**FACTORS ASSOCIATED WITH PARENTAL OBSERVATION OF SIDE EFFECTS FOLLOWING THE CHILD FLU VACCINE**

**Information Sheet**

We would like to invite you to take part in this study. You should only take part if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve.

**What is the purpose of this research?**

Since 2012, the flu vaccine has been offered to young children. The aim of this research is to understand what parents believe about the child flu vaccine and to measure whether parents observe side-effects in their child after they have been vaccinated. We are also interested in whether the presence of side-effects affects whether a parent will want their child to be vaccinated again in the future.

One possible factor that may influence health-related behaviours such as vaccinating ones’ child, are a person’s ‘cognitive biases.’ Cognitive biases are patterns of thinking that we all have that cause different people to interpret the same information in different ways. Cognitive biases have been linked to health-related behaviours in the past, such as applying sun cream. In this study we will also test whether there is any difference in patterns of thinking between parents who do and do not detect side effects following the flu vaccine and between those who do and do not vaccinate their child again in the next flu season (2017/18).

**Who can take part?**

You can take part in the survey if you are 18 or older, speak fluent English and are the parent or legal guardian of a child born between September 1st 2011 and August 31st 2014 who is about to have the child flu vaccine.

**What will I be asked to do?**

If you decide to take part, you will be asked to complete a short questionnaire before your child is vaccinated for flu. The questionnaire will include questions about what you have read or heard about the child flu vaccine, your child’s previous experience with routine vaccinations and whether you think your child is sensitive to medicines. You will also be asked to complete a short word sorting task. You can complete this in the waiting room of your child’s GP surgery on a tablet (in case of a technical malfunction, we may ask you to complete a pen and paper version of the questionnaire), or individually online before going to your child’s GP surgery. If you wish to complete this short survey online before going to the GP surgery, rather than in the waiting room of your child’s GP surgery, please go to: https://kcliop.eu.qualtrics.com/jfe/form/SV\_1BpWMjKVI17uw8B.

Three days after your child has been vaccinated we will ask you to complete another short questionnaire as well as a short word sorting task. This questionnaire will have questions about whether you thought the flu vaccine gave your child side-effects as well as whether you intend to vaccinate your child again next year. The questionnaire will also include questions about your vaccination appointment and your views about medication in general and other aspects of modern life, as well as how you generally feel. In the word sorting task you will be asked to unscramble words in order to make meaningful sentences; there are no right or wrong answers in this task. You will reorder five out of six scrambled words to produce grammatically correct sentences. It will take approximately 30 minutes to complete both the questionnaire and word sorting task.

You will then be given the option of completing some additional questions. These questions must be completed online. If you choose to answer the questions, you will read a series of passages of text and rate a series of answers related to the passages. These passages reflect a variety of situations that are commonly experienced. These questions should take about 30 minutes to answer. If you cannot complete the questions at this time, we will email you a link so that you can complete them in your own time.

One month after your child has been vaccinated, we will ask you to complete a final short questionnaire. This will ask again about any side-effects that your child might have experienced and whether you intend to vaccinate your child again next year. If you have not already done so, we will ask you to complete the additional questions at the end of this questionnaire.

At the end of the next flu season (March 2018), we would like to know if you vaccinated your child in the 2017/18 season. In order to do this, we will have to inform your child’s GP that your child has been enrolled in this study: we will not disclose any other information to them. If we cannot confirm your child’s vaccination status from their GP, we will contact you to ask you whether or not they were vaccinated. If you are not happy for us to speak to your child’s GP, then please let the researcher know.

**Are there any benefits to taking part?**

As a thank you for taking part, we will donate £20 to one of three charities (Save the Children, the NSPCC, or Great Ormond Street Hospital) when you have completed the study. You can choose which charity we make the donation to. At the end of the study, we will send you a thank you letter and a summary of our results.

**Are there any risks associated with participation?**

There are no known significant risks associated with this study. All the content used is the type of information that people generally encounter in everyday life, for example in newspapers or on television. However, there is a small chance that you may find some of the content of the tasks unpleasant.

You have the right to decline or withdraw from the study at any time. You can also contact researchers if you feel concerned about anything. Please note you have the right to decline or withdraw from the study at any point without giving a reason.

**Confidentiality – who will know I am taking part in the study?**

All the information that we collect will be kept strictly confidential and in accordance with the UK Data Protection Act 1998. An identification number will be used to substitute your name on all personal data to ensure anonymity.

In order to access your child’s flu vaccination status for the 2017/18 flu season we will have to ask your child’s GP for their records and as a result, your child’s GP will know that you have enrolled in the study. All of your answers will be kept confidential and we will not disclose anything to your child’s GP.

**What will happen to the results of the study?**

The team from King’s College London hope to publish the results of this study in a scientific journal. If you would like to receive a copy of their final report, you can contact the lead researcher (louise.7.smith@kcl.ac.uk) for more information. The anonymous results from this survey may also be shared with other researchers who are interested in this work in the future.

**Who has funded and approved the research?**

This work is funded by King’s College London and the Economic and Social Research Council (ESRC), with additional support from the National Institute for Health Research Health Protection Research Unit in Emergency Preparedness and Response. It has been approved by the NHS Research Ethics Committee (IRAS ID: 192325, REC reference: 16/LO/1003). The study is part of a PhD project at King’s College London.

**Do I have to take part?**

No. It is up to you to decide whether to take part or not. If you decide to take part you are free to withdraw from the survey at any time.

You are free to keep a copy of this information sheet and if you do decide to take part, you can also keep a copy of the consent form.

**If I want to take part in the study, what do I do?**

If you have booked your child’s vaccination appointment, then you can register your interest with a researcher; this is useful as it is not guaranteed that the researcher will be at your child’s GP at the time of your child’s appointment. If you would like to take part, please let the researcher know that you are interested and give them your child’s vaccination appointment details. You can do this either online, or by telephone (contact details below).We will ask you for some of your details (including contact information) and details of your child’s vaccination appointment.

If you prefer, you can complete the first part of the study online rather than in the waiting room of your child’s GP surgery. You can do this by going to [insert link to study]. Doing this should take less than 10 minutes. There is one question that you will need to answer on the *same day, but before* your child’s vaccine appointment. If you choose to complete the first part of the study online, a researcher will contact you before your child’s vaccination appointment to ask you this question.

Sometimes the doctor will decide on the day of the vaccination that the child should not be vaccinated. If this happens and your child is not vaccinated, you will not be asked to take part in the study at this point.

**How can I find out about the results of the study?**

The results of the study will be published on the Emergency Preparedness and Response Health Protection Research Unit website (http://epr.hpru.nihr.ac.uk/). Alternatively, you can contact the lead researcher (Louise Smith, louise.7.smith@kcl.ac.uk) directly and she will let you know the results of the study in due course.

**Who should I contact for further information?**

If you would like more details about the survey, please contact the lead researcher at King’s College London (Louise Smith). Her details are:

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To take part in the first part of the study online, please go to https://kcliop.eu.qualtrics.com/jfe/form/SV\_1BpWMjKVI17uw8B

For further information about the vaccination programme, please refer to the NHS Choices website at:

<http://www.nhs.uk/pages/home.aspx>

**What if I have further questions, or if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

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In the event that something does go wrong and you are harmed during the research then you may have grounds for legal action for compensation against King’s College London but you may have to pay your legal costs. King’s College London maintains adequate insurance to cover any liabilities arising from the study. This is separate from the provision of the standard indemnity related to the vaccination.