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Informed Consent Form

Study Title	**Assessing the Effectiveness of Active Bleeding Control/Stop-the-Bleed: A Pilot Life-Saving First Aid Training Program in Kenya**
Investigator(s)	Kirstin Henley, MD +1(331) 625-2577- (PI) Mukami Brenda Kunga, MD +254 721 225092 (Co-PI) Bhupi Reel, MD +1254 722 555712 Amelie von Saint Andre-von Arnim, MD +1(206) 313-6997 Vinay Nadkarni, MD +1(610) 764-3700 Samuel Kafoe, MD +254 741871018 Nancy Moore, MSW +1 (513) 620-4236
Study Sponsor(s)	Laerdal Foundation, Africa Fire Mission
Collaborators	

Part I: Information Sheet

Why is this project important?

Many people in Africa get hurt in car accidents, and this can cause a lot of bleeding. If it takes a long time to get to a hospital, knowing how to stop the bleeding can save lives.

Our team wants to teach people how to help stop bleeding in an emergency. You will learn 5 steps to stop bleeding and how to use bandages and a tourniquet.

Our research group is made up of partners from the original Active Bleeding control team in India and the U.S.A. who helped make this teaching, volunteers from Africa Fire Mission (AFM) and Pediatric ICU doctors from the U.S.A., and ICU and emergency doctors from Kenyatta National Hospital and University of Nairobi.

Who can join this study?

Can join: Anyone who wants to volunteer.

Cannot join: People who can't make decisions for themselves, don't want to volunteer, or can't speak English or Swahili.

Voluntary participation

It is your choice to participate: It is up to you if you want to join this study. You can stop at any time or choose not to join this study, without any problems.

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What will you do in this study?
First, you will answer questions about what you know. The questions will be asked on paper surveys or your phone and collected before the training. This will take about 10 minutes. Then, you will join a 90-minute training to learn how to stop bleeding and get a kit to help with that. You might also be asked to come back for an interview or to show your skills.

Some volunteers will be chosen to participate in interviews. We will also allow them to show their skills before and after the training programs and tell us the difficulties and strengths of current training. All interviews will be recorded for analysis.

Since this study will contain photographs, videotaping, and sound recordings, you will be required to fill out a separate consent form.

If changes are made to the study or new information becomes available, you will be informed.

How long will the project last?
The study will last 3 years. You will have one 90-minute session and can attend review sessions every 6 months.

Are there any risks?
There are no risks to you in this study.

What are the benefits?
You will learn important skills to help others in emergencies and receive a bleeding control kit and a certificate.

How will your information be protected?
We will keep your information private and safe, without your name on it.

What will happen with the study results?
We hope to share our findings with others, like the World Health Organization (WHO), to help teach more people in Africa.

Can you change your mind?
Yes, you can stop participating at any time by telling the research members. Your information will not be used without your consent if you withdraw from the study.

Will you get paid?
No, there is no payment for participating in this study.

Who can I contact?

If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact:

- Kirstin Henley, +1(331) 625-2577, kirstin.henley@bcm.edu or
- Mukami Brenda Kunga, MD +254 721 225092, mukami.kunga@gmail.com.

If you have questions about your rights as a study subject, you may contact:

The Secretary ESRC
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

Do you have any questions at this time?

I have read and understood this form about joining the study. I've had the chance to ask questions, and I don't have any more questions right now. I know where to find more information if I need it.

Part II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Print name of Subject	
Signature of Subject	
DD/MM/YYYY	

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If visually impaired, physically impaired, mentally impaired or illiterate

I have witnessed the accurate reading of the Consent Form to the potential study subject, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Subject	
Thumb/Foot print of Subject	
Signature of Witness	
DD/MM/YYYY	

I confirmed that the person was able to ask questions about the study, and I answered all their questions as clearly as I could. I also confirm that they agreed to be part of the study on their own, without any pressure or force.
A copy of this Informed Consent Form has been provided to the study subject.

Print Name of researcher/person taking the consent	
Signature of researcher/person taking the consent	
DD/MM/YYYY	