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NYU Langone Health

Research Subject
Parent Informed Consent Form

UNIVERSITY OF NAIROBI

Title of Study:	**Testing the Effectiveness of a Digital Adolescent Behavioral Health Screening, Literacy, and Low-Intensity Intervention for Common Adolescent Mental Health Problems in Kenya**
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study. People who agree to take part in research studies are called "subjects" or "research subjects". These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, school staff, or head of the Community Health Organization (CBO) in your community. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form for you to keep.

2. What is the purpose of this study?

University of Nairobi and New York University are partnering with youth service and educational organizations in Kenya to test a new digital approach of behavioral health and wellness promotion for adolescents. The digital approach is named mHealth Toolkit for Screening & Empowering Lives of Youth (mSELY). The digital toolkit is designed for adolescents ages 11-14, and two versions will be developed and tested. The mSELY-Adolescent version is designed for adolescents to self-evaluate and learn strategies to manage behavioral health and wellbeing. The mSELY-Parent version is designed for caregivers to self-evaluate their adolescent's development and wellbeing, gaining awareness, and wellness promotion strategies to support their adolescents.

You are being invited because you are a parent of an 11-14 years old adolescent. Depending on the program that your child's school is participating in, either your child, or both you and your child might be invited to participate in the program. If you or/and your child are participating, we are asking you or/and your child to try out the digital toolkit and provide us feedback about the program. You or/and your child will be asked to share your perspective and experience through Surveys/Questionnaires using tablets and Individual/group Interviews. You and/or your child's feedback will help improve the digital tool design that may benefit more families.

3. How long will I be in the study? How many other people will be in the study?

We will ask you and/or your child to be in the study for 4-6 months (after the first session). We are expecting 2400 families (including 1 adolescent, or both parent and adolescent from each family) to be in the study.

4. What will your child and you be asked to do in the study?

All Adolescent:

- Your child will participate in the mSELY-A toolkit. A trained community or school health partners will work with your child's school to schedule time for toolkit use. The toolkit will take 45 min to 1 hr.
    - Because we are unable to offer mSELY-A to everyone at the same time we will work with your child's school to offer the toolkit either this school year (2023-2024) or next school year (2024-2025).

Subset of Adolescent

- We will also be inviting a random subset of adolescents to participate in a more indepth evaluation. A maximum of 50 adolescents will be selected to participate in each school.
    - We will be asking these adolescents to participate in 2 assessment/evaluation activities/meetings that will happen either at the same time they use mSELY-A or before they use the mSELY-A toolkit. These additional assessments will take approximately 30 minutes and be 4-6 months apart.

Subset of Parents

- For schools participating in the mSELY-Parent program and the Health information program we are also inviting a random subset of parents to participate. Approximately 150 parents will be invited in the mSELY-Program and 150 families will be invited in the Health information program. A maximum of 50 parents from your child school will be selected.
    - Those in the mSELY-Parent Program will get to use the mSELY-P toolkit. Those participating in the Health information program will have access to digital health tools and information. Parents will receive support from community or school health partners as needed.
    - Parents will also be asked to participate in 2 assessment/evaluation activities/meetings. Each assessment meeting will take about 1 hour and be 4-6 months apart.

Subset of Families

- A subset of families will also be invited to participate in a focus group at the end of the programs to provide feedback on overall experience.

Identifiers will be removed from the identifiable private information. After such removal the private information may be used for future research studies or shared with other researchers and we will not request additional informed consent from you to use these specimens as we have noted here.

5. What are the possible risks or discomforts?

Risk of Study

There is minimal risk involved in participating in the study. The main risk of this study is a breach of confidentiality. This risk will be minimized by storing contact information and identifiers such as names separate from the research data collected and limiting access to this information to the research team.

Unforeseeable Risks: The research may involve risks that are currently unforeseeable.

Other Risks

You may become uncomfortable by some of the questions asked in the questionnaires. You have the opportunity to not answer any questions that make you feel uncomfortable. If you experience any discomfort or have concerns, please contact the PI listed on top of the first page directly.

What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

6. What are the possible benefits of the study?

Results from this study will be used to develop programs to help young children succeed in school in the future

7. What other choices do I have if I do not participate?

Participation is voluntary and you can choose to not participate in the study.

8. Will I be paid for being in this study?

For the subset of families participating in the assessment/evaluation activities/Focus group, parents will receive Ksh 1000 (approximately $7 USD) after completing the surveys or focus group. For adolescents doing the additional assessment/evaluation activities/focus group, they will receive a notebook or small gift after completing the surveys or focus group.

9. Will I have to pay for anything?

It will not cost you anything to participate in this study.

10. What happens if I am injured from being in the study?

It is not expected that your participation in this study will result in any injury, however, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but

you may also be responsible for some of them. For medical emergencies contact 999 from your landline or 112 from your mobile phone. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. There are no plans for the NYU School of Medicine and/or University of Nairobi to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

11. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. If you decide to take part in the study, you may stop at any time without penalty. If you wish to stop participating, all you have to do is let the research staff know you wish to stop participating in the study.

This study may also be stopped or your participation ended at any time by the PI, or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

12. How will you protect my confidentiality?

To help us protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you. Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a legal subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a Kenya national, district, or local law that requires disclosure (such as to report child abuse or communicable diseases). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

13. HIPAA Authorization

As noted in the Confidentiality section above, US and Kenyan law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are

asking for your permission (authorization) to use and share your research information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study. We will not NOT share any of your information with your employers. Therefore, your employment and service outside of this study and benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: NIMH
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Nairobi University College of Health Sciences
- National Database for Clinical Trials related to Mental Illness (NDCT)

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal information for this study will never expire unless you withdraw it.

14. The Institutional Review Board (IRB) and how it protects you
The IRB reviews all human research studies – including this study. The IRB follows US and Kenya Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 011-1-212-263-4110. IRB review board are made up of:

- Researchers, doctors, nurses, non-scientists, and people from the Community

15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health or Amref Review Board (IRB) at The Research Officer, Amref Health Africa in Kenya, Wilson Airport, Lang'ata Road, Office Tel: +254 20 6994000, Mobile No: 0795746777, Fax: +254 20 606340, P.O Box 30125-00100, Nairobi, Kenya.

When you sign this form, you are agreeing to let you or your child to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your child will also be asked to provide assent.

Name of Adolescent (Print)		
Name of Adult Caregiver (Print)	Signature/Finger Print of Adult Caregiver	Date
Name of independent witness	Signature of independent witness	
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date