

**SUUBI4STIGMA: ADDRESSING HIV-ASSOCIATED STIGMA AMONG  
ADOLESCENTS**

**National Clinical Trial (NCT) Identified Number:**

NCT04528732

**Multiple Principal Investigators:**

Proscovia Nabunya, PhD

Fred M. Ssewamala, PhD

**Sponsor:**

Washington University in St. Louis

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Suubi4Stigma: Addressing HIV-Associated Stigma Among Adolescents

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**Caregiver Consent Form**

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## English Guardian Consent Form

**Suubi4Stigma:  
Addressing HIV-Associated Stigma Among Adolescents**

**Research Collaborators:**  
Washington University in St. Louis  
Reach the Youth-Uganda

**Principal Investigators: Dr. Proscovia Nabunya  
Dr. Fred Ssewamala**

**In-Country Principal Investigator: Dr. James Mugisha**

**24-Hour Numbers:**

Flavia Namuwonge, Project Coordinator: **0793-888-706/0705-790-932**  
Raymond Atwebembere, Project Coordinator: **0793-888-725/0785-474-676**  
Dr. Abel Mwebembezi, Reach the Youth -Uganda: **0793-888-711**  
Dr. James Mugisha, In-country Principal Investigator: **0772-587-098**  
Dr. Proscovia Nabunya's local line in Uganda: **0793-888-719** or office line: **(001) 314-935-9087**  
Dr. Fred Ssewamala's local line in Uganda: **0793-888-700** or office line: **(001) 314-935-8521**

### INTRODUCTION

We have approached you because your child receives healthcare from a clinic that collaborates with the International Center for Child Health and Development (ICHAD) and Reach the Youth Uganda. We are inviting you and your child to participate in a study involving research among adolescents living with HIV, between the ages of 10-14 years, and living in the greater Masaka region. The purpose of this form is to give you the information you will need to help you decide whether you and your child will participate in the study or not. You may ask any questions about this study, including possible risks and benefits, yours and your child's rights as a potential participant, and anything else about the research, or this form that is not clear to you. This process is called 'informed consent.' You will be provided with a copy of this form for your records. Most importantly, know that you are allowed to say "no" to yours and your child's participation today or at any point in the future without suffering any negative consequences.

### PURPOSE

The study we are inviting you and your child to participate in concerns research about strategies to help reduce stigma associated with living with HIV/AIDS, and its negative impact on the health outcomes of children and their families. This research project is a collaboration between Washington University in St. Louis (USA) and Reach the Youth-Uganda.



### EXTENT OF PARTICIPATION

This is a two-year study that will involve 90 HIV-positive adolescents, just like your child, and their caregivers. We will ask you/your child to participate in three confidential (private) interviews with a member of our research staff, such as myself and/or through audio computer-assisted devices. Each interview will last between 60-90 minutes. One interview will be done today or at a date in the near future, the second will be done in 3 months, and the third will be done in 6 months. The information we collect during interviews is for research purposes only.

**Subject matter:** During the interviews, we will talk to you and your child about your relationship with your family members, HIV medication and adherence, whether you have experienced stigma because of your HIV status, your mental health wellbeing, as well as the socio-economic status of your family. We will also ask about how you feel about yourself, your family, and your future plans.

**Withdrawal:** You and your child may refuse to participate, or you can withdraw from the study at any time, for any reason, with no explanation, and you will not be penalized in any way. You both can also refuse to answer any questions at any time. None of your choices will impact the services you receive from your health clinic. You both have the right to review any materials and request that we erase any of your responses. I will also ask you to give permission for your child to be in this study, but even if you agree, your child can still decide not to be in the study. When we finish, I will ask your permission to contact you and your child in 3 months and to follow-up with a second interview very similar to the one we do today or on a day in the near future.

### RISKS

During the interviews, you/your child may feel embarrassed or uncomfortable when answering sensitive and personal questions. If you/your child is uncomfortable with a particular topic, you can tell me that you prefer not to discuss it and we will move on.

### COMPENSATION

If you agree to participate and allow your child to participate, and if your child agrees to participate in the study, your family will receive a monetary compensation of Uganda Shillings 40,000/= (forty thousand shillings), upon completion of each interview. The compensation is for the time and the valuable information you/your child may provide during the interviews.

### BENEFITS

During the course of the study, you/your child may learn ways to improve your relationship with family members, as well as improve your health wellbeing, including your child's adherence to medication. In addition, your participation will help in the successful completion of this study, which is designed to help us develop effective strategies that can be used to reduce HIV associated stigma and its negative impact on adolescent health, as well as among their families.





## PROTECTION

The information you/your child give will be used by Washington University in St. Louis, only for the purpose of research. Washington University will have access to all de-identified data and will be involved in dissemination of findings. All of the information that you/your child provide will be kept confidential. We will not share any information or answers with any of your family members, friends, healthcare providers, or community leaders, including church leaders. Only our research staff will have access to the interviews, and yours/your child's identity will not be disclosed when findings from this study are published. For record-keeping purposes only, we will assign each of you a unique study identification number; only this number – not your names – appear on research generated forms. The questionnaires we complete while interviewing you will be locked in a filing cabinet to which only the Principal Investigators, Drs. Proscovia Nabunya and Fred Ssewamala, and the research staff will have access. The only exception is the Office of Human Research Protections, the Washington University Institutional Review Board, the Uganda Virus Research Institute (UVRI) Research Ethics Committee (REC), and the sponsor of the study who may have access to the data for oversight and monitoring purposes to ensure the protection of the rights and welfare of the study participants. Similarly, the only exception to confidentiality would be the risk of immediate harm. For example, if you tell us that either you or your child is going to hurt themselves or someone else, or that someone else is hurting you or your child, in such circumstances your answers will be shared with the local district probation and child welfare offices.

## CONTACT INFORMATION

If you have any questions about this study, you are encouraged to contact:

**Flavia Namuwonge**, Project Coordinator at: 0793-888-706/0705-790-932 or **Atwebembere Raymond**, Project Coordinator at: 0793-888-725/0785-474-676. You may also contact **Dr. Abel Mwebembezi**, Reach the Youth -Uganda at: 0793-888-711/0702-789-517 or **Dr. James Mugisha**, In-country PI at: 0772-587-098; or you may also write to them at P.O. Box 1988, Masaka.

You may also contact **Dr. Proscovia Nabunya** at Washington University in St. Louis George Warren Brown School of Social Work, Campus Box 1196, One Brookings Drive, Brown Hall, Room 112, St. Louis, MO, 63130, USA; or at the local line in Uganda: 0793-888-719; or at telephone number (001) 314-935-9087. You may also contact: **Dr. Fred Ssewamala** at Washington University in St. Louis George Warren Brown School of Social Work, Campus Box 1196, One Brookings Drive, Goldfarb Hall, Room 343, St. Louis, MO, 63130, USA; or at the local line in Uganda: 0793-888-700; or at telephone number: (001) 314-935-8521.

If you have any questions regarding your rights as a research participant, or if at any time you have comments regarding the conduct of this research, you may contact the Executive Secretary, Uganda National Council for Science and Technology (UNCST) at 041-470-5500; as well as the Dr. Tom Lutalo, Chair, Uganda Virus Research Institute (UVRI) Research Ethics Committee (REC) at 0414-321-962 or 0716-321-962. Additionally, you may contact the Washington University Institutional Review Board by telephone at (001) 314-747-6800. The Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.



## STATEMENT OF PARTICIPANT CONSENT

I \_\_\_\_\_ have been asked to participate in a research study. The principal investigator's representative \_\_\_\_\_ has explained the study including potential risks and benefits. I have been given the opportunity to ask questions about the project and my participation. All questions were answered to my understanding. I understand I can withdraw at any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn. The procedures regarding confidentiality have been clearly explained.

I voluntarily agree to participate in this study. I am signing my name below to indicate my consent and to allow my child to participate in this study. We will be given a copy of the signed consent form at the baseline visit and may obtain another copy at follow up visits if I need one.

Your Child's Name (Please Print): \_\_\_\_\_

Your Name (Please Print) \_\_\_\_\_

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

Thumbprint

### If guardian cannot read the form themselves, a witness must sign here:

I was present while the benefits; risks and procedures were read to the participant. All questions were answered, and the participant has agreed to take part in the research.

Name of Witness (Please Print): \_\_\_\_\_

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

Thumbprint

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

\_\_\_\_\_  
(Name of Person who Obtained Consent - printed)

\_\_\_\_\_  
(Signature of Person who Obtained Consent)

Date

