**PARTICIPANT INFORMATION STATEMENT**

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| **HREC Project Number:** | HREC ID 200775 |
| **Project Title:** | Reframe the pain: Using attention and language to manage needle pain and distress in children |
| **Division/Unit:** | Division of Health Science, School of Health Sciences |
| **Principal Investigator:** | Dr Tasha Stanton, PhDTasha.stanton@unisa.edu.au |

Dear Parent/Guardian,

You and your child have been invited to participate in our research project aiming to manage needle pain and distress in children. Before signing the consent form, it is important that you read and understand the following explanation. If you have read the information below and would like your child to take part, please complete the consent form (attached below) and return it to the school/return in the reply-paid envelope/log onto survey monkey and complete the consent form.

**What is the study about?**

Many people don’t like needles. This fear often stems from a bad experience as a child, as getting a needle for some kids can be a painful, distressing experience.

Talking to children in helpful ways after a needle can be really helpful in having them think about it in a less negative way and this might also help them cope better with needles in the future. We also know that there are ways that we can distract or direct attention that can help reduce pain. This may help decrease fear of future needles by making the experience of a needle, itself, less painful.

South Australia Health highly recommends that children over the age of 6 months receive an annual influenza vaccine if they wish to reduce the likelihood of getting the flu. Our research aims to reduce the negative impact of needle procedures in children. Specifically, we aim to test two different strategies (directing their attention, talking to them in helpful ways after the needle) for their ability to reduce needle pain and fear in children that are undergoing flu vaccinations in South Australia. Importantly, we will also test if these strategies, when combined, have even better effects. This will allow us to determine if we can reduce fear-related vaccine hesitancy.

**Does my child have to participate?**

No. As with all research at the University, participation is completely voluntary. If you do decide to participate, you and your child are free to withdraw at any stage, without prejudice. You will have up to one week after the telephone interview to withdraw your data. If you decide to no longer participate, but you do not notify the research team of your withdrawal, some of the information previously collected may be used (without identification).

**Who can participate?**

Your child can participate if they are aged between 8-12 years, attending school in South Australia, and consent to receive the yearly flu vaccination. Children with a history of severe allergic reaction (e.g., anaphylaxis) after a vaccine, severe egg allergies (e.g., respiratory distress/required epinephrine), a diagnosed anxiety disorder or post-traumatic stress disorder, or moderate-severe illness (with/without fever) on the day will be excluded.

The researcher will take every care to remove responses from any identifying material as early as possible. Likewise, individuals' responses will be kept confidential by the researcher and not be identified in the reporting of the research. However, the researcher cannot guarantee the confidentiality or anonymity of material transferred by email or the internet.

**What will I have to do?**

Injections will be given either on-site at your child’s school or at the University of South Australia, City East Campus (the Clinical Trials Centre, Level 1, Bonython Jubilee building or the Physiotherapy Clinic, Level 8, Centenary building). Initially you and your child will be asked to complete some questionnaires. This includes questionnaires measuring general information, anxiety, confidence in managing pain, anxious thinking about pain, quality of past vaccine experience, and expectations about needle-related pain and fear. Then, directly after receiving the flu vaccination your child will be asked about their pain and fear and you will be asked some questions about how you perceived your child’s pain and fear and your confidence in reducing your child’s pain. Two weeks after the vaccination, we will complete a short interview with you and your child on the phone. This interview will ask questions about what your child remembers about getting the needle. Using similar scales that your child completed before, the interview will specifically ask how scared they were and how painful they remember the needle to be as well as how they feel about future needles. We will audio-record this interview so that we can fully capture your and your child’s answers.

Your child will be randomly assigned (like flipping a coin) to one of four groups: 1) usual care; 2) divided attention; 3) positive post-needle language; 4) positive post-needle language and divided attention. All children will receive either touch on their arm from the nurse (using their finger or a rubber end of a pencil) or vibration on their arm (applied through a sleeve fitted over their shoulder). Children may or may not be asked to determine which area of their arm they feel a small vibration or touch on. If using the sleeve, all children will have the chance to see the sleeve and feel the vibration before they put it on their arm. If they do not like the sleeve and do not wish to wear it, the nurse will merely touch their arm instead with a finger or using the rubber end of a pencil. We will video-record this session so that we can make sure that each child got the correct intervention. It will also help us to understand how the session went.

Your child will be placed (randomly) into one of four different groups and that they will not be told which group they are in, nor can we cannot guarantee which group they are placed in. After the follow up telephone call you will be given the opportunity to ask questions and will be given information about the group they were in. However, it is important to note that all children will receive best usual standard of care. Three quarters of the children will receive an enhanced intervention. All children in all groups will have their flu vaccinations provided by a clinical nurse experienced in paediatric vaccinations and trained in the study procedures.

The total time commitment required for your child is approximately 60 minutes. This includes the time taken to complete the initial baseline questionnaires before the vaccination (approximately 10-15mins), the injection (+/- enhanced care strategy), the questionnaires immediately post-vaccination, and a wait period to monitor response (together approximately 25-30 mins) and the telephone interview (approximately 15mins). The total time commitment for you is approximately 30 minutes. This includes the time to complete the initial baseline questionnaires (approximately 15 minutes) and the telephone interview (approximately 15 minutes).

**Are there any risks?**

It is not anticipated that there are any risks to participation in this study beyond those encountered during normal flu vaccinations. With all vaccinations there are potential risks including arm stiffness, soreness, redness, or swelling where the shot was given, drowsiness, tiredness, low grade fever, aches and distress. If these side effects occur they are usually mild and go away within a few days, usually without any treatment.

The risk of a flu shot causing serious harm or death is extremely small. However, a vaccine, like any medicine, may rarely cause serious problems, such as severe allergic reactions. We will be screening participants based on history of allergy (particularly to eggs) or previous severe reaction to flu vaccine. Almost all people who get influenza vaccine have no serious problems from it.

All children will have their flu vaccinations completed by a clinical nurse experienced in paediatric vaccinations and trained in the study procedures to minimise these effects and provide the best standard of care. The clinical nurse will watch for any signs of serious allergic reaction (e.g., breathing problems, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat, or dizziness) after the flu vaccination given that if these reactions do occur it is usually within a few minutes to hours after receiving the shot.

The clinical nurse will also watch for any signs of distress/anxiety such as increased breathing rate, sweating, restlessness, pacing, etc… and will use established strategies of deep breathing, distraction and relaxation to combat this.

**Are there any benefits?**

The research we have proposed will have direct benefit for all children in South Australia. Children that participate in our study will receive best standard care or enhanced care when receiving their flu vaccination. Additionally, our research may have future benefit for the children that participate in our study by decreasing the fear of needles in future procedures and potentially preventing disabling phobias of needle procedures that can occur.

**Who will have access to my information?**

After completing the questionnaire, your child will be given an identification number and personal identifiable information will be separated. Neither you nor your child will be identified in any way in the analysis of the data or when the results are published in scientific journals. Also, information on the questionnaire will be grouped for reporting and individual responses will not be presented in any way. All information supplied will remain confidential and be stored in a locked filing cabinet in room C7-26, School of Health Sciences, City East Campus, UniSA, for 5 years and the researcher will not supply this information to the public without explicit permission, unless required by law. Every effort is made so that the information you supply will remain completely confidential. Furthermore, you and your child have the option to withdraw your information collected from the study up to one week after the telephone interview.

**What happens next and who can I contact about the research?**

Your involvement in this study would be greatly appreciated. If you are interested, please complete the attached consent form and send it back to school with your child or mail it in the supplied envelope or log-on to survey monkey <INSERT URL HERE>.

If you would like more information please contact either **Dr** **Emily Watson** (emily.watson@mymail.unisa.edu.au), or **Dr Tasha Stanton** (tasha.stanton@unisa.edu.au).

**Will you tell me the results of the research?**

Yes. A summary of the results can be provided to you at the completion of the study as well as a copy of the transcript of your and your child’s phone interview if you indicate you would like this information on the consent form.

This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant please contact the Executive Officer of this Committee, Tel: +61 8 8302 3118; Email: vicki.allen@unisa.edu.au.

If you wish to lodge a complaint about either the study or the way it is being conducted please contact the Executive Officer of UniSA HREC in the first instance, email: humanethics@unisa.edu.au or tel: 8302 3118.