University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Thrive4LifeWI Study

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

Lead Researcher:
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Important things to know about research studies:

- Taking part in research is voluntary. You can choose not to be in this study or stop at any time.
- 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, and you will not lose medical care or any legal rights.
- You don't have to be in this study to get testing or services related to injection drug use.

What is this study about?

We are trying to learn about health problems that can result from injecting drugs and ways to reduce the risk of HIV, hepatitis C, and overdose. We are inviting you because you have injected drugs in the past.

What will happen during the study?

If you decide to join, you will be in the study for about 6 months.

You will attend 4 Prevention Navigation sessions by phone, video call, or in-person over the next 3 months. The goal of Prevention Navigation is to help reduce your risk of infectious diseases and overdose and address any other issues you may currently face. Each Navigation session will take 45-90 minutes depending on your needs and availability. You will be taking a survey before your first navigation session, and then

again in 3 months and 6 months. At each of these visit, we will ask you to get tested for HIV and hepatitis C virus at Vivent Health by scheduling an appointment with a Vivent Health employee. As part of their services, Vivent Health staff will provide counseling and follow-up related to your test results.

The research team will collect information about you and your health. We will get this information directly from you and Vivent Health. As part of the study, the research team will also link your information to databases like the Wisconsin Immunization Registry and Medicaid to understand how people who inject drugs use health care resources. The kinds of information we will collect include:

- Demographic information, like your age, education, ZIP code, and living situation.
- Health information like your medical history, past HIV and hepatitis C test results, your alcohol and drug use, and past behaviors like sexual behaviors that could indicate you are at risk for infectious diseases. Information about your mental health and coping techniques. Results of your HIV and hepatitis C tests.

We will also ask you to refer other people you know who inject drugs to participate in this study. You may receive a maximum of two coupons to give to people you know so that they can learn about the study and contact us if they are interested in participating. You will receive one coupon at your first Prevention Navigation session, and the second coupon at your following session. The coupons will have a code that links you to the people whom you refer to the study.

Will being in this study cost me anything?

No. There is no cost to you for the Prevention Navigation sessions, survey, or testing that are part of this research study.

Will I be paid or receive anything for being in this study?

We will pay you $20 for completing each research assessment, totaling $60 over the 6 months (paid 3 times). A research assessment includes testing for HIV and hepatitis C and the research survey. Additionally, you will receive $10 for each eligible peer recruit who enrolls in the study using your referral coupon code.

Could being in the study help me?

Yes. We hope that the Prevention Navigation sessions will help you reduce your risk of infectious disease and overdose. You may get linked to other care resources related to injection drug use.

What are the main risks of taking part in the study?

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 relationships 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, because of the confidentiality protections the research team will use.

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. We will also store this information securely. This study is protected by a Certificate of Confidentiality from the National Institutes of Health. This means even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study. 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 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 services 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.

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.

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.

Matching Study Data

If you participated in Phase I of our study (e.g. the Rural-Urban Health Study), we will combine your data to compare across time. These prior results include testing for HIV and hepatitis C and your survey answers. Combining information across studies could potentially increase the value of your participation beyond what is learned in any individual study and help researchers learn more about health problems that can result from injecting drugs and ways to reduce the risk of HIV, hepatitis C, and overdose.

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.

What questions do you have for me?

Please answer true or false to the following statements to assess your understanding of the study.

1. My participation in this research is voluntary. If I decide not to participate, my relationship with Vivent Health and UW Madison will not be affected. (T)
2. My personal health information collected by Vivent Health and UW will be shared with researches at UW-Madison, Tulane University, the CDC, and Vivent Health if I choose to participate in this study. (T)
3. My involvement in this study will consist of 4 sessions with the prevention navigator over the course of 3 months. I will also complete a survey and testing for HIV and Hepatitis C by appointment before my first session, in 3 months, and in 6 months. (T)
4. All Vivent Health and research staff will protect my personal information as best they can, and my name will never be published with my data. (T)

Agreement to participate in the research study

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

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

Do you agree to be in this study?

Are you also willing to allow members of the research team to contact you in the future about participating in other studies?