

[\*\*\*Hospital letter head\*\*\*] Local lead investigator: [\*\*\*local\_lead\*\*\*]

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections**

**INFORMATION SHEET FOR ADULT PATIENTS**

**WITH VIRAL HAEMORHAGIC FEVER INFECTION**

**04 March 2016. Version 7.2**

The International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) in collaboration with the World Health Organization (WHO) are undertaking a research study involving people with severe infections including the Viral Haemorrhagic Fever ebolavirus. This is why we have approached you and we are inviting you to take part in this study.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary and will not affect your care or treatment in any way.

**What is the study about?**

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. This research study will gain important information about viral haemorrhagic fever so we can try to find better ways to manage and treat them in the future.

**What will happen if I take part in this study?**

We will first collect information from your routine clinical records such as participant’s signs and symptoms, medications that he/she is taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalise. This will happen every day while you are in hospital.

If you agreed, samples will be collected which are in addition to what would normally be collected for your medical care.

We will ask on some days for extra blood to be collected for research analysis. This would only be taken when blood is being taken for clinical reasons, and then only with the approval of the attending clinicians. You will never have additional venesection (blood draws) taken for research while you are in isolation.

The extra blood collected will be at most 15mls (3 teaspoons) on any day.

After you have left the isolation unit you may have additional blood samples taken only for research.

We are asking for this extra blood for research to be collected within the first 24hours of admission, then every second day over the next eleven days, and then once every week for as long as you are unwell up to a maximum of 100 days. We will also invite you to go to a hospital or clinic convenient to you in 3 months and then again at 6 months to have one blood sample taken.

When any samples of blood, urine, stool or respiratory secretions are taken for your normal care, and if there is any sample leftover after the tests requested by your doctors are done, we will store what is leftover for research purposes.

**What will happen to the information and samples?**

All information about you will be kept confidential – anonymised - by those working on this study, your name will not be used in any reports about this study. The results of the study will be shared as quickly as possible with health authorities, and doctors to help them treat patients with VHF Ebolavirus.

If samples are taken we will use the blood samples to look at how the body fights the infection and how treatments given to you work in the body. We may also use the blood sample to analyse your DNA. We may compare your DNA together with DNA from many other people to try to find out what makes some people more likely to get an infection. Some of the tests may be done in different countries.

All information about you will be handled in confidence and only the people responsible for your care and for this study will know that you were a part of the study. We will review your medical records and keep limited information about you on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to you personally.

With your permission, we would also like to store your samples and use them for future ethically approved medical research. The data and samples collected during this study may be looked at by regulatory authorities, authorized individuals from University of Oxford, from the NHS Trust(s) or public health agencies.

Your GP will be informed that you are taking part in this study.

**Are there any benefits to taking part in this study?**

There is no benefit to you personally. The information gained from this study may not be available in time to affect your care. Any results available while you are in hospital will be given to your treating doctor. The information we learn may help in caring for other patients in the future.

**What are the risks of being in the study?**

If you take part in the study and only clinical data is collected from the routine medical records there is a minimum risk, all information will be used anonymously (no one will know that this belonged to you).

If agreed to collect samples, being a part of this study means that more blood samples may be taken than are needed for normal care. These samples will only be taken at the same time as regular samples to avoid extra venesection (blood draws).

If DNA testing is done it will be conducted anonymously. There is a small chance that the results could suggest a genetic condition that could affect your future health. No-one on the study team will know that such a result applies to you. In any case there is considerable uncertainty about the implications of a research DNA test result for individual health. For these reasons we would not inform you or your doctors of any results from research DNA testing.

**Who is responsible and what if something goes wrong?**

The research is organised by the University of Oxford with the support of collaborators at this hospital, none of who will benefit financially from the study. It has been reviewed and given a favourable opinion by Oxford C Research Ethics Committee (Ref 13/SC/0149).

The University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided.

[\*\*\*insert sponsor and contact details\*\*\*]

**Can I request that I be withdrawn from the study at any point?**

Yes, you can withdraw at anytime without giving a reason and without affecting your care. Any data and samples that have not already been analysed can be withdraw / destroyed anytime you or the participant request it

**What if I have any problems or would like further information about the study?**

If you would like more information about the study you can contact the Lead Investigator in your hospital [\*\*\*local\_lead\*\*\*] or telephone the study coordinator’s office on [\*\*\*phone\_number\*\*\*].