Consent Form (for parents)
Phase 2 RCT

Project Title: **The effectiveness, mechanisms of change, and acceptability of Family Focused Psycho-Social Support (FFPSS) for at-risk adolescents in Lebanon**

Protocol Number: **SBS-2020-0133**

Principal Investigator(s): **Dr. Tania Bosqui**

Address: **American University of Beirut**

Phone: **01 350-000 ext. 4370**

Dear Parents,

This is a consent form for you and your child(ren) to participate in a research study. It contains important information about this study and what to expect if you decide to take part.

You and your child's participation is voluntary.

Please consider the information carefully before you decide to participate. If you decide to participate, you will be asked to sign this form or voice your agreement and will receive a copy of the form.

What is this study about?

We are inviting you and your child to participate in a research study that aims to develop and test a family program called Sawa A2wa for young people and their families facing adversity in Lebanon. We have developed an intervention based on what we think will be helpful for families. In this part of the study we want to deliver the intervention to 351 families to test how helpful it is.

Who is the study conducted by?

The study is conducted by a team of researchers and practitioners from several agencies and universities, including the American University of Beirut and [NAME OF PARTNER ORGANIZATION].

What will my child and I be asked to do?

1. First of all, we will ask you and your child some questions about how they feel and about any difficulties they or your family has. We will do this at your home or at a clinic or community center, and we will talk separately to you and your child. If we are unable to meet in person due to COVID-19, we will meet over the phone, and we will cover the cost of the call. If our assessment shows that this program is not

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suitable for you and your child, you will still have access to any other available programs more suited to your child's needs.

2. If we deem the program to be suitable, then you and your child will be offered the Sawa A2wa Family Program provided by a trained facilitator over 7 weekly 2 hour sessions. You will be offered the family sessions straight away or in 2-3 months time. Whether you receive the family sessions straight away or after 2-3 months is chosen randomly, which is like flipping a coin to see if you get heads or tails, so each family has an equal chance of being offered sessions straight away or later. We do this so that we can better test whether the family sessions are helpful.

   The sessions will take place in or near your home, in a clinic or community center, or another private space. During the family sessions, the facilitator will be working with you and your child to improve coping and to help deal with any difficulties your child or family are having.

3. When the sessions are complete, and 3 months after the sessions are complete, we will ask you and your child the same questions as at the start. We might also ask you and your child to take part in an additional family interview about how the family program went. We will audio record this so that we can accurately put in written form what you tell us. If you don't want to be recorded, a second person will sit in the interview and make notes.

Do we need to take part in the study?

Participation in this study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits or relationship with any organization in any way. If at any time and for any reason, you would prefer not to answer any questions, please feel free to skip those questions. If at any time you would like to stop participating or wish for your child to stop participating, you are free to do so without any negative consequences. We can take a break, stop and continue at a later date, or stop altogether.

Will my information be confidential?

Your individual privacy and confidentiality of the information you provide will be maintained at all times and in all published and written data analysis resulting from the study. Responses on the questionnaires will be stored anonymously (not linked to your name) using a unique number for each family, on a secure password protected server. Audio recordings will be stored on secure, password protected computers only until they have been transcribed (put in written form). Once they have been transcribed they will be deleted/destroyed. Information you give will be stored on secure, password protected computer systems and will only be available to authorized members of the study team. We will store this information for 5 years after the end of the study, and then it will be destroyed. We may share your and your

child's answers to the questions with other researchers who are also doing research about the family program. They will not be given any information that will identify you or your child.

However, please note that the Institutional Review Board monitors records and may audit our records. This is to check that the study is being carried out correctly and to high standards.

If there is a serious risk of harm to your child (e.g., risk of suicide or harm by others) then we will need to disclose this information to other agencies in order to get appropriate help for your child. Referrals and disclosure of information will be made to relevant services on a need-to-know basis. We will aim to do this with your knowledge and consent, if possible, unless this would delay vital treatment or services for your child.

Are there any risks or benefits to taking part?

The intervention you will be receiving is based on programs that have been found to help children and families in other places, and we think that it might help you to cope better with your difficulties.

Answering questions about you and your child's difficulties and experiences of the family sessions may cause you to feel some anxiety and sadness. However, we anticipate that any discomfort you experience will pass quickly. If you or your child's discomfort does not pass quickly, your interviewer will refer you to the appropriate services.

Will I be compensated for my participation?

You will not receive compensation for attending the intervention. However, you will receive 25,000 LBP at the beginning of each research interview to compensate for transport or mobile data costs associated with study participation. The interview will take around 1.5 hours to complete.

Who should I talk to if I have any concerns or questions?

If you have any questions, you are free to ask them now. If you have questions, concerns or complaints about this research study later, you may contact the study Principal Investigator at the American University of Beirut:

Dr. Tania Bosqui [English and French speaking]
American University of Beirut
Tel: 01 350-000 ext 4370
Email: tb33@aub.edu.lb

Zahraa Shaito [English and Arabic speaking]
American University of Beirut
Tel: 01-350000 ext 4367

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Email: zs35@aub.edu.lb

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about research or the rights of your child as a research participant, please contact the AUB Social & Behavioral Sciences Institutional Review Board (SBSIRB) at AUB: 01-350000 Ext. 5444/5445, email**:** irb@aub.edu.lb

Who has reviewed this study?

The study has been reviewed by the Institutional Review Board at the American University of Beirut to ensure that it is conducted in an ethical and legal way.

	Yes	No
I have read (or someone has read to me) this form and I am aware that I am being asked consent for me and my child (or child under my guardianship) to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I will be given a copy of this form.		
I understand that participation is voluntary and that I and my son/daughter are free to withdraw at any time, without giving up any legal rights or medical care.		
I agree that I and my child/child under my guardianship can participate in this study.		
I understand that all data we provide will be anonymous and will be kept for at least 5 years after the end of the study.		

TO BE COMPLETED BY MOTHER IF CONDUCTED IN PERSON

I the undersigned (Name): _____; Parent of (child's name): _____

Date: _____ Signature of mother: _____

TO BE COMPLETED BY FATHER IF CONDUCTED IN PERSON

I the undersigned (Name): _____; Parent of (child's name): _____

Date: _____ Signature of father: _____

TO BE COMPLETED BY RESEARCHER

Name of researcher taking consent: _____

Date: _____ Signature of researcher: _____

IF ORAL CONSENT IS OBTAINED, TO BE COMPLETED BY INDEPENDENT WITNESS

Name of witness to consent: _____

Date: _____ Signature of witness: _____

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