Participant Information Letter

PLEASE NOTE THIS WILL BE ONLINE

Project Title	**ENVISAGE: EN**abling **VIS**ion **A**nd **G**rowing **E**xpectations
HREC Number	**2019-18H**
Chief Investigators	Dr Laura Miller: Australian Catholic University Professor Peter Rosenbaum: *CanChild,* McMaster University
Co-Investigators	Professor Jenny Ziviani: Children's Health Queensland Professor Christine Imms: Australian Catholic University Dr Andrea Cross: *CanChild,* McMaster University Ms Vicki Cavalieros: Cerebral Palsy Support Network, Parent Researcher Ms Rachel Martens: *CanChild,* McMaster University, Parent Researcher
Research Coordinators	Ms Abha Balram: Australian Catholic University Ms Debbie Hughes: *CanChild,* McMaster University
Post Doctoral Students	Dr Kinga Pozniak: *CanChild,* McMaster University Dr Andrea Cross: *CanChild,* McMaster University
PhD Student	Ms Monika Novak Pavlic: *CanChild,* McMaster University
Administration Support	Ms Alison Stokes: Australian Catholic University
Version Number:	**4.0**

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Thank you for taking the time to read this **Participant Information Letter and Consent**. We would like to ask you to participate in a research project, explained below, that we think you might be interested in.

IT IS OK TO SAY NO!

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is provided to help you decide whether you would like to take part in the research. Please read this Information Statement carefully.

Before you decide if you want to take part, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Important things to know

- It is your choice whether you take part in the research. You do not have to agree if you do not want to.

- If you decide you do not want to take part, no one else will know, and your choice will not affect the treatment and care you or your child receives through any services.

If you would like to take part in the research project, please select the "I agree" button at the end of this letter. By clicking "I agree" you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project

If you do not wish to participate select the "I do not agree" button and you will be exited from the screen.

1. What is the research project about?

We wish to engage with parents raising children with developmental challenges. Our goals for this project are to empower parents and caregivers by sharing with them some of the new and different ways we are thinking and talking about childhood 'disability'. We want to find out if our series of five weekly online interactive workshops, called ENVISAGE, improve parents' mental well-being and help them feel more competent and empowered.

What is ENVISAGE?

ENVISAGE stands for **ENabling VISion And Growing Expectations**. It involves five caregiver-friendly online workshops for parents/caregivers of young children new to the journey of parenting a child with a neurodisability. The workshops aim to provide early exposure to modern thinking about childhood disability. Our aim is to empower caregivers to take a strengths-based, 'developmental' approach to their child and family's situation.

The overall aims of ENVISAGE are to:

- Enhance caregivers' understanding of their own capacities, competence and capabilities to parent their child with an early onset neurodisability successfully and with confidence;
- Promote caregivers' understanding and promote lived experience of family-centred service, strengths-based approaches and contemporary views of childhood disability; and
- Empower caregivers to be confident in decision-making regarding their child's development and the services they access.

What's the issue?

Parenting is a tough task! Parenting a child whose development might be complicated by a disability can be even harder. We know that parents want to do a good job with their kids. We also know that there can be a lot of extra stress and strain on parents as they work to do all the right things when their child has a disability.

What's new?

The field of childhood disability has changed a lot - and we strongly believe that these changes are for the better. ENVISAGE aims share these ideas with parents and provide helpful information and support to parents starting on their journey as parents of a child with developmental challenges.

What are these ideas?

The five **ENVISAGE** online workshops will discuss:

- The **World Health Organization's** way of thinking and talking about 'health', and how the **'F-Words in Childhood Disability'** have taken these ideas to families.
- The importance of **development** - of children and of families - as a key way to think about everything we all do in our work together with children with developmental challenges.
- **Parenting** as "a dance led by the children", and how to dance when the partner doesn't know the steps.
- **Looking after yourself so you can look after your family** - because that's good for you, your children and the important people in your life!
- Focusing on **Communication, Collaboration, Connection** - strategies about how to belong to the community and be an effective connector to services.

2. Who is funding the research project?

This project is funded by the Canadian Institutes of Health Research (CIHR). The project is being undertaken in both Australia and Canada.

3. Who is undertaking the project?

Our **ENVISAGE** team is made up of Australian and Canadian parents, clinicians and childhood disability researchers. This project is being led by Dr. Laura Miller at Australian Catholic University (ACU) in Brisbane and Professor Peter Rosenbaum at CanChild, McMaster University in Canada. **Dr. Miller** is an occupational therapist with 20 years of clinical experience in paediatric rehabilitation. She has extensive experience working with children with disabilities and their families. Her research interests focus on motivation and engagement, parent empowerment and enablement and models of service delivery. **Professor Rosenbaum** is the cofounder of CanChild Centre for Childhood Disability Research. He has more than 45 years of experience as a developmental paediatrician and health services researcher. His special interests include how services are offered to families of kids with impairments, parent and family wellbeing, and how to focus on the 'positive'.

Professors Christine Imms and Jenny Ziviani have PhD qualifications and extensive research and clinical experience in childhood disability and supporting families. Christine is a qualified occupational therapist who has specialised in paediatric rehabilitation. Christine's current research focus is participation for children, youth and adults with childhood onset disabilities. Jenny is a qualified occupational therapist who has an extensive research career. Jenny was the Co-Chair of Children's Allied Health Research with Children’s Health QLD and University of QLD,and is currently a Professor of Occupational Therapy at The University of QLD.

Dr. Andrea Cross completed her PhD in Rehabilitation Science with a focus in childhood disability, knowledge translation, and family engagement in research. Andrea is a sessional instructor with the Masters of Health Management Program at McMaster and is interested in online education research. Andrea's postdoctoral fellowship research focuses on an online education training program for graduate student research trainees and families of children with neurodevelopmental disabilities to build capacity in family engagement in research.

Dr Kinga Pozniak completed her PhD in anthropology. She has extensive experience in qualitative research methods. Kinga has experience with families of children with disabilities through CanChild Centre for Childhood Disability Research and is also a parent of a child with a disability.

Rachel Martens and Vicki Cavalerios are parents of children with disabilities who now hold advocacy and parent support positions in Canada and Australia. Rachel and Vicki are 'parent as partners' collaborators on the project and they advise the team as parents of a young person with a disability and consumers of services.

Ms. Monika Novak Pavlic has bachelor degrees in Rehabilitation and Physiotherapy and a Master of Science degree in Rehabilitation. Monika has been working with children with disabilities and their families in a variety of settings. Monika is currently a PhD student and her research focuses on family-centred care and empowering families that are caring for a child with a disability.

Ms. Abha Balram has honours degrees in psychology and a Masters in Occupational Therapy. Abha is an experienced occupational therapist specialising in paediatric disability and adolescent/adult mental health and has experience in research.

Ms Debra Hughes has worked in the field of health as a staff nurse and more recently as a Pediatric Research Assistant. Since joining McMaster University in 2005, Debbie has worked at McMaster’s Offord Centre for Child Studies on a transition to school research project for children with special needs, in Pediatrics on a neonatal study, and in Psychiatry in the field of child and youth mental health.

Ms. Alison Stokes has worked in the School of Allied Health at ACU for approximately four years as an administrator and clinic receptionist. She is also a parent to a child who is on the Autism Spectrum and has a personal understanding of what many parents have gone and are going through regarding diagnoses and treatment options for their children. Alison is an experienced Office Administrator and experienced Internal Communication Specialist.

4. Who can participate in the project?

We are asking parents raising a child with a disability to participate in this research project. We would like to know if our five workshops improve outcomes for families new to the journey as parents of a child with developmental challenges and to ensure the workshops are useful for these families.

To be eligible for this study we have some specific criteria for participants:

(1) caregivers of children with an identified neurodisability ;

(2) caregivers from Australia or Canada

(3) your child with a disability is aged less than six years of age.

Unfortunately, you are not able to participate in this study if you are currently going through diagnostic processes and your child has not yet been formally identified as having a neurodisability.

Neurodisability describes a group of congenital or acquired long-term conditions that are attributed to impairment of the brain and/or neuromuscular system and create functional limitations. Conditions may vary over time, occur alone or in combination, and include a broad range of severity and complexity. The impact may include difficulties with movement, cognition, hearing and vision, communication, emotion and behaviour.

You can discuss this criteria with the research team if you have any questions:

ENVISAGE Australia		Email: Envisage@acu.edu.au
Dr Laura Miller	Phone: 07 3623 7843	Email: laura.miller@acu.edu.au
ENVISAGE Canada		Email: envisage@fhsadmin.csu.mcmaster.ca
Dr Peter Rosenbaum	Phone: 905-525-9140	Email: rosenbau@mcmaster.ca

5. What will I be asked to do?

This research project involves your participation in several stages outlined below. Further details of each stage are provided following this list:

Stage One: Completion of pre-workshop online questionnaires (40 mins)
Stage Two: Engagement in a series of five online workshops (60 mins self paced review of workshop materials, 60 mins online discussion and 5 questions re: feedback on workshop)

Stage Three: Completion of post-workshop online questionnaires immediately following completion of the workshop series, then again at 3, 6 and 12 months post workshops (40 mins each time point)
Stage Four: Engagement in an online interview immediately following completion of workshops and again at 12 months post workshops (optional extra stage– 60 mins each interview)

Stage One: Completion of pre-workshop online questionnaires

In this first stage, you will be allocated a unique code that is specific to your information and responses. This code enables us to de-identify your data. You will be asked to provide some demographic information about your child and family (e.g. your child's age, child's diagnosis, etc.). You will also be asked to complete several online questionnaires which we call 'baseline' measures chosen to help us work out if the five workshops are effective in improving outcomes for families. To help us do this we will ask you to complete these questionnaires again in stage three. The online questionnaires including the following and will take approximately 45-60 minutes to complete:

a. Demographic Questionnaire: General information about your child and your family.
b. About My Child: Seeks to understand the functional needs of children and priorities of families.
c. Family Empowerment Scale: Measures parent's sense of empowerment in families of children with disabilities.
d. Family Hardiness Index: Explores patterns of family functioning.
e. PROMIS: Global Health Scale: Assesses general domains of health and functioning.
f. Measures of Processes of Care: Evaluates parents' perceptions of family-centeredness of their services.

Stage Two: Engagement in a series of five online workshops – Online Resources and Online Discussion

During this stage you will be asked to take part in five ENVISAGE workshops, which will be available to you online via a password. These workshops will include resources for you to save and download if you wish. The resources are videos, written materials, activities and presentations for you to do and watch. We anticipate it will take you approximately 60 mins to review the resources for the workshop. You can do this at times that are convenient to you in the week before the online workshop discussion. The online workshop discussion will be approximately 60 mins in duration and will be held using ZOOM – an online videoconferencing service. We will provide you with technical support to access the workshop resources and Zoom if you require support or assistance. The online workshop discussion will be held with up to 10 other parents who are participating in the research project. These discussions will be facilitated by two or more members of the ENVISAGE research team and will include a parent collaborator. The purpose of these discussions is to explore the workshops in more detail and answer questions you may have about the workshop resources and materials. These online discussions will be recorded as will any text in the 'chat' boxes and discussion board.

Before each workshop we will ask you to identify what you hope to gain from attending the workshop. Following each workshop, we will ask you what you found useful in the workshop and what you would like included or excluded in future workshops. These questions will be answered online and will help us to refine workshop content based on your feedback.

Stage Three: Completion of post-workshop online questionnaires

As outlined in stage one you will be asked to complete the online questionnaires again immediately following the completion of the workshop series and then again at 3 months after the end of the workshops; 6 months after the end of the workshops, and 12 months after the end of the workshops.

Stage Four: Online interview (optional extra)

As part of the consent process, you will be asked if you wish to participate in an interview immediately following the end of the workshop series and then again at 12 months. Interviews will be online using ZOOM videoconferencing and will take approximately 60 minutes to discuss your experiences in more detail. This interview will be recorded. You do not have to participate in an interview if you do not wish and you can still participate in the previous stages of the project even if you do not do the interview. Your interest to participate in an interview will be asked at the end of this letter and then again at completion of the workshop series. It is OK if you change your mind.

The project will be entirely online. Participation in the questionnaires, workshops and interview is voluntary and all information will be confidential.

Since this is a joint study between Canada and Australia, the information you provide will be analysed in both countries. De-identified data will be shared using the confidential and secure online platform called CloudStor. This platform is approved by Australian universities for storing and sharing confidential data.

The research team listed on this application will have access to data described above. In addition, IT support services for REDCap and Moodle will have access to data based on the online nature of these platforms. These staff are employees of ACU and McMaster and are bound by research integrity, ethical codes of conduct and confidentiality requirements of the universities.

6. What if I wish to withdraw from the research project?

If you decide to participate, you are free to withdraw consent and to discontinue your participation at any time. The decision to withdraw from the study will not affect your child's medical or health treatment or their relationship with the people treating them.

When you finish the questionnaires, you will be asked again whether you want to submit your responses. At this time you can choose to submit your response or you can exit and not submit your data. You can choose to withdraw your data up to the point that we begin our data analysis. We will not be able to remove your data/information/responses once we have begun analysing our data as it will be combined with other participant’s data.

7. What are the possible benefits for my child and other people in the future?

You may find the information presented in the workshops helpful to you and your family. You will also be contributing to the relatively limited body of research on interventions that aim to support parents and families of children with an early onset neurodisability at the time of diagnosis. Findings from this study will assist us to empower and enable families new to the journey of parenting a child with a disability. The perspectives of people like you and the findings from this research project may be very useful to future families.

8. What are the possible risks, side-effects, discomforts and/or inconveniences?

Participation involves participation in 5 online workshops, reviewing related materials, completing questionnaires, and participating in online discussions. Most people find these tasks interesting, however there is the inconvenience of a time commitment and effort required in doing these tasks. These have been outlined above.

Additionally, some of the issues raised during the workshops may cause some distress or discomfort as we will be asking you to reflect on your own journey in childhood disability and your experiences with health professionals and service providers. We will do everything we can to ensure that being involved is a positive experience for you. We will help you find support if the workshops, questionnaires or discussions make you feel distressed, upset or uncomfortable.

Participating in all parts of this study is optional and you may withdraw. If you feel any level of distress because of your participation, please feel free to contact the primary investigators listed at the end of this participation information letter or families can contact:

(1) ACU Psychology and Counselling Clinics in Melbourne (03 9953 3006), Strathfield (02 9701 4708 or Brisbane (07 3623 7453)
(2) Cerebral Palsy Support Network on (03) 9478 1001 or 1300 277 600
(3) Queensland Paediatric Rehabilitation Services on 07 3068 1111

9. What will be done to make sure my information is confidential?

Online Questionnaires:
In Stages one and three you will be asked to complete questionnaires before starting the workshops and after you complete the final workshop. You will be asked to provide your name and email address to receive the link for the online workshops. This information will be recorded in an online system with your questionnaire answers. Your identifying information will only be accessed by specific research personnel. Your questionnaires will be allocated a unique identifying code so your responses will be analysed and stored separate to any identifying information.

Workshops and Discussion:
All information shared by participants in the workshops is confidential. Participants will be asked to agree to a workshop charter at the beginning of the online workshops discussions to ensure confidentiality and group rules are adhered to (such as listening to all participants, respecting participants). As it is an online workshop you may choose to use a pseudonym rather than disclosing your name. The written 'discussion board' and online ‘chat’ which workshop members

may participate in during the discussion will be saved. The workshops will be audio and video recorded and transcribed so the researchers have a copy of what you say. An external professional transcription service may be used to transcribe the interview data. The recordings, transcriptions, chat and written discussion board will only be available to the research team. What you tell the research team will remain confidential. Nothing that you say will be shared or reported in a way that will identify you, except as required by law

Interview:
All information shared by participants in the interview is confidential. The interview will be video, and audio recorded and transcribed, so the researchers have a copy of what you say. The recordings and transcriptions will only be available to the research team in Canada and Australia. What you tell the research team will remain confidential. An external transcription service may be used to transcribe the interview data. Nothing that you say will be shared or reported in a way that will identify you. You will be provided a copy of your interview transcript following the interview and you can choose to redact any information you do not wanted included in the analysis.

Please note that research data may be accessed by auditors, ethics committee or regulatory authorities as part of research compliance. All data collected will be stored in a de-identified or format. Email addresses remain identifiable; however, these will be stored separately to any data collected as part of the research project. All data will be stored on a secure, password protected computer and deidentified data will be shared using the secure platform Cloudstor.

Research data gathered from the results of the study may be published in peer reviewed journals or presented at conferences, however, identifying data are not used and only summary information will be published. Your individual responses and personal information will remain confidential.

10. Will I be able to find out the results of the project?

We will send every participant in the study a plain-language report of what we learn in this research project. This will be sent at the conclusion of the study in 2021.

11. Who should I contact for more information?

If you would like more information about the project or if you need to speak to a member of the research team please contact:

AUSTRALIA

ENVISAGE Email:	Envisage@acu.edu.au
CI Name:	Laura Miller
Telephone:	07 3623 7843
Email:	Laura.Miller@acu.edu.au
RA Name:	Abha Balram
Email:	Abha.Balram@acu.edu.au

CANADA

CI Name: Peter Rosenbaum
Telephone: 905-525-9140, ext 27834
Email: rosenbau@mcmaster.ca

If you are interested in participating in the study, please proceed to the consent form below.

What if I have a complaint or any concerns?

AUSTRALIA

The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (Review number 2019-18H).

If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics and Integrity Committee care of the Office of the Deputy Vice Chancellor (Research).
Manager, Ethics and Integrity c/o Office of the Deputy Vice Chancellor (Research)
Australian Catholic University North Sydney Campus PO Box 968 NORTH SYDNEY, NSW
2059 Ph.: 02 9739 2519 Fax: 02 9739 2870 Email: resethics.manager@acu.edu.au

CANADA

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB) and received ethics clearance(2019-5769-GRA). If you have concerns or questions about your rights as a participant or about the way the study is conducted, please contact:
Office of the Chair of HiREB
Telephone: (905) 521-2100 ext. 42013