

# **KEMRI WELLCOME TRUST RESEARCH PROGRAMME: Patient Information Sheet and Consent Form**

## **F.1 INFORMATION SHEET – Parent/Guardian of Child Control**

**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
KEMRI-CGMRC	Amina Abubakar, Charles Newton, Martha Kombe, Dorcas Kamuya
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) 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.

### **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 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 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. If you agree, overall this will involve your child giving a sample of blood and saliva and answering some questions.

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

For those who agree that their child will 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 your child's behaviour using a set of special tests. These tests involve activities such as solving a puzzle or playing 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 also look at your child's (or ward's) medical records to find out about his or her health. Then a nurse or other trained professional will ask your child to give a sample of blood or saliva.
- Your child (or ward) will give about two teaspoons (10 ml) of blood, collected in two small tubes. If your child gives saliva, he or she will give less than half a teaspoon (0.75 - 2 ml) of saliva.

**Are there any risks or disadvantages to me / 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, 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 your child may have a small bruise or feel dizzy.
- 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.
- If someone has another sample with 'genes' from you or your child (or ward), 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/my child (or ward) of taking part?**

- There are no direct benefits to you or your child for 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?**

- 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 child's sample 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.
- We may retain and store personal information for as long as necessary for the purposes 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 and in the United States.
- 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 name, 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 care in this hospital or school.
- If you decide that you don't want him/her to participate anymore and you do not want his/her blood or saliva to be used in this study. Please let us know and we will destroy the blood, saliva or samples of their genes. However, if the sample has already been shared with other researchers, those samples cannot be returned.
- If your child's (or ward's) sample has been already tested at the time you change your mind, his or her 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 child's 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 Secretary - KEMRI/Scientific and Ethics Review Unit, P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541 Mobile: 0722 205 901 or 0733 400 003.

**G.1 CONSENT FORM - Parent/Guardian of Control for Child Participation**

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

Please tick the box below where relevant:

- I agree for my child (or ward) take part in this research.
  - I give permission for me and my child (or ward) to be interviewed and for my answers and my child’s answers to be recorded.
  - I give permission for a sample of my child’s (or ward’s) blood to be taken.
  - I give permission for a sample of my child’s (or ward’s) saliva to be taken.
  - I give permission for my child’s (or 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 ward’s) blood (and, if given, saliva) and my child’s 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 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 my child’s personal information.
- I agree to be contacted in the future for additional information.

Signature or thumb print: \_\_\_\_\_ 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 trial 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** \_\_\_\_\_

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

## KEMRI WELLCOME TRUST RESEARCH PROGRAMME

### I.1 ASSENT FORM – Adolescent Control

**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
KEMRI-CGMRC	Amina Abubakar, Charles Newton, Martha Kombe, Dorcas Kamuya,
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.
- TheBroad 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 behaviour-related problems.
- The reason we want to understand whether 'genes' have any role in learning, physical and behavior-related problems is that this knowledge may help to develop better ways of treating or helping such people in future. However, it is important to realize that information about 'genes' for each individual 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 people who have these conditions and we hope to improve the care available in future.
- In this study, we are asking about 1700 parents 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. If you agree, overall this will involve you giving a sample of blood and saliva and answering some questions.

#### What does participation in this study involve for me?

If you agree and choose to participate

- We will ask you some questions about your health and development and observe your behaviour using a set of special tests. These tests involve activities such as solving a puzzle or playing games to see what you understand. Here is an example of some of the activities (show pictures of some of the test items). This will take approximately one hour and 30 minutes.
- We will also look at your medical records to find out about your health. Then a nurse or other trained professional will ask you to give a sample of blood or saliva.
- You will give about two teaspoons (10 ml) of blood, collected in two small tubes. If you give saliva, you will give less than half a teaspoon (0.75 - 2 ml) of saliva.

**Are there any risks or disadvantages to me taking part?**

- Our priority for every participant is his or her wellbeing.
- You may experience distress or discomfort when answering questions about yourself. 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 may experience a small amount of pain, as with a pin prick. The pain should go away quickly. It is possible that you may have a small bruise or feel dizzy.
- 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.
- If someone has another sample with ‘genes ‘from you, 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/ of taking part?**

- There are no direct benefits for taking part in this study.
- If we find that you have symptoms of health problems for which you not already receiving care we will refer you to appropriate clinics and services within the County that are able to help. If there are other support services available within the County that are likely to help you (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.

**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 here 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 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 a special 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.
- We may retain and store personal information for as long as necessary for the purposes of the study. The link between your 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 might be identified from their genes as science progresses in future.

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- 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 and in the United States.
- 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 name, 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 must 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 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 care in this hospital or school. If you decide that you don't want to participate anymore, and you do not want your blood or saliva 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 sample has already been shared with other researchers, those samples cannot be returned.
- If your sample has been already tested at the time you change your mind, your 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 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 you turn 18, you will have the right to decide for yourself 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 seek us 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 Secretary** - KEMRI/Scientific and Ethics Review Unit, P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541 Mobile: 0722 205 901 or 0733 400 003.

**KEMRI-Wellcome Trust Research Programme**

*[Optional: If child is able to sign]*

**KEMRI-Wellcome Trust Research Programme Assent form for The Genetic Characterization of Neurodevelopmental Disorders in Kenyan Populations (NeuroDev Kenya)**

I, \_\_\_\_\_ (name of Participant), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily.

- **I agree to take part in this research**
- **I agree to samples being stored and used for future research**
- **I agree to samples being exported**

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

**Subject's signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Subject's name:** \_\_\_\_\_ **Time** \_\_\_\_\_

(Please print name)

Thumbprint of the subject as named above if they cannot write: *[Following section is recommended, and in some cases, must be signed by person undertaking informed consent]*

I have followed the study SOP to obtain consent from the [participant]. S/he apparently understood the nature and the purpose of the study and consents to participation in the study. S/he 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 PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP**