

Cover Page: Consent form
We The Village Counselor Training Study
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IRB PROTOCOL #2202
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Consent Form

**We are asking for your consent in order to participate in the We
The Village CRAFT Counselor Training Study.**

You are eligible and have indicated interest in being part of the WTV CRAFT Counselor Training Study.

Before you move forward, we need to share a few more details to help you understand the process and make the decision to enroll in our study or not.

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 consent for us to contact you. If you are not sure about participating, you can always opt out later.

You can always contact us to ask any questions that might come up for you. Call us at [267-353-4762](tel:267-353-4762), or submit your number for us to call you back ([Click here to request a call back](#)) or email us at hello@craftprostudy.com.

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

Important Things to Know About This Study

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 the form, you are agreeing to be in this study.
- You should not click "I agree" unless you are confident at this time that you are interested in participating in this study.
- Please note: in this consent form we use 'counselor' to refer to a person working in a counselor-related role, meaning you have (or are qualified and could have) individual client sessions.
- The purpose of this study is to test different components of an online counselor training program in Community Reinforcement and Training (CRAFT), an empirically supported intervention for helping family and concerned significant others (CSOs) who have a loved one who has a problem with opioids. CRAFT's goals are to change the CSO's communication with their loved one, improve their self-care, and help them get the loved one into treatment.

The study will examine which combination of training components:

- a. Are acceptable, satisfactory, and useful to counselors;
- b. Improve counselor knowledge and skill in implementing CRAFT; and
- c. Result in greater treatment entry and retention for the CSO's loved one.

If you agree to be in the study, you will:

- a. Be randomly assigned to one of three online training programs
- b. Be asked to participate in online training activities over 12 weeks; and
- c. Complete three surveys.

This study involves very few risks, and we have plans in place to lower these risks.

- Most counselors who engage in these training programs in-person improve their knowledge and/or skills in implementing CRAFT, but you may not benefit from being in this study.
- For this study you will be asked to share information with us about yourself including your training, experience, expectations, satisfaction, and opinions about the training program you receive. We have plans in place to keep your information confidential.
- This form will explain all of this to you in more detail.

You can always contact us to ask any questions that might come up for you. Call us at [267-353-4762](tel:267-353-4762), or submit your number for us to call you back ([Click here to request a call back](#)) or email us at hello@craftprostudy.com.

1. What is the purpose of this study?

We are testing different online training programs that teach counselors to implement CRAFT, an empirically-supported treatment for helping family and concerned significant others (CSOs) who have a loved one with a problem with opioids. The goal of the study is to see which combination of training components (tutorial only, training materials, coaching) is most acceptable, satisfactory, and useful to counselors, best increases their knowledge and skills in CRAFT, and results in better treatment entry and retention of their clients' loved ones with opioid use problems.

2. Who is in charge of this study?

This study is being led by We The Village (WTV), Inc. WTV is a company with an online platform providing access to effective training and support for CSOs affected by the substance use disorder of a loved one. Using science and educational expertise, WTV is now developing an online training program to give counselors the knowledge and skills to implement CRAFT with their clients independently or in conjunction with the online platform for CSOs.

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.

Three researchers on this project- Jane Macky, Calum Handley, and Kimberly Kirby- are financially involved with We The Village, Inc. (WTV). WTV is being paid to carry out this research and may benefit from any resulting research products. The analysis will be carried out by a third party with no financial interest. Ask the research team if you have any questions about how this information may affect your participation.

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 someone who is interested in learning how to implement CRAFT
- Your answers to the screening questions indicated:
 - You are of legal age to consent to research (over 19 years old)
 - You live in the United States
 - you are working in a counseling-related profession
 - you have not previously been trained in CRAFT
 - you provide 45 minutes of individual counselling sessions each week to 5 or more clients (either CSOs or individuals with substance use disorder)
 - if you are not already providing care to CSOs, you could do so
 - your work involves clients affected by OUD or could be expanded to include them
 - you are able and willing to submit the required session audiotapes and participate in the training activities (tutorial, training materials, and coaching) as assigned over the 12-week study period
 - you have access to a computer or smartphone with internet access, email, and word processing capabilities

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 do not agree to all of the study procedures
- You do not complete the initial assessment

- You do not reside in the United States
- You are not English-speaking

4. Who will be in this study?

Counselors who work or want to work with people who have loved ones with an opioid use problem. We are enrolling up to 45 participants in this study. People will be recruited through online, professional, and personal referrals from anywhere in the United States.

5. How long will I be in this study?

Active participation in the study is scheduled to last for 12 weeks, however, it may take you a few weeks longer to schedule and complete your last videotaped session. So, from beginning to end you will be in the study for approximately 3 months from completing this form.

6. What are you asking me to do?

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

a. Complete surveys at the beginning of the study, after the tutorial, and at 12 weeks after beginning of the study. Each survey will take about 30 to 45 minutes to complete.

- The first survey will include questions about your demographic characteristics, training and experience, expectations regarding training, and knowledge of CRAFT.
- The next two surveys will again ask questions about your knowledge of CRAFT and also about your satisfaction with the training program, your opinion about the program's usefulness in clinical practice, about how easy it is for the learner to use, the likelihood that it could be implemented widely, and its price value.
- The last survey will also ask you to report on the number of CSOs you have worked with over the past 10 weeks, how many of them you implemented CRAFT with, and how many of those CSOs had a loved one who entered new treatment.

b. Complete online mock counseling sessions with an actor portraying a CSO at the beginning of the study, after the tutorial, and at 12 weeks after beginning the study.

c. Agree to be randomly assigned to one of three training programs. 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 and the online mock counseling session.

- We will use a computer-generated random number to assign you to training A, B, or C. The computer program ensures that everyone has the same chance to be in each of the three programs that we are testing. Program A is a standard online tutorial training program and Programs B and C are experimental programs that include additional training components.

d. Provide us with your contact information. We will ask for:

- Your name, address, phone number, and professional and personal email addresses
- 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 a close family member or friend 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 secure online links to complete your surveys
- to send you reminders to complete surveys
- to send you check-in or reminder messages regarding the training program or coaching sessions
- to keep you up to date on the study's progress and findings, as well as to share new training programs or services that may become available after the study ends.

e. Participate in your assigned program activities for 12 weeks.

See a brief description of each program with the time commitment expected from CSOs here:

STUDY ACTIVITIES BY TRAINING PROGRAM		
Standard Training Program	Experimental Training Programs	
Program A	Program B	Program C
<ul style="list-style-type: none">• Commit up to 6 hours over 2 weeks to complete the online tutorial• Commit 15-30 minutes weekly for the next 10 weeks for CRAFT training• Review online tutorial materials• Receive weekly emails encouraging you to review specific modules and continue using the online training program	<ul style="list-style-type: none">• Commit up to 6 hours over 2 weeks to complete the online tutorial• Commit 30 minutes weekly for the next 10 weeks for CRAFT training• Complete new online training exercises and materials• Receive weekly emails encouraging you to complete specific exercises, review materials and continue using the online training program	<ul style="list-style-type: none">• Commit up to 6 hours over 2 weeks to complete the online tutorial• Commit up to 2 hours weekly for the next 10 weeks for CRAFT training• Complete new online training exercises and materials• Audio tape sessions with CSO clients, and• Meet with a CRAFT trainer(via videoconference) to receive feedback on taped sessions• Receive weekly emails encouraging you to complete specific exercises, review materials, meet with your CRAFT trainer and continue using the online training program

f. If you are randomly assigned to Program C you will be required to submit audio taped sessions with clients (up to 12 allowed), for which you will digitally receive written feedback and live video-call coaching. You will be encouraged to re-submit your audio taped sessions until you meet the criteria needed for certification in the CRAFT procedure or until the phase is over (whichever occurs first).

We will provide you with forms for consenting clients to participate in audio recordings. We ask that you use these forms as they contain specific information and wording required because the tapes will be used as part of a research project. If your place of work also has required forms for audiotaping client sessions, you may ask clients to complete both forms, or seek special approval from your superiors to use our form instead. You will need to store this form in a secure place where you normally keep confidential patient materials. Audiotapes must be submitted without any client identifiers as part of the file name. These tapes will be accessed only by certified CRAFT trainers and research team members who need access to complete study activities.

7. Will my information be kept confidential?

Yes, we will do our best to keep your personal information and any client information you share with us confidential. We cannot promise total confidentiality. It is possible that others may learn that you are in this study or learn 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.
- All participants will be instructed not to use last names for their username when logging onto the training platform. Usernames will never be shared with anyone outside of the study.
- Some participants will receive online coaching sessions using Zoom, a secure video conferencing/chat platform. Some Zoom sessions will be recorded so that we can check on the quality of the coaching participants are receiving. These recordings will be seen only by trained quality control staff and CRAFT trainers.
- If you are randomly assigned to Training Program C, you will be asked to attain client consent to audiotape sessions and to avoid using client identifiers (e.g., last names) when recording and labelling tapes so that they remain unidentified.

- We tell participants to be in a private location for coaching sessions to maintain privacy.
- We will only share participant information with the research team members.
- 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.
- Participant research records will not have names on them. We will use a code number instead. The code number will be kept secure and separate from participant names and usernames. Only research staff on this study will have access to the document linking code numbers to 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 training activities or study 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:

1. Any information about child abuse or intent to harm self or others will be reported to authorities, as required by law.
2. We will also break this agreement 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 Disappointment with the randomly assigned training program
4. Risk Resulting from Possible or Perceived Invasion of Privacy
5. Risk Resulting from Possibility of or Perceived Coercion or Undue Influence to participate in the study.

i. There may be a breach of confidentiality.

- We will do our best to keep your information and any client information you share confidential. It is still possible that your information may be seen or heard by someone who should not see or hear it.

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. Recorded Zoom sessions will be stored in password protected files on secure servers.
- Participants create their own usernames and can change them at any time during the study.
- 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.
- If you are randomly assigned to Training Program C, you will be asked to attain client consent to audiotape sessions and to avoid using client identifiers (e.g., last names) when recording and labelling tapes so that they remain unidentified.

ii. Some parts of this study may make you feel uncomfortable or stressed.

- **During the surveys when answering questions about areas of your life.**
- **While conducting mock sessions, audio recording actual sessions, or during online coaching sessions and discussion forums.**
- **While trying to identify clients to audiotape sessions with if you are assigned to Training Program C.**

We have taken these steps to lower this risk:

- **You can skip any survey question you do not want to answer.**
- **We will help you to understand feeling uncomfortable when conducting mock sessions or submitting audio tapes for evaluation is usually transitory and that our goal is to evaluate the training programs, not your abilities per se.**
- **We can help facilitate a client match for you from our We The Village community of family members if you are having trouble finding a CSO client with a loved one struggling with OUD to audiotape sessions with.**
- **You can leave the study at any time.**

iii. You may be disappointed by the training program you are randomly assigned to receive. It is possible that you will be disappointed with the training condition to which you are randomly assigned.

- **If you are assigned to Program A (Tutorial only) or Program B (Tutorial and Online Training Materials) you may be disappointed that you did not receive a more intensive training opportunity that could allow you to attain certification as a CRAFT counselor.**
- **If you are assigned to Program C (Tutorial, Online Training Materials, and Coaching) you may be disappointed that you did not receive a less intensive training program that would not require as much of your time.**

We have taken these steps to lower this risk:

- **If you are assigned to Program A (Tutorial only) or Program B (Tutorial and Online Training Materials) and wish to pursue certification through We The Village's training program after you**

have completed the study, you will not be charged for the components you have already received and can complete certification at a reduced cost.

- **You can leave the study at any time.**

iv. You may experience or perceive an invasion of privacy when participating in online mock counselling sessions, and if you are assigned to Training Program C, when completing training activities via the Zoom video conferencing platform, or audio taping sessions with clients. If you are assigned to Program A (Tutorial only) or Program B (Tutorial and Online Training Materials) you may be disappointed that you did not receive a more intensive training opportunity that could allow you to attain certification as a CRAFT counselor.

We have taken these steps to lower this risk:

- **You will receive instruction on protecting your identity**
- **We will remind you to engage in training and research activities when you have privacy and enough time to complete them.**
- **If you are in Training Program C: We will tell you how to protect the anonymity of clients in your audio taped counseling sessions**
 - **Your coaching will be conducted on a one-to-one format with a certified CRAFT trainer**
 - **We will use the more secure Zoom account that is HIPAA compliant. Zoom is a secure, video conferencing platform.**
 - **We will randomly select 25% of Zoom sessions to be recorded for purposes of monitoring the quality of the coaching participants receive. Recorded Zoom sessions will be stored in password protected files on secure servers.**

v. You may experience or perceive coercion or undue influence to participate in the study if you learn of the training pilot study from your employers and feel pressured to participate or to answer questions or give feedback in a particular way.

We have taken these steps to lower this risk:

- All employers who are approached to assist with recruitment will be told that research participation must be voluntary, and they cannot require counselors to participate or give consequences to counselors who do not participate.
- Employers will be told that counselors must meet eligibility criteria to participate, so the fact that a counselor does not participate does not mean that they refused to do so. Should an employer inquire about the reasons a counselor did not participate, they will be told the person was not eligible (voluntary participation is an eligibility criterion) and reminded that they should not pressure employees to participate.
- We will not provide any information about your participation (i.e. whether you agreed to participate or your responses) to any outside parties.

What are the

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

This study may help you increase your knowledge and/or skills in a leading evidence-based protocol related to your profession as a counsellor or in a counsellor related role, but this may not happen for you. The information we get from this study may help us find ways to distribute effective training programs to more counselors 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 training 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 \$150.00 in Amazon gift cards for completing these tasks:

- You will receive a \$50.00 gift card for completing each of three surveys

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 Jane Macky. Jane Macky is the Principal Investigator (the person in charge of this study). She can be reached at phone number 917. 684. 4267 and email address at jane@wethevillage.co. We will not ask you for more information, but we will keep the information we got before you changed your mind.

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 can find other counselor trainings online or consult Dr. Robert J Meyer’s webpage (www.RobertJMeyersPhD.com) to see if there are CRAFT trainings planned at a location in the USA that you may join.

15. Can I be asked to leave this study?

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

- 1. You refuse to participate in the online mock counselling sessions or, if you are assigned to Training Program C and refuse to submit audio tapes of clients**
- 2. You break the confidentiality and share personal information of your clients**

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 training programs.
- 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 CRAFT Counselor Training 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.

- Finish reading the consent form
- Click the box below next to “I agree to join the study”
- You will be asked to call a study staff person or opt to be called by a study staff person after you agree to be in the study
- Provide your contact information by filling out a brief online form
- Click on the link when we send you the study’s first survey

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?

The Institutional Review Board (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.

If you have questions about the research study and program activities, you can contact Jane Macky, Principal Investigator, at 413-438-4673 or at jane@wethevillage.co.

If you have questions related to screening and data collection, you can contact Jaime Kishpaugh, Research Coordinator at PHMC, at 267.353.4762 or at jkishpaugh@phmc.org.

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.

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?

Please write the initials of your name 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.:

*

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 training programs.
- 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.

Today's Date (mm/dd/yyyy)

Email address