

**Consent Document for BRIDGE cluster Randomized Clinical Trial  
Task-Shifted Care**

**Principal Investigators:** Aminu Taura Abdullahi, MBBS (Kano); Hafsat Ahmad, MBBS (Zaria);  
Folorunsho Nuhu, MBBS (Kaduna).

**Date:** \_\_\_\_\_

**Study Title:** Bridging the Childhood Epilepsy Treatment Gap in Africa (BRIDGE)

**Institutions/Hospitals:** Aminu Kano Teaching Hospital (AKTH)  
Ahmadu Bello University Teaching Hospital (ABUTH)  
Federal Neuropsychiatric Hospital (FNPH)

**Data Coordinating Center:** E. Trevathan, MD, Vanderbilt Institute for Global Health (VIGH)  
Vanderbilt University Medical Center

---

This consent document applies to parents/guardians of children in Kano who have diagnosed epilepsy and who are candidates for the Task-Shifted Epilepsy Care at a Primary Healthcare Center.

**Name of Parent/Guardian:** \_\_\_\_\_

**Sponsor(s) of research:** This study is funded by the US National Institutes of Health.

**Background:** Your child has been diagnosed with seizures, or epilepsy, that may benefit from medical treatment. We know that there are many other children like your child in northern Nigeria who also have untreated seizures. Untreated seizures may harm children and may cause disability. Untreated prolonged seizures may even cause death in children. Most children with seizures can achieve control of their seizures with medication; these children often live otherwise normal lives.

**Purpose(s) of research:** We know that children with epilepsy benefit from treatment for their seizures, and that there are many children with epilepsy in northern Nigeria who do not receive treatment they need. The purpose of this research is to determine whether children with untreated epilepsy benefit most by one of the two methods of care.

- “Enhanced Usual Care” in which children are referred to a physician for treatment of their child’s seizures, plus primary health care provided by a specially trained community health extension worker, or
- “Task-Shifted Epilepsy Care” in which children receive epilepsy treatment from community health workers (CHWs) with special additional training in epilepsy, plus referral to a physician with expertise in epilepsy when specific questions arise.

We believe that either method of care is better than no treatment. The purpose of this research is to determine how we can best deliver epilepsy care to children who need this special treatment.

The closest primary healthcare center to your home participating in our research is providing task-shifted childhood epilepsy care with CHWs with additional special epilepsy training. We are asking for you to consent for your child to participate in this study at the participating PHC closest to your child's home.

**Expected Duration of research and of participants' involvement:** We do not know how long your child will require treatment for her/his seizures. However, the minimum amount of time typically required for children to be treated for seizures is two years, or 24 months. We ask for your child to be enrolled in this study for about 2 years.

**Research Procedures, what each participant will be asked to do, and the total number of participants involved in the study:** First, the community health worker (CHW) who will follow your child will make an appointment for you to be seen by the CHW at a primary healthcare center for the evaluation and treatment of your seizures. Then there will be two to three different health care providers who will care for your child's seizures.

1. The community health worker (CHW) with epilepsy training. This CHW will evaluate and manage your child's epilepsy at specific times in the participating primary health care center closest to your home. Specifically, your child will be seen at the primary healthcare clinic in 1 week (in person or by telephone). Then after that time your child will be seen in the primary health care center at 1 month, 2 months, 4 months, 6 months, 9 months, 12 months, 15 months, 18 months, and 24 months after enrolling in the study. The CHW will examine your child and ask important questions about her/his progress, seizures, and medication. The CHW will examine your child and ask questions about possible effects of the medication prescribed. The CHW will be able to provide you with information about your child's seizures and answer your questions. The CHW will make medication adjustments for your child. The CHW also may provide usual primary healthcare services at the primary healthcare center as well. The CHW can help you find a pharmacy to buy medication and can help you find help if you have difficulty paying for your child's medication.
2. Epilepsy Physician Specialist. This physician's role is to clearly document your child's progress, and to monitor your child's safety. This physician, paid by the study at no cost to you, will evaluate your child at 1 month after enrollment, and then at 6 months, 12 months, 18 months, and 24 months after enrollment. The epilepsy physician specialist will ask you questions and will examine your child. This physician will record your child's progress and monitor your child to determine if there are urgent problems that need to be addressed. This physician should not be told the name of your child's CHW or of your child's physician(s), or which primary health care center cares for your child. If your

child has any serious complications related to epilepsy, this physician specialist will report this concern to the BRIDGE study lead physician in your city.

3. Study Physician with Expertise in Epilepsy. This physician is paid by the study and supervises the CHWs who provide the task-shifted epilepsy care. If needed, the CHW may at any time ask this physician her/his opinion about your child. These conversations between the CHW caring for your child and this physician may not require your child's presence. However, in some situations the CHW will refer your child to this physician for specific questions, an examination, and consultation. If your child is evaluated by this physician, he/she will then do whatever tests she/he believes are best for your child. Then this physician will send her/his recommendations back to the CHW, who will continue care of your child. Depending upon how well your child responds to medication, your child may never need to see this physician, or may need to see this physician several times. During your enrollment in the study, there will be no cost to you for this physician's time. There may be costs for tests this physician orders, if they are required.

#### Interviews and Questionnaires

We are interested in learning about your opinions and concerns regarding your child's health and your opinions regarding the healthcare system. You will be asked to complete a brief interview with one of our researchers about your impressions of healthcare and epilepsy and seizures, as well as your concerns and opinions regarding your child. These interviews will occur in the very near future, and then again in one year, and at the end of the second year of the study. If your child is 15 years or 16 years of age at the time of enrollment in the study, they will also be asked to complete the interview.

You may be one of 60 selected parents/guardians who will be interviewed at in one year and then again in 2 years after starting the study. Our researchers will want to learn about your experiences with the CHW who cared for your child, and also learn about your other experiences working with our healthcare team.

#### **Costs to the participants, if any, of joining the research:**

- There are no costs to you for the study, including the costs of your child being evaluated by the CHW and the physicians who are part of the study
- There is no cost to you for the care provided by the CHW.
- There is no cost to you for the care provided by the Epilepsy Physician Specialist who will monitor your child's condition.
- Because all of the medications used to treat epilepsy in this study are approved drugs used by physicians in the community, the study will not pay the cost of drugs prescribed by physicians to treat your child's seizures. If you have difficulty paying for your child's medication, you should discuss this issue with your child's treating physician. You may also discuss this problem with the CHW, who will provide you with information regarding where you might find the medication at a good price, and where you might find assistance.

- If your child sees a physician who orders blood tests or other studies, there may be a cost of these tests that you will be expected to pay.

**Benefits:** The study may help your child receive medical care for her/his seizures. This study provides more careful medical follow-up for children with epilepsy than does most available epilepsy care outside of the study.

**Risks:** The risks of the study, overall, may not be different than the risk of routine care for seizures and epilepsy outside of the study. However, this study will require more time from you and your child for clinic visits.

The community health workers, and physicians, diagnose epilepsy by listening to the answers to questions asked about your child. The healthcare professionals will do their best to carefully listen to your answers, carefully examine your child, and make a correct diagnosis. Most of the time their diagnosis is correct, but mistakes in diagnosis can happen. The community health workers, and physicians, will ask you questions whenever they evaluate your child to make sure they are making the best diagnosis for your child. If a community health worker, or physician, has questions about whether your child's diagnosis of epilepsy is correct, they may ask for your child to see another healthcare professional or physician.

**Due inducement(s):** There is no cost for you or your child to participate in this study. If you and your child travel a long distance for an appointment required for the study, we will be able to help provide funds for your transportation. For prolonged visits (e.g., visits at 6, 12, 18, and 24 months when there are epilepsy physician specialist exams, and maternal interviews) we will provide lunch for your child, you, and any of your other accompanying children. Small inexpensive tokens of appreciation for participating in the study may be provided.

**Confidentiality:** All information collected in this study will be confidential. Your child will only be identified by a unique "study number" assigned to help the researchers distinguish one child from another. All of the information collected as part of this study will be connected to the children by their unique study numbers. Only healthcare professionals working on this study will see your child's name, or your name associated with your answers to the survey questions. Neither your name nor any personal identifier will be used in any publication or reports from this study. We are responsible for conducting this research properly; therefore, research officials from the Aminu Kano Teaching Hospital (AKTH), Ahmadu Bello University Teaching Hospital (ABUTH), Federal Neuropsychiatric Hospital (FNPH), Vanderbilt University Medical Center (VUMC), and/or the US National Institutes of Health (NIH) may review study records in order to assure the safety of the children enrolled in our studies.

**Your participation in this research is voluntary.**

**Alternatives to participation:** If you choose not to participate, this will not impact your continuing access to primary healthcare in this or any other community.

**Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:** You can also choose to withdraw from the research at any time. Please note that some of the information that has been obtained about you before you choose to withdraw may have been used in reports and publications. Your name and your child's name will not be published or made public and will remain confidential.

**What happens to research participants and communities when the research is over:** The researchers will inform you of the outcome of the research through the local health personnel. During this research, you will be informed about any information that may affect your continued participation, or your child's health.

**Statement about sharing of benefits among researchers and whether this includes or excludes research participants:** We do not believe that the knowledge produced from this research will lead to any commercial product. Once this research project is complete, all of the materials and tools we have developed to improve epilepsy screening and diagnosis will be made available free of charge to health care providers

**Any apparent or potential conflict of interest:** None of the researchers own financial interest or shares in any seizure-related technology or a drug company. We are not aware of any other information that may cause the researchers not to do their work without objectivity.

**Statement of person obtaining informed consent:**

I have fully explained this research to the parent/guardian of a child eligible to participate in this study and have given sufficient information, including risks and benefits, to make an informed decision.

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

Name: \_\_\_\_\_

**Statement of parent/guardian giving informed consent:**

I have read the description of the research or have had it translated into a language I understand. I have also talked it over to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks, and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and an additional information sheet to keep for myself.

Date: \_\_\_\_\_ Parent/Guardian Signature: \_\_\_\_\_

Parent/Guardian Name: \_\_\_\_\_

Child's Name: \_\_\_\_\_

Witness' Signature (if applicable): \_\_\_\_\_

Witness' Name (If applicable): \_\_\_\_\_

**Detailed contact information including contact address, telephone, fax, email, and any other contact information of researcher(s), institutional Health Research Ethical Committee (HREC) and head of the institution:**

This research has been approved by the Ethical Committee of Aminu Kano Teaching Hospital, and. The contact for the ethical committees is shown below.

AKTH Ethical Committee contact is Professor Borodo at 2348033268903.

This research has also been approved by the Vanderbilt University Medical Center Internal Review Board (IRB). In addition, if you have any questions about your participation in this research, you can contact the study coordinator, Ibrahim Sodangi, whose phone number is 08034231942. You may also contact the principal investigator of this study; Dr. Aminu Taura Abdullahi (Kano) at AKTH at 08037004272.

***PLEASE KEEP A COPY OF THE SIGNED INFORMED CONSENT.***