**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**

**What is it?**

REMAP-CAP is a clinical trial designed to understand the best treatment options for COVID-19, influenza, or other 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.

The treatments for COVID-19 are: - low or a middle dose heparin, immunoglobulin therapy or no treatment.

The treatments for flu are: - oseltamivir, baloxavir, dexamethasone, hydrocortisone, tocilizumab, baricitinib or no treatment.

The treatments for other pneumonia are: - dexamethasone, hydrocortisone, antibiotics (ceftriaxone, piperacillin-tazobactam, amoxicillin-clavulanate, moxifloxacin or levofloxacin) with macrolides (azithromycin, clarithromycin, or erythromycin), or no treatment.

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 are. Many of the treatment options listed above also include a ‘no treatment’ option and so the person you are consenting for may not receive any of these treatments if you choose for them to participate.

**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 so that balanced groups are compared, and this allows us to understand which way is best to treat patients. Additionally, this study uses adaptive randomisation. This means that the chances of being assigned to any of the treatment options may change based on the study results, in favour of the most promising treatment.

**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 patients 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 you will be updated by the clinical team as soon as practical. This summary can be used to provide some simple information. Full detailed information sheets are also available. 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 does want to take part that is your choice and will be respected. This will not affect the standard of care that they receive.

**Consent Form for Participants 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** |  |
| **Patient Name** |  | | |
| **Name of Principal Investigator** |  | | |

**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 read and understand 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: - **immunoglobulin domain, influenza antiviral domain, steroid domain, immune modulation domain, antibiotic domain,** or **macrolide domain** (d*elete domains site is not participating in and strikethrough domain if representative does not agree)* |
|  | 3. I understand that I am giving this consent based on what I believe would be the person for whom I am providing consent’s wishes. In my opinion they would be willing to participate. |
|  | 4. I understand that sections of any of my relative/friend/other’s medical notes may be looked at by responsible individuals’ 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. |
|  | 5. I consent that I believe my relative/friend/other’s will not seek to restrict the use to which the results of the study may be put. |
|  | 6. I understand that my relative/friend/other will be contacted by ICNARC or the local hospital in six months to ask about their quality of life and wellbeing. |
|  | 7. I understand that minimal randomisation data collected about my relative/friend/other will be transferred outside of the EEA.  *(Note if this point is refused the patient cannot be included in the trial)* |
|  | 8. 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. |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Personal Legal Signature Date

Representative *(If in England/*

*Wales/Northern Ireland)*

Name of Nearest Relative/Guardian/

Welfare Attorney *(if in Scotland)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of staff member Signature Date

*(Listed on study delegation log)*

*If the personal legal representative (England/Wales/Northern Ireland) or Nearest Relative/Guardian/Welfare Attorney (Scotland) is* ***not able*** *to write/sign due to condition or weakness, please ensure a witness signs the section of the consent form below. The witness will be a member of the clinical team who is not part of the study team (not listed on the delegation log)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of witness Signature Date

*\*Independent of the REMAP-CAP study team*

1 copy for participant; 1 copy for Principal Investigator; 1 copy to be kept with 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