IRB NUMBER: 2020-12018
IRB APPROVAL DATE: 07/21/2021
IRB EXPIRATION DATE: 07/20/2022


# Albert Einstein College of Medicine Consent to Participate in Research

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| **Study Title:** | Long term outcomes of therapy in women initiated on lifelong ART because of pregnancy in DR Congo |
| **Researcher:** | Marcel Yotebieng, MD, PhD; Pelagie Babakazo, MD, PhD |
| **Sponsor:** | USA National Institute of Health |

**This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate.

**Your participation is voluntary.**

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

**Purpose:** The main purpose of this research study is to find ways to increase the number of pregnant women diagnosed with HIV who attend regular visits and receive appropriate medical services for their own health and to prevent transmission of the virus to their infant. Many pregnant women who are identified with HIV during pregnancy do not go to receive available services to prevent passing the virus to their infants and maintain their own health. The exact reasons for not returning to the clinic may vary from person to person and the best way to help those mothers and their infants stay in care is not known. In this study, we want to set up a small committee in clinics like this one, which in collaboration with the health zone bureau, and the provincial bureau of National AIDS Control Program (PNLS) will meet on regular basis to look at the problems affecting the quality of care for HIV-infected mothers and their infants at each clinic, identify ways to solve these problems, and implement the identified solutions. The circle will be repeated every three months for about 2 years.

The three largest clinics from each of the 35 health zones (districts) in Kinshasa are included in the study. The health zones are organized in two groups: in the first group, quality improvement teams are set-up to work with clinic to improve the quality of HIV care they provide in maternal and child health clinic. In the second group, clinics continue to provide care as usual. In both groups all HIV-infected pregnant or breastfeeding mothers and their HIV-exposed infants are eligible to be part of the study.

We expect to enroll about 3000 HIV-infected pregnant or breastfeeding mothers and their infants and to follow-them up through the end of the study.

A description of this clinical trial is available on https://clinicaltrials.gov/ct2/show/NCT03048669, 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.

**Procedures/Tasks:**
If you agree to take part in the study, we will ask you a series of questions about your understanding of mother-to-child transmission risk and HIV disease, and difficulties to accessing and adhering to services to prevent transmission of HIV from mother to the child including social, cultural, and financial difficulties. We will also ask you questions about the way you feel about the care you receive in this clinic, about your partner, the way you feel in general, and the way you intend to nurse your baby. The interviews will take place here in the clinic today, after you give birth, when you return for your 6-week visit after giving birth, and every 6 months thereafter. Your answers will be written down during each interview so that we can remember them later. Each interview will take between 30 minutes and one hour. For your time, a small compensation of $2 will be given to you after each interview.

If you agree, we may also asked you to provide blood or urine for some tests that might be helpful to you and your baby but that are not regularly done, like screening for diabetes and testing the virus in your blood. Your doctor will receive the result of those tests immediately when they become available.

**Duration:** Depending on when you are enrolled, your time in this study will be between 2 to 4 years. You may leave the study at any time. If you decide to stop participating in the study, your decision will not affect your future relationship with this clinic.

**Risks and Benefits:**
Some of the issues that we will be discussing with you are personal and sensitive. You may experience emotional discomfort/distress when discussing these questions and you may refuse to answer any question for any reason. You will be linked to services to help you if you need them. You can also request support services at any time for any reason. You may ask to stop the interview or your participation in the study at any time if you do not wish to continue. In addition, if you happen to be in the group of health zones that will work to improve the quality of care, you may see some changes in the way the personnel of the clinic care for you and your baby. Refusing to participate in this study at any time will not affect routine medical care or medicines that you or your baby will receive. Part of your routine care involves obtaining blood sample from you and your baby. There may be a risk of discomfort or pain from blood draws, including a reaction or injury from the needle. If such problems occur, the researchers will help you get medical care. You will also be asked to permit storage of some part of the blood sample from you and your baby for future research use. This is explained in a separate consent form. You do not have to agree to sample storage in order to participate in this research study.

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury

from collection of a blood sample. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The Kinshasa School of Public Health and Albert Einstein College of Medicine have not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

**Confidentiality:**

Participation in research may involve a loss of privacy. Study records that contain information about you will be handled as confidentially as possible. All research records will be coded so that no person outside the study group can identify you personally. Only the people who are doing the study will look at the answers given during the interviews or at any information obtained from your clinic record. Because your name will not be stored with your answers, no one will know that you are the one who said something. Your name will not be used in any report or publication about this study. The researchers will keep all the information they learn in the study in a locked cabinet at the study's offices in Kinshasa or on a computer that is protected by a password.

The NIH issues Certificates of Confidentiality for all NIH-funded studies, including this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable information collected about you as a part of this study in a lawsuit or legal proceeding. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, if NIH that is funding this study requests the information.

Please talk to your study team, or contact the staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at +1 718-430-2253 or irb@einstein.yu.edu, if you have questions.

Please visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

**Incentives:**

You will not be paid to be part of this study. However, as indicated above, for each interview, you will receive a $2 to compensate for your time.

**Participant Rights:**

You may refuse to participate in this study your decision will not affect the way you or your baby are treated in this clinic.

If you choose to participate in the study, you may discontinue participation at any time. Your decision will not affect the way you or your baby are treated in this clinic. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

The Institutional Review Boards responsible for human subjects research at The Kinshasa School of Public Health and at Albert Einstein College of Medicine reviewed this research

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project and found it to be acceptable, according to applicable DRC, New York state, and USA federal regulations and the two Universities policies designed to protect the rights and welfare of participants in research.

**Contacts and Questions:**

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Prof. Pelagie Babakazo at 099 994 5183.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Prof. Bongopasi Moke Sangol, Deputy Chair of the Ethics Committee at the Kinshasa School of Public Health. You may reach him at 099 995 2341. You may also contact the staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at +1 718-430-2253 or irb@einstein.yu.edu.

## Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

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| **Printed name of subject** | **Signature of subject** |
| | **AM/PM** |
| | **Date and time** |
| **Printed name of person authorized to consent for subject (when applicable)** | **Signature of person authorized to consent for subject (when applicable)** |
| | **AM/PM** |
| **Relationship to the subject** | **Date and time** |

## Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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| **Printed name of person obtaining consent** | **Signature of person obtaining consent** |
| | **AM/PM** |
| | **Date and time** |