**REMAP-CAP**

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

**Personal Legal Representative - Information Summary and Consent Form**

*If in Scotland*

**Nearest Relative/Guardian/Welfare Attorney – Information Summary and Consent Form**

***To be used for patients who are NOT capable of giving their consent.***

**What is it?**

A respiratory tract infection (an infection that affects the nose, throat, airways or lungs) such as Pneumonia can be caused by bacteria or viruses like flu (influenza) and COVID-19. When a patient becomes ill because of this, there are several types of treatments that may help them recover. REMAP-CAP is a clinical trial designed to understand the best treatment options for this type of infection.

**What are the study treatments?**

We are testing various treatments both on the ward and in the ICU.

Antibiotics:

We are not taking part at this hospital

The following are being compared (only those in bold): ceftriaxone and a macrolide, piperacillin-tazobactam and a macrolide, amoxicillin-clavulanate and a macrolide, moxifloxacin or levofloxacin.

Macrolides:   
We are not taking part at this hospital

The following are being compared (only those in bold): azithromycin, clarithromycin, or roxithromycin.

Corticosteroids:

We are not taking part at this hospital

The following are being compared (only those in bold): dexamethasone (for up to 10 days), hydrocortisone (if your relative/friend/other has septic shock, which is when their infection is causing organ failure), or no corticosteroids.

Influenza (flu) antivirals:

We are not taking part at this hospital

The following are being compared (only those in bold): oseltamivir (a short or long course), baloxavir, the combination of both oseltamivir and baloxavir, or no antiviral.

Immune modulators:

We are not taking part at this hospital

The following are being compared (only those in bold): baricitinib, tocilizumab, or no immune modulator.

Immunoglobulin therapy:

We are not taking part at this hospital

We are comparing convalescent plasma with no convalescent plasma treatment

*(please bolden treatment(s) that the site IS participating in, and/or tick as appropriate, in the text above)*

Your relative/friend/other’s doctor will know which set of treatments are suited to your relative/friend/other in the study. We may use a combination of these treatments because it is important to understand which combinations are best. Many of these treatment comparisons also include a ‘no additional treatment’ option, so your relative/friend/other may not receive any of these treatments, but your relative/friend/other will still receive the standard of care at their hospital.

**Will all treatments be offered to the patient?**

Your hospital can select which treatments they would like to participate in. The person you are consenting for will be randomised to all treatment options available at this hospital. REMAP-CAP is a randomised trial which ensures that balanced groups are compared, and this allows us to understand which way is best to treat patients. The study looks at the results on an ongoing basis and uses these results to make some changes to the randomisation process with the aim of increasing the chances of getting treatments that are looking better for new patients in the study, but there is no guarantee.

As this is an emergency situation, treatment should be started as quickly as possible, and you will be updated by the clinical team as soon as it is practical. This summary can be used to provide some simple information. An information sheet with the full details is also available from the doctor, nurse, or researcher should you wish to read it. All conversations will be documented in the medical records of the person you are consenting for. If you decide that the person you are consenting for would not want to take part, your choice will be respected. No further information will be collected about them, and this will not affect the standard of care that they receive.

**Informational video**

Please feel free to watch a short video that summarises the study by scanning the QR code below with your phone’s camera:

**A qr code on a white background

Description automatically generated**

A logo with blue lungs and text

Description automatically generated

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

***Note to the Investigator****: This consent form should be used in the event the patient is incapacitated and is UNABLE to give verbal or written consent for this study.*

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

I have been asked to give consent for the study participation of the following person:

Patient’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

My relationship to the patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I confirm that I have the legal right to give consent for study participation on behalf of the patient.

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

|  |  |
| --- | --- |
|  | 1. I confirm that I have read (or had read to me) and understood this document 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 domains 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*