**REMAP-CAP**

**Video Consent Form**

**For parents/guardians/caregivers of children aged 0 to 15 years old**

**with capacity or now recovered capacity**

**Consent video**

We are inviting people who have been admitted to hospital with a respiratory tract infection (an infection that affects the nose, throat, airways or lungs) such as pneumonia to participate in our research study. This can be caused by bacteria or viruses like flu (influenza). We have generated a video which provides information about the study, the treatments we are using, and risks and benefits of taking part. Once you have watched the video and are happy to continue, please review and sign this consent form. You will also be provided with a full information sheet and privacy notice. This information is also available on our website: <https://remapcap.co.uk/patients>

You can watch the video by scanning the QR code below with your phone’s camera (or the doctor/nurse will open it on another device for you):

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**CONSENT FORM FOR PARENTS/GUARDIANS/CAREGIVERS** **OF CHILDREN**

**AGED 0 TO 15 YEARS OLD (WITH CAPACITY or now RECOVERED CAPACITY)**

**REMAP-CAP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Study ID**  |   | **Site #**  |  *(add number/name)* |
| **Name of Principal Investigator** (use CAPITALS)  |  *(add name)* |

**Please initial each box if you agree with the following:**

I, *(forename and surname)*………………………………………………………………………………………………. freely agree for my child,

*(your child’s forename and surname)*………………………………………………………………………………………………, to take part in the study.

|  |  |
| --- | --- |
|   | 1. I confirm that I have read (or had read to me) and understood this patient information sheet for the above study and have been able to ask questions which have been answered fully.   |
|   | 2. I agree to for my child take part in the following domains: **corticosteroids, influenza (flu) antivirals, or immune modulators** (*delete domain(s) that the site is not participating in)* *(strike through domain(s) if the patient does not agree)*   |
|   | 3. I understand that my child’s participation is voluntary, and we are free to withdraw consent for this at any time, without giving any reason, and without my child’s medical care or legal rights being affected.   |
|   | 4. I understand that my child’s identity will never be given to any third parties, and any information collected will remain confidential.   |
|   | 5. I agree that my child’s medical records and other personal data generated during the study may be looked at by representatives of the sponsor (UMC Utrecht), by people working on behalf of the sponsor, by representatives of regulatory authorities, ICNARC, and NHS Digital, where it is relevant to my child taking part in this research.    |
|   | 6. I agree that I will allow the researchers to decide how to use the results of this study.   |
|   | 7. I understand that I will be contacted by ICNARC or my local hospital in six months to answer questions about my child’s quality of life and wellbeing.    |
|   | 8. I understand that minimal randomisation data collected about my child will be transferred outside of the EEA where the privacy rules of the European Union do not apply. I understand that an equivalent level of protection will be ensured for my child’s data. *(Note: if this point is refused, the patient cannot be included in the trial)*  |
|   | 9. I give consent for nose swabs collected from my child to be used to support other research or in the development of a new test, medication, or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which the sponsor - UMC Utrecht - has ensured to keep secure).   |

Parent/guardian/caregiver’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                   Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent** date (dd/mmm/yyyy):        /        /           Time:       :       (24hr)

**To be completed by the impartial witness\*** *in the event the patient/parent/guardian/caregiver is competent but unable to read, or unable to sign or date the informed consent form.*

**I confirm that the patient information and informed consent have been accurately explained to the patient/parent/guardian/caregiver, the informed consent has been apparently understood by the patient/parent/guardian/caregiver, and the patient/parent/guardian/caregiver has voluntarily agreed to consent to participate in the study.**

Impartial witness’ name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *\*An impartial witness is independent of the study, who cannot be unfairly influenced by people involved with the study (e.g., an independent nurse or a patient visitor)*

 Date (dd/mmm/yyyy):        /        /                                          Time:       :         (24hr)

**To be completed by the delegated site staff obtaining consent**

I hereby declare that I have provided complete and accurate information about the study, and I have answered all questions.

If new information becomes known during the study that could affect the consent for participation, I will inform the patient/parent/guardian/caregiver in good time.

Investigator name (or delegate): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date (dd/mmm/yyyy):        /        /



**ASSENT FORM FOR CHILDREN WHO ARE 0-15 YEARS OLD**

 **(to be completed by the child and their parent/guardian/caregiver)**

**REMAP-CAP**

**Child or young person (or if unable, parent on their behalf) to circle all they agree with:**

|  |  |
| --- | --- |
| Do you understand what this study is about?   | Yes/No  |
| Have you asked all the questions you want?   | Yes/No  |
| Do you understand the answers that were given to your questions?   | Yes/No  |
| Are you happy to take part?   | Yes/No  |

If any answers are ‘no’ or you don’t want to take part, do not write your name below.

 If you do want to take part, you can write your name below:

 Your name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Date (day/month/year): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

The doctor or nurse who explained this study to you needs to sign too:

 Print name: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Sign: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 Date (dd/mmm/yyyy): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Thank you for your help.

*1 original copy for ISF; 1 copy for participant; 1 copy for hospital notes.*

*To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented, and stored in double sided format*