IntERact: Preventing Risky Firearm Behaviors Among Urban Youth Seeking Emergency Department Care

NCT05109325

Date of IRB Approval: January 8, 2024

CONSENT TO BE PART OF A RESEARCH STUDY

Part 1 of 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study title:	Project IntERact V2
Company or agency sponsoring the study:	Centers for Disease Control and Prevention (CDC)

1. KEY INFORMATION ABOUT THIS STUDY

You, or your young adult, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a young adult's participation in the research, note that in the sections that follow the word 'you' refers to 'your young adult'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying a new way to improve prevention programs for young adults who may engage in risky behaviors, things such as alcohol and drug use, fighting, and carrying a weapon. You may not be involved in all these behaviors but may have seen your friends or people in your community getting involved in. For this research study, you will be asked to complete a baseline survey. Then, you will be randomly assigned to one of the two study groups. More detailed information is provided later in this document about these different study groups. You will be asked to complete brief daily surveys for 4 weeks as well as follow-up surveys at 3- and 6-months after your baseline survey. Some of you will be asked to meet with a Health Coach after the baseline survey either over the telephone, video chat service (e.g., Zoom), or in-person and 2 more times during the following month. A health coach is a trained professional in our study team who will meet with study participants to discuss their health behaviors and help them reach their goals. The health coach focuses on promoting a healthy lifestyle by providing motivation and support. Your participation in this study will be over after you finish the 6-month survey.

This study involves a process called randomization. This means that the intervention (activities involved in the study) you receive in the study is not chosen by you or the researcher. The study design divides study participants

into separate groups, based on chance (like the flip of a coin), to compare different interventions. If you decide to be in the study, you need to be comfortable not knowing which study group you will be placed in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feelings of discomfort, anxiety, or loss of privacy. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping us improve new prevention programs for youth who may engage in risky behaviors. More information will be provided later in this document.

We expect your participation in this study will be over after you finish the 6-month follow-up survey. You can decide not to be in this study. Alternatives to joining this study include asking your medical team for resources and seeking out community resources.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

We want to learn more about the health behaviors of young adults. Health behaviors include relationships, physical and mental health, alcohol and drug use, fighting, and carrying a weapon. The purpose of this study is to develop and test a program to help young adults reduce risky behaviors, such as fighting, alcohol and drug use, and carrying a weapon. We want to learn how speaking with a health coach can help young adults reduce these risky behaviors and compare this to receiving community resources only. We also want to learn about the helpfulness of the health coach and the type of materials discussed. These may be things you're not even doing, but that you've seen your friends or people in the community getting involved in.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Youth and young adults ages 16-30 years who completed the eligibility screen and were selected may take part in the study.

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

3.2 How many people are expected to take part in this study?

This is a multi-site study, meaning that it will be conducted at more than one site in Michigan. About 400 young adults are expected to complete the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to join the study, this is what will happen:

- At your first interaction with study staff, you will be asked to complete an online survey which will take about 30-40 minutes to finish. The survey asks about how you deal with your feelings and motivations, conflicts with others, alcohol and drug use, and behaviors such as carrying a weapon and other risky behaviors. If you cannot complete the survey at the first interaction with study staff, you can contact us

later in the next few days to set up a phone or video appointment to complete the survey. You may also receive a gun lock either in person or in the mail.

- After the survey you will be randomly put into one of two groups (random means by chance, like "flipping a coin"). The research staff and you will not know which group you will be placed in until after you complete the survey.

  Group 1: After the survey you will have a private 30-minute meeting (either over the telephone, video chat service (e.g., Zoom), or in-person if requested) with a health coach to review the prevention program and talk about your goals, values, thoughts about violence, alcohol and drug use and carrying a weapon. The session will be audiotaped recorded (voice only) and you can give your permission for this later in this form. You will then have two more sessions that you will schedule with your Health Coach over the next 30 days. These will be similar to the first session and will be audiotaped recorded (voice only).

  You will also download and set up the *Project* IntERact app on your personal smartphone. You will be asked to enter up to 3 locations that you may become involved in risky situations so that the app may send you notifications when you are near those locations. (This is optional) and identify someone who can help you if you find yourself in a difficult situation.

  You will receive a brochure with community resources in your area.

  After your first health coach meeting, each day for 30 days, you will receive a notification on your phone to complete a brief 10-minute survey in the *Project* IntERact app. This daily survey will include questions about your day, including things like exercise, how you are feeling, and behaviors such as carrying a weapon, and any fights you may have been involved in. You will receive daily health messages and read a young adult's story about how they handle situations via notifications, and you can access additional resources.

  Group 2: You will receive a brochure with community resources in your area. You will download and set up the *Project* IntERact app on your personal smartphone. After the baseline survey, each day for 30 days, you will receive a notification on your phone to complete a brief 10-minute survey in the *Project* IntERact app. This daily survey will include questions about your day, including things like exercise, how you are feeling, and behaviors such as carrying a weapon, and any fights you may have been involved in.

- At about 3-months and again at 6-months from the time you completed your first survey, we will contact you to fill out another survey. Like the first survey you completed, you'll answer questions on our tablet computer and that will take about 45 minutes to complete. The survey asks about how you deal with your feelings and motivations, conflicts with others, alcohol and drug use, and behaviors such as carrying a weapon and other risky behaviors. If you were in group 1 and 2 the survey will ask additional questions about your experiences with the *Project* IntERact app and additionally for group 1 you will be asked about your experiences with the health coach. You may complete these 3 and 6-month surveys online. If you would prefer to meet with a research staff in person for any appointment that can be arranged at a convenient location. For telephone interviews, the research staff member will read the questions from the survey and enter your answers. For online surveys, you'll get an email invitation with a link and password to enter the survey (see section 9 for information about online survey security and privacy).

- With your permission, we will obtain and review police and court records of participants 18 years of age and older 12 months pre-and post-study enrollment. You can sign the criminal justice section of this

consent to allow the research team to collect that information. If you do not agree to the research team collecting this information, you CAN STILL take part in the study.

- If your first interaction with the study staff is in the Emergency Department (ED), we'll look at your medical record for this ED visit and any other visits from one year before you joined the study to 6-months after. We will collect information about the number and nature of ED visits such as visit dates, your reason for visit, your diagnosis, where you were discharged to, days of hospitalization, insurance information etc.

- If you're under 18 and become an adult (turn 18 years old) while you are in this study, we'll ask you if you want to continue to be in this study as an adult and have you give your consent again.

- You will be given referral information including suicide hotlines, substance use and mental health treatment and violence prevention services.

We have set up an email account to be used for study participants to contact study staff or for study staff to send appointment and follow-up reminders to subjects. The account is: um-project-interact@med.umich.edu

See Part 2 *Site Information* for details about any special procedures at your site.

4.2 How much of my time will be needed to take part in this study?

It will take about 1-2 hours to learn about the study, complete the baseline survey, load the *Project* IntERact app onto your phone, and meet with the Health Coach (if in group 1). During the 30 days after the baseline survey, the daily survey will take 5-10 minutes. Reading notifications and stories may take about 5 minutes each day. Phone/video chat sessions with the Health Coach will last about 30 minutes for each session you have. The 3 and 6-month follow-up surveys will take about 45 minutes each to complete.

4.3 When will my participation in the study be over?

You'll be done with the study after your 6-month follow-up visit.

4.4 What will happen with my information used in this study?

Your collected information may be shared with the Sponsor listed above.

With appropriate permissions, your collected information will be added to all the other information from the study and used to understand how well this program works. This information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Some of the questions that will be asked are about sensitive or personal information such as questions against school or parental rules, illegal behaviors, and your alcohol or drug use. These questions may make you feel uncomfortable or anxious. You may skip any question you don't want to answer, and you are free to leave the study at any time.

Study staff will conduct sessions and surveys in private spaces to ensure privacy. You will be asked during sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording.

Be safe—just as you would not text while driving, do not complete the daily surveys while driving. Wait until you are in a safe place to do any study-related activities.

Additionally, there may be a risk of loss to confidentiality or privacy. See Part 2 Site Information Section 9 for more information on how the study team will protect your confidentiality and privacy. As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in the Part 2 *Site Information* section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Some people may find that answering survey questions is helpful. You may learn more about your health behaviors and ways to reach your goals in life. You will also receive information for national and community resources, including crisis hotlines and substance use and mental health treatment services. We hope to use our results to improve programs for young adults who may be involved in risky behaviors.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Participation in this study is voluntary.

7. ENDING THE STUDY

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please email us at um-project-interact@med.umich.edu or please tell one of the study team persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

We do not expect that you would experience any harm if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.
- Other administrative reasons or unanticipated circumstances that might arise.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. You might incur data costs on the smartphone due to taking the daily surveys on the Project IntERact app and for text messaging if you go past the limits on the 60-day phone/data plan that will be provided by the study. If you choose to use your own phone, you may incur data costs due to taking the daily surveys on the Project IntERact app. If you do not have an unlimited data plan or do not connect your phone to Wi-Fi, you may be charged for data usage on your personal phone bill.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive $40 after completion of the survey today.

You will also be provided with a smartphone and a 60-day phone/data plan (valued at about $70). This will allow you to have access to a phone to use to complete daily surveys and interact with the research staff. The research staff will set up the phone plan on the phone and help you create the IntERact app. The phone/data plan will expire after 60 days. You may keep the smartphone but you would have to set up your own plan in order to continue using it.

You will also receive $50 after you complete the 3-month and $60 after the 6-month follow-up survey. You will receive an additional $5 (up to two times) for scheduling your survey or letting us know you changed phone numbers or address.

The money you earn for taking your daily surveys will vary by chance and will depend on how many daily surveys you complete. For each survey you complete, you will receive a small prize ($2 which is most likely), a medium prize ($5) and a large prize ($15 least likely) prize. You will also earn a $15 bonus for every five out of seven days that you complete the survey. The maximum that can be earned is $174 over 30 days. You will be informed of the amount that you will receive right after you complete the survey.

You can also earn extra money for referring others to our study. You will receive five coupons that you can pass along to other 16 to 30 year olds who live in the Flint, Saginaw, or Detroit area, and are interested in participating in the study. Each time a different person uses one of your coupons to complete a screening survey for the first time, you will earn $10. You can earn an extra $50 for referring others. All referrals are confidential.

The total maximum amount you can earn for participating in the entire study is $384 in addition to the smartphone and a 60-day phone/data plan (valued at about $70). Payments will be made in the form of cash, gift card, or other digital payment methods.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers directing this study. If you interested in participating, we will ask for your contact information so that we can contact you about the study and send you your gift cards. This personal information will not be connected to any of your survey answers. Your surveys will be coded with a unique ID number and stored in a file that is separate from your name, email address, or any other contact information. Computer data files will be kept on secure restricted servers at the University of Michigan and saved with password protection. Any reports or articles that we write will not contain any information that could allow somebody to identify you. All paper forms will be stored in locked file cabinets

The computerized surveys are designed and administered using the online Qualtrics Survey platform through the University of Michigan (http://www.qualtrics.com). Qualtrics meets the rigorous privacy standards imposed on health care records by the Health Insurance portability and Accountability Act (HIPAA). There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. No identifying information is linked to your answers. For more information, Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statment.

The Project IntERact app was developed by the University of Michigan Center for Health Communications Research (CHCR). To ensure that the data are protected, CHCR will use servers maintained by the Michigan Medicine Health Information Technology Services (HITS). To protect the data, CHCR and HITS will use a three-layered security approach. This prevents anyone else on the network from interfering and viewing the content that is being provided by you or to you. In order to maintain security, CHCR has teamed up with the Information Assurance department within Michigan Medicine, where they will ensure that the project meets the standard practices and guidelines set forth by U of M Standard Practice Guide for information technology. For more information regarding privacy of the IntERact app please visit https://www.project-interact.org/privacy.

No identifying information is directly linked to your answers. All personally identifiable information is stored in separate encrypted files behind the University of Michigan firewall.

The remote health coach sessions conducted through video chat software will be audio recorded only. Although every reasonable effort will be taken, confidentiality and security of the sessions is dependent on the privacy policies of the software used. All efforts will be made to use HIPAA compliant programs for remote sessions and your confidentiality will be kept to the degree permitted by the technology being used.

Audio-recorded sessions will be stored in a password protected, HIPAA compliant research server maintained by the Michigan Medicine Health Information Technology Services (HITS). The participants name and no identifying information will be verbally communicated during the recorded sessions.

This research project is covered by a Certificate of Confidentiality from the Center for Disease Control. The researchers with this Certificate may not disclose or use information, documents, or biospecimens 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 court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the Centers for Disease Control and Prevention (CDC) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such issues as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article or presented at a scientific meeting but would not include any information that would let others know who you are.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

Study title: Project IntERact V2

Site Name: Covenant Medical Center

8(A) FINANCIAL INFORMATION (CONTINUED)

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

See the Part 1 *General Information* section 8.1 for additional information on this topic.

There is no site-specific information for this section, please see Part 1 *General Information* section 8.1 for additional information on this topic.

8.2 Will I be paid or given anything for taking part in this study?

See the Part 1 General Information section 8.2 for additional information on payment.

Total potential compensation for participating in the entire study is $384 in addition to the smartphone and 60-day phone/data plan (valued at about $70). Payments will be made in the form of cash, gift card or other digital payment methods.

8.3 Who could profit or financially benefit from the study results?

See the Part 1 *General Information* section 8.3 for additional information on this topic.

9(A) CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION (CONTINUED)

9.1 How will the researchers protect my information?
See the Part 1 *General Information* section 9.1 for additional information on this topic.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

See the Part 1 *General Information* section 9.2 for additional information on this topic.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you for purposes of this research study may be obtained from other hospitals, doctors, and other health care providers involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.) and dental records
- Alcohol/substance abuse treatment records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment

- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Potential for information to be re-disclosed by the recipient whose actions may not be regulated by HIPAA.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10 CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Site Principal Investigator:	Ben Schoener, MD
Site Principal Investigator Contact:	900 Cooper Ave, Saginaw, MI 48602 Telephone: 989-583-6372
Site Study Coordinator *(if applicable)*:	Lynn S. Massey, LMSW
Site Study Coordinator Contact *(if applicable)*:	2800 Plymouth Rd., NCRC 10-G080, Ann Arbor, MI 48109 Telephone: 734-936-9312

You may also express a question or concern about a study by contacting the Institutional Review Board responsible for the review of the study:

University of Michigan Medical School
Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

Covenant Medical Center Institutional Review Board
1447 N. Harrison
Saginaw, MI 48602
Phone: 989-583-6486
Fax: 989-583-1097
Email: irb@chs-mi.com

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT]

_____.

My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: _____

Reason subject is unable to consent: _Subject is between 16-17 years of age

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact University of Michigan IRBMED.

Sig-B

Consent/Assent to audio recording solely for purposes of this research

This study involves audio recording. If you do NOT agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Subject Signature: _____

Parent/Legal Guardian Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent for Future Contact:

We may contact you again in the future in order to offer you opportunities to participate in new follow-up phases of this study. If you are contacted and are willing to participate in a new study, you will be asked to sign a separate consent form or assent form (if you are still under the age of 18) for that study. Your contact information will be maintained by the research investigators and stored in a password protected computer data file or locked file cabinet. It will only be available to the Investigators and research staff of this study (Project IntERact) and their future studies. If you do not want to be contacted in the future, you may still participate in this study. If you have questions, feel free to ask them.

Subject: Yes (consent) ____ No ____

Subject Signature: _____ Date: _____

Parent/Legal Guardian: Yes (consent) ____ No ____

Signature: _____ Date: _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____