

University of Wisconsin-Madison Research Participant Information and Consent Form Addendum

Study Title for Participants: Thrive4LifeWI Study

Formal Study Title: Community-based, client-centered prevention homes to address the rural opioid epidemic (ACHESS-Control and Prevention Navigation-Immediate)

Lead Researcher:

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Invite

We invite you to participate in the ACHESS application component of this study. We ask you to provide your authorization and consent for the activities described in this addendum because you are participating in the main study (control or intervention group). To continue participation, all participants will be required to create an account on an application called ACHESS. This application will be used to complete three surveys throughout the study. All other aspects of the ACHESS application are optional.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

If I take part in the study, what will I do?

If you decide to join, the study team will ask you to create an account on a smartphone application called ACHESS. Study staff will have access to your account information, such as username, and password, to assist with resetting your password. This application can be used on a smartphone or web browser. ACHESS will be used to complete the three study surveys (initial, 3-month, and 6-month surveys). If you have

previously completed a survey using a different application, all future surveys will be completed using ACHES.

Optional study activities

This part of the consent form is about additional research activities that you can choose to take part in. You can still take part in the main study even if you decide not to take part in these activities. This information will not be collected or used for research.

- Posting on discussion boards or using private messaging in ACHES. This is a way to talk with other study participants without ever needing to share your name or seeing them. You can also use the private messaging function to talk to study team members.
- Find local community resources and their contact information (i.e. emergency numbers, food assistance, parenting and childcare assistance, etc.).
- View and save motivational quotes of the day, and log thoughts of gratitude.
- Access UW-Madison and Vivent Health staff member's contact information.

Will being in this study help me in any way?

Being in this study and using the ACHES app will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about health problems that can result from injecting opioids and other drugs and ways to reduce the risk of HIV, Hepatitis C, and overdose.

What are the study risks?

The main risk of taking part in this study is that information about your drug use and health could become known to someone not involved in this study. If this happens, it could affect your relationship with family and friends, your employment, or make it harder to get insurance or a job. It could expose you to legal risks or damage your reputation. The risk of your information becoming known outside the study is low, however, because of confidentiality protections the research team will use.

Optional study activity risks

- The ACHES system allows you to share your views, opinions, photos, and personal experiences. However you do not have the right to post content on the ACHES site that promotes racism, bigotry, hatred, nudity, or physical harm of any kind against any group or individual. A research staff member will review and delete any messages deemed inappropriate. A research staff member will then follow up with the author of the inappropriate content.
- You could receive wrong information from the Internet and/or discussion boards. However, we will provide simple tips to help you figure out whether you can trust the information you receive from these sources.

- Information you enter into ACHESSE can be viewed by UW research staff. Study staff may occasionally monitor discussion boards and post information on there. Also, study staff may reach out to you via ACHESSE messaging.
- Upon account setup, you will be asked to create an account screen name. This screen name will be listed with responses to discussion board posts and included in a list of participants that can be private messaged. To reduce the risk of other participants identifying you, we recommend that you choose a screen name that will not include any identifiable information such as your first name, last name, date of birth, address, etc.
- Other participants will have access to any information you post to the discussion boards. There is a risk that other participants could identify you based on the information you provide in your discussion board posts.
- There is a risk that other study participants may send you private messages including unwanted or inappropriate content. If this happens, we ask that you report this information to the study team at 608-294-7446. All study participants will have the option to turn off private messaging within the ACHESSE app. Please contact us at the same number if you wish to disable your account's private messaging abilities.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information. We will limit who has access to your name, address, phone number, and other information that can identify you within ACHESSE. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study or through ACHESSE content that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts). Pregnant women who abuse illegal drugs or alcohol may be reported to county social service under Wisconsin state law.

Agreeing to take part in this study means that you are authorizing Vivent Health to release your health information to UW-Madison and the research team to release your health information to certain people or groups for the purposes described in this form. Once your health information is released outside UW-Madison it may not be protected by privacy laws and might be shared with others.

Your authorization for researchers to use your protected health information does not have an end date. However, you can choose to take back your authorization by writing to the Lead Researcher, Ryan Westergaard, at
5223 UW Medical Foundation Centennial Building
1685 Highland Avenue
Madison, WI 53705

If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you. If you take back your authorization, you will not be able to take part in the research study.

Who at UW-Madison can use my information?

- Members of the research team.
- Offices and committees responsible for the oversight of research.
- The UW-Madison Institute of Research on Poverty, who may use your information to link your Medicaid records.

Who outside the UW-Madison may receive my information?

- This research study is part of a collaboration with scientists at other institutions including the U.S. Centers for Disease Control and Prevention (CDC), The University of Washington, and Tulane University. Some information about you may be shared with researchers at these other institutions. Information we share with others outside UW-Madison may include your ZIP code but cannot directly identify you.
- Because this study is federally funded, federal agencies like the National Institutes of Health, and U.S. Office for Human Research Protections can inspect study records.

Will being in this study cost me anything?

No. There is no cost to download or use ACHES.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher Ryan Westergaard (contact information listed on page 1). If you have any questions about your rights as a research subject or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems. If you have any questions regarding to the ACHES app, login assistance, or need to report a problem or harassment, please contact the study team at 608-294-7446.

Agreement to participate in the research study

If you select “I agree to be in this study” it means that:

- You have been told about the study procedures, risks, and benefits.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You give authorization for your health information to be used and shared in the ways I’ve described.
- You want to be in this study.