



Swine Flu (Novel Influenza A H1N1) Vaccine Study

Consent Form

Child's full name:..... Participant code:

If you agree with each statement please initial in each box below;

I confirm that I have read the *Information booklet Swine Flu (Novel Influenza A H1N1) Vaccine Study Version 3 dated 18th September 2009*. I have had the opportunity to consider the information, discuss the study, to ask questions and have had these answered satisfactorily.

I understand that data collected during the study may be looked at by authorised individuals from the University of Oxford, MHRA, Health Protection Agency and study monitors where it is relevant to my taking part in this research. I permit these individuals access to my research records.

I understand that I am free to withdraw my child from the study at any time, without having to give a reason for leaving and without affecting his/her medical care.

I agree to you informing my GP and Child Health Department of my child's participation in this study.

I agree to my child being examined by a study doctor as required for this study.

I agree to my child receiving two immunisations with a swine flu (novel influenza A H1N1) vaccine.

I agree to you taking and storing blood samples from my child as required for this study.

I agree that my child's medical records may be read by study investigators.

I agree that some identifiable data such as my child's first name on the diary and memory cards, will be sent to the HPA.

For children over 7 years of age:

The study has been discussed with my child and they are happy to participate.

If all of the above are initialled, meaning "yes", then please continue:

I voluntarily agree to my child taking part in this study

Please note that your child can still participate in this study whether or not you agree to the next statement:

I agree that blood from my child may be used for analysis of genetic factor related to vaccine reactions.

I agree that any remaining blood from my child may be stored and used in future research related to vaccines and infectious diseases (with the exception of the Human Immunodeficiency Virus [HIV]).

Name:.....

Relationship to Child:

Signature:..... Date:

Investigator/Study nurse's name (*please delete as appropriate*):

Signature:

