



## Person Responsible/Medical Treatment Decision Maker/Research Decision Maker Information Sheet and Consent Form

### COVID-19: Pandemic infection is either suspected or proven

**Interventional Study** - *Person Responsible/Medical Treatment Decision Maker/Research Decision Maker consenting on behalf of participant*

<b>Title</b>	<b>Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia</b>
<b>Short Title</b>	<b>REMAP-CAP</b>
<b>Protocol Number</b>	X 17-0199
<b>Project Sponsor</b>	Monash University
<b>Coordinating Principal Investigator</b>	Professor Madiha Hashmi
<b>Local Principal Investigator</b>	Dr. Ashok Kumar
<b>Location</b>	Ziauddin University

## Part 1 What does participation involve?

### 1 Introduction

As the 'Person Responsible'/'Medical Treatment Decision Maker' for the participant, you are invited to consider the participant's participation in this research project. This is because they have a condition called pneumonia which is an infection of the lungs caused by a new Coronavirus. The disease is called COVID-19.

Most patients with pneumonia due to COVID-19 who are being treated in an Intensive Care Unit (ICU) will receive many different treatments, as many as 20 or 30 different treatments, that act together to treat both the infection and its effects on the body. For this research project:

- Several treatments may be tested, at the same time, in the same patient.
- We will tell you if the participant is not eligible for all options that are tested in the study.
- You can choose the parts of the study the participant participates in.
- Because COVID-19 is a new disease, doctors don't already know which treatments work best and the side effects of some treatment options.
- The study looks at its results as it goes and uses the results so that new patients in the study have a better chance of getting better treatments.
- The different treatment options are tested to tell which are the best. The study only tests options where it is not known which treatments are best.

Medications, drugs and devices have to be approved for use by the government. The drugs used in this study are approved for treating other diseases however they are not approved for

the treatment of pneumonia caused by COVID-19. This study will be conducted with the approval of the Drug Regulatory Authority of Pakistan (DRAP). This allows the investigators to use these products for medical research purposes once the research has been assessed and approved by an authorised Ethics Review Committee (ERC).

## 2 About this Information Sheet and Consent Form

This Information Sheet/Consent Form tells you about the research project. It explains the treatments involved and how it is determined which treatments the participant will receive. Knowing what is involved will help you decide if you want the participant to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the participant can take part, you might want to talk about it with a relative, friend or the participant's local doctor.

Participation in this research is voluntary. If you don't wish for the participant to take part, the participant doesn't have to. They will receive the best possible care whether or not they take part.

If you decide you want the participant to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to the participant taking part in the research project
- Consent to the participant having the tests and treatments that are described, so long as their doctor thinks they are appropriate
- Consent to the use of the participant's personal and health information as described.

You will be given a copy of this Information and Consent Form to keep.

## 3 What is the purpose of this research?

The purpose of this research is to study drugs that might improve survival and recovery for patients with pneumonia caused by COVID-19. This study might not directly benefit the participant but may lead to the development of treatment options for patients like them. As explained later, the trial uses a technique to use information from participants already enrolled in the trial to increase the likelihood that they will receive treatments that are effective.

We understand that the participant being a patient with pneumonia can be very concerning. The doctors and the team associated with this research project are dedicated to giving the participant the best possible treatments.

In general, patients with pneumonia receive many different treatment options as part of standard care but doctors aren't always sure which of these treatments are best.

In this project, different aspects of treatment are being evaluated:

- 1. Use of influenza antiviral medications.** When a participant has pneumonia caused by an influenza virus, some doctors will prescribe a drug called Oseltamivir, an antiviral medication. Some doctors do not routinely use Oseltamivir, and those who do may prescribe it for different lengths of time. At this site, this project evaluates:

Oseltamivir for five days

Oseltamivir for ten days

The doctors in this ICU have selected these options because they do not know which of them is best, but believe that all of these options are safe and effective. Therefore, these options are different types of "standard care". The participant will only receive these treatments if they have pneumonia that is believed or known to be caused by Influenza.

#### **4 How is this study being paid for?**

This research has been sponsored by Monash University.

No money is paid directly to individual researchers or doctors.

#### **5 What does participation in this research involve?**

This research project is called a Platform Trial. The design means that the researchers analyse the results as the trial occurs rather than just at the end of the trial. The longer the study is going on for the more information the researchers can work with. This means that people who participate in the study once it has been running for a while have a better chance of getting a better treatment.

During the study the participant's doctor will know what treatment they are getting at all times (that is they are not 'blinded'). This means the doctor can change the participant's treatment if they need to.

The participant's doctor has already decided that all treatment options that the participant might receive in the study are appropriate and suitable for them.

There are no additional costs from being in the research. All medication, tests and medical care required as part of the research project will be provided to the participant free of charge.

#### **6 What does the participant have to do?**

##### **In hospital**

Some of the treatments the participant receives will be determined by the study but all other treatments and tests will be those that the participant needed anyway. No additional tests, examinations or samples of blood are required for this research study. Members of the research team will collect information about the participant from their medical record and put this information in a database so it can be analysed.

##### **Following discharge from hospital**

Either you or the participant will be contacted by a trained research co-ordinator by telephone at approximately 3 months after the participant started in the study. This phone call is to determine how well the participant is recovering and should take no longer than 5 minutes.

At approximately 6 months after the participant started in the study a phone call will also be made to you or the participant to collect information about their recovery. The trained research coordinator will ask about the participant's quality of life including whether they are able to walk, look after themselves and how they are generally going. It is expected this phone call will take about no more than 10 minutes. In order for this phone call to take place, we will ask the participant to supply contact phone numbers. The questions may be mailed a few weeks before the phone call to save some time during the call.

#### **7 Other relevant information about the research project**

This study is also being conducted in Australia, New Zealand, Europe and Canada.

#### **8 Does the participant have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish for the participant to take part, the participant does not have to. If you decide that the participant can take part and later change your mind, you are free to withdraw the participant from the project at any stage.

If you do decide that the participant can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Please be assured that your decision whether the participant takes part or does not take part or takes part and then withdraws, will not affect the medical treatment or relationship with those treating the participant or their relationship with Ziauddin University.

## **9 What are the alternatives to participation?**

The participant does not have to take part in this research project to receive treatment at this hospital. If you decide the participant will not participate in this research project, their doctor will choose their treatment (but will not have access to the results of the study).

## **10 What are the possible benefits of taking part?**

We cannot guarantee that the participant will receive any benefits from being a participant in this research.

## **11 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. The risks from side effects are similar if you choose not to be in the study. The participant's doctor will know what treatment they are receiving at all times, and so the doctors will be looking out for side effects. As these are all drugs, medications and therapies that have been used in other diseases previously, the doctors and nurses who will be caring for the participant while in the ICU are trained to recognise the risks associated with them. A staff member will highlight what those potential risks are for the component for which you are may be involved. If side effects occur and the doctor thinks it is best to stop that treatment that is what will happen. There are no reported side effects of Oseltamivir.

If the participant could be pregnant or are breast feeding the study will only give treatment options that are recommended for use in these situations.

## **12 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team, in combination with a group of independent doctors and research experts (known as the Data Safety Monitoring Board) may decide how best to take this new information into account.

## **13 Can the participant have other treatments during this research project?**

Whilst the participant is participating in this research project, they may not be able to take some or all of the medications or treatments they have been taking for their condition or for other reasons. It is important to tell the participant's study doctor and the study staff about any treatments or medications the participant may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the participant's study doctor about any changes to these during the participant's participation in the research project. The participant's study doctor should also explain to you which treatments or medications need to be stopped for the time the participant is involved in the research project.

## **14 What if I withdraw the participant from this research project?**

If you decide to withdraw the participant from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing. Even if the participant stops participating in the study, the de-identified information obtained for the whole study period is critical to determining the study question. We would request that we continue to collect data on treatment received whilst in ICU and information on the participant's health status for up to 90 days from the day the participant entered the study.

## **15 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug/treatment/device being shown not to be effective
- The drug/treatment/device being shown to work and not needing further testing

## **16 What happens when the research project ends?**

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified. The study website [www.remapcap.org](http://www.remapcap.org) will provide updates on the studies progress and publications.

## **Part 2 How is the research project being conducted?**

### **17 What will happen to information about the participant?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential. Information relating to the study will be kept indefinitely. The participant's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The data collected in this study will be analysed at Monash University in Melbourne, Victoria, by members of the REMAP-CAP research team. Patients in many other countries are being included in this study and the participant's data may be shared with other members of the REMAP-CAP research team located in other countries. The data collected in this study may also be joined with data from other studies to help reach answers more quickly or with more accuracy. This includes data derived from an individual study participant but, if this occurs, no information related to your name, date of birth, or any form of address will be included in the data that are shared. The data from this study will be used to determine if treatments work and results from the study will be used to help the design of future research on COVID related treatment.

The participant's health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Monash University, the institution relevant to this Participant Information Sheet, Ziauddin University, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

All research information will be collected by the research staff at Ziauddin University from the participant's medical record. This study information will be kept in a locked filing cabinet or a password protected computer in the secure research office at Ziauddin University which is only accessible to the research staff. The research study results will be held securely at the coordinating centre.

No personal identifying data will be provided to the research team. The value of this information is that it provides additional information about episodes of ICU care and can be used to provide information about outcomes into the future. The custodian of data is the Director of this ICU and data will only be provided with their agreement.

Information about participation in this research project may be recorded in the participant's health records.

In accordance with relevant national privacy and other relevant laws, you have the right to request access to the participant's information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project and for the future research that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## **18 Complaints and Compensation**

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for the participant.

In addition, the participant may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if the participant's injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). The participant does not give up any legal rights to compensation by participating in this study.

## **19 Who is organising and funding the research?**

This research project is being conducted by the Australian and New Zealand Intensive Care Research Centre, Monash University.

Ziauddin University will receive a payment from Monash University for undertaking this research project.

No member of the research team will receive a personal financial benefit from the participant's involvement in this research project (other than their ordinary wages).

## **20 Who has reviewed the research project?**

This study has been approved by the Ethics Review Committee of Ziauddin University (ERC). Any person with concerns or complaints about the conduct of this study should contact the ERC and quote approval reference 2680920AKPUL.

## **21 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor, Dr Madiha Hashmi on 021 35862937 Ext. 4460/4461 or the following person:

### **Clinical contact person**

Name	Dr Ashok Kumar
Position	Site Principal Investigator
Email	a.kumar@zu.edu.pk

For matters relating to research at the site at which the participant is participating, the details of the local site complaints person are:

**Complaints contact person**

Name	Ethics Review Committee - Ziauddin University
Email	zu.erc@zu.edu.pk

# Consent Form – Person Responsible/ Medical Treatment Decision Maker/Research Decision Maker

## COVID-19: Pandemic infection is either suspected or proven

<b>Title</b>	<b>Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia</b>
<b>Short Title</b>	<b>REMAP-CAP</b>
<b>Protocol Number</b>	X
<b>Project Sponsor</b>	Monash University
<b>Coordinating Principal Investigator</b>	Professor Madiha Hashmi
<b>Local Principal Investigator</b>	[Insert Local Principal Investigator]
<b>Associate Investigator(s)</b>	[Insert Associate Investigator(s) if required]
<b>Location</b>	[Insert location where the research will be conducted]

### **Consent Agreement**

I am the Person Responsible/ Medical Treatment Decision Maker/ Research Decision Maker for \_\_\_\_\_ (the Participant).

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I believe that the participation of the participant in this study is not contrary to their best interests/their preferences and values and their social wellbeing.

I freely agree to the participant participating in this research project:

**Use of influenza antiviral medications**

Yes  No

I understand that I am free to withdraw the participant at any time during the research project without affecting their future health care.

I am aware of my responsibilities as the Person Responsible/ Medical Treatment Decision Maker/Research Decision Maker for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Ziauddin University concerning the participant's disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

**Declaration by Person Responsible/Medical Treatment Decision Maker/Research Decision Maker**

Name of Participant (please print) \_\_\_\_\_

Name of Person providing consent (please print) \_\_\_\_\_

Relationship of Person providing consent to Participant \_\_\_\_\_

Signature of Person providing consent \_\_\_\_\_ Date and time \_\_\_\_\_

**Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the Person Responsible/medical treatment decision maker/Research Decision Maker has understood that explanation.

Name of Study Doctor/  
Senior Researcher<sup>†</sup> (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date and time \_\_\_\_\_

<sup>†</sup> A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the participant's study treatment, the participant and I may be asked to attend follow-up visits to allow collection of information regarding the participant's health status. Alternatively, a member of the research team may request my permission to obtain access to the participant's medical records for collection of follow-up information for the purposes of research and analysis.

# Form for Withdrawal of Participation – Person Responsible / Medical Treatment Decision Maker / Research Decision Maker

## COVID-19: Pandemic infection is either suspected or proven

**Title** Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia  
**Short Title** REMAP-CAP  
**Protocol Number** X  
**Project Sponsor** Monash University  
**Coordinating Principal Investigator** Professor Madiha Hashmi  
**Local Principal Investigator** [Insert Local Principal Investigator]  
**Associate Investigator(s)** [Insert Associate Investigator(s) if required]  
**Location** [Insert location where the research will be conducted]

### Declaration by Person Responsible/Medical Treatment Decision Maker/Research Decision Maker

I wish to withdraw the participant from the following aspects of the above research project:

**Use of influenza antiviral medications**  **Withdraw**  **Continue**

I agree to the use of data that has been collected prior to withdrawal of consent:

**Yes**  **No**

I agree to the use of medical record for collection of vital status at ICU & hospital discharge:

**Yes**  **No**

I agree to the use of medical record to collect vital status at day 90 & 180:

**Yes**  **No**

I agree to be contacted at day 90 & 180:

**Yes**  **No**

I understand that such withdrawal will not affect the participant's routine treatment, relationship with those treating them or their relationship with Ziauddin University.

**Declaration by Person Responsible/Medical Treatment Decision Maker/Research Decision Maker**

Name of Participant (please print) \_\_\_\_\_

Name of Person providing withdrawal (please print) \_\_\_\_\_

Relationship of Person providing for withdrawal for Participant \_\_\_\_\_

Signature of Person providing withdrawal \_\_\_\_\_

Date and time \_\_\_\_\_

**Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

Name of Study Doctor/  
Senior Researcher (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date and time \_\_\_\_\_

<sup>†</sup> A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project. Note: All parties signing the consent section must date their own signature.