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

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Study Title for Participants: The ENHANCE Project

Formal Study Title: ***Mobile health strategies to support longitudinal engagement in harm reduction services***

Lead Researcher:

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Key Information

The information in this form is to help you decide whether or not to be a part of this study. Ask questions about anything that is not clear. Taking part in this study is voluntary. This research is being conducted by the University of Wisconsin-Madison in partnership with Vivent Health.

Why are researchers doing this study?

We want to better understand how to make harm reduction services more accessible and identify the physical and psychological factors that make harm reduction services most effective.

What will I need to do in this study?

The research team will ask you to complete a series of surveys over the course of twenty-four months. You will be asked to complete five monthly surveys and an additional four surveys completed every 6 months. Today's visit will last between 60 to 90 minutes.

We will also ask you to refer other people you know who use drugs to participate in this study. You may receive a maximum of three coupons to give to people you know so that they can learn about the study and contact us if they are interested in participating. The coupons will have a code that links you to the people whom you refer to the study.

What are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
● Comfortable answering questions about drug and alcohol use, mental health, and other personal topics. ● Willing to complete surveys and participate in the study for 24 months. ● Interested in contributing to scientific knowledge on to make harm reduction services more accessible and effective.	● Are nervous about sharing information about drug and alcohol use, mental health, and other related topics. ● May not have time to complete study surveys over the course of 24 months.

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 your healthcare or 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.

Detailed Information

The following is more detailed information about this study.

How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study activities and procedures are not for your health care.

Who can I talk to about this study?

Please take as much time as you need to think about if you want to participate in this study or not. If you have any questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at (608) 572-3514. 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 I take part in the study, what will I do?

If you decide to participate in this research study, here are the <u>required activities:</u>

Today, you will create your study passcode to access and complete your first online survey, also referred to as the baseline survey. You will complete future surveys on your own time using your phone, computer, or visiting the Vivent Health clinic or mobile van for the next 24 months. The location where you decide to complete surveys on your own time is up to you.

***Surveys*:** We will ask you to complete ten surveys using the ENHANCE web link. Surveys will collect information directly from you. Surveys will be used to collect information about sensitive and potentially distressing topics such as drug and alcohol use, mental health, and other related areas. All questions are voluntary. You are free to not answer questions that you do not feel comfortable answering.

<u>Survey Schedule:</u>

Today: 45-minute baseline survey which will ask about the most recent time you used drugs, your mental health, and overdose and harm reduction behaviors.

Follow-up surveys: The first follow up survey will be completed in the calendar month after the completion of the baseline survey. For the next five months you will be asked to complete a monthly survey which will take about 30 minutes to complete. This will be a mixture of questions from the baseline survey as well as sets of new questions. After completing the 5 monthly surveys, we will transition to asking you to complete a survey every 6 months. These follow up surveys will be completed 6, 12, 18, and 24 months after your completed baseline survey.

We will collect the following information from you in this study: Name, age, gender identity, address, zip code, race and ethnicity, education, marital status, alcohol and drug use, types of health care you have received, mental health, and other related items.

Database Linkage: As part of the study, the research team will also link your information to administrative databases like the Wisconsin Medicaid claims data and hospitalization registry. By “link your information to databases,” we mean that we will use the information collected in this study to identify health care services you have received. The reason for doing this is to understand how people in your community use health care services and identify ways to improve the health care system for people who use drugs.

Research: All information that could identify you (for example, your name, date of birth, and contact information) will be removed from the research record for this study at the end of the study. After we remove all identifiers, the information you provide during the

study may be used for future research, analysis, or shared with other researchers without your additional informed consent.

Lifepoint Syringe Services Program Data: Each time you visit Lifepoint at Vivent Health or in the mobile van, Vivent Health staff will ask you to provide your secret code. This will help the research team to learn more about what services you get at the syringe service program. Staff who are not a part of the research study at Vivent Health will not have access to your name or other identifying information that would tie you to your secret code. This information will remain confidential.

Collaborating with other research sites: The deidentified information will be stored on secure servers at the other research sites and the data coordinating center at RTI International during the study. We plan to keep your data indefinitely, but your name and any other information identifying you will not be part of that dataset. Having information collected from many people helps researchers identify trends and discover better ways to work with communities to improve harm reduction services. Researchers can use the stored information to research additional scientific questions.

Anticipated or Unanticipated Events

If you decide to take part in this study, certain situations may occur during the 24-month study period. Below are some common scenarios and the process that would be followed if you are in one of these situations.

- If you are no longer visiting your usual Vivent Health location or if you move, you may continue to participate in the study. Contact our study team at (608) 572-3514 to provide your new contact information.
- If you are incarcerated, no research activities will occur during the time of incarceration. You can contact the study team at (608) 572-3514 when you are released to discuss participating in the study. If you are under criminal justice supervision and are prohibited from using internet-enabled devices, it is your responsibility to ensure that your study participation is allowable under the terms of your supervision.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth, address, and zip code. In this study, we will use the following kinds of PHI:

- Things you report in the surveys about your health.
- We will look at dates and type of health care received for the Medicaid record review.
- We will also ask for your contact information and the contact information of people you know in case we have trouble reaching you.

Who at UW-Madison can use my information?

- Members of the research team

- Offices and committees responsible for the oversight and funding of this research, such as the Human Research Protection Program
- 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?

- Vivent Health staff who are part of the study team
- RTI International (Data Coordinating Center)
- Study team members at Tulane university

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your health care or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you decide to leave the study, data collected prior to you fully withdrawing will still be used and shared with others, but the researchers will no longer be able to collect NEW information about you. Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher at rpw@medicine.wisc.edu or mailing address:

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Will being in this study help me in any way?

Being in this study will not necessarily help you directly. Your participation in the study may benefit you and other people in the future by helping us learn more about how best to expand and improve harm reduction services.

What are the study risks?

1. Answering questions on sensitive issues (like drug and alcohol use, mental health, etc.) in surveys may cause anxiety, distress, embarrassment, or feelings of sadness. You do not have to answer any questions that you do not want to.

2. There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

Here are the ways your risks will be minimized:

1. Embarrassment or stress

Staff are trained to help you reduce any embarrassment or stress that you might feel when talking about sexual behavior or HIV risk. If you need additional support because of embarrassment or stress, staff can refer you for help.

2. Confidentiality

Information you share will be kept confidential. Data will be saved in a password-protected computer. The data that you provide will be identified by a unique number, not your name.

What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We limit who has access to your health information, your name, address, phone number, and other information that can identify you. We will also store this information securely on HIPAA compliant servers at the UW-Madison School of Medicine and Public Health and UW Institute for Research on Poverty. We may publish and present what we learn from this study, but none of this information will identify you directly.

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 cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program and U.S. Department of Health and Human Services.

WE WILL report information in the following circumstances to the appropriate authorities (e.g., child protective services, law enforcement, health care providers):

- If you tell us that you are planning to harm yourself or another person.

- If you tell us something that causes us to believe that a child or vulnerable adult (i.e, elder) is being abused.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate confidentiality protections, we might use information that we collect during this study for future research or share it with other researchers without additional consent from you.

Will information from this study go in my medical record?
None of the information we collect for this study will go in your medical record.

What else do I need to know?

Will I receive anything for participating?
If you agree to take part in this research study, we will pay you for your time and effort. Please note that payment depends on the successful completion of specific surveys at different time points during the 24-month study period.

- You will be paid $50 for completing the baseline survey today.
- You will receive $20 for completing each monthly survey, totaling $100 over 5 months (paid 5 times).
- Another $40 is available for completing each 6-month survey, totaling $160 over 18 months (paid 4 times).
- Additionally, you will receive $10 for each eligible peer recruit who enrolls in the study using your referral coupon code (up to 3).

You can pick up cash compensation at the Vivent Health location where you are today. If you prefer, you can receive a virtual gift card, bank transfer, Venmo or Paypal payment from Tremendous, a third-party payment service. We will need to provide your email or phone number to Tremendous for you to receive the compensation.

How many people will be in this study?
We expect about 400 people will be in this research study.

Who is funding this study?
The National Institutes of Health is funding this research study.

Because data from this research study can be useful for many different kinds of research, organizations like the National Institutes of Health (NIH) have created large databases that collect data from research studies. We will put data from this study in a federal database or in other public scientific resources to make the information broadly available. We cannot predict how this information will be used in the future. Because it

can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in.

Will my data be used for future research?

Survey data: The UW-Madison research team will keep your deidentified data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called “banking.” The banked data will be kept on HIPAA compliant secure servers at the School of Medicine and Public Health at UW Madison for use by researchers.

This is what will happen with your banked data:

- The banked data will be labeled in a way so that no one can identify which data came from you. This means that if you decide later that you do not want your data used, we will not be able to remove your data from the bank.
- We may use the data in future research projects about harm reduction, substance use, overdose prevention, or other related areas.
- Banked data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- Banked data will NOT be shared with you or your health care providers.
- Medicaid linkage:The banked data will retain service dates and will be coded in a way so that no one can identify which data came from you.

Permission to communicate about the study by email

We are requesting your email address so we can notify you of survey reminders and you can receive payment for completing the surveys (if you choose to receive payment via the Tremendous platform). Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately about a health issue, you should call 911 or contact your health care provider. You do not have to provide your email address to participate in this study.

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.

2. If I choose to participate in this study, my personal health information collected as a part of the study will be shared with researchers at UW-Madison, Tulane University, the NIH, RTI International, and Vivent Health.
3. My involvement in this study will consist of a baseline survey, 5 surveys at monthly intervals, and 4 surveys at six-month intervals.
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.

Agreement to participate in the research study

You do not have to agree to this form. If you refuse to agree, however, you cannot take part in this research study.

If you say “Yes, I agree to take part in this study” it means that:

- You have read this consent form.
- 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 protected health information to be used and shared as described in this form.
- You want to be in this study.

Do you agree to be in this study? Please click yes or no.

□ Yes, I agree to take part in this study

□ No, I do not agree