# COVER PAGE

**Project Title:** Reaching 90% target of HIV viral suppression: The role of point of care VL monitoring in resources constrained settings in Nigeria
**NCT Number:** 03533868
**Principal Investigator:** Dr. Oche Agbaji
**Project Sites:** Jos University Teaching Hospital (JUTH), Comprehensive Health Centre Zamko (Zamko)
**Project Sponsor:** United States (U.S.) Centers for Disease Control and Prevention (CDC)
**Document version date:** 21 February 2018

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2. **PARENTAL/GUARDIAN PERMISSION FORM** (5 pages): Parents/guardians of children aged <18 years

3. **CHILD ASSENT FORM** (3 pages): Children aged 7-17 years

Participant ID:_____

**Project Title: Reaching 90% target of HIV viral suppression: The role of point of care VL monitoring in resources constrained settings in Nigeria**
**Principal Investigator: Dr. Oche Agbaji**
**Project Sites: Jos University Teaching Hospital (JUTH), Comprehensive Health Centre Zamko (Zamko)**
**Project Sponsor: United States (U.S.) Centers for Disease Control and Prevention (CDC)**

# TRIAL
# ADULT INFORMED CONSENT FORM
**(Adults aged 18+ years)**

You are invited to take part in this research study because you are starting antiretroviral therapy (ART) for HIV at either Jos University Teaching Hospital (JUTH) or Comprehensive Health Centre Zamko (Zamko). The purpose of this research is to compare point-of-care (POC) viral load (VL) monitoring to standard of care (SOC) VL monitoring. A VL test measures the amount of HIV virus in your blood. After you start taking ART drugs, your doctors will monitor, or keep track of, your VL to check your health and see how well your drugs are controlling the virus. It can take around 2 months to get standard VL test results. A new POC VL test can give results in 2 hours. This study will help us learn if VL monitoring with the POC test is acceptable and can improve patients' health outcomes.

This form provides important information about taking part in research. Someone will explain this research study to you. You have the right to take your time in deciding if you want to take part in this research. Feel free to ask all the questions you want before you decide.

This study is funded by the United States (U.S.) Centers for Disease Control and Prevention (CDC), a government agency that promotes health and protects against health threats.

## Taking part is voluntary
It is your choice whether to take part. If you choose to take part now, you may change your mind at any time. Deciding not to take part or leaving the study will not be held against you and will not change your care at this clinic now or in the future.

## What can I expect if I take part in this research?
About 794 people will take part in this research trial for a period of about 12 months.

If you agree to take part, you will randomly be placed in either the SOC VL group or the POC VL group. You will have a 50% chance of being in either group. You will not get to choose which group, but we will tell you which group you are in.

If you are in the SOC VL group:

> You will get the same HIV services that you would normally get at the clinic. This includes having a blood sample collected from your arm by needle 6 and 12 months after starting ART for standard VL testing.

If you are in the POC VL group:

> The 6- and 12-month samples for VL testing will be collected as usual from your arm, but will be tested immediately using the new POC VL test.

You will then be asked to wait around 2–3 hours to get your VL results. Your doctor will discuss the VL results with you, and decide on the best plan for your care. Besides getting the POC VL test instead of the standard VL test, all other parts of your HIV care will be the same as what you would normally get at the clinic.

All adults taking part in this study will have 6 mLs (a little more than a teaspoon) of blood drawn from your arm by needle to measure your VL when you start ART. This blood draw will require a needle stick.

If you agree to take part in this study, you are also allowing the research team to see and use your medical records for this research.

We also ask you to take part in a survey when you start the study. This survey will ask questions on your ability to take your drugs as instructed. If you are in the POC VL group, we will also ask you to take part in a survey at the end of the 12-month trial. This survey will ask what you think of the POC VL test that you received.

After the 12-month trial, all those who took part will get the same HIV care that you would normally get at the clinic. Your doctors will continue to monitor your VL with the standard test used for all patients who did not take part in this trial.

In addition, we would like to store any leftover sample and data collected for this study for future research studies. Future studies may help us learn more about HIV/AIDS and other related diseases. Any future research that uses your sample or data will be reviewed by an ethics committee(s). You do not have to agree to this future research – you may refuse, and still take part in this study.

## What are the risks and possible discomforts?

You will have extra blood (6 mLs) taken when you start ART to measure your starting VL. This blood draw will require a needle stick. The risks of a blood draw include temporary pain, possible bruising, redness, swelling, bleeding, lightheadedness, and rarely fainting or infection.

If you are in the POC group, you will need to wait 2–3 hours to get your VL result. This will overlap with the time that you normally wait to see the doctor. There is a small chance that the POC test may give an invalid result. If this happens we will need to re-run the test and might ask you to wait another 2–3 hours for the result. If you cannot wait for the result, you will meet with your doctor as usual that day, and we will call you to tell you the result. If your VL is high, we will schedule you to return to the clinic as early as possible to discuss this result with a counselor.

For all those taking part, there is a risk that someone without permission may accidentally see some of your private information that can identify you. The researchers will make every effort to protect your privacy and prevent anyone from accessing your information.

If you are injured from taking part in this study, although JUTH's policy is not to provide compensation, medical treatment will be available. This includes first aid, emergency treatment, and follow-up care as needed. In making medical treatment available, or providing it, the researchers are not admitting that your injury was their fault. You are not giving up any of your legal rights by signing this form.

## Are there any benefits from being in this research study?

There is no direct benefit to you or others from your taking part in this research. However, if you are in the POC group, you will learn if your VL is low or high at the same clinic visit. This means your doctor may be able to make quicker decisions for your care, including a switch to new ART drugs if needed.

Whichever group you are in, your taking part in this research will help us learn about POC VL monitoring and its usefulness. This may lead to important changes in VL monitoring that could help HIV patients in this program and others.

You will not be paid for taking part in this research, nor will it cost you anything to take part in this research other than your time.

## If I take part in this research, how will my privacy be protected? What happens to the information you collect?

All samples collected for this study will be labeled with your patient identification number. Your name or other information that can identify you will not be on the samples.

All paper records with your name or other information that can identify you will be locked in file cabinets in secure medical record rooms. All VL test results will be entered in the databases that currently store your medical records at JUTH or Zamko. Survey responses will be entered in a separate study database. All databases will be stored safely on computers in locked data rooms. The data can only be accessed with passwords by members of the research team. If data needs to be transferred, it will be emailed safely in encrypted, or coded, files that can only be opened with a password. Your name and any information that can identify you will not be used in any report or presentation that may result from this research. If you leave the study, your VL test results will remain in your medical records so your doctors can access them and you can continue to get the standard care to which you are entitled. Any other information and leftover sample collected from you for this study will be destroyed.

If you allow your leftover sample to be used for future research, it will be stored at JUTH. If you do not allow your sample to be used for future research, or if you do but change your mind later, any leftover sample collected for this study will be destroyed.

By signing this form, you are allowing the research team to see and use your study data and health information until the study is completed. The research team includes staff and researchers at JUTH, Zamko, the Harvard T.H. Chan School of Public Health (Harvard, Boston, MA, U.S.), and the U.S. CDC. Data collected, including information that can identify you, may be seen by the Ethics Committee/Institutional Review Boards (IRB) of JUTH, Harvard, and the U.S. CDC that oversee the research. The role of these groups is to protect the rights of those taking part in research studies. Your data may also be seen by those who fund this research and others involved in overseeing this study as permitted by law. If outside researchers wish to use your sample or data from this study for approved research, they will NOT receive your name or other information that can identify you.

As the study sponsor, the U.S. CDC may monitor or audit study activities. The reason for this would be to make sure that the study is being done the way it is supposed to be done. It would also make sure that your rights and health are protected. Your personal medical information will be kept confidential.

Participant ID:_____

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

## CONTACT INFORMATION

If you ever have questions, concerns, or complaints, or if you think the research has harmed you, you no longer want to take part in it, or you wish to remove your sample or data from future research, contact the Principal Investigator of this study – Dr. Oche Agbaji, Head of APIN PEPFAR HIV program at JUTH: tel. 0803-349-1851; oagbaji@yahoo.com

This research was reviewed by the JUTH Ethics Committee and a Harvard University IRB. If you would like to contact someone outside of the research team for questions, concerns, or complaints, or have questions about your rights as a person taking part in a research study, contact:

- JUTH Health Research Ethics Committee: tel. 0803-616-6952
- Mrs. Ihedi Otoh, Research Coordinator and IRB liaison to Harvard Office of Human Research Administration (OHRA): JUTH HIV clinic, 2 Murtala Mohammed Way, Jos, Nigeria; ihediotoh@yahoo.co.uk

**If you have any questions on anything in this consent form, you should ask the study interviewer before signing.**

## STATEMENT OF CONSENT

I have read (or have been read to) the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I know that I can withdraw at any time without penalty or loss of benefits to which I am otherwise entitled. I have been offered a copy of this form.

**Check below if you would like to take part in this research, as appropriate:**

☐ I consent to take part in the study.

☐ I consent to allow my leftover sample and data collected for this study to be included in the APIN PEPFAR Sample/Data Bank for use in future research.

**Your signature below indicates your agreement to take part in this research.**

_____
Name of participant (First, Last)

_____ _____
Signature of participant Date

Participant ID:_____

| | |
|---|---|
| Signature of person obtaining consent | Date |
| Name of person obtaining consent (First, Last) | |
| Signature of witness (required if participant is illiterate) | Date |
| Name of witness (First, Last) | |

Participant ID:_____

**Project Title: Reaching 90% target of HIV viral suppression: The role of point of care VL monitoring in resources constrained settings in Nigeria**
**Principal Investigator: Dr. Oche Agbaji**
**Project Sites: Jos University Teaching Hospital (JUTH), Comprehensive Health Centre Zamko (Zamko)**
**Project Sponsor: United States (U.S.) Centers for Disease Control and Prevention (CDC)**

# TRIAL
# PARENTAL/GUARDIAN PERMISSION FORM
**(Parents/guardians of children aged <18 years)**

You and your child are invited to take part in this research study because your child is starting antiretroviral therapy (ART) for HIV at either Jos University Teaching Hospital (JUTH) or Comprehensive Health Centre Zamko (Zamko). The purpose of this research is to compare point-of-care (POC) viral load (VL) monitoring to standard of care (SOC) VL monitoring. A VL test measures the amount of HIV virus in your child's blood. After your child starts taking ART drugs, his/her doctors will monitor, or keep track of, your child's VL to check his/her health and see how well the drugs are controlling the virus. It can take around 2 months to get standard VL test results. A new POC VL test can give results in 2 hours. This study will help us learn if VL monitoring with the POC test is acceptable and can improve patients' health outcomes.

This form provides important information about taking part in research. Someone will explain this research study to you and your child. You and your child have the right to take your time in deciding if you want to take part in this research. Feel free to ask all the questions you and your child want before you decide.

This study is funded by the United States (U.S.) Centers for Disease Control and Prevention (CDC), a government agency that promotes health and protects against health threats.

## Taking part is voluntary
It is your and your child's choice whether or not to take part. If you choose to take part now, you or your child may change your mind at any time. Deciding not to take part or leaving the study will not be held against you or your child, and will not change your or your child's care at this clinic now or in the future.

## What can I expect if my child takes part in this research?
About 794 people will take part in this research trial for a period of about 12 months.

If you and your child agree to take part, your child will randomly be placed in either the SOC VL group or the POC VL group. Your child will have a 50% chance of being in either group. You and your child will not get to choose which group, but we will tell you which group your child is in.

If your child is in the SOC VL group:

> Your child will get the same HIV care and treatment services that he/she would normally get at the clinic. This includes having a blood sample collected from his/her arm by needle 6 and 12 months after starting ART for standard VL testing.

If your child is in the POC VL group:

The 6- and 12-month samples for VL testing will be collected as usual from your arm, but will be tested immediately using the new POC VL test.

You and your child will then be asked to wait around 2–3 hours to get the VL test results. The doctor will discuss the VL results with you and your child, and decide on the best plan for your child's care. Besides getting the POC VL test instead of the standard VL test, all other parts of your child's HIV care will be the same as what s/he would normally get at the clinic.

All children taking part in this study will have 4 mLs (a little less than a teaspoon) of blood drawn from their arm by needle to measure their VL when they start ART. This blood draw will require a needle stick.

If you and your child agree to take part in this study, you are also allowing the research team to see and use your child's medical records for this research.

We also ask parents/guardians to take part in a survey when you and your child start the study. This survey will ask questions on your child's ability to take the drugs as instructed. If your child is in the POC VL group, we will also ask you and your child to take part in a survey at the end of the 12-month trial. This survey will ask what you and your child think of the POC VL test that your child received.

After the 12-month trial, all those who took part will get the same HIV care that they would normally get at the clinic. The doctors will continue to monitor your child's VL with the standard test used for all patients who did not take part in this trial.

In addition, we would like to store any of your child's leftover sample and data collected for this study for future research studies. Future studies may help us learn more about HIV/AIDS and other related diseases. Any future research that uses your child's sample or data will be reviewed by an ethics committee(s). You and your child do not have to agree to this future research – you may refuse, and still take part in this study.

## What are the risks and possible discomforts?

Your child will have extra blood (4 mLs) taken when he/she starts ART to measure his/her starting VL. This blood draw will require a needle stick. The risks of a blood draw include temporary pain, possible bruising, redness, swelling, bleeding, lightheadedness, and rarely fainting or infection.

If your child is in the POC group, you and your child will need to wait 2–3 hours to get his/her VL result. This will overlap with the time that you and your child normally wait to see the doctor. There is a small chance that the POC test may give an invalid result. If this happens we will need to re-run the test and might ask you and your child to wait another 2–3 hours for the result. If you and your child cannot wait for the result, you will meet with your doctor as usual that day, and we will call you to tell you the result. If your child's VL is high, we will schedule you and your child to return to the clinic as early as possible to discuss this result with a counselor.

For all those taking part, there is a risk that someone without permission may accidentally see some of your child's private information that can identify him/her. The researchers will make every effort to protect your child's privacy and prevent anyone from accessing his/her information.

If your child is injured from taking part in this study, although JUTH's policy is not to provide compensation, medical treatment will be available. This includes first aid, emergency treatment, and

follow-up care as needed. In making medical treatment available, or providing it, the researchers are not admitting that your child's injury was their fault. You and your child are not giving up any of your legal rights by signing this form.

## Are there any benefits from being in this research study?

There is no benefit to you, your child, or others from your and your child's taking part in this research. However, if your child is in the POC group, you and your child will learn if his/her VL is low or high at the same clinic visit. This means the doctor may be able to make quicker decisions for your child's care, including a switch to new ART drugs if needed.

Whichever group your child is in, your and your child's taking part in this research will help us learn about POC VL monitoring and its usefulness. This may lead to important changes in VL monitoring that could help HIV patients in this program and others.

You and your child will not be paid for taking part in this research, nor will it cost you anything to take part in this research other than your time.

## If we take part in this research, how will my child's privacy be protected? What happens to the information you collect?

All samples collected for this study will be labeled with your child's patient identification number. Your child's name or other information that can identify him/her will not be on the samples.

All paper records with your child's name or other information that can identify him/her will be locked in file cabinets in secure medical record rooms. All VL test results will be entered in the databases that currently store your child's medical records at JUTH or Zamko. Survey responses will be entered in a separate study database. All databases will be stored safely on computers in locked data rooms. The data can only be accessed with passwords by members of the research team. If data needs to be transferred, it will be emailed safely in encrypted, or coded, files that can only be opened with a password. Your child's name and any information that can identify you or your child will not be used in any report or presentation that may result from this research. If you and your child leave the study, your child's VL test results will remain in his/her medical records so the doctors can access them and your child can continue to get the standard care to which s/he is entitled. Any other information and leftover sample collected from your child for this study will be destroyed.

If you allow your child's leftover sample to be used for future research, it will be stored at JUTH. If you do not allow your child's sample to be used for future research, or if you do but change your mind later, any leftover sample collected for this study will be destroyed.

By signing this form, you are allowing the research team to see and use your child's study data and health information until the study is completed. The research team includes staff and researchers at JUTH, Zamko, the Harvard T.H. Chan School of Public Health (Harvard, Boston, MA, U.S.), and the U.S. CDC. Data collected, including information that can identify you or your child, may be seen by the Ethics Committee/Institutional Review Boards (IRB) of JUTH, Harvard, and the U.S. CDC that oversee the research. The role of these groups is to protect the rights of those taking part in research studies. Your data may also be seen by those who fund this research, and others involved in overseeing this study as permitted by law. If outside researchers wish to use your child's sample or data from this study for approved research, they will NOT receive your child's name or other information that can identify him/her.

As the study sponsor, the U.S. CDC may monitor or audit study activities. The reason for this would be to make sure that the study is being done the way it is supposed to be done. It would also make sure that your child's rights and health are protected. Your child's personal medical information will be kept confidential.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. 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.

## CONTACT INFORMATION

If you ever have questions, concerns, or complaints, or if you think the research has harmed you or your child, you or your child no longer want to take part in it, or you or your child wish to remove your child's sample or data from future research, contact the Principal Investigator of this study – Dr. Oche Agbaji, Head of the APIN PEPFAR HIV program at JUTH: tel. 0803-349-1851; oagbaji@yahoo.com

This research was reviewed by the JUTH Ethics Committee and a Harvard University IRB. If you would like to contact someone outside of the research team for questions, concerns, or complaints, or have questions about your or your child's rights as a person taking part in a research study, contact:

- JUTH Health Research Ethics Committee: tel. 0803-616-6952
- Mrs. Ihedi Otoh, Research Coordinator and IRB liaison to Harvard Office of Human Research Administration (OHRA): JUTH HIV clinic, 2 Murtala Mohammed Way, Jos, Nigeria; ihediotoh@yahoo.co.uk

**If you have questions on anything in this consent form, you should ask the study interviewer before signing.**

## STATEMENT OF CONSENT

I have read (or have been read to) the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I know that my child and I can withdraw at any time without penalty or loss of benefits to which we are otherwise entitled. I have been offered a copy of this form.

**Check below if you would like your child to take part in this research, as applicable:**

☐ I agree for my child to take part in the study.

☐ I agree to allow my child's samples and data collected for this study to be included in the APIN PEPFAR Sample/Data Bank for use in future research.

**Signature Block for Child: Parental/Guardian Permission**

**Your signature below indicates your permission for the child named below to take part in this**

Participant ID:_____

**research**.

_____

Name of participant (First, Last)

_____ _____

Signature of first parent or guardian (required) Date

❑ Parent
❑ Guardian

_____

Name of first parent or guardian (First, Last)

_____ _____

Signature of second parent (if available) Date

_____

Name of second parent (First, Last)

Assent

☐ Obtained

_____

Signature of person obtaining consent and assent

_____ _____

Name of person obtaining consent and assent Date

My signature and date indicates that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally authorized representative, and that informed consent was freely given by the participant or the legally authorized representative.

_____ _____

Signature of witness Date
(required if parent/guardian is illiterate)

_____

Name of witness (First, Last)

Participant ID: _____

**Project Title: Reaching 90% target of HIV viral suppression: The role of point of care VL monitoring in resources constrained settings in Nigeria**
**Principal Investigator: Dr. Oche Agbaji**
**Project Sites: Jos University Teaching Hospital (JUTH), Comprehensive Health Centre Zamko (Zamko)**
**Project Sponsor: United States (U.S.) Centers for Disease Control and Prevention (CDC)**

# TRIAL
# CHILD ASSENT FORM
## (Children aged 7-17 years)

I am a researcher at the Jos University Teaching Hospital (JUTH)/Comprehensive Health Centre Zamko (Zamko). I am trying to learn more about HIV viral load (VL) testing. HIV VL is the amount of virus in your blood. HIV drugs work by keeping your VL low. A VL test measures your VL, which tells us if your drugs are working. I want to see if there are better ways to measure VL.

To do this, I am asking you and other children to take part in my research study. A research study is a way to learn more about something. You are being asked to join this research study because you are about to start receiving HIV drugs. This form explains the study.

If you agree to join this study, I will randomly put you in one of two groups. By random, we mean that you or I cannot choose the group, but you will have the same chance of being in either group:

- **Group A**: You will receive the same HIV care and tests as all children in the JUTH/Zamko HIV program. This includes having a blood sample collected from your arm by needle for the regular VL test.
- **Group B**: You will receive mostly the same HIV care and tests, except we will use a different test to measure your VL. After your blood sample is collected from your arm, we will ask you to wait 2–3 hours to get the test results, while you are waiting to see your doctor. Your doctor will tell you the test results and if your HIV drugs are working.

If you are in either group, we will also collect about 1 extra teaspoon of blood from your arm at your lab visit today. This will be used to measure your starting VL. This blood draw will need a needle prick. The risks include pain, bruising, redness, swelling, bleeding, feeling lightheaded, and rarely fainting or infection.

We also ask you and your parents to take a survey when you start the study. This survey will ask questions on your ability to take your drugs. If you are in Group B, we will ask you and your parents to take another survey at the end of the study. This survey will ask what you think of the VL test you got.

This study will last for 12 months. You will have to come to JUTH/Zamko for your regular HIV clinic visits. After the 12 months, everyone will receive the same care that is usually given by the clinic.

We also would like store any leftover sample and data collected for this study in a Sample/Data Bank for future research studies. Future studies can help us learn more about HIV and other diseases. You do not have to agree to this and can still take part in this study.

Being in this study will not directly help you. If you are in Group B, you will have to wait 2–3 hours for the results of the test. However, you will get to know if your VL is low or high at the same visit, and if your HIV drugs are working. Whichever group you are in, there is a chance that someone who is not supposed to see your private information might accidentally see it. We will do our best to protect your private information. By being in this study, you may help us learn something that will help other children with HIV.

Other people will not know if you are in my study. The information we write down about you and other children will be safely locked up. When we tell other people or write a report about my research, we will not use your name. This way, no one will know that you took part.

As the study sponsor, the United States (U.S.) Centers for Disease Control and Prevention (CDC) may monitor or audit study activities. The reason for this is to make sure that the study is being done the way it is supposed to be done. It also makes sure that your rights and health are protected. Your personal medical information will be kept confidential.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your parents or guardian have already said it is OK for you to be in the study. However, you get to choose if you want to do it or not. Before you decide, I will answer any questions you may have. You can also talk to your mom and dad or your doctor.

You do not have to join this study. It is okay if you don't want to be in the study or if you change your mind later and stop. No one will be mad at you. You can say no even if your mom and dad (or guardian) say yes.

You can contact Dr. Oche Agbaji, JUTH, Jos – tel. 0803-349-1851, or oagbaji@yahoo.com – if you have questions about the study or if you decide you do not want to be in the study any more.

If you agree to take part in this study, please sign your name below. I will give you a copy of this form to keep.

## AGREEMENT

I have read (or been read to) the information in this assent form. The researcher has answered all my questions. I know that I do not have to take part in this study, and can leave the study at any time. I have been offered a copy of this form.

**Check below if you would like to take part in the study:**

☐ I agree to take part in the study.

Participant ID: _____

☐ I agree to allow my leftover sample and data collected for this study to be included in the Sample/Data Bank for future research.

_____
Name of Study Participant (First, Last)

_____ _____
Signature of Study Participant Date

_____ _____
Signature of Researcher Date

_____
Name of Researcher (First, Last)

_____ _____
Signature of Witness (required if participant is illiterate) Date

_____
Name of Witness (First, Last)