

1667 Cole Blvd. Suite No. 220 Golden, Colorado 80401 Main Phone: 303.565.4321 Fax: 303.565.4320

Email:info@kleinbuendel.com

## **Cover Page**

**Research Subject Information Sheet -**

**Randomized Control Trial** 

**Protocol #:** 1R44AA029364 - 01

Date: 4/22/2022

Title:

**CLINICAL TRIALS COVER PAGE** 

## Research Subject Information Sheet Randomized Control Trial

TITLE: WayToServe Plus: In-service Professional Development

Component To Improve Responsible Alcohol Service

**PROTOCOL NO.:** 1R44AA029364 - 01

IRB Protocol #20211770

SPONSOR: NIAAA

**INVESTIGATOR:** Gill Woodall, PhD

1667 Cole Blvd, Ste 225 Golden, Colorado 80401

**United States** 

STUDY-RELATED

**PHONE NUMBER(S):** Gill Woodall, PhD

303-565-4321 (24 hours)

You are being asked to be in a research study. The goal of this part of the study is to get your feedback for an in-service professional development component to the *WayToServe®* online RBS training for alcohol servers. Responsible beverage service (RBS) training for alcohol servers is a promising intervention for reducing driving while intoxicated (DWI) by alcohol.

WayToServe® teaches content common to most RBS training but also provides unique skills and tools for both servers and premise managers and is compliant with content requirements of the laws in your state.

Your participation will involve completing an online training course. The online course is similar in scope to the training provided to alcohol servers and sellers in many states and conforms to your state's regulations. We ask that you complete the training within four weeks from original registration. As you complete each of the modules in the training, you will take a quiz. When you complete the entire training you will complete a test in order to receive your certificate.

You will be randomly selected to complete either the *WayToServe* training or the *WayToServe Plus* training. If you are chosen to receive the *WayToServe Plus* training, you will be instructed to "friend" the Community Manager for the *WayToServe* Facebook page and will be compensated \$50.

## Confidentiality

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study. The consent form signed by you may be looked at and/or copied for

research or regulatory purposes by the sponsor and/or copied for research or regulatory purposes by the Department of Health and Human Services (DHHS) agencies, and/or the WCG IRB.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

As compensation, servers who complete the training will receive a \$35 gift card and new server training certificate from NMABC or WSLCB free of charge.

Dr. Woodall and David Buller are both co-owners of Wedge Communications LLC, WayToServe's commercial licensee and marketer. Please feel free to ask any further questions you might have about this matter.

There are no known risks associated with being in this research. There is the risk of a loss of confidentiality of your research-related information.

You may not receive a direct benefit if you agree to participate. However, people in the future may benefit from the information obtained from this research. Your alternative is to not participate in this study.

Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform the full intent of the study will not be explained during the consenting process.

Contact Dr. Gill Woodall at 303-565-4321 (24 hours) for questions, concerns, or complaints about the research or if you think you have been harmed as a result of joining this research. Contact the WCG IRB if you have questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research: 1019 39th Avenue SE Suite 120, Puyallup, Washington 98374-2115, Telephone:855-818-2289, or E-mail: <a href="mailto:researchquestions@wcgirb.com">researchquestions@wcgirb.com</a>. WCG IRB is a group of people who perform independent review of research. WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation in this study is completely voluntary and you may decide to not participate or withdraw from the study at any time with no penalty or loss of benefits to which you are otherwise entitled. All your responses will be kept in secure storage and only trained study

staff will have access to your files. You will not be identified and no information will be publicly disclosed that would make it possible for anyone to identify you in any presentation or written reports about this study. When all the data is collected from everyone who has agreed to participate, all responses will be grouped together in any reports or presentations. There will be no way to identify individual participants. This information is shared so the research can be conducted and properly monitored.

This permission will not end unless you cancel it. You may cancel it by sending written notice to the study investigator at gwoodall@kleinbuendel.com.

Your decision to be in this study is voluntary. You will not be penalized or lose benefits if you decide not to participate or if you decide to stop participating. Your decision to participate or not to participate in this research study will not impact your employment status.

## **CERTIFICATE OF CONFIDENTIALITY**

Since this study involves collecting information on the use of drugs or other addictive products, Klein Buendel has obtained a Certificate of Confidentiality from the National Institutes of Health. This will help us protect your privacy. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

Do you consent to participate in this study? (Click one button)
Yes (Go to registration page)
No (Exit)