

PLAIN LANGUAGE STATEMENT: Parent of Primary School Students



"Testing a new survey to screen for epilepsy in students using animations"

You are invited to participate in the above research project, which is being conducted by Dr Wendyl D'Souza, an epilepsy specialist and researcher at St Vincent's Health, The University of Melbourne. I am funded by a fellowship grant from the National Health & Medical Research Council of Australia and this project is funded by a grant from St Vincent's Health Research Endowment Fund. I have asked your school to invite you and your child to take part in this research project. We do not have your name or contact details but only have an identification number matched to your child. This has been done to protect your privacy so that you can accept or decline our invitation to participate by returning the reply letter back to school without us knowing directly who you are. This project has been approved by the University of Melbourne Human Research Ethics Committee.

Epilepsy is the most common serious brain condition with about 10% of people having a seizure at some stage in their life. Seizures are like an electrical short-circuiting in the brain, and look different depending on which part of the brain is affected. The aim of this study is to test a new method to screen for epilepsy in children. If successful it will make it easier to screen for epilepsy when children are unable to visit a doctor e.g. in rural and remote regions.

Should you agree to participate in this project it would involve three parts. In **part one** I would need one parent or guardian to complete a 10-minute survey on the web page (www.sparks.org.au). This would involve watching five short seizure animations and giving 'yes' 'no' answers to questions. If you do not have access to broadband-internet your child will be given a DVD and a one page written survey for you to complete at home. To check the reliability of our results we would also need the survey to be repeated two weeks later by some parents. **Note: The survey is not a diagnostic test. Answering 'yes' to any of the questions doesn't mean your child has epilepsy, as many common harmless conditions such as daydreaming, or fainting can look very similar. If you have any concerns please don't hesitate to contact us on pilot@sparks.org.au; ph: 9288 3341 or mobile: 0437 933 867.**

The **second part** involves you taking part in a 20-30 minute interview by myself or another epilepsy specialist to measure the accuracy of our survey. It will be performed if you answer 'yes' to any of the questions and on some people answering 'no' to all of the questions. This can be done either at school, or if preferred, at home or by telephone. We would like this interview to take place within 1-2 weeks of you completing the survey in part one. The **final part** involves an EEG test and will ONLY be performed if I suspect your child has epilepsy or I am uncertain. This is a method of measuring a person's brain waves by placing a cap on your child's head, similar to one worn when swimming, but with metal buttons attached to the inside. The test is painless and usually takes about 30 minutes.

The results of this study will be reported as group data only. No individual information will be identifiable in the report. To further protect you and your child's confidentiality and anonymity, we will store all name and contact details in a separate, locked cabinet from the data you supply. All computer files will be accessible to the researchers only, and will be password protected. You should note that these measures are only able to guarantee confidentiality within the limits of the law.

Once the publication arising from this research has been completed, a brief summary of the findings will be available to you through your school. It is also possible that the results will be presented at academic conferences. The data will be kept securely in the Department of Medicine, St Vincent Health, The University of Melbourne for seven years from the date of publication, before being destroyed. If epilepsy is diagnosed during the course of the study, I can arrange a meeting with you

to explain how this may affect your child, arrange immediate specialist referral (within 1-2 weeks) and provide a letter for your regular medical practitioner. This school will not be informed of your child's results.

Please be advised that your participation in this study is completely voluntary. Should you or your child wish to withdraw at any stage, or to withdraw any unprocessed data you have supplied, you are free to do so without prejudice. The researchers are not involved in the ethics application process. Your decision to participate or not, or to withdraw, will be completely independent of your dealings with the ethics committee, and we would like to assure you that it will have no effect on your relationship with the researchers or St Vincent's Health.

If you would like to participate, please indicate that you have read and understood this information by signing the accompanying consent form and returning it in the envelope provided. You may then go to the website (www.sparks.org.au) and complete the survey.

Should you require any further information, or have any concerns, please do not hesitate to contact myself; Dr Wendyl D'Souza, The Department of Medicine, St Vincent's Health, The University of Melbourne, on ph: 9288 3341, or fax: 9288 3350. Should you have any concerns about the conduct of the project, you are welcome to contact the Executive Officer, Human Research Ethics, The University of Melbourne, on ph: 8344 2073, or fax: 9347 6739.



**DEPARTMENT OF MEDICINE, ST VINCENT'S HEALTH
THE UNIVERSITY OF MELBOURNE**

PROJECT TITLE: "TESTING A NEW SURVEY TO SCREEN FOR EPILEPSY IN STUDENTS USING ANIMATIONS"

Name of primary school parent/guardian participant: _____

Name of investigator(s): Wendy D'Souza, Udaya Seneviratne, Simon Harvey, Mark Cook _____

1. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.
2. I understand that after I sign and return this consent form it will be retained by the researcher.
3. I understand that my participation will involve a **survey** and I agree that the researcher may use the results as described in the plain language statement.
4. I understand that my participation may involve an **interview with an epilepsy specialist and a brain wave test for my child** and I agree that the researcher may use the results as described in the plain language statement.
5. I acknowledge that:
 - (a) The possible effects of participating in the **survey, interview and brain wave test** have been explained to my satisfaction;
 - (b) I have been informed that I am free to withdraw from the project at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;
 - (c) The project is for the purpose of research;
 - (d) I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements;
 - (e) The results of this study will be reported as group data only. Individual information will not be identifiable in any publications arising from the research;
 - (f) Once the publication arising from this research has been completed, a brief summary of the findings will be available through my child's school.

Primary school parent or guardian signature: _____

Date: _____