

# KEMRI WELLCOME TRUST RESEARCH PROGRAMME INFORMATION SHEET & CONSENT Form

## B.1 INFORMATION SHEET – Parent/Guardian of Case

**Study Title: The Genetic Characterization of Neurodevelopmental Disorders in Kenyan Populations (NeuroDev Kenya)**

**Lay Title:** A study of genes contributing to the development of neuro-disability in Kenyan Children

Institution	Investigator
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Broad Institute	Victoria de Menil, Elise Robinson

### Who is carrying out this study?

- This study is being carried out by KEMRI (The Kenya Medical Research Institute) in partnership with the Broad Institute at Harvard University.
- KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.
- The Broad Institute (whose legal name is The Broad Institute, Inc.) and KEMRI-CGMRC will determine how your personal data and samples will be used in this study.

### What is this study about?

- In this study, we are trying to understand better the causes of different learning, physical and behavior-related problems that develop in childhood among people living in Africa. At the moment, we are specifically looking at this issue in Kilifi County and Mombasa. We know that in some cases these problems may be linked to factors called genes that run in families, but sometimes, changes that do not run in families occur in genes, these can also lead to learning, physical and behaviour-related problems.
- The reason we want to understand whether 'genes' have any role in learning, physical and behavior-related problems in children is that this knowledge may help to develop better ways of treating or helping such children in future. However, it is important to realize that information about 'genes' for each individual child in this study is very unlikely to directly influence their health or care in any way. Instead, it will help to learn about patterns of illness across all children who have these conditions and we hope to improve the care available in future.
- In this study, we are asking parents of about 1700 children if their child can take part in this study, including about 850 who have a learning, physical or behavior-related problem and 850 who do not have these problems. We are asking if your child can participate because they have a disability of this type. If you agree, overall this will involve your child giving a sample of blood and saliva and answering some questions.
- In addition, **(if you are the biological parent)** we are asking if you and your child's other parent will agree to participate by answering some questions about your child's development and behavior and providing a sample of blood. These details will be explained to you and the child's other parent in full before you are asked if you agree to either your child's or your own participation

## **What does participation in this study involve for my child (or my ward)?**

For those who agree to participate, the following activities will take place:

- We will ask you some questions about your child's (or ward's) health and development and observe his or her behaviour using a set of special tests. These tests involve activities such as solving a puzzle or playing games to see what they understand. Here is an example of some of the activities (show pictures of some of the test items). This will take approximately two hours and 30 minutes.
- We will look at your child's (or ward's) existing medical records in the health facilities they attend to find out about his or her health.
- In order to look at your child's genes, we will take a sample of blood and a sample of saliva from your child (or ward). We will take about two teaspoons (10 ml) of blood from your child's arm, collected in two small tubes. We will also collect about half a teaspoon of saliva from your child in one small tube or using a cotton swab.
- We will also take a photograph of your child (or ward). These photos will be used for training, education and research purposes only both here in Kenya and in the United States by the members of the study team. Depending on the findings of this study, some photos will be selected to be used in teaching health professionals how to diagnose people with similar conditions. If your child's (or ward's) photo is among those selected, we will contact you again, give you more explanation of how the photo will be used and seek further consent from you. If the photo is not selected, we will not contact you about it but the photo will be kept in within the study records for a period of 10 years after data collection has been completed to be used for research, training and education purposes. In this case only scientists who have permission, based on the KEMRI data governance rules on permissions for future use, can see the photos.

## **(For Parents) What does participation in this study involve for me, the parent?**

- If you agree to take part in this study you will be asked to give a blood sample. The primary goal of this study is to understand the factors that do or do not run in the family that contribute to different learning, physical and behavior-related problems for children living in Africa. We would like to request your blood sample to examine genes.
- If for any reason you do not want to give us your blood sample it is Ok, you can give permission for your child's participation. However, we cannot take your blood sample without permission for your child's blood sample to be taken.

## **Are there any risks or disadvantages to me or my child (or ward), of taking part?**

- Our priority for every participant is his or her wellbeing.
- You may experience distress or discomfort when answering questions about yourself or your child. You do not have to answer questions if they make you uncomfortable. You may also ask to take a break at any time.
- When giving blood, you or your child (or ward) may experience a small amount of pain, as with a pin prick. The pain should go away quickly. It is possible that there may be a small bruise or feeling of dizziness.
- There is a small risk that infection may occur at the site of the blood draw, in which case this can be treated with antibiotics.
- Although we will not label photographs with names, if a photograph is shared outside the research team, such as in a scientific paper published on the internet, it may be seen by someone who recognizes your child (or ward). Photographs of your face and body may also be embarrassing to some participants.
- If someone has another sample with 'genes' from you or your child, which has not been protected, it is possible that you could be identified from your sample. This would happen if the two samples

were matched, and one of them was linked to your name. The risk of this happening is very small but may grow in the future as genetic processing is more widely used.

- There may be other risks to privacy that we cannot foresee, because science is progressing so quickly.

**Are there any advantages to me or my child (or ward), of taking part?**

- There are no direct benefits to taking part in this study.
- If we find that your child (or ward) has symptoms of health problems for which they are not already receiving care, we will refer you to the clinic and services within the County that are able to help you. We will also provide transport or the costs of transport to access these services in the first instance. If there are other support services available within the County that are likely to help your child (such as social services or counselling support), we will also set up referrals to these services with your agreement.
- We hope that the results of this study will help scientists to learn more about physical, learning and behavioural problems that develop in childhood and lead to better care being available for these conditions in future.

**Will I be compensated for costs and time spent?**

- As reimbursement for time spent in the study activities, we will give you a sum of Ksh 300 per day plus the amount you spent on fares travelling for the study.

**What will happen to the saliva or blood?**

- Individual names will be removed from the saliva and blood samples and replaced by codes, to ensure that as far as possible samples can only be linked to the participants by people closely concerned with the research. However, please note additional information on this risk provided in the following paragraph.
- Some of the research tests that will be done on the sample will be done in Kenya. However, for some tests that cannot be done in Kenya, part of the samples will be sent to Laboratories overseas in the USA. The names of these laboratories are: 1) the Broad Institute and 2) the National Institute of Mental Health Repository and Genomics Resource.
- With your permission, your samples and those of your child will be stored for a very long time, possibly longer than you are alive. Some of the blood or saliva sample will be kept in the lab in KEMRI and some will be stored in the United States of America.

**What will happen to the information?**

- Your name and contact information will not leave KEMRI and will be carefully stored in a locked cabinet and on a password protected secure computer.
- Your child's (or ward's) photos will be stored separately from his or her name and any other identifying information. They will be put on locked computers and made available for scientists.
- We may retain and store personal information and photos for as long as necessary for the purposes of the study. The link between your, or your child's (or ward's), identity and the information will be destroyed at the conclusion of the study.
- In future, information collected or generated during this study may be used to support new research by other researchers in Kenya and other parts of the world to understand health problems related to genes. We will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes.

- For the samples stored in Kenya, any future research using information from this study must first be approved by a local expert committee to make sure that the interests of participants and their communities are protected.
- All reasonable steps will be taken to protect your privacy. However, although we take every measure possible to make sure that participants in our studies cannot be identified from the information or samples that they provide, there is a very small risk that this could happen in studies that involve identifying people's genes. It's important that we also let you know that we cannot at present predict all the ways in which you or your child (or ward) might be identified from their genes as science progresses in future.

### **Who will have access to the samples and information I give?**

- Researchers may write papers and give presentations on the research they do with the samples and information that you have provided. These papers and presentations will not include your name, but may include the summary information such as how often particular genetic changes occurred in the people who participated in this study. This kind of summary information will also be made available in databases that anyone can see (for example, on the internet). These databases will be located both in Kenya or in the United States. Papers and presentations may also include the photo we may take of our child. However, this photo will not be placed in a database without additional consent from you.
- The samples, and genetic and health information will be stored in laboratories both in Kenya and the USA and shared with other researchers at universities, hospitals, government agencies and companies around the world, but without identifying you by name.
- In order to use the samples, genetic or health information, researchers will have to apply for and get permission to use the samples or information. Samples and information shared with researchers will not be labeled with your name or other information that could be used to identify you.
- The samples, genetic and health information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, the study of human behaviors, or the study of where different groups of people may have come from.
- Although we will not give researchers your or your child's names, we will give them basic information such as your race, ethnic group, geographic region, age range, sex and other non-identifying health information that you tell us during the study. This information may help researchers study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you.

### **Who has allowed this research to take place?**

- All research at KEMRI has to be approved before it begins by several national committees who look carefully at planned work. This research was reviewed and approved by the Scientific and Ethic Review Committee at the Kenya Medical Research Institute and the Institutional Review Board at the Harvard T.H. Chan School of Public Health (USA). They agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

### **What happens if I refuse to participate?**

- All participation in research is voluntary. You are free to decide if you want you or your child (or ward) to take part or not. If you do agree, you can change your mind at any time without any consequences and this will not affect your child's (or ward) care in this hospital or school.

- If you decide that you don't want him/her to participate anymore and you do not want any blood or saliva from you, your child (or ward) to be used in this study. Please let us know and we will destroy the blood, saliva or samples of your genes. However, if the samples have already been shared with other researchers, those samples cannot be returned.
- If you or your child's (or ward's) sample has been already tested at the time you change your mind, the results and other information may have already been shared with other investigators. In that case, we will not be able to destroy this information. However, we can remove the information linking your personal information and the data we have collected.

#### **Your rights**

- You are entitled to request access to any of your information you have provided to us, subject to certain restrictions. You are also entitled to request that your information be corrected. In order to ensure that your information is up to date, please let us know about any changes to the information you have supplied.
- You may also request that your information be deleted or ask for us to stop using it, and we will comply with your request wherever possible and required by the law. If you revoke permission to use your information, or withdraw yourself from the study, please know that we will not be able to take back information or specimens that have already been used or shared with others.
- If you would like to exercise any of the rights mentioned above, please contact us using the contact details below.

#### **Future Contact**

- Since the data we are collecting will not affect your child's health or management in any way at the moment, we will not come back to bring back the results of the tests done to you or your family.
- When your child turns 18, he/she has the right to decide for himself/herself whether to participate in research studies, including the right to withdraw from past studies, such as this one. However, we will not get back in touch at that time, unless you or your child seeks to do so.
- In future, we may do more research as part of our work on learning, physical and emotional disabilities in children. In this case, we may contact you again to see if you would be interested in enrolling your child in another study.
- You have the right to withdraw your consent for future contact at any point in the future.

#### **What if I have any questions?**

- You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below.

Dr. Amina Abubakar - KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: [0705073853] or Martha Kombe, Telephone: 0741558723.

#### **If you want to ask someone independent anything about this research please contact:**

Community Liaison Manager - KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386.

*And*

The Head - KEMRI/Scientific and Ethics Review Unit, P. O. BOX 54840-00200, Nairobi, Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org.

**KEMRI-Wellcome Trust Research Programme consent form for “Genetic Characterization of Neurodevelopmental Disorders in Kenyan Populations (NeuroDEV Kenya).”**

**C.1 CONSENT FORM – Parent/Guardian of case for child or ward to participate**

I, the parent/legal guardian of \_\_\_\_\_ have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

**Please tick the box below where relevant:**

- **I agree for my child (or my ward) take part in this research.**
- **I give permission for me and my child (or my ward) to be interviewed and my answers and my child’s answers to be recorded.**
- **I give permission for a sample of my child’s (or my ward’s) blood to be taken.**
- **I give permission for a sample of my child’s (or my ward’s) saliva to be taken, if needed**
- **I agree for photos to be taken of my child (or my ward), which will be used for research and educational purpose only.**
- **I give permission for my child’s (or my ward’s) sample to be stored at 1) KEMRI, 2) the National Institute of Mental Health Repository and Genomics Resource in the United States and 3) the Broad Institute in the United States.**
- **I give permission for my child’s (or my ward’s) blood (and, if given, saliva) and health information to be shared for future research and/or commercial purposes. I do not expect direct medical benefit, or future financial benefits.**

**If I withdraw this consent, I understand that my child’s (or my ward’s) stored blood (and, if given, saliva) will be destroyed if it has not already been distributed to the research community, and otherwise it will be unlinked from his or her personal information.**

**I agree to be contacted in the future for additional information**

I understand that I can change my mind at any stage and it will not affect me in any way

**Signature or thumbprint:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Parent/guardian Name:** \_\_\_\_\_ **Time:** \_\_\_\_\_  
*(please print name)*

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*Where a parent/guardian cannot read, a witness may observe the consent process and sign below:*

I attest that the information concerning this research was accurately explained to and apparently understood by the subject and that informed consent was freely given by the subject.

**Witness' signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness' name:** \_\_\_\_\_ **Time** \_\_\_\_\_

*\*A witness is a person who is independent from the study or a member of staff who was not involved in gaining the consent.*

***[Following section is recommended, and where verbal consent is obtained, must be signed by person undertaking informed consent.]***

I have followed the study SOP to obtain consent from the [participant]. He/She apparently understood the nature and the purpose of the study and consents in the study. He/She has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator's signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Designee/investigator's name :** \_\_\_\_\_ **Time** \_\_\_\_\_

(Please print name)

**THE PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**