 

**ISARIC/WHO Severe Acute Respiratory Infection Biological Sampling Study**

**INFORMATION SHEET FOR YOUNG PEOPLE AGE 12 TO 16 YEARS OLD**

**13th May 2013. Version 2.5.0**

We are undertaking a research study involving people with severe new chest infections. We have come you to ask if you would be willing to help us because you have a chest infection.

Before deciding if you want to be involved, it is important for you to understand why this research is being done and what it would involve for you. 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

**What is the study about?**

* Infectious diseases affect millions of people around the world every year.
* New infections appear. Most cases are mild, but some people become very unwell.
* There is a lot that we do not understand about these new infections.
* By understanding why young people like you are unwell we can try to find better ways to manage and treat people in the future.

**Do I have to take part?**

* It is up to you and your parents to decide if you should be involved in helping us.
* If you don't want to be involved, then you don't have to.
* Either way, your decision will not affect your care and treatments in any way.
* **The choice is yours.**

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

We will collect information and samples that are extra to what would normally be collected for your normal care in hospital:

* a blood sample
* a throat swab (a wipe with a cotton bud) from your throat
* a swab from any sore skin
* a bit of sputum (chest spit / phlegm) sample
* a urine sample (wee)
* a stool sample (poo) or rectal (bottom) swab.

The amount of blood will be small and will depend on your weight so that we only take a safe amount. The study staff can tell you how much blood will be taken at each visit.

Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures.

We will take the same samples again over the next two weeks , every other day, .. When you are better will ask you to return to the hospital or clinic in 3 and 6 months time to give us one more blood sample.

If there are any leftovers from other samples taken for your regular care, we will store these leftovers for this research.

When you have recovered we will also ask you to return to the hospital or clinic in 3 months and 6 months to have a blood sample taken.

**What will happen to my samples?**

We will use your blood samples to look at how your body fights the infection and how the treatment given works in your body. We will also examine your DNA together with the DNA from many other people to try to find out what makes some people more likely to get severe infection. Some of the tests may be done in different countries.

**What will happen to my information?**

All information about you will be kept private and confidential. Only the people responsible for your care and for this study will know that you were involved in this study. If you agree, we will also store your samples and use them for future approved related medical research. The data and samples collected during this study may be seen and shared with public health agencies.

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

No. By helping us find out more about why you are ill, we will be able to help look after young people better in the future.

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

There is a small risk of pain or irritation when samples are taken.

 

**YOUNG PERSON (12 YEARS AND OLDER) ASSENT FORM**

**Emerging Severe Acute Respiratory Infection Observational Study**

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.

Please tick (✔) the boxes if you agree.

* I have read the leaflet about the study and understand it.
* I know I do not have to take part if I don't want to and can change my mind - the doctors and nurses will still look after me.
* I do not mind if someone doing the research looks at my medical records to see if the study is done in the right way. I know the people doing the research will keep personal things about me private.
* I agree to take part in the study.
* I agree to let someone talk to me about another study in the future, after this study ends.

Patient name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_

Person taking consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_