**REMAP-CAP**

**Professional Legal Representative – Information Summary and Consent Form for children aged 0 to 17 years old**

***To be used for patients who are NOT capable of giving their consent, AND ONLY IF there is also no parent/guardian/caregiver who can be asked to give consent on behalf of the patient.***

**What is it?**

REMAP-CAP is a clinical trial designed to understand the best treatment options for a respiratory tract infection such as pneumonia. When a patient becomes ill because of these conditions, there are several types of drugs that may help them recover. REMAP-CAP has been designed to test different types of drugs and the various combinations of these treatments.

**What are the treatments?**

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

**Corticosteroids**: dexamethasone (for up to 10 days) or no corticosteroids.

**Influenza (flu) antivirals**: oseltamivir (a short or long course), baloxavir, the combination of both oseltamivir and baloxavir, or no antiviral.

**Immune modulators**: baricitinib, tocilizumab, or no immune modulator.

*(Please delete domain(s) and/or treatment(s) that the site is not participating in)*

Patients in this study may be treated with any combination of these drugs because it is important to understand what the best combination of treatments is. Many of the treatment options listed above also include a ‘no treatment’ option, so the patient may not receive any of these treatments if you decide that they should participate.

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

Your hospital can select which treatments they would like to participate in. The patient will be randomised to all treatment options available at site. 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 (it has an ‘adaptive’ design), but there is no guarantee.

**Current findings**

Due to our ‘adaptive’ model we can evaluate treatment options quickly and have so far discovered that the use of hydrocortisone reduces the need for organ support in patients with COVID-19. We also demonstrated that the immune modulators tocilizumab and sarilumab both improve outcomes in critically ill patient with COVID-19. These interventions are now Standard of Care in ICUs in the UK.

As this is an emergency situation, treatment should be started as quickly as possible and may need to be started before we can speak to the patient (child) and/or their parent/guardian/caregiver to seek formal consent. As soon as it is practical, the parent/guardian/caregiver and patient should be informed. This brief summary can be used to provide some simple information. Information sheets with the full details are also available. Please document all conversations with the parent/guardian/caregiver and patient, in the patient’s notes. If the patient or parent/guardian/caregiver do not want the patient to take part, that is their choice and should be respected, and it will not affect the standard of care that the patient receives. Please document their wishes in the notes so that they do not get included in an emergency situation.

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

**Professional Legal Representative children aged 0 to 17 years old**

**REMAP-CAP**

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

***Note to the Investigator****: This consent form should be used in the event the patient is incapacitated and is UNABLE to give oral or written consent for this study* ***AND*** *if you are also unable to speak to the patient’s parent/guardian/caregiver/relative/friend/other.*

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

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 this patient to take part in the study.

|  |  |
| --- | --- |
|  | 1. I confirm that I have read 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 this patient to participate in the following domains: **corticosteroids, influenza (flu) antivirals, or immune modulators**  *(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 this patient’s (and/or their parent’s/guardian’s/caregiver’s) wishes would be. In my opinion they would be willing to participate. |
|  | 4. I understand that this patient’s identity will never be given to any third parties, and any information collected will remain confidential. |
|  | 5. I understand that this patient’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 this patient (and/or their parent/guardian/caregiver) will allow the researchers to decide how to use the results of this study. |
|  | 7. I understand that this patient (or their parent/guardian/caregiver) will be contacted by ICNARC or the local hospital in six months to answer questions about their (or their child’s) quality of life and wellbeing. |
|  | 8. I understand that minimal randomisation data collected about this patient 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 this patient regains capacity or once their parent/guardian/caregiver is reached, this consent form no longer has merit and will be superseded by the patient’s (and/or their parent’s/guardian’s/caregiver’s) informed consent. |
|  | 10. I give consent for blood samples/nose swabs collected from this patient 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). |

Professional Legal Representative’s name

(**not** listed on the study delegation log) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent** 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 professional legal representative in good time.

Investigator name (or delegate)

(listed on the study delegation log): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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*