



## Information statement and consent form

### Participant Information Sheet/Consent Form – Parent/Guardian Interventional Study - Parent/Guardian consenting on behalf of participant

<b>Title</b>	Dance PaRticipation for Extremely prEterm children with Motor Impairment at prEschool age: a feasibility study
<b>Short Title</b>	Dance PREEMIE- feasibility study
<b>Protocol Number</b>	
<b>Project Sponsor</b>	The University of Melbourne
<b>Coordinating Principal Investigator</b>	A/Professor Alicia Spittle
<b>Associate Investigator(s)</b>	Ms Kate Cameron, A/Professor Jeanie Cheong, A/Professor Jennifer McGinley, Dr Kim Allison
<b>Location</b>	Murdoch Children's Research Institute



## Part 1 What does the child's participation involve?

### 1 Introduction

This is an invitation for you and your child (or children if you have twin or triplets) to take part in this research project because your child is part of the Victorian Infant Collaborative Study and was born early or low birthweight. The research project is testing a new dance intervention for children born extremely preterm or extremely low birthweight who are at risk of movement difficulty at preschool age.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want you and your child to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not you and your child can take part, you might want to talk about it with a relative, friend or the child's doctor or care team.

Participation in this research is voluntary. If you do not wish your child to take part, they do not have to. Your child will receive the best possible care whether or not they take part.

If you decide you want you and your child to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to you and your child taking part in the research project
- Consent for you and your child to have the intervention and assessments that are described
- Consent to the use of your and your child's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

### 2 What is the purpose of this research?

Children born at less than 28 weeks gestational age or less than 1000g are at risk of movement difficulties as they reach preschool and primary school age. Movement difficulties can include things like poor balance, difficulty with activities such as throwing and catching or difficulty with day-to-day tasks such as getting dressed. The Dance PREEMIE study aims to help children with their movement skills while they are still at preschool age, prior to starting school. Children will be given the opportunity to attend a dance class in their local area, with a dance teacher that has been provided with extra training. We want to know if the Dance PREEMIE intervention is feasible for premature children and their families. Specifically, we want to know if parents felt that their children could attend the classes and found them to be enjoyable. If the Dance PREEMIE intervention is successful, we hope to offer it to more preterm children and their families.

The results of this research will be used by Kate Cameron to obtain a PhD.

Investigator Kate Cameron is supported by an Australian Government Research Training Program Scholarship to coordinate the study.

### **3 What does participation in this research involve?**

A member of the research team will have contacted you to provide an overview of the study and the time commitment required. You have been given this detailed participant information sheet and consent form to allow you time to read through the information.

A member of the research team will contact you again to see if you are interested in being part of the study and answer any questions. If you indicate that you want you and your child to participate, you will be asked to sign the consent form and the researcher will collect some information from you (such as your contact details, details about your child and their birth such as birth weight, medical complications and treatments).

Your child will be participating in a feasibility study. All children in this study will receive the intervention i.e. participation in the dance classes.

Once you have consented to you and your child participating in the study, a suitable dance class will be negotiated for your child in your local area. Dance classes will occur once per week for a school term (8 weeks), and you will be assigned to attend the class in either term 4 2019 or term 1 2020.

#### Assessments:

You and your child will be asked to come into the Royal Children's Hospital twice for assessments. These will occur just before and just after the duration of the dance program. You will also be contacted 3 months after your child has completed Dance PREEMIE and invited to complete a short online questionnaire.

First Assessment: During the first assessment, a physiotherapist will assess your child's movement skills. You will also be asked to complete a short questionnaire about your child's participation in physical activity. This assessment will take approximately an hour.

Second Assessment: During the second assessment, a physiotherapist will assess your child's movement skills a second time and you will be asked to complete another short questionnaire. You will also be asked to complete a brief face-to-face interview (or telephone interview) with a member of the research team. This interview will be recorded. During this interview, you will have the opportunity to tell us what you liked and what you didn't like about the Dance PREEMIE program. This assessment will take approximately an hour and 30 minutes.

#### Costs and reimbursement

Fees for the dance classes your child attends as part of the study will be fully subsidised, so you will not need to pay for classes. There may be other expenses involved, such as transport or dancewear, which you will need to pay for yourself. You will be provided with free parking when attending the two assessments at the Royal Children's Hospital.

### **4 What does your child have to do?**

#### Dance class

Your child will attend a dance class once per week for one school term. The dance class your child attends will be a typical community dance class. Most of the children in the class will not be in the study. Dance classes for preschool age children are lots of fun. They can involve moving to music, jumping and balancing activities and creative play.

Your child will have to attend two assessments at the Royal Children's Hospital, one before and one after the dance program. At each of these assessments your child will participate in a series of games designed to assess their motor abilities. Children generally find this assessment enjoyable.

**5 Other relevant information about the research project**

We plan to recruit 10 preschool aged children and up to 10 dance teachers. If this study has favourable outcomes, we hope to do another research project involving more children.

**6 Does the child have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish for you and your child to take part, you do not have to. If you decide that you and your child can take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide that you and your child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your child's routine treatment, relationship with the researchers, or relationship with the Royal Children's Hospital or Murdoch Children's Research Institute.

**7 What are the alternatives to participation?**

You and your child do not have to take part in this research project to receive treatment and usual care at this hospital. Other options are available; accessing physiotherapy through Medicare.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that your child will receive any benefits from this research; however, possible benefits for participating in this study may include:

- positive effects on your child's movement skills and balance
- positive effects on your child's fitness
- contributing towards 180 minutes of physical activity a day as recommended by the Australian Movement Guidelines for pre-schoolers.
- positive effects on your child's social skills and self-esteem
- an assessment of your child's motor skills by a physiotherapist

We hope your child will have fun being part of this project.

**9 What are the possible risks and disadvantages of taking part?**

We do not anticipate any risks or side-effects from participation in this study. There is a small risk that your child may hurt themselves during the dance class. This risk is the same for all children participating in supervised, structured physical activity classes. Participating dance schools will have trained first aiders present during your child's class. During the dance class, your child may experience muscle soreness, especially if they are trying a new activity. This discomfort should resolve within 48 hours. Assessments will be stopped if your child becomes upset. If you have any concerns or questions related to the study please contact A/Professor Alicia Spittle Chief Investigator on (03) 9035 5340.

**10 What will happen to your child's assessment information?**

We will store all information securely in locked filing cabinets and password protected computer files at the Murdoch Children's Research Institute. We will not disclose your child's assessment results to anyone outside the study team without your permission (with the exception of the Royal Children's Hospital Ethics Committee or if required by law). We will send you a written report based on your child's movement assessment at the completion of the study. This report will contain details of your child's motor performance compared to other children of the same age, and we encourage you to share the results of the report with your GP or health provider.

**11 What information about my child will be given to the dance teacher?**

Your dance teacher will know that your child is part of the Dance PREEMIE study. The dance teacher will not share this information with other parents or children in your child's class. Prior to beginning the dance intervention, the dance school will ask you to fill out an enrolment form. This will be the same enrolment form the other children in the class will have been asked to fill out. Typically, this form will ask about any pre-existing health conditions, such as asthma. Filling in these forms as accurately as you can will help keep your child safe during the dance class.

**12 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the intervention that is being studied. If this happens, the study coordinator will tell you about it and discuss with you whether you want you and your child to continue in the research project. If you decide to withdraw you and your child, you will continue to receive usual clinical care. If you decide that you and your child can continue in the research project, you will be asked to sign an updated consent form.

**13 Can the child have other therapy during this research project?**

Participation in this research project will not influence whether you and your child can access other therapy or interventions. We will ask you to write down any other therapy or interventions in a questionnaire. Information on whether or not your child accesses therapy or interventions will help the researchers determine the effect of the Dance PREEMIE intervention.

**14 What if you withdraw yourself and your child from this research project?**

If you decide that you and your child can take part in the study, but then change your mind, you are free to withdraw from the study and all the study follow-up at any time. If you decide to withdraw from the study, we will offer and encourage you to still attend the follow-up assessments with your child unless you specifically request us not to contact you.

If you decide to withdraw fully from the study and all study follow-up, we will not contact you for any further follow-up visits. If you decide to withdraw fully from the project, the researchers will keep the personal and/or health information about you and your child that has already been collected. If you do not want the researchers to use this information, you must contact them in writing. Your decision whether or not to take part in the study, and whether to withdraw from the study will not affect your relationship, or your child's relationship, with the researchers, Royal Children's Hospital or Murdoch Children's Research Institute.

**15 What if my dance teacher withdraws from the research project?**

The dance teachers involved in this study have also consented to be involved in the study. Although unlikely, just like you and your child, the dance teachers have the option to withdraw from the study at any time. If your dance teacher does decide to withdraw from the study, all reasonable effort will be made to find another class for your child to attend.

**16 What happens when the research project ends?**

The Dance PREEMIE intervention ends after your child has completed one school term equivalent of dance classes and attended the final follow-up appointment. After the project is finished, you will be able to continue with the same dance class as a paying member of the public (with the agreement of your dance teacher). When the project is completed a summary of the findings will be sent to you.

## Part 2 How is the research project being conducted?

### 17 What will happen to information about you and your child?

By signing the consent form you consent to the relevant research project staff collecting and using personal information about you and your child for the research project. Any information obtained in connection with this research project that can identify you or your child will remain confidential except as required by law and will only be used for the purpose of this research project. Only the researchers involved with this project and the Royal Children's Hospital ethics committee can have access to this information. We can disclose the information only with your permission except as required by law.

Information about your child and their birth may be obtained from their health records held by the Victorian Infant Collaborative Study for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your child's participation in this research project.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, we will report information about the whole group of participants and information will be provided in such a way that you cannot be identified, except with your permission.

The information will be re-identifiable. This means that we will remove your names and give the information a special code number. Only the research team can match your names to your code numbers, if it is necessary to do so.

All information will be stored securely in locked filing cabinets at the Murdoch Children's Research Institute and once all analyses have been performed, the data will be securely archived. Electronic information will also be stored on a password-protected computer database at the Murdoch Children's Research Institute for 7 years after the youngest child in the study turns 18, after which time it will be destroyed. Only the project researchers will have access to the data.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

### 18 Complaints and Compensation

The A/Prof Alicia Spittle Chief Investigator will be available throughout the study if you have any questions, and is happy to take concerns at any time. Her contact details are: (03) 9035 5340. This project has been approved by the ethics department at the Royal Children's Hospital. You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

In the very unlikely event that you or your child suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate treatment. If your family is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**19 Who is organising the research?**

This research project is being conducted by the Victorian Infant Collaborative Study, and will be supported by an Australian Government Research Training Project Scholarship.

**20 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Royal Children's Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**21 Further information and who to contact**

If you want any further information concerning this project, or if you have any problems which may relate to your involvement in the project, please contact A/Prof Alicia Spittle Chief Investigator on (03) 9035 5340.

## Consent Form – Parent/Guardian

<b>Title</b>	Dance PaRticipation for Extremely prEterm children with Motor Impairment at prEschool age-feasibility study
<b>Short Title</b>	Dance PREEMIE- feasibility study
<b>Protocol Number</b>	
<b>Project Sponsor</b>	The University of Melbourne
<b>Coordinating Principal Investigator</b>	A/Professor Alicia Spittle
<b>Associate Investigator(s)</b>	Ms Kate Cameron, A/Professor Jeanie Cheong, A/Professor Jennifer McGinley, Dr Kim Allison
<b>Location</b>	Murdoch Children’s Research Institute

### Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my child’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Murdoch Children’s Research Institute concerning my child’s medical condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I will be given a signed copy of this document to keep.

### **Declaration by Parent/Guardian – for Parent/Guardian who has read the information**

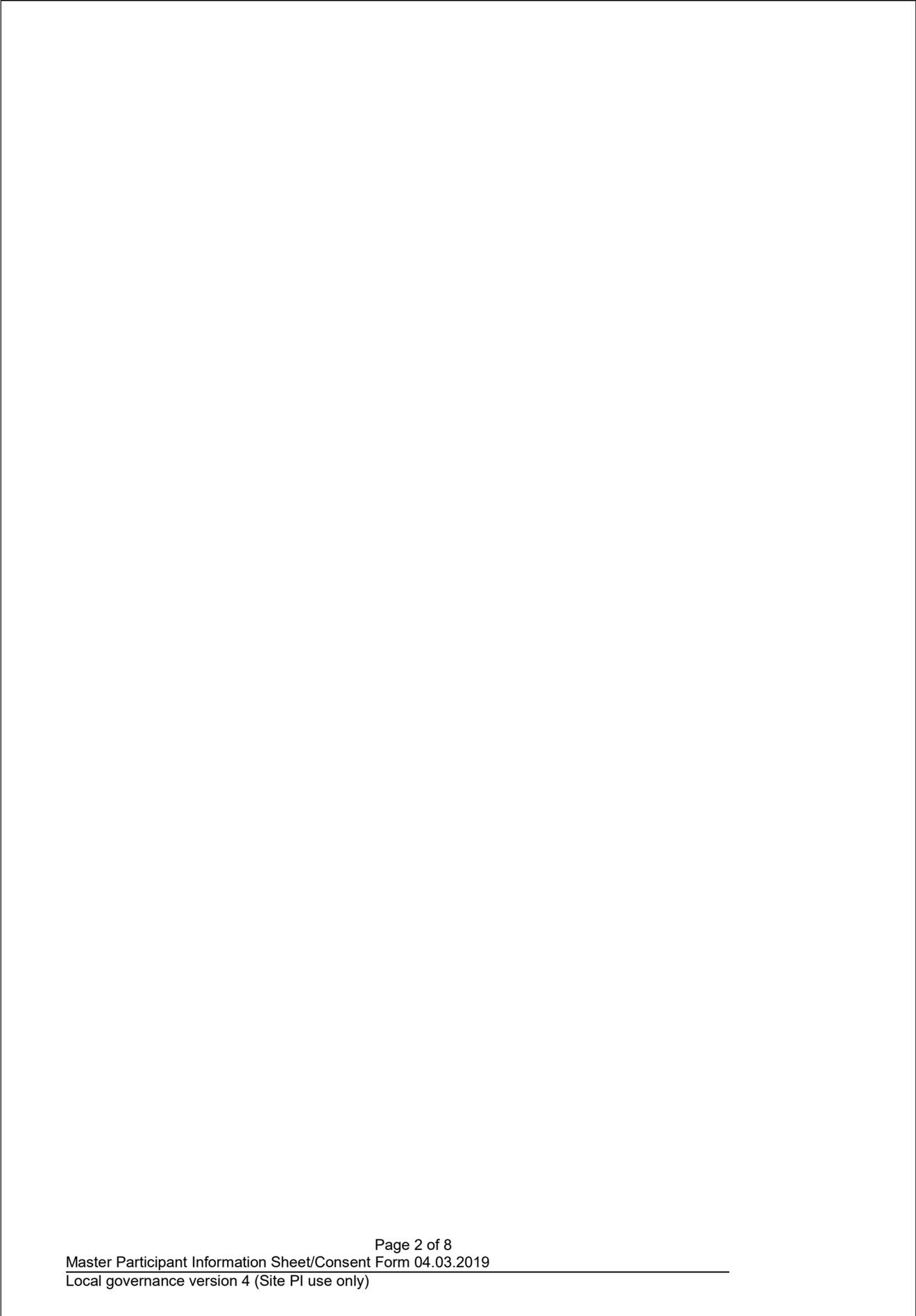
Name of child (please print) _____
Name of Parent/Guardian (please print) _____
Signature of Parent/Guardian _____ Date _____

### **Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study coordinator/ researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.



## Form for Withdrawal of Participation – Parent/Guardian

<b>Title</b>	Dance PaRticipation for Extremely prEterm children with Motor Impairment at prEschool age- feasibility study
<b>Short Title</b>	Dance PREEMIE- feasibility study
<b>Protocol Number</b>	
<b>Project Sponsor</b>	The University of Melbourne
<b>Coordinating Principal Investigator</b>	A/Professor Alicia Spittle
<b>Associate Investigator(s)</b>	Ms Kate Cameron, A/Professor Jeanie Cheong, A/Professor Jennifer McGinley, Dr Kim Allison
<b>Location</b>	Murdoch Children's Research Institute

### Declaration by Parent/Guardian

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect their routine treatment, relationships with those treating them or the relationship with the Royal Children's Hospital or Murdoch Children's Research Institute.

Name of Child (please print) _____
Name of Parent/Guardian (please print) _____
Signature of Parent/Guardian _____ Date _____

*In the event that the parent/guardian's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

--

### Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the parent/guardian has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.