

*Patient name:*

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

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

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

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (SARI)**

**CONSULTEE DECLARATION FORM**

**04 March 2016. Version 7.3**

|  |  |  |
| --- | --- | --- |
|  |  | **Please initial box** |
| 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 dated [dd/mm/yyyy] version [ ]. 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 the participant's medical care or rights being affected. |  |  |
|  |  |  |
| I understand that data will be collected from the participant's medical records including medications and laboratory results by study staff during the study. I agree that these individuals may have access to the participant's 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 the participant taking part in this research. I give permission for these individuals to have access to the participant’s 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 also looked at by authorized individuals from regulatory authorities, University of Oxford, from the NHS Trust(s), or public health agencies. I agree that these individuals may have access to the participant's research records and their study results. |  |  |
|  |
|  |  |  |
| I understand that the participant's GP should be informed that the participant is taking part in this study. |  |  |
|  |  |  |
| * I understand that the participant's information can be collected, analysed, reported and shared with others within and outside Europe as part of this study. I understand that the participant's name will not be used and they will not be identified. |  |  |
|  |  |  |
| I understand that the 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, TICK HERE ❑ |  |  |
|  |  |  |
| I understand that the participant's samples, including the participant's DNA and any samples left-over after tests requested by his/her 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 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, TICK HERE ❑ |  |  |
|  |  |  |

Name of consultee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Relationship to participant Signature Date

Person taking consent:

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

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_   
  
Contact details of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address Phone number

**Witnessed Declaration:**

***If the consultee 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:\_\_\_\_\_\_\_\_\_\_\_\_