Hunter Genetics
The Genetics of Learning Disability (GOLD) Service
(Incorporating the Fragile X Program)
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Hunter Genetics
Children, Young People and Families

PARTICIPANT INFORMATION SHEET

Project: The support needs of fathers of children with Fragile X Syndrome

If you are a father of a child (or children) diagnosed with Fragile X syndrome we would like to invite you to participate in our study.

Why am I being asked to participate?

- We are contacting you as you have one or more children with a diagnosis of Fragile X syndrome (FXS). We would like to explore your experiences surrounding your child/children being diagnosed with FXS and since the diagnosis. We are particularly interested in learning about the support(s) you had over this time, including your interaction (if any) with a genetics service.
- This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.
- Participation in this research study is voluntary. If you do not wish to take part, you don't have to participate. By giving your consent to take part in this study you are telling us that you:
    - Understand what you have read.
    - Agree to take part in the research study as outlined below.
    - Agree to the use of your personal information as described.
- You will be given a copy of this Participation Information and Consent Form to keep

Who is carrying out the study?

- The research is being conducted by the NSW Genetics of Learning Disability (GOLD) service in partnership with the Fragile X Association of Australia (FXAA) and University of Sydney. This collaboration is dedicated to improving the level of support fathers experience when receiving their child or children's FXS diagnosis and after this diagnosis. Researchers include:
    - Dr Melanie Leffler, Associate Genetic Counsellor, melanie.leffler@health.nsw.gov.au
    - Dr Elizabeth Palmer, Clinical Geneticist, Elizabeth.Palmer@hnehealth.nsw.gov.au
    - Dr Michael Field, Director, GOLD service, Mike.Field@hnehealth.nsw.gov.au
    - Ms Jacintha Luermans, Master of Genetic Counselling student, jlue@uni.sydney.edu.au
    - Associate Professor Kristine Barlow-Stewart, Director Master of Genetic Counselling Program, Kristine.Barlowstewart@sydney.edu.au
    - Ms Carolyn Rogers, Senior genetic counsellor, Carolyn.Rogers@hnehealth.nsw.gov.au
    - Dr Jane Fleming, Associate genetic counsellor, Jane.Fleming@sydney.edu.au
    - Ms Rosie O'Shea , Senior Genetic Counsellor, Rosie.OShea@sydney.edu.au

What does the study involve?

This research is being conducted in two parts:

Part 1: The research involves a semi-structured 30-60 minute telephone interview. The interviewer (Jacintha Luermans, student researcher) will ask a range of questions about your experiences before and after your child (or children) was diagnosed with FXS, and your opinion on whether any additional assistance or support would be useful for families undergoing genetic counselling for FXS.

Part 2 This part of the research study involves completion of a 40 minute anonymous online survey (a hard copy of the survey can be provided upon request). Questions will be asked about your experiences as outlined in Part 1 of the project.

If you are invited to participate in both part 1 and part 2, you can choose to participate in the telephone interview and/or the online questionnaire. Details on how to participate are included below in the section *'What do I need to do to participate?'*.

How much time will the interview and questionnaire take?

Part 1

- We estimate that the interview will take approximately 30-60 minutes. The questions do not have to be answered all in one sitting and you have the right to discontinue your participation at any time.

Part 2

- The follow-up questionnaire will take approximately 40 minutes to complete.

What choice do I have?

Part 1: telephone interview questions

- Participation in this research project is entirely voluntary and your responses will be kept strictly confidential. Only individuals who give written informed consent will be included in the telephone interviews. If you decide to participate, you may withdraw from the project at any time without giving a reason

Part 2: online survey questionnaire

- Participation in this research project is entirely voluntary and your responses will be anonymous and strictly confidential. As the questionnaire is anonymous, completion and return of a survey will be taken as your consent for the use of your responses in this research study. If you decide to participate, you may withdraw from the project at any time prior to submission of your questionnaire.

Part 1 and 2

- Your decision about whether or not to participate will not disadvantage you or your child or relative(s) in any way and will not affect the care you receive from your genetic service.
- Any information that would identify you to the GOLD service or Fragile X Association Australia (FXAA) will be removed by the research team prior to the GOLD Service accessing the data collected.

What are the risks and benefits of participating?

- The information about your experiences obtained from the study may help to inform and improve current genetic counselling practice and policy.
- Participating in the interview and/or completing the questionnaire may raise difficult emotions for some participants.
- If this occurs for you, genetic counselling is available through the GOLD service, FXAA* or your genetic service. Alternatively, if you prefer, a referral can be made to an independent counselling service in the strictest confidence. If you feel you or your family need further support, please contact certified Genetic Counsellor Associate Professor Kristine Barlow-Stewart on Kristine.Barlowstewart@sydney.edu.au or (02) 9926-4607. The *Fragile X Association of Australia (FXAA) has a part time counsellor available for in-person, phone or skype consultations, who can be contacted on 9977-0074 or 1300 394 636.

What do I need to do to participate?

- If you decide to participate in the study, please return your signed completed consent form using the details provided on the consent form, or in the provided reply paid envelope (only applicable if you received this information in the post). Interviews will be arranged in the first half of 2017, and the online questionnaire will be open to participants in late 2017. A link and further information about the online questionnaire will be sent to you when it is open to participants.
- When your completed consent form is received, and if it indicates you are happy to participate in the interview, Jacintha Luermans, will make contact to arrange a convenient time to conduct the interview via telephone.
- If you would prefer to have a paper copy of the survey sent to you please return your signed completed consent form in the reply paid envelope or contact Rosie O Shea, Associate Lecturer, Master of Genetic Counselling Program at rosie.oshea@sydney.edu.au or 02 99264684. A paper copy of the questionnaire will then be sent to you with a self-addressed envelope for your completion and return.

How will my privacy be protected?

Part 1 telephone interviews

- Jacintha Luermans will remove any information that could identify you or your family to the GOLD service. Jacintha and the non-clinical research team will be the only people who will have access to your contact information on the consent form. The clinical team/GOLD service will not know who has elected to participate in the research.
- All of your contact details and any de-identified information will be stored in a locked filing cabinet in Associate Professor Kristine Barlow-Stewart's office at the University of Sydney Medical School – Northern, Kolling Institute, St Leonards NSW 2065.

Phase 2 online questionnaire

- All of your anonymous responses to the questionnaire will be kept in a secure database that only the researchers will be able to access. Your IP address will not be collected and no identifying information will be stored with your questionnaire – the researchers will not know which one is yours. In addition, the clinical research team/GOLD service will not know who has participated in the study.
- Any publications reporting the results of this study will use de-identified information and you will not be individually identifiable.

Can I tell other people about the study?

- You are free to share information about this study. You are also welcome to give our contact details to your relatives or other FXS families who may be interested in participating.

What if I require further information about this study and my involvement in it?

- If you would like to learn more about this study or have any questions or concerns prior to agreeing to participating, please contact Jacintha Luermans at jlue@uni.sydney.edu.au or Rosie O Shea, Associate Lecturer, Master of Genetic Counselling Program at rosie.oshea@sydney.edu.au or 02 99264684.
- You can receive a one-page summary of the group results upon completion of the study. If you are interested in a summary of the research findings, please indicate your interest on the participant consent form or follow the link after submitting your online questionnaire and fill in your details. This information will not be linked to your responses in the questionnaire. A one-page summary of the group results will also be available on the FXAA website.

Complaints about this research?

- This research has been approved by HNELHD Ethics Committee (Reference number: 16/11/19/4.06)
- Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, please contact a member of the research team. If an independent person is preferred, please contact Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305 telephone: 02 49214950 Email: HNELHD-HREC@hnehealth.nsw.gov.au

Yours sincerely,

Dr Melanie Leffler
Associate Genetic Counsellor
GOLD Service

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PARTICIPANT CONSENT FORM
Project: The support needs of fathers of children with Fragile X syndrome

I, ...[name] of

..... [address]
have read and understand that the study will be conducted as described in the Participant Information Sheet, a copy of which I will keep.

I confirm that I am (please tick):

- ☐ Over 18 years of age
- ☐ Have at least one child (young or adult) with a Fragile X syndrome diagnosis
- ☐ The first diagnosis of FXS was made over 12 months ago
- ☐ I do not myself have a Fragile X genetic result in the premutation or full mutation range

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect, and of their implications as far as they are currently known by the researchers.

I agree to participate in this study and understand that I can withdraw at any time without providing a reason.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I hereby agree to participate in this research study, including (please tick for the sections of the study you consent to participate in):

☐ An interview (to be conducted in early 2017)
☐ I understand that the interview will be audiotaped, and I agree to this.

BEST CONTACT NUMBER(S): _____

BEST CONTACT DAYS/TIMES: _____

☐ An online anonymous questionnaire (to be sent upon completion of the interviews, in approximately late 2017)

☐ I wish to receive a paper copy of this questionnaire to my home address or the email address written below.

NAME: _____

SIGNATURE: _____ **DATE:** _____

EMAIL: _____

☐ I would like to receive a summary of the research findings upon completion of the project sent to (please tick your preferred option):

☐ **Email** _____ ☐ **Mail** _____

Please email your signed consent form to: Kristine.barlowstewart@sydney.edu.au or post in the reply paid envelope provided to Kristine Barlow-Stewart, University of Sydney Medical School – Northern, Kolling Institute, St Leonards NSW 2065.