

Cover Page: Consent

We The Village Family Support Study

NCT04250077

Document Date: 02.12.2020

Please note: the informed consent format was optimized to be better delivered and understood via digital survey on the above date, all prior consented study participants were re-consented using the updated digital survey per this most recent IRB approval.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102



Approved by
PHMC
IRB

Approved 01/30/2020
Expires 05/14/2020

We are asking for your consent in order to participate in the We The Village Family Support Study.

We're so glad you're eligible and interested in being part of the WTV Family Support Study. Before you move forward, we need to share a few more details to help you understand the process and make a decision to enroll in our study.

1. We will ask you to read through the following pages of the consent form (about 5 minutes). This is a technical form required for research participation. If you find it overwhelming or difficult to understand, don't worry. We will review it with you when we contact you.
2. If after looking over the consent form you think you are still interested, we will ask you to give your consent so you can share a phone number and email address with us. If you are not sure about participating, you can always opt out later.
3. We will use your contact information to call you, so we can discuss the study with you and answer any of your questions. We need you to complete these steps before you can enroll in the study.

You can always call us to ask any questions that might come up for you. Call us at 215.985.2542

After reading the consent form, click the **NEXT** or **RIGHT ARROW** button located at the bottom of the page to continue the enrollment process.

Important Things to Know About This Study

- We are asking you to be in a research study. Your participation is voluntary. If you click the “I agree” option at the end of this form, you are agreeing to be in this study.
- You should not click “I agree” unless you are sure you want to be in this study and all of your questions about this study have been answered.
- The purpose of this study is to test different online support approaches for helping family and friends:
 - a. communicate with a loved one who has a problem with opioids with the goal of engaging their loved one to receive treatment; and
 - b. feel happier and healthier.
- If you agree to be in this study, you will:
 - a. be asked to speak briefly with a study staff person over the phone to complete and pass a brief consent quiz and confirm enrollment;
 - b. be randomly assigned to one of three online support programs;
 - c. be asked to participate in online activities over 12 weeks; and
 - d. complete two surveys.
- This study involves very few risks, and we have plans in place to lower these risks.
- Most people who engage in these support programs in-person report their mood and relationship with their loved one improve, but you may not benefit from being in this study.
- You will be asked to share information with us about yourself for this study. We have plans in place to keep your information confidential.
- This form will explain all of this to you in more detail.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

1. What is the purpose of this study?

We are testing three online support programs for family members and friends (herein referred to as Concerned Significant Others or CSOs) of people who have a problem with opioids. The goal of the study is to learn more about online delivery of support programs to help CSOs communicate and engage with their loved one in order to increase their loved one's readiness for treatment, and to increase the health and wellbeing of the CSO.

We are inviting up to 84 CSOs in the United States to join this online study.

2. Who is in charge of this study?

This study is being led by We The Village (WTV), Inc. WTV is a company that built a technology powered platform providing access to effective training and support for friends and families affected by substance use disorders. Using science and online community support, without the stigma, WTV helps families through addiction and recovery.

The Research & Evaluation (R&E) Group at Public Health Management Corporation in Philadelphia, Pennsylvania is responsible for collecting all of the data for the study.

3. Why am I being asked to be in this study?

We are asking you to be in this study because:

- You identified yourself as the concerned significant other (CSO) of someone with an opioid problem
- Your answers to the screening questions showed you have concerns about:
 - your loved one's use of opioids
 - your loved one is resistant to receiving treatment or additional treatment

You cannot be in this study if:

- You do not have personal access to a smart phone with data or a computer with internet
- You have been diagnosed with a substance use disorder and have not been in recovery for at least two years
- You are not residing in the United States

4. Who will be in this study?

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

CSOs with loved ones who have an opioid use problem. We are inviting up to 84 CSOs to be in this study. People will be recruited through online and personal referrals from anywhere in the United States.

5. How long will I be in this study?

You will be in this study for approximately 3 months.

6. What are you asking me to do?

If you agree to be in this study, you will be asked to:

- 1) Speak briefly with a study staff person to complete and pass a brief consent quiz and confirm your enrollment into the study.
- 2) Complete surveys. You will be asked to complete surveys about your physical and mental health, your work, relationship happiness with your loved one, knowledge of skills taught in the program, your loved one's treatment (if any), and your level of satisfaction with the We The Village Family Support Study program. These surveys will be done online using a secure survey link. You will be asked to complete one survey within one week after you confirm your enrollment with a study staff person, and a second survey about 12 weeks from now. Each survey will take about 30 to 45 minutes to complete.
- 3) Provide us your contact information. We will ask for:
 - Your name, address, phone number, and email address
 - User name or handle for social media platforms, such as Facebook, Twitter, and Instagram for private contact purposes only
 - The name and contact information for two close family members and/or friends who you stay in touch with and could relay a message for us if we are unable to reach you

We will use the contact information you share with us for the following reasons:

- to send you a secure online links to complete your surveys
- to send you reminders to complete surveys
- to send you check-in messages to attend program sessions or discussions and to complete activities.
- to keep you up to date on the study's progress and findings, as well as to share new services that may become available after the study ends.

During the study we will contact you one month from now and two months from now to confirm and update your contact information.

4) Be randomly assigned to one of three programs: A, B, or C. Random assignment is like rolling dice. Everyone has the same chance to be assigned to any program. No person decides which program someone is in. This includes you, other participants, and the research team. Once you agree to join the study, you will find out your program assignment after you complete your first survey.

We will use a computer-generated random number to assign you to program A, B, or C. The computer program ensures that everyone has the same chance to be in each of the three programs that We The Village Family Support Study is testing. Two programs (Program A and Program B) are the experimental programs and Program C is the standard care program.

5) Participate in your assigned program activities for 12 weeks.

Click the next button or right arrow button for a brief description of each program with the time commitment expected from CSOs.

STUDY ACTIVITIES BY PROGRAM		
Experimental Programs		Standard Care Program
Program A & Program B		Program C
• Commit 1½ to 1¾ hours a week	• Commit 1 to 1½ hours a week	
• Watch a 12-module online support program delivered weekly	• Join a private online support forum for people with a loved one with an opioid use problem	
• Each module will be 30 to 45 minutes in length	• Gain access to knowledge and experiences of fellow CSOs shared in peer-led forum discussions	
• Attend weekly 60-minute online sessions facilitated by a CRAFT coach via Zoom or phone	• Post your own questions specific to your current situation and receive support from peers and WTV moderators	
• Review content from the weekly module	• Share your knowledge and experience to answer fellow CSOs' questions and to support others through their journey	
• Participate in a Question and Answer segment		
• Practice content with role-plays		
Program A	Program B	Program C
• Weekly sessions are in a small group with a WTV coach and 3 to 8 study participants using Zoom	• Weekly sessions are one-to-one with a WTV coach using Zoom • Weekly sessions are tailored to the individual	• Discussions are self-initiated and ongoing • Engagement can occur at any time of the day or night • Benefit from the extensive database of shared peer experiences

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

• Weekly sessions follow a course outline and schedule		
--	--	--

7. Will my information be kept confidential?

Yes, we will do our best to keep your personal information confidential. We cannot promise total confidentiality. It is possible that others may learn that you are in this study or about information you tell us.

We have done several things to protect your information:

- All research surveys will be stored in a secure password-protected computer system. Only select research staff will have access this information.
- Online coaching sessions will occur using Zoom, a secure video conferencing/chat platform.
- All participants will be instructed not to use last names for their user name. User names will never be shared with anyone outside of the study.
- All participants will agree not to disclose any information shared during discussions in coaching sessions or forum.
- We instruct participants to be in a private location for coaching sessions because participants are visible to coaches and other participants during Zoom coaching sessions (in Program A).
- We will only share your information with the research study staff.
- Any information kept on a computer will be in a password-protected file. Only research staff on this study will know the password.
- Any paper information will be kept in a locked filing cabinet. Only research staff on this study will have access to this cabinet.
- Your research records will not have your name on them. We will use a code number instead. The code number will be kept secure and separate from your name and user name. Only research staff on this study will have access to the linked code numbers and names.
- We will also protect your privacy when we try to contact you. We may contact you to confirm your enrollment, for missed sessions and to send reminders to complete surveys. We will only contact you using information you have agreed to share with the research team.
- We will not share that you are in the study, but you can still share information about yourself or tell others that you are in this study, if you choose.

Exceptions to confidentiality. There are times when we will break this confidentiality agreement with you:

- Any information about child or elder abuse or intent to harm self or others will be reported to authorities, as required by law.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

- We will also break this agreement to get you help if you are having a medical emergency or if your safety is at risk.

8. Will my research information be used or shared for future research studies?

We will keep information that can identify you (like your name and date of birth) secure and separate from your research information. We may use or share your de-identified research information for future research studies without asking for your consent again.

9. What are the possible risks of being in this study?

This study involves the following risks:

- 1) Risk Resulting from Breach of Confidentiality**
- 2) Risk Resulting from Discomfort or Distress completing research surveys and procedures**
- 3) Risk Resulting from Possible or Perceived Invasion of Privacy**

1) There may be a breach of confidentiality.

- We will do our best to keep your information confidential. It is still possible that your information may be seen or heard by someone who should not see or hear it.
- It is possible that someone in the group session or forum may share what you say with other people outside of the research.

We have taken these steps to lower this risk:

- The surveys you complete for this study will not have your name on them.
- We will keep your personal information separate from your study information.
- All paper information will be kept in a locked filing cabinet at We The Village and PHMC. Only research staff on this study will have access to this cabinet.
- All electronic information will be kept in password-protected computer and website systems. Only research staff on this study will know the password.
- We will use a more secure Zoom account that is HIPAA compliant.
- We will ask everyone involved in group activities not to use last names of participants or to discuss other participants outside of the group. We also will provide a brief training on the importance of respecting confidentiality when participating in groups.
- Participants create their own user names and can change them at any time during the study.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

- When we try to contact you, we will only use the information you agreed to share. If we call you or send you a direct message, we will say it is about a health survey.

2) Some parts of this study may make you feel uncomfortable, upset, or stressed.

- During the surveys when answering questions about areas of your life.
- During online coaching sessions and discussion forums.

We have taken these steps to lower this risk:

- You can skip any survey question you do not want to answer.
- You can choose not to provide information that makes you uncomfortable or talk with program staff or CSO peers to come up with ways to help you feel better.
- We will help you to understand feeling uncomfortable for a while is sometimes necessary for things to change.
- You can leave the study at any time.

3) You may experience or perceive an invasion of privacy.

- Participating and sharing in program activities via Zoom, video conferencing platform, or the discussion forum
- Identifying as someone with a loved one with an opioid use problem

We have taken these steps to lower this risk:

- All participants must have a loved one with an opioid use problem to enroll in the study.
- Everyone will receive instruction on protecting their identity and not sharing another person's information
- We will use the more secure Zoom account that is HIPAA compliant. Zoom is a secure, videoconferencing platform. Also, Zoom sessions will not be recorded or saved.
- We will remind participants to engage in research activities when they have privacy and enough time to complete them.
- Session and forum discussions will be monitored by WTV staff to ensure all participants are adhering to WTV rules and regulations.

10. What are the possible benefits of being in this study?

You may not get any benefits from being in this study. This study uses approaches that when delivered face-to-face have been shown to help people interact with their loved ones using healthier strategies, but this may not happen for you. This study may make you feel more supported. WTV platform members have reported feeling less alone is a benefit to them. The information we get from this study may help us find ways to distribute effective support programs to more CSOs like you.

11. Do I have to pay to be in this study?

No, you do not need to pay anything to be in this study. The programs and services we are testing are free for you as a participant. You will be required to have access to a smart phone with data or a computer with internet. The study will not reimburse you for the data or internet usage that may incur from participating in this online study.

12. Will I be paid for being in this study?

We will pay you for completing some study tasks. In total, you can earn \$40.00 in Amazon gift cards for completing these tasks:

- You will receive a \$20.00 gift card for completing the baseline survey
- You will receive a \$20.00 gift card for completing the 12-week follow-up survey

You will be paid with an Amazon gift card within two days after completing each survey. The Amazon gift cards will be sent to you through the email address you provided to the study team. If you drop out of the study or are asked to leave the study, you will still be able to keep any gift cards you were given.

13. Do I have to be in this study?

No, you do not have to be in this study. No one will treat you differently if you do not want to do this. You will not get in trouble if you do not want to be in this study. If you do not want to be in this study, check the box at the end of the page "I do not agree to be in the study." If you want to be in this study, please read the consent form to the end of the page and check the box "I agree to be in the study."

You can say 'yes' now and change your mind later. If you do not want to be in this study anymore, you can tell Calum Handley. Calum Handley is the Principal Investigator (the person in charge of this study). He can be reached at 413.438.4673 and email address at calum@villagehelps.com. You can also tell Jane Macky, CEO and Founder of We The Village. She can be reached at phone number 917. 684. 4267 and email address at jane@villagehelps.com. We will not ask you for more information, but we will keep the information we got before you changed your mind.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

14. What other choices do I have if I choose not to be in this study?

If you do not want to be in this study, you will still be able join the We The Village online forum.

15. Can I be asked to leave this study?

We may ask you to stop being in this study if:

- 1) You engage in hostile behavior with other participants during online interactions
- 2) You break the confidentiality and share personal information of other participants.

16. Will I be contacted in the future about this study?

We will contact you in the future if:

- There is new or important information that may make you change your mind about being in this study.
- We learn important information about your health, safety, or rights after the study ends.

We would like your permission to contact you in the future for the following reasons:

- To ask you to provide more information for this study. The information we may ask for in the future may be similar to the information we ask for now.
- To share study results, updates, or additional services.
- To ask for clarification or feedback about the web-based support programs and peer support forum.
- To ask for clarification or feedback about any answers and your experience in the study

You can decide now if you want to be contacted in the future for these reasons. If you agree now, you can change your mind later.

17. What else will I need to complete to enroll in this study?

We will ask you to complete the following activities before you are considered a participant in the We The Village Family Support study.

- Finish reading the consent form

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

- Click the box below next to “I agree to join the study”
- Read and agree to the HIPAA authorization form
- You will be asked to call a study staff person or provide contact information to be called by a study staff person after they agree to be in the study

18. Is there anything else I need to know about this study?

Information about this research study can be found on www.ClinicalTrials.gov. This web site will not have information that can identify you. You can search for this project on this web site at any time.

19. Who can I call about my rights as a participant in this research study?

If you have questions about the research study and program activities, you can contact Calum Handley, Principal Investigator, at 413.438.4673 or at calum@villagehelps.com.

If you have questions related to screening and data collection, you can contact Mary Milnamow, Senior Project Manager at PHMC, at 215.985.2542 or at marym@phmc.org.

In addition to the above people, you can also contact the study's Institutional Review Board (IRB). The IRB makes sure that this study is being done right. You can call the PHMC IRB at 1-800-335-9874 or email ResearchCompliance@phmc.org if:

- You have questions about your rights as a study participant.
- You want to make a complaint about this study.
- You get an injury from being in this study.

Documentation of Consent

- I have read, or been read, this form.
- All of my questions were answered.
- I understand why this study is being done and what I will be asked to do.
- I agree to be in this study.
- I will get a copy of this form to keep.

Please check the box next to your choice:*

I agree to join the study.

I do not agree to join the study.

I am not sure I want to join the study because I have questions.

Logic: Hidden unless: Question "Please check the box next to your choice: " is one of the following answers ("I agree to join the study")

Please check the box next to your choice: *

I agree to let someone from the WTV Family Support Study contact me in the future.

I do not agree to let someone from the WTV Family Support Study contact me in the future.

Logic: Hidden unless: Question "Please check the box next to your choice: " is one of the following answers ("I agree to let someone from this study contact me in the future.")

Please check the reasons that we may contact you in the future:

To share study results and updates.

To share additional or new services.

To ask for clarification or feedback about the web-based support programs and peer support forum.

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

- To ask for clarification or feedback about any answers or your experience in the study.
- To ask you to provide more information for this study. The information we may ask for in the future may be similar to the information we ask for now.

Logic: Hidden unless: #1 Question "Please check the box next to your choice: " is one of the following answers ("I agree to join the study.")

First and Last Name *

First Name:

Last Name:

Today's Date (mm/dd/yyyy):



Page entry logic: This page will show when: #1 Question "Please check the box next to your choice:

" is one of the following answers ("I agree to join the study.")

Thank you for agreeing to be a part of the We The Village Family Support Study.

Before we can complete the consent process, you need to speak to someone from the research team to complete and pass a brief consent quiz and to confirm your enrollment.

Please call Jaime at 215.985.2500 Ext. 4382. If we do not answer, please leave a message and we will return your call within one business day.

You can also complete a brief contact form to have someone on the research team call you.

[Click Here to Complete Brief Contact Form](#)

Page entry logic: This page will show when: #1 Question "Please check the box next to your choice:

" is one of the following answers ("I do not agree to join the study.")

IRB Protocol # 1906
Calum Handley
Principal Investigator
Telephone #: 413-438-4673
Email: info@villagehelps.com

Public Health Management Corporation
Centre Square East
1500 Market Street, 15th Floor
Philadelphia, PA 19102

Thank you for your time. In a few words, please let us know why you do not wish to join the study at this time?

Logic: Hidden unless: #1 Question "Please check the box next to your choice: " is one of the following answers ("I am not sure I want to join the study because I have questions.")

Thank you for your time. You indicated you may have some questions about the study. If you wish to speak to someone from the research team, please call Mary at 215.985.2542. If we do not answer, please leave a message and we will return your call within one business day.

Thank You!

Thank you for your interest in We The Village Family Support Study.

[We The Village](#)