

*Patient name:*

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

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

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

**ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections PARENT/GUARDIAN and PARENTAL AUTHORITY CONSENT FORM**

**For parents or guardians of all children and young people under 16 years old, and those aged 16 years to 18 years who are unable to give their own consent for any reason.**

**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 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 including medications and laboratory results by study staff during the study. I agree that these individuals may have access to his/her research records and 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 him/her taking part in this research. I give permission for these individuals to have access to his/her records. |  |  |
|  |
|  |  |  |
| I understand that if samples are taken laboratory results from samples collected during the study might be reported to study staff. This information may be 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 his/her research records and their study results. |  |  |
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|  |  |  |
| I understand that his/her GP should be informed that he/she is taking part in this study. |  |  |
|  |  |  |
| I understand that his/her information can be collected, analysed, reported and shared with others within and outside Europe as part of this study. I understand that his/her name will not be used and will not be identified. |  |  |
|  |  |  |
| I understand that 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 him/her susceptible to severe infection. |  |  |
| OR IF YOU DO NOT AGREE, TICK HERE ❑ |  |  |

|  |  |  |
| --- | --- | --- |
| I understand that his/her 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 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, TICK HERE ❑ |  |  |

Name of parent/guardian/person with parental authority:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Relationship to child or young person Signature Date

Person taking consent:

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

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

Contact details of participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Address Phone number

**Witness Declaration**

***If the parent/guardian/person with parental authority 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 parent or person with parental authority in their first language, that they have understood, and that the declaration was freely given by the consultee.

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Name of witness Signature Date

**ASSENT OF COMPETENT YOUNG PEOPLE**

Consistent with best practise, and when appropriate, children and young people should be invited to indicate they are willing to participate in this study (assent). Should a competent young person decline to being involved, our study protocol is that the young person’s decision should be respected.

Where a child or young person is unable to express their wishes for reasons of acute illness (or otherwise), their views should be sought and recorded at the earliest opportunity once recovered.

**Separate assent forms are available for young children (age <12 years) and young people (age 12 to 16 years)**