Title: Evaluating Outcomes for Youth Receiving Hospital-based Violence Prevention With and Without a Community-level Initiative

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Evaluating outcomes for youth receiving hospital-based violence prevention with and without a community-level initiative

VCU INVESTIGATOR: Nicholas D. Thomson, Ph.D. Assistant Professor, Department of Surgery. 804-628-5541

SPONSOR: National Center for Injury Prevention and Control: Centers for Disease Control and Prevention

NOTE: In this consent form, "you" always refers to the research participant (you).

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to find out if a hospital-based violence intervention (Bridging the Gap) is effective for reducing youth violence. We think that youth who receive the Bridging the Gap will see greater improvements than youth who do not receive the intervention. This study will allow us to learn more about the intervention's effectiveness. We also want to understand if the violence intervention affects other behaviors, such as drug use, aggression, risky behaviors, and rates of violent re-injury.

What will happen if I participate?

You will be asked to complete surveys about your child's behavior, personality, and experiences, as well as your own behaviors, personality, and experiences. These surveys take about 45-60 minutes to complete. You will complete these questionnaires before your child completes the intervention and then again 6 months later. We will arrange a time to meet with you to conduct the second set of surveys. If this is not convenient we will arrange a time to complete the surveys over the phone or the internet.

Your participation in this study will last up to 6 months. Approximately 408 individuals will participate in this study.

What alternative treatments or procedures are available?

You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
• Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. • The study questionnaires ask questions that are sensitive, personal, and may be upsetting in nature and may make you feel uncomfortable or upset. Some of these questions discuss the use of drugs and criminal activities.	The information from this research study may lead to improved violence interventions in the future for violently injured youth.

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

During your first study visit (Visit 1), you will be interviewed by the study staff and fill out questionnaires about your child and yourself to see if you are eligible to be in the study.

We will also ask you complete surveys about your child and yourself. These surveys cover topics from parenting, personality traits (e.g., anxiety, depression), childhood experiences, aggressive behaviors, exposure to violence, emotional management, and substance use. We anticipate that the surveys will take about 45-60 minutes for you to complete. This information will be collected twice during your participation in the study (today and in 6 months). In 6 months, we will contact you to complete the second assessment (Visit 2) by phone to schedule a convenient time for you to complete the same surveys as Visit 1. If meeting in-person is not convenient, we will conduct the interviews over the phone or by the internet.

WHAT ALTERNATIVES ARE AVAILABLE?

You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey.

WHAT ARE THE COSTS?

The sponsor is paying for everything in this study. You will not be charged for any study visits, tests, or procedures.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $10 for the first study visit, and $15 for the second study visit. Your child will receive $25 for each study visit. You will receive cash after completing each assessment.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions

- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services and Centers for Disease Control and Prevention

In general, we will not give you any individual results from the study. If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

Project findings and reports prepared for dissemination will not contain information that can reasonably be expected to be identifiable.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers may share information about you or your participation in the research project without your consent if disclosure is made, such as child or elder abuse or neglect, or harm to self or others.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Nicholas Thomson, PhD.
Assistant Professor of Surgery
Phone: (804) 628-5541
Email: Nicholas.Thomson@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT AND/OR PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent and permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent and permission, I have not waived any of the legal rights or benefits to which I and my child otherwise would be entitled. My signature indicates that I freely consent to participate and give permission for my child to participate in this research study. I will receive a copy of the consent and permission form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date