Informed Consent Form Cover Page for ClinicalTrials.Gov Record

Official Study Title: Tailoring Treatment Targets for Early Autism Intervention in Africa

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY
VERSION 3

Title of the Research Project: "Tailoring Treatment Targets for Early Autism Intervention in Africa"

PRINCIPAL INVESTIGATOR: Dr Lauren Franz

ADDRESS: Division of Child and Adolescent Psychiatry, 46 Sawkins Road, Rondebosch, Cape Town, 7700 Tel: 021-685 4103

We want to see how a treatment for young children with autism that can be taught to parents works in South Africa. The name of this treatment is the "Parent Early-Start Denver Model". This treatment has been shown to work with parents and their children with autism in the United States. From working with you and your child we would like to learn how well this treatment can work for South African families. You will be taught different ways to play with your child to build your child's language and social skills. We will work with you and your child at your child's school for 1 hour per week for 12 weeks. We will do testing in clinic at 2 different times (before you start the study and after 12 weeks) to see how the treatment is working for you and your child. In the testing you will be asked to fill out questionnaires, play with your child, and your child will do some play based testing. Each testing session will last about 3 hours. After the 12-weeks of treatment, we may ask you to meet with us to tell us what you thought of the training we did.

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or health care provider any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied and that you clearly understand what this research is about. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town.** The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- This study will happen in a clinic in the Cape Town Metropolitan area.
- We want to understand more about how young children who live in South Africa develop, communicate, and play with their parent/caregiver.
- 60 parents/caregivers and their children will take part in the study.
- We will do testing in clinic once.
- In the testing you will be asked to fill out questionnaires, play with your child, and your child will do some play based testing. The testing session will last about 3 hours.
- To be part of the study your child must be between 18 and 72 months old and either have normal development or some developmental challenges.
- You must be over the age of 18, and have the legal right to sign this consent form for both you and your child, because your child is too young to sign this form.

- We will read through this form with you. Please ask if there any words that you do not understand. If you agree to be part of this study, you will sign this form.

Why have you been invited to participate?

- We are working with people who can help us understand understand more about how young children who live in South Africa develop, communicate, and play with their parent/caregiver. You are a parent or legal caregiver of a young child who lives in South Africa, who either has normal development or some developmental challenges. That is the reason we have asked you to be a part of this study.

What will your responsibilities be?

- We ask that you and your child come to the clinic to do testing once.
- We will ask that you come to the assessment on time and take part as fully as you can. This means that you will answer questions and perform tasks as fully and honestly as possible. If there are questions or activties you do not want to or cannot answer/engage in, you should say so. You do not have to participate in any activities that you do not want to.

Will you benefit from taking part in this research?

- We want you and your child to have a good time working with us. You will be able to talk with us about your child.
- You will help us learn how we need to change a treatment so it can work for South Africa families.
- We will give you a report on the all the testing your child had during the study.

Are there risks involved in your taking part in this research?

- There are no significant risks for you or child if you take part in this study. It may be hard for you to talk about some things. Your child might find some of the play activites confusing or boring. If there are questions you do not want to or cannot answer, or play that you do not want to do, you can say so. You do not have to do any activities that you do not want to.
- We will make every effort to keep your information confidential and protected. No information will be shared with anyone outside of the study team, including your health care providers. All documents and recordings will be stored in a locked filing cabinet or on a password protected computer. Your study information will be identified only by a number, not your name. Any documents containing your name and personal information will be kept separate from other study records, and will be stored in a secure way. If we write about this work, your identity will remain anonymous.
- The only time where we would not keep information confidential would be if we had reason to believe, that a) you are a potential harm to yourself or others; or, b) a child currently under age 18 had been physically, emotionally, or sexually abused, or emotionally neglected. We would be obliged to report such information to protect you and others. In such a case, the research staff member would report the information to the Project Director, who would then take immediate steps to intervene as appropriate. However, if the risk is imminent (i.e. about to take place) the research staff member will take action immediately.
- These are the main risks. Please tell us if you have any worries about this information.

A grant from the National Institutes of Mental Health in the United States will sponsor this study. Portions of the research team's salaries will be paid by this grant.

Because the study is funded by the National Institutes of Mental Health it may be audited. If information in this study is looked at in an outside review for an audit, it may be further disclosed by them and may not be covered by the federal privacy regulations.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying children's health to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information (such as name, address, and phone number) is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about children's health more quickly than before.

During and after the study, we will send de-identified information to NDAR. Other researchers nationwide can then file an application with the NIMH to obtain access to your or your child's de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDAR. The information provided to NDAR may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDAR data. However, you will not be contacted directly about the data you contributed to NDAR.

You may decide now or later that you do not want to share your or your child's information using NDAR. If so, contact Dr. Franz and she or a research study staff member will tell the NIMH Data Archive (NDA), which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at https://nda.nih.gov.

Please indicate below whether you want us to share your or your child's de-identified information using NDAR for future research. (initial /date below)

_____ Yes, I give permission that my study information can be stored in NDAR

_____ No, I do not want that my study information be stored in NDAR.

The testing will be sent to Duke University in the United States. It will sent to Duke University so:

- The person who is testing your child is doing it right.
- We can ways we can improve how we work with children and famlies.

Who else will be part of the study team?

- The study team will include a primary clinician who will work with you and your child. There will also be a different clinician who will do all the testing with you and your child.

If you do not agree to take part, what alternatives do you have?

- You are free not to take part or to withdraw at any time during the study. Your child's care will not be affected. You may continue to attend the the Divison of Child and Adolescent Psychiatry at the University of Cape Town. It would be helpful for the study team to let us know why you have decided not to take part, but you are free to not give a reason.

Who will have access to your medical records?

- If your child is in the group with developmental challenges, we will review your child's medical record at their Red Cross clinic so we can better understand what developmental challenges they may have.

Will you be paid to take part in this study and are there any costs involved?

- There will be no costs for you to take part in this study. The study staff will give you R300 for the testing session with you and your child come to.

May you choose to not participate or to withdraw from this study?

- You may choose not to be in the study. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, we will not ask for any more information from you. All data that have already been collected for the study will be kept.

How will videos be stored?

- The video recordings of the therapy sessions and the testing will be kept in a secure electronic folder at Duke University in the United States. The video recordings will not have the names of individuals or any information about the person or group that could be used to identify them. These videos will never be destroyed. The University of Cape Town Principal Investigator (Prof Petrus de Vries) and the Duke University Principal Investigator (Dr Lauren Franz) will be in charge of managing these videos.

In case of an emergency or if you feel you need to contact the Principal Investigator about questions or problems, you can do so by phoning: Dr. Lauren Franz at tel no 021-685 4103
(lauren.franz@duke.edu)

- You can also contact the Human Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town 021-4066338 (lamees.emjedi@uct.ac.za) if you have any concerns or complaints that have not been adequately addressed.

Declaration by participant

By signing below, I ……. agree to take part in a research study entitled: "Tailoring Treatment Targets for Early Autism Intervention in Africa"

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of participant

Declaration by participant on behalf of their child

By signing below, I ……. agree for the following child in my care ……for whom I am the parent or legal caretaker to be involved in the research study entitled: **"Tailoring Treatment Targets for Early Autism Intervention in Africa"**

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I am over the age of 18, and have the legal right to sign this consent form for both myself and my child

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of participant

Declaration by treatment partner/associate/ relative of participant (IF UNABLE TO READ OR WRITE)

By signing below, I …….. have read and understood this consent form about the research study entitled: "Tailoring Treatment Targets for Early Autism Intervention in Africa", on behalf of

…….(name of participant), and state that he/she understands the study

……(relationship to participant)

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of treatment partner/associate/relative of participant

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Declaration by investigator/study coordinator

I *(name)* …… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I will maintain confidentiality at all times.

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

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Signature of investigator