

*Patient name:*

*Patient study identifier* ([\_\_\_][\_\_\_][\_\_\_] -[\_\_\_][\_\_\_][\_\_\_][\_\_\_])

[\*\*\*Hospital letter head\*\*\*]

Local lead investigator: [\*\*\*local\_lead\*\*\*]

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

**INFORMED CONSENT FORM FOR ADULT PATIENT**

**04 March 2016. Version 7.3**

|  |  |  |
| --- | --- | --- |
|  |  | **Please initial box** |
| * I have read (or it has been read to me) the information sheet for this study dated [dd/mm/yyyy] version [ ]. 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, including medications and laboratory results by study staff during the study. I agree that these individuals may have access to my research records and their study results. |  |  |
|  |
|  |  |  |
| I understand that data collected during the study may be looked at by authorized individuals from University of Oxford, from regulatory authorities, from the NHS Trust(s), or public health agencies, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. |  |  |
|  |
|  |  |  |
| * I understand that if samples are taken laboratory results from samples collected during the study will be reported to study staff. This information may be looked at by regulatory authorities, authorized individuals from University of Oxford, from the NHS Trust(s), or public health agencies. I agree that these individuals may have access to my research records and study results.
 |  |  |
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|  |  |  |
| * I understand that my information can be collected, analysed, reported and shared with others within and outside Europe 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 my GP should be informed of my participation in this study.
 |  |  |
|  |  |  |
| 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, TICK HERE ❑ |  |  |
|  |  |  |
| I agree that my samples, including my DNA or those already taken as part of my routine care, and any samples left-over after tests requested by my doctor, 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, TICK 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, TICK HERE ❑ |  |  |

Patient name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

Person taking consent:

(Research team member or health professional trained in taking consent for this study)

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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_