Version: 10/21/2021
Title: Project IntERact Study
NCT03940716

UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Project IntERact (Assent/Consent Part 1)

Principal Investigator: Patrick Carter, MD

GENERAL INFORMATION

You, or your teen, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a teen's participation in the research, note that in the sections that follow the word 'you' refers to 'your teen'.
We're doing a study to learn more about the health behaviors of young adults who come to the Emergency Department (ED) for medical care. Health behaviors include relationships, physical and mental health, alcohol and drug use, and conflicts with others. You may be asked to participate in a second part of this study.
To get information, we'd like 1,300 people to answer a survey. We expect it to take about 20 minutes to complete the survey.

Answering this survey is voluntary. You don't have to answer it if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our survey won't affect the medical care you might receive at the Hurley Medical Center.

It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

To keep your information confidential, we will label your survey with a code, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won't include any personal information that could reveal who answered the survey.

The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). Qualtrics is dedicated to protect all customer data using industry best standards. 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 directly 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-statement.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 SPONSOR 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 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.

Answering our survey won't benefit you directly. We hope what we learn will help other people in the future.

With appropriate permissions, your collected 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.

To thank you for taking part in our study, you will be able to choose a gift worth about $1.00 after you take the survey.

A description of this clinical trial may be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

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. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- 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.
- The University of Michigan or a government agency 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, or 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.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.
- 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.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

[redacted]	[redacted]

[redacted]	[redacted]

You may also express a concern about a study by contacting the Institutional Review Board:

[redacted]

[redacted]

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111 or Hurley IRB at 810-262-9974.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Parent/Legal Representative (if applicable):

Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other: _____

[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 the IRBMED.]

Reason subject is unable to sign for self:

_____

_____

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.

Legal Name:
_____

Title:
_____

Signature:
_____

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

UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Project IntERact **(Part 2 Assent/Consent)**
Company or agency sponsoring the study: National Institute of Health (NIH**)**
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Patrick Carter, MD, Department of Emergency Medicine, University of Michigan

1.1 Key Study Information

You, or your teen, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a teen's participation in the research, note that in the sections that follow the word 'you' refers to 'your teen'. This form contains information that will help you decide whether to join the study or not. 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 in order to help others improve their health. 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 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. 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 seen in Emergency Departments who may engage in risky behaviors, things such as alcohol and drug use, fighting, and weapon carriage. You may not be involved in all these behaviors but may have seen your friends or people in your community getting involved in. This study involves a process called randomization. The study design divides study participants into separate groups, based on chance (like the flip of a coin). If you decide to be in the study, you need to be comfortable not knowing which study group you will be 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 seek treatment in the Emergency Department (ED).

We expect your participation in this study will be over after you finish the 4-month follow-up assessment. You can decide not to be in this study. Alternatives to joining this study include asking your medical team in the ED for resources and seeking out community resources. If you should choose not to participate, your treatment in the ED will not be affected in any way.

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 who come to the Emergency Department (ED) for medical care. Health behaviors include relationships, physical and mental health, alcohol and drug use, and conflicts with others. The purpose of this study is to improve prevention programs for young adults seen in ED and to develop and test a prevention program to help young adults reduce risky behaviors, such as alcohol and drug use, fighting, and weapon carriage. We want to learn how speaking with a health coach both in the ED and after the ED visit 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.

We hope this project will help us determine if using smartphone app and speaking with a health coach is possible as well as improve new violence prevention programs for youth who seek treatment in the ED.

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? Patients ages 16-24 years seeking care at Hurley Medical Center ED and who completed the first survey may participate in part 2 of this study.

3.2 How many people are expected to take part in this study? About 70 people are expected to complete part 2 of this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you are interested in taking part in part 2 of the study, you will be asked to complete an online survey on a computer tablet (15 minutes) and another part with the research staff (15 minutes). The survey asks about how you deal with your feelings and motivations, conflicts with others, weapon carriage, alcohol and drug use, and other risk behaviors. The questions asked by the research staff will be audio taped. The tapes will be used only to make sure the researchers are completing the forms properly. You will not be identified in any way on the audio tapes. You can give your permission later in this form.

You will also be asked to voluntarily provide a urine specimen for drug testing while in the Emergency Department. The results of your urine drug test will be given ONLY to you. They will NOT be put on your medical records, or shared with your doctors, nurses, parent, or guardian unless you tell them.

If you cannot complete the part 2 baseline survey during your ED visit, you will have 72 hours to come back to the ED to complete the survey and/or provide the urine drug specimen.

You will be randomly assigned (like flipping a coin) to one of two study groups. The research staff and you will not know which group you will be placed in until after you complete the baseline.

You may also receive a gun lock during your ED visit.

Group 1: IntERact Group

If placed in the IntERact group, you will have a 30-minute private meeting with your health coach either in person, over the phone, or using a live 'video meeting room' on your smart device. The health coach will help you find strategies that you feel will be the most helpful for dealing with challenges you face in life. Your meetings with your health coach will be audio and/or video recorded. After you leave the ED you will have 5 more meetings over the next several weeks with your health coach. You can give permission for that in section 12.

You will also have the *Project* IntERact app downloaded and set up on your personal smartphone. You will be asked to enter up to 3locations 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)

After you leave the ED, each day for a period of 35 days, you will be sent at 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 any fights you may have been involved in. You will receive two daily health messages via notifications and can access additional resources.

Group 2: Community Resources Group

If placed in the community resources group, you will receive a pamphlet of community resources during your ED visit. You will not have access to the IntERact app.

For both groups:

Both groups will also be asked to complete a follow-up interview about 4 months after you first enroll in the study. This online survey will take about 35 minutes to complete (some parts will be done verbally by research staff (15 minutes) and will be audio taped). You will have the option to complete this survey in person, online, or over the phone.

If you cannot be present for the 4-month follow-up interview, you have the option to take part of the survey online. You will be sent a link to take the survey on the Qualtrics site and an additional password may be given to you in order for them to access to the site. If you complete in person, you will also be asked to voluntarily give a urine specimen at this time.

If you are in jail/prison during the follow-up period, you may be contacted at your jail/prison for the follow-up assessment at 4-months from today. You will be interviewed either in-person at the jail/prison or by phone, depending on prison rules/regulations. Your participation will in no way impact your standing with the parole board or influence the amount of time of your confinement

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 subjects 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.

Signing the consent will allow us to review your medical records at Hurley Medical Center during the time that you are in the study and for one year before the study. At the 4-month follow-up, we will take another look at your Hurley medical chart to see if you had any ED visits since being part of the study.

We will not share any information from your medical records with anyone. We will be looking at how long you were in the ED, where you were discharged to, and your diagnosis.

4.2 How much of my time will be needed to take part in this study?
Part 2 of this study will take about 60-75 minutes to complete in the ED this includes the surveys, urine drug screen, setting up the IntERact app on your phone, and your 30-minute session with the heath coach.

Four months after your initial Emergency Department visit, you will take a 45-minute follow-up survey plus the time required to provide a urine specimen.

Additionally, **if you have been placed in the IntERact group**, you will take 10 minute daily surveys over the course of a 35-day follow-up period. These will not occur in the Emergency Department. These daily surveys will be sent to your personal smartphone via the free smartphone application. You will also have five 30-minute meetings with your health coach over the course of 5 weeks (about 1 per week).

4.3 When will my participation in the study be over? Your participation in this study will be over after you finish the 4-month follow-up.

4.4 What will happen with my information?
With appropriate permissions, your collected information will be added to all the other information from the study and used to understand how well this prevention program works. This information may also be shared with other researchers, here, around the world, and with companies. NO DATA THAT IDENTIFIES YOU WOULD BE USED. We call this stripping identifiers from data. Your data may be 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.

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 Section 9 of this document 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 Section 10 about any injuries, side effects, or other problems that you have during this study.

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. Some people may find that answering survey questions is helpful. By viewing the app content, you may learn more about your health behaviors. You will also receive information for national and community resources, including crisis hotlines and substance use and mental health treatment services. We hope this study will help us better understand how to deliver appealing and helpful interventions using a mobile phone app.

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. If you should choose not to participate, your treatment in the ED will not be affected in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
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 um-project-interact@med.umich.edu or tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
It is not anticipated that any harm would be experienced if you decide to leave the study before it is finished. Your decision to withdraw your authorization (consent) for the research use and disclosure of your medical record information will have no effect on your current or future medical care at a Hurley Medical Center, an affiliated health care provider or your current or future relationship with a health care insurance provider.

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.

- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

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 may incur data costs due to using the IntERact mobile phone app. As with any other phone app, if you do not have an unlimited data plan or do not connect your phone to wifi, 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 $20 after completion of the baseline survey today, plus an additional $5 if you provide a urine specimen for drug testing during the ED visit.

For the 4-month follow-up survey you will receive $40 for the computerized follow-up survey, $5 if you provide a urine specimen for drug testing, and $5 if you notify us of any address/telephone changes and/or if you schedule/confirm your follow-up interview.

If you are in the IntERact group, the money you earn for interacting with the IntERact app will vary by chance and how many tasks you complete. You have the chance getting a small prize ($3, which is most likely), a medium prize ($10), and a large prize ($25, least likely). The more surveys you complete, the more likely it is that you will receive a medium or large prize. The maximum that can be earned is $206 over 35 days.

The total maximum amount you can earn ranges from $75 (those not using the app) - $281 (using the app). Payments will be made in the form of cash or a gift card.

If you complete a follow-up assessment while you are in jail/prison, you will receive payment according to the institution's specific policy so that it is consistent with prison rules/regulations.

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

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..

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

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.

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 of this study. If you are interested in participating, we will ask for your contact information so that we can contact you about the study and send 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 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 Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). Qualtrics is dedicated to protect all customer data using industry best standards. 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 directly 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-statement.

All data collected through the IntERact app will be regularly uploaded to a secure computer server. This data will rest on your phone within the app when internet connection is not available. You will have the ability to push the data if you don't think it's been sent to the server. Data will be encrypted before being stored locally on your phone and/or transmitted to the server. We strongly encourage you to set a security passcode or TouchID on your phone in order to protect all locally stored data. You can also set a password in the app itself for further protection. The IntERact app will not collect or store your full name or contact information; all data stored on the server will instead be coded with your unique ID number. Data will be stored on the server until we complete the study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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 SPONSOR 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 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.

If you are put in the jail/prison during the follow-up period, we will keep study participation and test results confidential from parole officers and the department of corrections officials.

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 Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) 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.

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 may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- 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:

- 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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.

- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- 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.
- 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, but would not include any information that would let others know who you are.

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.)

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

10.1 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
- Leave the study before it is finished
- Express a concern about the study

[redacted]

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111 or Hurley IRB at 810-262-9974.

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.)*

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: _____

Subject 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 IRBMED.

Sig-B

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

This study involves video and/or audio recording. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

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

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 for that study (if you are still under the age of 18). 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 the Project IntERact study 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.

I agree to be contacted for future phases of this study. I understand that if I do not want to be contacted for future studies, I may still participate in this study.

Subject: Yes (consent) ____ No ____

Parent/Guardian Yes (consent) ____ No ____

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): _____