**REMAP-CAP**

*If in England/Wales*/*Northern Ireland*

**Personal Legal Representative – Video Consent Form**

*If in Scotland*

**Nearest Relative/Guardian/Welfare Attorney – Video Consent Form**

**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) and COVID-19. 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):

****


**CONSENT FORM FOR PATIENTS UNABLE TO GIVE CONSENT THEMSELVES**

 **Personal Legal Representative** *(if in England/Wales/Northern Ireland)*

**Nearest Relative/Guardian/Welfare Attorney** *(if in Scotland)*

**REMAP-CAP**

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

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

I, *(forename and surname)*………………………………………………………………………………………………, consent for my relative/friend/other to take part in the study.

|  |  |
| --- | --- |
|  | 1. I confirm that I have watched (or listened to) and understood the consent video and have read/received a copy of the appropriate information sheet for the above study and have been able to ask questions which have been answered fully. |
|  | 2. I give consent for my relative/friend/other to participate in the following domains: **antibiotics, macrolides, corticosteroids, influenza (flu) antivirals, immune modulators, or immunoglobulin therapy***(delete domain(s) that the site is not participating in)**(strikethrough domain(s) if the representative does not agree)* |
|  | 3. I understand that I am giving this consent based on what I believe my relative/friend/other’s wishes would be. In my opinion they would be willing to participate.   |
|  | 4. I understand that my relative/friend/other's identity will never be given to any third parties, and any information collected will remain confidential. |
|  | 5. I understand that my relative/friend/other’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, and by representatives of regulatory authorities, ICNARC, and NHS Digital, where it is relevant to their taking part in this research.  |
|  | 6. I consent that I believe my relative/friend/other will allow the researchers to decide how to use the results of this study. |
|  | 7. I understand that my relative/friend/other will be contacted by ICNARC or the local hospital in six months to answer questions about their quality of life and wellbeing.  |
|  | 8. I understand that minimal randomisation data collected about my relative/friend/other 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 their data.*(Note: if this point is refused, the patient cannot be included in the trial)* |
|  | 9. I understand that once my relative/friend/other regains capacity, this consent form no longer has merit and will be superseded by my relative/friend/other’s informed consent. |
|  | 10. I give consent for blood samples/nose swabs collected from my relative/friend/other 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). |

 Personal Legal Representative’s name

(*If in England/Wales/Northern Ireland*)

Nearest Relative/Guardian/

Welfare Attorney’s name (*if in Scotland*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**To be completed by the impartial witness\*** *in the event the personal legal representative (England/Wales/Northern Ireland) or Nearest Relative/Guardian/Welfare Attorney (Scotland) 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 personal legal representative *(England/Wales/Northern Ireland)* or Nearest Relative/Guardian/Welfare Attorney *(Scotland)*, the informed consent has been apparently understood by them, and they have voluntarily agreed to consent for the patient 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 personal legal representative *(England/Wales/Northern Ireland)* or Nearest Relative/Guardian/Welfare Attorney *(Scotland)* in good time.

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

Date (dd/mmm/yyyy):       /       /

*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*