and this study? You can check www.covidkids.nl

Consent form children aged 12 to 15

- I understood the information. I was also able to ask questions. My questions have been answered.
- I had enough time to decide if I want to participate in this study.
- I know I am not obligated to participate.
- I understand that I can quit at any time if I don't want to participate any longer.

Please tick the boxes that apply:

I give permission to use data from my electronic patient file for the benefit of this study. (If you chose "No" you won't be able to participate in this study*)*	☐ Yes ☐ No
I give permission to retain my personal data for 15 years and to use it for future research concerning COVID-19	☐ Yes ☐ No
I give permission to retain my body material after this study for up to 15 years to use for follow-up study into COVID-19 as is stated in the information letter.	☐ Yes ☐ No
I was admitted to the Intensive Care Unit (ICU) and I give permission to retrieve information from the outpatient clinic, including the results of neuro-psychological research like intelligence testing.	☐ Yes ☐ No ☐ I did not stay at the ICU
I give permission to send me a questionnaire 6 weeks after my visit/admittance to hospital.	☐ Yes ☐ No
I give permission to approach me later for follow-up research.	☐ Yes ☐ No

I agree to take part in this study.

Name participant:

Signature: Date : __ / __ / __

<u>This part is for the researcher:</u>

I hereby declare to have fully informed this participant, about the study concerned. If, during the course of the study, information emerges that might impact the consent of the participant, I will inform him or her timely.

Name researcher (or their representative):

Signature: Date: __ / __ / __

<*if applicable*> Additional information was given by:

Name:

Function:

Signature: Date: __ / __ / __

The participant will be given a complete information letter, together with a signed version of the consent form.

Appendix D: Information form

Information Form 16 years and older

The 'Coronavirus' in children

Official title:
Clinical features of COVID-19 in Pediatric Patients (COPP-study).

Preface

Dear…….

We want to ask you to participate in this study about the 'Coronavirus' (COVID-19). You received this letter because you are sick with the Coronavirpus. Participation is voluntary. Will you participate? You can always change your mind and quit (at any time). Before you decide whether you participate in this study or not, it is important to have more information. Read this information letter. You can discuss it with your parents/guardians or other people you know if you want to.

Do you have any questions after reading this letter? You can discuss them with the researcher, Dr E.P. Buddingh; she knows a lot about the study. You can also send her an e-mail at copp@lumc.nl. Do you want to discuss the study with a doctor who is not involved in the study? Send an e-mail to Dr Meijer: c.r.meijer-boekel@lumc.nl.

1. General information

This is a study about the Coronavirus in children and is conducted by the LUMC, but also in other hospitals in The Netherlands. Around 250 children and/or youngsters are participating. The study has been verified by a special team, the Medical Ethical Committee of the LUMC (METC-LDD). They have determined that this study hardly causes any discomfort.

2. Why this study?

This study deals with the new illness caused by the 'Coronavirus'. This new virus causes adults, but also children, to become ill. We don't know exactly how it works yet. That is why we want to know how it affects you. For example, we want to know how long you were sick, what medication you received and how you got well again. We also want to know how the illness affected your daily life.

3. Background of the study

Since December 2019, a new virus has emerged, the Coronavirus, or SARS-CoV-2. This virus causes the disease COVID-19. Due to the spread of this virus, there was a large worldwide outbreak. Adults can become ill from it but so can children. It appears that children become ill less frequent and not as severe as adults. We do not yet understand why this is the case. We also do not yet know why some children become ill and others do not. With this study we hope to gain a better understanding of it.

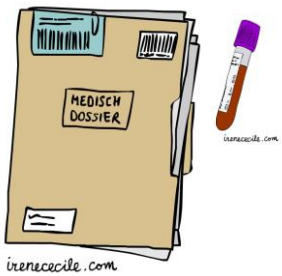
4. What does it mean to participate?

Will you participate? You don't have to do anything extra to participate in the study.

Participation in the study consists of three parts:

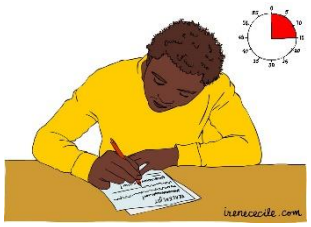
1. The doctors will note down all information about your illness on the computer. This is your digital 'patient file'. We want to use the information in your patient file for our study. For example: the symptoms you suffered, your blood levels and what medication you are given.

   Were you admitted to the Intensive Care Unit (ICU)? Then we will ask separate permission to gain access to the information from the routine outpatient clinic visit after this ICU stay. That means the results from tests that doctors do to see how you are doing after having been admitted to the ICU. For example your general health, ability to concentrate and an intelligence test.



2. During your time in the hospital, maybe a blood sample was being taken from you. Is there any left over from that? Then we would like to use that. We will ask separate permission.

3. Finally, we ask separate permission for sending you a questionnaire. 6 weeks after your visit or admittance to the hospital, we want to send you a questionnaire. This has questions about your complaints after you got home and how you are doing in general (think mood, sleep and contact with friends) The filling out of the questionnaire will take about 10 - 20 minutes.



We will ask separate permission for participation in follow-up research. Do you give permission? That means we can approach you in the future about follow-up research.

5. What is expected of you?

We really want the study to go well. That is why we are making the following agreements with you:

- If you give permission to participate in the study, we can collect the encoded data about your illness.
- If you give permission for the filling out of a questionnaire, you will fill out the questionnaire we send you.

If you wish to retreat from the study, you have to contact the researcher about this.

6. Possible inconveniences

You will experience no inconveniences during the collecting of your personal data. The filling out of the questionnaire which will be sent to your home, will take about 10-20 minutes, depending on your symptoms.

7. Possible advantages and disadvantages

Consider the advantages and disadvantages carefully before you decide whether you want to participate in this study. You yourself will have no benefit from participating in this study. But it will help us to gain more knowledge about the disease COVID-19 and the treatment against it. It will cost you about 10 to 20 minutes to fill out the questionnaire.

If you do not want to participate or want to stop participation in the study.

You yourself decide whether you participate in the study or not. Participation is voluntary. If you decide not to participate, this will have no adverse consequences. Your treatment will continue as normal.

You can always stop your participation, also during the study. You do not need to give a reason why you quit the study. You will have to inform the researcher right away. The data collected up to that point will be used in the study.

8. End of the study

Participation to the study will stop if:

- You are discharged from the hospital and the data from questionnaires and potential follow-up research have been collected.
- You wish to stop participating in the study. You can do so at any moment. Inform the researcher right away. You do not need to give a reason for quitting.

The study is completed if enough data has been collected about the Coronavirus and its effects on children. The study is also finished if not enough patients participate in the study (for example because there are too few new Coronavirus infections in the Netherlands). After processing all the data, the researcher will inform you about the most significant findings of the study. This will happen about a year after your participation.

9. What about privacy?

For the benefit of this study, the researchers will be collecting, using and saving your personal information. It concerns for instance personal data like age, gender and results of your blood tests. Your personal data and body material (blood) are necessary to be able to answer the questions that are asked in this study and to be able to publish the results. We ask permission to use your personal data and body material.

Confidentiality of your personal data and body material.

To protect your privacy, the personal data and body material will be coded. The name and other information that would identify you, are removed. Only with the key to the code can the information be led back to you. The key to the code is safely stored at the local research facility (LUMC). In reports and publications regarding the study, the information cannot be traced back to you either.

Access to your personal data for verification

A few people receive access to your personal data at the research facility (LUMC). Also to the data which has not been coded. This is necessary for the purpose of verifying that the study has been conducted properly and is reliable. These following people can access the research results for the purpose of verification of the study: An inspector who works for the LUMC. They keep your personal data confidential. We ask for your permission for this.

Retention period personal data and body material

The personal data we collect for this study needs to be kept at the research location (LUMC) for 15 years. Your body material is not destroyed after use. We save it and keep it at the LUMC. It is kept for 15 years to, as the study advances, be able to make new determinations with it that pertain to this study. As soon as it is no longer needed, we destroy the body material.

Saving and use of personal data and body material for other research

Your personal data and body material might be significant for other scientific research related to the Coronavirus and its effect on children. Do you agree with the use of it after this study? In that case, your body material will be retained for 15 years at the LUMC. Do you not agree? Then you can still participate in the current study. You can express your preference on the consent form.

Revoke permission

You can revoke your permission at any time. Your personal data will no longer be used from that moment on. This is the case for this study and also for the retaining of data and its use in future research. The collected data up to the moment of the revoking of your permission, will still be used in this study. Your body material will be disposed of upon the revoking of your permission. If the body material has already been used for measurements, this data will still be used.

More information on your rights concerning the processing of personal data

You can find general information on your rights concerning the processing of personal data on the following website: (https://autoriteitpersoonsgegevens.nl/).

For questions regarding your rights, or questions or complaints about the processing of your personal data, you can contact the entity responsible for processing your personal data. In this case that is the LUMC.

You can also contact the Data Protection Officer of the LUMC or the Authority Personal Data. In **Appendix A** you can find all the contact information and the website of the LUMC.

Where can I find more information regarding this study?

Information regarding this study can be found on www.covidkids.nl. There is no personal data visible on this website. On this website you can find a summary of the results of this study (in the dashboard).

10. Insurance for participants

You don't run any additional risks by participating in this study. Therefor there is no need for the researcher to provide extra insurance.

11. Compensation for participation

There is no compensation for participating in this study.

12. Do you have any questions?

For questions, you can contact the researcher. For independent advice on participation in this study, you can contact the independent physician Dr Meijer. She knows a lot about this study but is not involved in it.

Do you have any complaints about this study? You can discuss this with the researcher or your attending physician. Do you prefer not to? Then you can address the Complaints Officer of the LUMC. You can find all the information in **Appendix A**: Contact information

13. Your decision

The consent form

Do you agree to participate? Then you can sign the consent form. You can also choose whether we can approach you later on for follow-up research. We will give you information about the new study later on, then you can decide whether you want to participate.

Find out more?

Do you want to find out more about medical research or about your rights? Check www.kindenonderzoek.nl

On this website you will also find the comic 'Anne en de Groeneneuzengriep' (Anna and the GreenNoseFlue") about research.

Do you wish to learn more about the Coronavirus and this study? You can check www.covidkids.nl

Consent form for children of 16 years and older

The 'Coronavirus' in children

Official title: Clinical features of COVID-19 in Pediatric Patients (COPP-study).

- I have read the information letter for children of 16 years and older. I was also able to ask questions. My questions were answered satisfactory. I had enough time to decide whether I want to participate.
- I understand that participation is voluntary. I also know that I can decide at any moment to revoke my permission. I am not required to give a reason for that.
- I understand that for the purpose of verifying the study, a few people may receive access to my personal data. These people are mentioned in this information letter. I give my consent to allow access for these people.

I give permission to use data from my electronic patient file for the benefit of this study (In case of a negative answer you won't be able to take part in this study)	☐ Yes ☐ No
I give permission to retain my body material after this study for up to 15 years to use for follow-up study into COVID-19 as is stated in the information letter.	☐ Yes ☐ No
I give permission to retrieve information from the outpatient clinic after I was admitted to the ICU, including the results of the neuro-psychological tests.	☐ Yes ☐ No ☐ N. A.
I give permission to send me, and perhaps my parents/guardians, a questionnaire: this will happen 6 weeks after my admittance /visit to the hospital.	☐ Yes ☐ No
I give permission to retain my personal data for 15 years and to use it for future research concerning COVID-19	☐ Yes ☐ No
I give permission to approach me again after this study for a follow- up study.	☐ Yes ☐ No

I agree to participate in this study.

My e-mail address is: _____

Name participant:

Signature: Date : __ / __ / __

This part is for the researcher:
I hereby declare to have fully informed the participant mentioned above, about the study concerned. If, during the course of the study, information emerges that might impact the consent of the participant, I will inform him or her timely.

Name researcher (or their representative):
Signature: Date: __ / __ / __

<<if applicable>> Additional information was given by:
Name:
Function:
Signature: Date: __/__ /__

The participant will be given a complete information letter, together with a signed version of the consent form.