ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

INFORMATION SHEET FOR PATIENT

18th August 2014. Version 3.0

We are undertaking a research study involving people with severe [*** insert as appropriate 'respiratory infection (H5N1 or H7N9 or Mers-CoV)', or 'viral haemorrhagic fever'***], which is why we have approached you.

You are invited to take part in this study.

Before you decide 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. The decision you make 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 [*** insert as appropriate 'respiratory infections' or 'viral haemorrhagic fever infections' ***] 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 collect information and possibly samples which are in addition to what would normally be collected for your medical care.

A blood sample may be taken now, together with a swab from your throat, a swab from any infected sites/sores, a sputum sample, urine sample and a stool sample or rectal swab. If samples are to be taken, you will be told in advance which samples are required and how often sampling will occur..

We may take the same samples again over the next two weeks, every second day and then every week for as long as you are unwell up to a maximum of 100 days. We will also invite you to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken. Each sample will take less than 15mls (3 teaspoons) of blood.

If any other samples are taken from you for regular care, and if there is leftover sample after the tests requested by your doctors are done, we will store the leftover to be tested.

What will happen to the samples and information?

If samples are obtained we will use the blood samples to look at how the body fights the infection and how the treatments work in the body. We will also use the blood sample to analyse your DNA. We will examine your DNA together with DNA from many other people to try to find out what makes some people more susceptible to 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 public health agencies.

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?
Being a part of this study means that If research samples are taken, then more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or irritation when samples are taken.

When DNA testing is done, there is a small chance that the results will show a genetic condition that could affect your future health. Since the tests will be conducted anonymously, no-one on the study team will know that such a result applies to you, and in any case there is usually considerable uncertainty about the implications of any research DNA test result for individual health. For these reasons we would not attempt to identify you or inform you of any results from DNA testing.

Who is responsible and what if something goes wrong?
[***insert sponsor and contact details***]

Can I request that I be withdrawn from the study at any point?
Yes, you can withdraw at any time without giving a reason and without affecting your care. Any samples that have not already been analysed can be destroyed anytime you request it.

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

[INSTITUTIONAL LOGO]

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

INFORMED CONSENT FORM FOR PATIENT

18th August 2014. Version 3.0

- I have read (or it has been read to me) the information sheet for this study. I understand the information and have had the opportunity to ask questions for clarification.
- I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected.
- I understand that data will be collected from my medical records by study staff during the study and that this information may be looked at by authorized individuals from public health agencies. I agree that these individuals may have access to my research records.
- I understand that my information can be collected, analysed, reported and shared with others within and outside the country as part of this study. I understand that my name will not be used and I will not be identified
- I agree that my samples may be sent elsewhere in the world to be analysed.
- I agree that DNA from my blood sample will be analysed to determine whether any genetic factors have made me susceptible to severe infection.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I agree that my blood sample, including my DNA, may be used in additional research in the future, if necessary in different parts of the world, as long as appropriate ethical approval is in place.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I agree to be contacted directly by the investigators with an invitation to participate in future research studies.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑

Patient name:_____ Signature/fingerprint:_____
Date:_____

Person taking consent:_____
Signature:_____ Date:_____

Witnessed Consent

If the consenting party cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the patient in language they can understand, and that informed consent was freely given by the patient.

Witness name:_____ Signature/fingerprint:_____
Date:_____

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

INFORMATION SHEET FOR CONSULTEE

18th August 2014. Version 3.0

We are undertaking a research study involving people with severe [*** insert as appropriate 'respiratory infection (H5N1 or H7N9 or Mers-CoV)', or 'viral haemorrhagic fever'***]. We are asking you about the participation of an individual who is not able to consent for themselves, because he/she lacks the legal capacity to do so. To help decide if he/she should join the study, we would like to ask your opinion whether or not he/she would want to be involved.

Before you decide it is important for you to understand why the research is being done and what it would involve for the participant. 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. The decision you make will not affect the participant's 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 [*** insert as appropriate 'respiratory infections' or 'viral haemorrhagic fever infections' ***] 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 collect information and possibly samples which are in addition to what would normally be collected for the participant's medical care.

A blood sample may be taken now, together with a swab from the participant's throat, a swab from any infected sites/sores, a sputum sample, urine sample and a stool sample or rectal swab. If samples are to be taken, you will be told in advance which samples are required and how often sampling will occur..

We will take the same samples again over the next two weeks, every second day and then every week for as long as the participant is unwell up to a maximum of 100 days. We will also invite the participant to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken. Each sample will take less than 15mls (3 teaspoons) of blood.

If any other samples are taken from the participant for regular care, and if there is leftover sample after the tests requested by the participant's doctors are done, we will store the leftover to be tested.

What will happen to the samples and information?

If samples are obtained we will use the blood samples to look at how the body fights the infection and how the treatments work in the body. We will also use the blood sample to analyse the participant's DNA. We will examine the participant's DNA together with DNA from many other people to try to find out what makes some people more susceptible to infection. Some of the tests may be done in different countries.

All information about the participant will be handled in confidence and only the people responsible for the participant's care and for this study will know that the participant were a part of the study. We will review the participant's medical records and keep limited information about the participant on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to the participant personally. With your permission, we would also like to store the participant's samples and use them for future ethically approved medical research. The data and samples collected during this study may be looked at by public health agencies.

Are there any benefits to taking part in this study?

There is no benefit to you or the participant personally. The information gained from this study may not be available in time to affect the participant's care. Any results available while the pariticipant is 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?
Being a part of this study means that if research samples are taken, then samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or irritation when samples are taken.

When DNA testing is done, there is a small chance that the results will show a genetic condition that could affect the participant's future health. Since the tests will be conducted anonymously, no-one on the study team will know that such a result applies to the participant, and in any case there is usually considerable uncertainty about the implications of any research DNA test result for individual health. For these reasons we would not attempt to identify the participant or inform the participant of any results from DNA testing.

Who is responsible and what if something goes wrong?
[***insert sponsor and contact details***]

Can I request that I be withdrawn from the study at any point?
Yes, you or the participant can withdraw at any time without giving a reason and without affecting the participant's care. Any samples that have not already been analysed can be destroyed anytime you or the participant request it.

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

[INSTITUTIONAL LOGO]

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

DECLARATION OF UNDERSTANDING FOR CONSULTEE

18th August 2014. Version 3.0

- I have been consulted about [ ]'s participation in this research project. I have read (or it has been read to me) the information sheet for this study. I understand the information and have had the opportunity to ask questions for clarification.
- I understand that the participant's participation is voluntary and that the participant is free to withdraw from the study at any time, without giving any reason and without my medical care or rights being affected.
- I understand that data will be collected from the participant's medical records by study staff during the study and that this information may be looked at by authorized individuals from public health agencies. I agree that these individuals may have access to the participant's research records.
- I understand that the participants' information and samples can be collected, analysed, reported and shared with others outside the country elsewhere in the world. I understand that participant's name will not be used and they will not be identified.
- I understand participant's samples may be sent elsewhere in the world to be analysed.
- I understand that DNA from the participant's blood sample will be analysed to determine whether any genetic factors have made him/her susceptible to severe infection.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I understand that participant's blood sample, including my DNA, may be used in additional research in the future, if necessary in different parts of the world, as long as appropriate ethical approval is in place.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I understand for the participant to be contacted directly by the investigators with an invitation to participate in future research studies.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑

Patient name:_____ Signature/fingerprint:_____
Date:_____

Person taking consent: _____
Signature:_____ Date:_____

Witnessed Consent

If the consenting party cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the patient in language they can understand, and that informed consent was freely given by the patient.

Witness name:_____ Signature/fingerprint:_____
Date:_____

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

INFORMATION SHEET FOR PARENT / GUARDIAN

18th August 2014. Version 3.0

We are undertaking a research study involving people with severe [*** insert as appropriate 'respiratory infection (H5N1 or H7N9 or Mers-CoV)', or 'viral haemorrhagic fever'***]. We are asking you about the participation of a child who is below the legal age at which he/she can consent to participate in research, because you are the parent or legal guardian of that child (hereafter referred to as your child). Where possible, we will also give your child the opportunity to express his/her views and assent to participate.

Before you decide it is important for you to understand why the research is being done and what it would involve for your child. 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. The decision you make will not affect your child's 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 [*** insert as appropriate 'respiratory infections' or 'viral haemorrhagic fever infections' ***] 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 collect information and possibly samples which are in addition to what would normally be collected for your child's medical care.

A blood sample may will be taken now, together with a swab from your child's throat, a swab from any infected sites/sores, a sputum sample, urine sample and a stool sample or rectal swab. If samples are to be taken, you will be told in advance which samples are required and how often sampling will occur..

We will take the same samples again over the next two weeks, every second day and then every week for as long as your child is unwell up to a maximum of 100 days. We will also invite your child to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken. Each sample will take less than 15mls (3 teaspoons) of blood.

If any other samples are taken from your child for regular care, and if there is leftover sample after the tests requested by your child's doctors are done, we will store the leftover to be tested.

What will happen to the samples and information?

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

All information about your child will be handled in confidence and only the people responsible for your child's care and for this study will know that your child were a part of the study. We will review your child's medical records and keep limited information about your child on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to your child personally. With your permission, we would also like to store your child's samples and use them for future ethically approved medical research. The data and samples collected during this study may be looked at by public health agencies.

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 child's care. Any results available while your child is 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?
Being a part of this study means that If research samples are taken, then more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or irritation when samples are taken.

When DNA testing is done, there is a small chance that the results will show a genetic condition that could affect your child's future health. Since the tests will be conducted anonymously, no-one on the study team will know that such a result applies to your child, and in any case there is usually considerable uncertainty about the implications of any research DNA test result for individual health. For these reasons we would not attempt to identify your child or inform your child of any results from DNA testing.

Who is responsible and what if something goes wrong?
[***insert sponsor and contact details***]

Can I request that I be withdrawn from the study at any point?
Yes, you can withdraw at any time without giving a reason and without affecting your child's care. Any samples that have not already been analysed can be destroyed anytime you request it.

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

[INSTITUTIONAL LOGO]

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections Study

PARENT and PARENTAL AUTHORITY CONSNET FORM

18th August 2014. Version 3.0

- I have been consulted about [ ]'s participation in this research project. I have read (or it has been read to me) the information sheet for this study. I understand the information and have had the opportunity to ask questions for clarification.
- I understand that his/her participation is voluntary and that I am free to withdraw him/her from the study at any time, without giving any reason and without his/her medical care or rights being affected.
- I understand that data will be collected from his/her medical records by study staff during the study and that this information may be looked at by authorized individuals from public health agencies. I agree that these individuals may have access to his/her research records and study results.
- I understand that his/her information and samples can be collected, analysed, reported and shared with others outside the country elsewhere in the world. I understand that his/her name will not be used and will not be identified.
- I understand his/her samples may be sent elsewhere in the world to be analysed.
- I understand that DNA from his/her blood sample will be analysed to determine whether any genetic factors have made me susceptible to severe infection.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I understand that his/her blood sample, including DNA, may be used in additional research in the future, if necessary in different parts of the world, as long as appropriate ethical approval is in place.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑
- I understand that I might be contacted directly by the investigators with an invitation for him/her to participate in future research studies.
  OR IF YOU DO NOT AGREE, CHECK HERE ❑

Patient name:_____ Signature/fingerprint:_____
Date:_____

Person taking consent:_____
Signature:_____ Date:_____

Witnessed Consent

If the consenting party cannot read the form: I have no interest or involvement in this research study and I attest that the information concerning this research was accurately read and explained to the patient in language they can understand, and that informed consent was freely given by the patient.

Witness name:_____ Signature/fingerprint:_____
Date:_____