Study Title: Computerized Tool for Preventing Prenatal Drinking

NCT Number: NCT02337361

Date of Document: May 1, 2015

PROTOCOL INFORMATION

Approved by the California Committee for Protection of Human Subjects, June 15, 2015

PROTOCOL INFORMATION:

1. Purpose of the study

a) Include a brief statement , less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

Prenatal alcohol use, a leading cause of preventable birth defects in the U.S., continues to be a public health problem (Ethen et al., 2009). Screening and brief intervention (SBI) reduces drinking but remains underutilized due to resource limitations in public health care. Delayed pregnancy recognition and stigmatization concerns related to disclosure of drinking (Jacobson et al., 2002) further hamper prevention efforts with pregnant women. Heavy drinking increases risk for unintended pregnancy and for prenatal drinking. Thus, high rates of heavy drinking and of unplanned pregnancies in women in the U.S. suggest the need for primary prevention with all women of childbearing age. Barriers to SBI with pregnant women indicate that innovative programs are needed to prevent prenatal alcohol use.

Our study seeks to adapt a self-administered, computerized screening and brief intervention (electronic SBI or "e-SBI") for drinking during pregnancy for use with *non-pregnant* women of childbearing age and to conduct a preliminary test of its efficacy. We previously successfully piloted the e-SBI for drinking with pregnant WIC clients. We now seek to test the efficacy of e-SBI in reducing drinking among non-pregnant women at two Northern California WIC sites.

Our e-SBI is innovative in several ways. It is self-administered and uses actual drinking vessels and photographs of drink containers to assess individuals' drink sizes. It then uses that data to provide personalized feedback about how much the individual is actually consuming in standard drink equivalents. Finally, our e-SBI is in English and Spanish and will address gaps in care for Hispanic women, an increasing portion of those attending public health clinics.

Our study design incorporates innovative methodological features, including studying if assessing drink size can reduce drinking by itself and if depression modifies e-SBI efficacy. This will provide preliminary information related to how and for whom the e-SBI works. We expect to disseminate our findings via publications in scientific journals and through networks of participating organizations as well as networks of the local county and state perinatal health professionals and substance abuse treatment professionals. Because it begins to build an evidence base for e-SBI efficacy for reducing prenatal alcohol use, our study is of significance for improved maternal and child health. Findings will also impact the larger literature on cost-effective strategies to reduce alcohol-related harm.

Specific aims of the study are to:

Aim 1. Adapt a computerized SBI (e-SBI) for drinking during pregnancy for use with women of childbearing age.

Aim 2. Conduct a small randomized trial of the e-SBI with an intervention group (e-SBI, n=100) and a control group (usual care, n=100) at two WIC program sites.

Aim 3. Use drink size assessment to better measure drinking outcomes, and explore efficacy for the drink size assessment component of the e-SBI.

Aim 4. Explore if depression modifies alcohol use outcomes for e-SBI. We expect that within the intervention and control group each, women reporting depression will reduce their drinking less than those without depression.

(484 words)

CITATIONS

Ethen MK, Ramadhani TA, Scheuerle AE, Canfield MA, Wyszynski DF, Druschel CM, Romitti PA (2009) Alcohol consumption by women before and during pregnancy. Matern. Child Health J. 13:274-285.

Jacobson SW, Chiodo LM, Sokol RJ, Jacobson JL (2002) Validity of maternal report of prenatal alcohol, cocaine, and smoking in relation to neurobehavioral outcome. Pediatrics 109:815-825.

b) What is the major research question to be addressed in this project?

The study examines efficacy of electronic screening and brief intervention for reducing alcohol consumption among women of childbearing age.

2. Study Procedures: ***All project types*****)**

a) Describe all study procedures. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section.

Data collection will be conducted at two sites of the Women, Infants and Children (WIC) program that are interested in participating in the proposed study, the Sonoma County WIC site in Santa Rosa, and the La Clinica de la Raza Fruitvale WIC (see letters of interest and organizational support). Data collection with human subjects involves the following: 1) Individual testing of e-SBI and assessment software by a total sample of 20 women at the clinic prior to software finalization to enhance its acceptability and usability for study participants; 2) recruitment of non-pregnant women attending the WIC clinic to participate in a short computerized screening, including that for alcohol use to identify study eligibility. Those reporting drinking 5 or more drinks in a day or 8 or more drinks in a week within the past year will be eligible for the trial. 3) computerized random assignment of c women eligible for the trial to one of two study conditions, i.e., to receive the e-SBI (experimental group) versus usual care (control group); 4) completion of a baseline assessment on alcohol use, any drug and *tobacco* use, sweetened beverage consumption, with the e-SBI for the experimental/intervention group only; 5) completion of 3-month follow-up computerized assessments; and 6) completion of 6-month follow-up computerized assessments.

Study procedures include several tasks as detailed next. Also see Figures 1 and 2 attached that provide an overview of expected recruitment numbers and study procedures.

Adaptation the e-SBI for use with non-pregnant women. Our first study aim is to adapt a recently piloted computerized SBI for drinking during pregnancy for use with non-pregnant women of childbearing age. The adapted e-SBI, like that for drinking during pregnancy, piloted at the Richmond WIC site in 2012-2013, will be self-administered via a computer with a touch-screen monitor. Adaptations include text changes to content to increase relevance of messages for reduced drinking relevant for non-pregnant women who potentially could become pregnant and drink prior to pregnancy recognition. Expert review (consultant, clinic staff) and feedback from women testing our study program in the preparatory period will be used finalize content modifications.

Development of the computerized study program. Most of the study procedures will be computerized. The computerized study program will include informed consent and all study assessments. It will also deliver the e-SBI to participants who screen eligible and are randomized into the intervention condition, and provide all needed referral information. Thus, the computerized study program will include a) the informed consent b) all study assessments including at baseline, 3 months and 6 months; c) a screening module to identify risky drinkers for study inclusion (those who drink 8 or more drinks in a week or five or more drinks in a day); d) computerized randomization of eligible participants to the two study trial conditions (intervention or the brief alcohol intervention **vs** control or usual care); e) at baseline: a brief alcohol intervention for the intervention group only; f) at the 3-month follow up: a booster (re-administration of) e-SBI for the intervention group; and g) at 3- and 6-month follow up: drink size assessment for both study groups. See study program flowcharts in the attachments for an overview of the modules of the computerized study program.

The Brief Alcohol intervention Like other SBIs, our e-SBI for drinking during pregnancy includes alcohol assessment and feedback, information on alcohol-related harms and benefits of reducing consumption, and a personalized plan for reducing consumption. The plan includes goal setting, an analysis of high risk situations for drinking, and suggested coping strategies. Two components of our e-SBI set it apart from prior interventions: 1) A drink-size assessment that uses *a display of* actual drinking vessels (9 glasses) *placed above the study computer* (*see the storyboards for the computerized study program for a picture of the vessels display)*; and photographs or other drink containers (glasses, bottles, cans) to assess beverage-specific drink sizes; 2) Drink size feedback that educates users about standard drink sizes and reviews discrepancies between their drink size and the standard

size for each beverage, highlighting that she may be drinking more than she thinks she does.

Preparatory Period: This will include testing of study procedures and computerized study program. Following beta testing and elimination of programming errors for the computerized study program, we will use a 2-month preparatory period to test and finalize our computerized study program and the recruitment and data collection procedures at both study sites. This is critical to identify any unanticipated problems and to ensure the study procedures do not impact staff work load.

We will recruit 10 non-pregnant women (5 English speaking and 5 Spanish speaking) at each of the two WIC sites to test the computerized study program. In our prior work with e-SBI for drinking during pregnancy at a Contra Costa county WIC site, we found individual testing of the e-SBI feasible and relevant and used it successfully.

Clinic staff will inform eligible participants about testing of the computerized study program, clarify that participation is voluntary and does not affect services received at the site in any way. Interested participants will approach the private study area where the research assistant will help them review and complete the informed consent. Participants will be paid $20.00 each for testing the program. No identifying information will be collected from these participants. However, we will ask participants for their WIC ID number to ensure that they do not participate again in the study.

Recruitment of participants for the study

Posters and recruitment flyers leaflets that provide basic information about the study as a health study will be used for recruitment (see attachment). Posters, with the same information as the flyers but in larger size, will be placed in visible areas identified in close consultation with staff at each site. WIC staff will inform eligible women about the study by providing them a copy of the recruitment flyer with brief study information at the end of their visit and will indicate where the private study area is located. WIC staff will clarify to clients that study participation is voluntary, they will not know who participated or not as no study data is shared with staff, and that study participation will not affect clients WIC services in any way. Interested women will then approach the Research Assistant (RA) on site.

In order to ensure that WIC clients do not feel pressured to participate in the study, particularly because several clients return every 2 to 3 months for their food checks, after 2 months of recruitment, WIC staff will not provide each participant the recruitment flyer. Instead, staff will ask eligible clients if they know about the study and only provide a copy of the recruitment flyer to a client who specifically asks for it.

Screening, administration of the computerized intervention, and follow up assessments will be completed by the computerized study program administered through a PC using a touch screen monitor placed in a private area of the site. Each study computer will have a drinking vessel display with 9 different glasses for use during the drink size assessment (see computerized study program storyboards attached for a picture of the drinking vessel display). We will use more than one computer and monitor to administer the study program if needed, providing privacy to each participant with the use of screens/room dividers as appropriate for the space at the specific site.

The RA will ask an interested participant, who approaches her and expresses interest in the study, for her WIC ID number. We propose recording the participant's WIC ID for purposes of identity verification only, needed for incentive payments and check-in for the follow up assessments. Clients at the WIC program typically check in with their WIC ID. Thus, this ID represents a convenient and reliable form of identification for participants to provide. The RA will explain to the participant that the WIC ID number is recorded for identification purposes to help avoid participants doing the program twice and that the ID information is not part of the study data. The RA will start the computerized study program by entering a unique study ID matched to the participant's WIC ID.

Study consent will be administered electronically. In reviews for our prior e-SBI study with pregnant women, electronic consent (by selecting "I agree" on the pertinent screen) was deemed acceptable for research purposes by both the Public Health Institute and the Contra Costa County Regional Medical Center Institutional Review Boards. A participant may decline or stop participation at any point during the study by pressing a stop sign present on each screen of the computerized study program. If the participant presses "stop", the computer will ask if it may store the data allowing the participant to select a response to eliminate the data. Because data on

where women stop the program is useful for program improvements, we will delete that participants data at the end of the day after recording which program screen she touched the stop button on. Women completing screening who report risky drinking will be eligible for the trial. The computer will randomly assign these women to receive the alcohol intervention or not and then to complete the baseline assessment

Women will use the computerized program independently, with the RA available on site to answer questions and address any unanticipated problems. At completion of the program, an encrypted email will be generated to the RA which includes the following password-protected information, none of which is personal identifying information: Study-ID and whether screening only vs full baseline assessment was completed. The program will also prompt participants to meet the RA to collect their payment and provide needed follow up information. The RA will a) provide the incentive payment (gift card); and b) obtain contact information for purposes of follow-up. Participants will be paid $5.00 if screened only and $30.00 each for baseline and follow-up assessments if enrolled in the trial. Contact information obtained will include the participants' name, phone number and other contact information needed to reach them to schedule their follow up appointments. All follow-up appointments will be schedule to coincide with subsequent visits to the WIC site. The RA will explain to participants that all identifying information collected will be confidential, secured and kept separate from the data.

We expect over 80% of participants to use cellphone and text messaging services based on use reported in a 2011 study at a southern California WIC program. Participants will also be provided with cellphone numbers to reach the RAs if needed. RAs will use contact information to check-in with participants once in the interim between interviews, specifically, 6 weeks after the baseline interview and 6 weeks after the 3 month interview in order to ensure that the contact information is current or to update this information as needed, and to send reminders regarding the follow-up assessments via text messages and/or telephone. In these phone calls and text messages, the following script will be used *"This is [name of RA] from the Health e-Wise study for Women. Your next appointment is on [*Date]*. Please call [number for RA] if your phone number has changed, if you need to change your next appointment, or have any questions. Thank you."* Voicemails and text messages will only be used with prior verbal consent of the participant, obtained when the contact information is collected and only when the participant cannot be reached by phone.

We will observe implementation periodically throughout the duration of the study to proactively address any problems.

b) State if audio or video taping will occur. Describe how the tapes will be maintained during and upon completion of the project. Describe what will become of the tapes after use (e.g., shown at scientific meetings, erased, etc.).

Audio-recording of feedback regarding the computerized study program will be obtained only from women testing the program with their consent (see consent form). The recordings will be erased once transcribed, within a week of the recording. No other identifying information will be obtained from women testing the study program (preparatory period of study).

c) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in the Attachment section.

Our study does not involve deception.

While the recruitment materials do not mention alcohol to reduce stigma for participants, the informed consent materials clearly indicate that the computerized study program asks about use of alcohol and includes our full organization name (Alcohol Research Group-Public Health Institute) in the title.

The informed consent also contains information that participants who screen eligible for the larger study (the trial) may receive the computerized brief intervention or not (usual care). See statement " *DrinkWise* may give you information on healthy drinking. "

3 Testing of a New Drug or Device ***(Common Rule projects only)***

If a new drug or device is being tested, are copies of the state and federal documents that permit the investigators to proceed attached? ☒ N/A

4. Study Affiliation: **(*All project types*)**

a. Is the name of the database or specimens, such as blood spots, listed? ☐ Yes ☐ No ☒ N/A

b. Is California Health and Human Services Agency staff, funding or state mental hospital patients identified? ☒ Yes ☐ No ☐ N/A

4a. If data or specimens from departments within the State of California are being requested, list the department name and the formal name of the data base or specimen registry.

Does not apply. No data or specimen are being requested from the organizations interested in participating.

4b. List any California Health and Human Services Agency department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

We seek to recruit participants at two WIC program sites in Northern California the Santa Rosa WIC and La Clinica De La Raza, Oakland's Fruitvale WIC. Non-pregnant clients at these sites who consent to participation will complete all study procedures at these sites during routine visits to the WIC program.

No staff from these sites will be involved in the research. Research staff for the project will be hired by the Principal Investigator's organization, the Alcohol Research Group-Public Health Institute (ARG-PHI).

Note: if neither of these categories are listed, the project may not be in CPHS' purview.

5. Subject Population: **(*All project types*)**

Is the subject population adequately described? This includes data elements being used, recruitment and screening methods, age, gender, ethnicity, vulnerable populations, and rationale for studying these populations. ☒ Yes ☐ No

5. Subject Population

In the space below, please describe the participants that you are requesting to recruit (include requested participant number and description of each group requested). For data-only studies, describe the databases or records to be accessed and the data elements to be obtained.

a) Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects, such as age, sex and ethnicity and number of participants.

Consenting non-pregnant women who are 18 to 44 years of age who have not been pregnant in the past 6 months will be eligible for the study screening. Participant self-reported information will be used to exclude pregnant women. Specifically, when a potential participant selects "yes" to the item "are you currently pregnant" on one of the first few screens of the computerized study program, the program will terminate and clarify that only women who are not pregnant are eligible for the study.

Women reporting at-risk drinking, defined as heavy (5 or more drinks in a day) or frequent (8 or more drinks in a week), drinking will be eligible for the randomized trial. These risky drinking criteria are used in prior brief intervention studies with women of childbearing age due to increased associated risk for birth defects and growth deficiencies. We

will not exclude women who report alcohol-related problems. Instead the computerized study program will provide referral information to these participants as per standard of care at the participating WIC sites.

There is no known safe drinking level during pregnancy. Since all participants in the trial will have met risky drinking criteria at baseline, the computerized study program will also provide referral information and brief information on harms associated with drinking to participants who become ineligible at follow up because of being pregnant. Among these participants, those who were assigned to the intervention at baseline will additionally receive information reminding them of the intervention they received (see storyboards for the computerized study program, screens 18A and 18B).

b) If existing data will be obtained, list the database(s) to be used, the time period(s) being requested. This may include requests for future data that is not available at this time. List or attach a list of variables (in the Attachment Section, Attachments) being requested and justify the need for each variable and for the quantity of data being requested. Also, will participants be involved in any other studies?

Does not apply as no existing data is being requested for the present study.

c) What is the rationale for studying the requested group(s) of participants?

Our study uses a follow-up design to examine the efficacy of e-SBI as a tool for low resource settings to improve access to care for diverse groups of childbearing age women. It is best conducted at Women, Infants and Children (WIC) program sites for three reasons. 1) WIC serves a large portion of childbearing age women, mostly of low-income and minority status. 2) WIC Clients return to the program site at least every 3 months for their food checks. This makes WIC the ideal location to recruit low income women of child-bearing age for a follow up study that can be completed at their convenience during a visit to the program. 3) Our prior work on e-SBI was also conducted at a WIC program site in Northern California.

d) Describe how potential subjects will be identified for recruitment. Examples include: class rosters, group membership, individuals answering an advertisement, organization position titles (i.e., Presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)? Attach recruitment materials in the Attachment Section, Attachments. Important to remember: subjects cannot be contacted before IRB approval.

Recruitment of participants for the study

Posters and recruitment flyers/leaflets that provide basic information about the study as a health study will be used for recruitment (see attachment). Posters will be placed in visible areas identified in close consultation with staff at each site. WIC staff will also inform eligible women about the study by providing them a copy of the study flyer at the end of their visit and will indicate where the private study area is located. WIC staff will clarify to clients that study participation is voluntary, they will not know how participated or declined as no study data is shared with staff and that study participation will not affect clients WIC services in any way. Interested women will then approach the research assistant in the private study area.

To minimize burden on WIC staff and to maintain the needed separation between the WIC program and the proposed study for clients as well as avoid staff influencing participation in any way, WIC staff will not answer any questions about the study or provide any other clarifications. Instead, if a potential participant has any queries, WIC staff will direct them to conger with the research assistant

e. Screening Procedures: If subjects will be screened prior to entry into the research, please address the criteria for exclusion and inclusion in the research. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual, should they not enter into the study.

Inclusion Criteria

All consenting non pregnant women who are 18 to 44 years of age and have not been pregnant in the past 6 months will complete a screening using the computerized study program. Given that our study focuses on examining the efficacy of a computerized brief intervention for drinking, women who report at-risk (5 or more drinks in a day) or frequent (8 or more drinks in a week) drinking will be eligible for inclusion in the trial. These criteria are used in prior intervention studies with women of childbearing age due to increased associated risk for birth defects and growth deficiencies. Because, WIC clients are predominantly of minority ethnic status, both women and minorities will be included in the study.

Given recruitment of women of age 18 to 44, the study will include participants ages 1*8*-20. Children below the age of 18 are expected to comprise a small portion (5% or less) of all non-pregnant WIC clinic attendees and will not be included in the study. Women age 18 to 20 are legally considered adults and not minors and can independently consent to medical care and provide informed consent for the study.

While brief interventions are typically not used with drinkers who need more intensive treatment than available in primary care settings, we will not exclude women who report alcohol-related problems. Instead, the computerized study program will provide referral information to participants who report alcohol-related problems as per standard of care at WIC. Usual care at WIC includes providing referral lists with names and phone numbers for diverse health care services, including for alcohol and substance use and depression.

Exclusion Criteria. Pregnant women will not be included in the study as the intervention being studied is for non-pregnant women. Hence if women enrolled in the trial become pregnant after the baseline assessment, we will exclude them from the follow-up assessments.

Screening data and data for participants who do not complete the study.

Data from participants who are screened only but not eligible for inclusion in the trial due to not drinking at risky levels are also of value to us as it provides us demographic and health information for the larger population of women attending WIC. Should women discontinue the computerized program at any point in time and wish to not participate, their permission will be sought to retain the data collected to the point they exited. If participants do not consent to their data being used, their data will be deleted.

f) Explain the amount, nature, e.g.; gift card, cash, and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.

Participants will be paid with gift cards (e.g., My Choice gift cards from Safeway). Participants will be paid $5.00 if screened only and additionally, $30.00 each for baseline, three-month and six-month follow-up assessments. Thus a participant who completes the study will be paid a total of $95.00 in gift cards. Given that the screening takes only 5 minutes, it would not be meaningful to prorate the $5.00 payment for screening. For those enrolled in the trial each assessment will take no more than 20-30 minutes, for which they are paid $30.00 each. Our consent form is clear about payment being made for completing the needed assessment. It states "For each part of the study you finish, you will be paid $30. So if you finish all 3 parts, you will make $90. This is in addition to the $5 you will be paid for completing the first set of questions.

However, prorated payments will be provided to each trial participant who returns for the follow up assessment and find that she is no longer eligible for the study because she is now pregnant. These participants will spend no more than a minute on the computerized study program as the initial screen confirms pregnancy status. We will pay these participants $5.00 instead of the $30.00 they would have received if they had remained eligible and completed the follow-up assessment.

g) Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected (e.g., This is a 2-year study. Participants will be interviewed 3 times per year; each interview will last approximately 2 hours. Total approximate time commitment for participants is 12 hours.)

We expect that we will need to screen consenting participants for roughly 10 months to identify 120 women with risky drinking for the randomized trial at each of the two study sites. With an estimated refusal rate of 20%, we would then enroll 100 participants at each site in this 10-month-period. The last enrolled participant (in month10) will complete the 6 month assessment. Thus we expect the duration of data collection to be 16 months. Hence, allowing for a two-month-study-preparatory period, to test the computerized study program and study procedures, we expect the total duration of the study to be 18 months.
Participants who screen eligible for the trial will complete 3 assessments, 3 months apart within a 6 month period. We expect each assessment to take a maximum of 25-30 minutes, with the total approximate time commitment for a participant being 1.5 hours.

6. Risks: **(*All project types*)**
Are the risks and risk level, minimal or greater than minimal risk, described and justified? ☒ Yes ☐ No
Risks (Input N/A if not applicable)

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) Provide description of risks, physical, psychological, social or economic, loss of data security and confidentiality to subjects. Describe and justify risk level (minimal, moderate or high).

This study includes data collection on sensitive information on alcohol, tobacco and drug use, and mental health. Hence associated risks are: 1)Embarrassment or awkwardness with answering very personal questions and associated increased awareness of alcohol use problems and depression due to the study assessment; 2) possible stigmatization due to alcohol use or poor mental health; and 3) potential risk of loss of confidentiality of personal, private information.

Based on our prior work with women of childbearing age and that reported in the larger scientific literature, we estimate that the risk of the study questions causing distress to participants will be minimal. However, several procedures will be used to provide protection against risks related to discomfort and stigmatization related to answering sensitive questions. We will ensure that participants are treated with the utmost respect and their privacy is safeguarded. Prior to study initiation, all study personnel will complete human subjects training procedures and other requirements for ensuring confidentiality, including a responsible conduct of research online course and signing a confidentiality statement for the study.

All study assessments will be conducted via computer in a private space within the WIC site. Additional privacy features, such as a privacy screen/room divider will be used when more than one participant is in the study area. We will make every attempt to space use of the computerized study program at least 10 minutes apart for participants to further maximize participant privacy.

Several features of the computerized study program are aimed at increasing participant privacy and autonomy and reducing any embarrassment or awkwardness. Obtaining consent electronically precludes the need for signatures and

removes barriers to refusing participation that an in-person interaction may engender. Additionally, participants can decline to participate or stop participating at any point during the study without penalty by pressing the "stop" button on the screen.

Explicit consent will be obtained for including study data for participants who choose to not complete the study. If the "stop" button is used, the computer asks the participant for permission to store any data collected. If the participant declines, her data will be deleted from the study data. Additionally, the informed consent specifies that refusal to participate will remain confidential and will not affect services received at WIC or the larger health care system WIC is a part of in any way.

Minimizing potential risks of loss of confidentiality of personal, private information is of utmost importance. Women receiving public health services may be particularly concerned about stigma related to substance use and mental health issues and may fear of losing health benefits if they disclose sensitive information. Therefore, several measures will be taken to reduce possible stigmatization for participants. Publicly available materials for the study (the study name, recruitment posters, flyers) will not mention alcohol or the risky drinking criteria for enrollment in the trial. All other study materials, computers and monitors used to administer the study program, drinking vessel display and referral information will be placed in a private area. The drinking vessel display does not have any alcohol bottles and the glasses displayed are commonly used glasses, often used in households for juice and water.

Finally, the referral information will be as per standard care at WIC. Women who report alcohol-related problems or depression will be presented with a screen that lists relevant referral information for services. The information on these screens will include a note that the referral information is part of standard WIC referral information materials and that the RA can help point out relevant services on the WIC referral materials if needed. In this way, participants will not have any materials that distinguish them from other WIC clients as study participants or those needing services for alcohol or mental health, thereby further reducing stigma-related risks.

Given that no study data will be shared with WIC, staff will have no way of know which participants completed screening only or were found eligible for the trial. This reduces risk of stigma related to participants being identified as risky drinkers. We will attend WIC staff monthly meetings to reiterate the importance of clinic staff not influencing participation in the study in any way. In these meeting we will stress that staff communicate to clients that the study is voluntary, does not affect services received in any way, and that data is kept confidential by the research staff and not shared with clinic staff.

To minimize risks related to loss of confidentiality of the information collected, which includes personal information for identification (WIC ID number) and for follow up purposes (name, phone number and other contact information) and study data, safeguards will be used, including:

1) Precluding identifying information, such as name, address, and other contact information in the computerized assessments and, thereby, study data. 2) keeping all study materials will be confidential and used for research purposes only. Access to data will be restricted to research staff and data from the study computers which will be encrypted (password-protected) to prevent access by non-research personnel. 3) Using additional procedures, also used in our recent, pilot implementation of e-SBI for pregnant women, to safeguard the data such as: i) Any electronic transmissions (e.g., from the study computer to the research staff) will not include personal information, but nevertheless will use encryption to ensure the maximum possible digital security; and ii) Data files on the study computers will downloaded and deleted daily to further protect privacy. 4)Identifying information obtained for identification and *follow-up only* information will be maintained separately from the data, used by research staff only, and will be physically and electronically locked when not in use. 5)Research staff will be trained on all procedures and protocols and closely supervised by Dr. Nayak (PI) to ensure confidentiality.

b) If death data is being used, include risk to estate of deceased or living person by use of the death data.

Does not apply

c) If audio/video taping will be used, state if it could increase potential risk to subject's confidentiality.

Audio-recordings will only be obtained for brief interviews on user experience following testing of the software during the preparatory period of the study. The interviews will not ask women testing the computerized study program for any personal information and nor will any personal information be linked to the audio-recordings. We will minimize

risks to participant confidentiality by destroying the audio-recording after transcribing the recording, within one week of the interview.

d) Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided state clearly.

We do not expect the e-SBI to increase alcohol use as it focuses on information on alcohol-related harms and outlines specific goals and a personalized plan to reduce drinking. The control group in our study receives only alcohol assessment, and not the intervention. Assessment alone has been shown to reduce drinking in control groups in many prior studies. Referrals for alcohol-related problems are available as part of usual care in the WIC clinic. Hence participants in the control group who may need services will receive information and referrals for care in the same way as those in the study intervention group.

The study could present risks for associated with screening and brief intervention, possibly increases in drug or *tobacco* use and depression as alcohol consumption decreases among participants. Such risks associated with alcohol intervention have not been evaluated in prior studies. Hence, there is no knowledge base to estimate the likelihood of these adverse outcomes. However, we will proactively address any need for further screening and intervention for participants who report drug use and significant depression, using established procedures used the WIC clinic.

e) In the case of overseas research, describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects.

Does not apply.

f) Describe any less risky methods and why they are not being used.

We include several procedures to minimize the minimal risks associated with the study, described previously. As additional safeguards, we will include:

Data Safety and Monitoring Plan.

Sensitivity to ethical concerns, including anticipating any adverse events and proactively minimizing risks related with the proposed study, is of critical importance. Therefore, we will include oversight of all study procedures at multiple levels, including the Institutional Review boards at the Public Health Institute, and the California State Committee for Protection of Human Subjects, and seek guidance from our consultant and county program staff, particularly those who work with women at risk for substance use problems and poor mental health.

Our trial does not involve drugs or biologics or devices and does not meet criteria for mandatory registration and result reporting requirements specified under Public Law 110-85 at www.clinicaltrial.gov. The trial proposed is a Phase I trial with an intervention with no known risks to participants. Therefore, it also does not meet criteria for requirements for the establishment of a data and safety monitoring board. However, our trial is also registered on the www.clinicaltrial.gov website (see https://clinicaltrials.gov/show/NCT02337361). Because the Contra Costa county WIC had been supported our study and provided a letter of support for our NIH grant application up until the end of February 2015, the information on clinicaltrials.gov shows that WIC program as a participating organization. We will revise and update the study site information on this website after obtaining CPHS approval and, subsequently the needed approval for the State WIC program.

A data safety and monitoring plan (DSM) is crucial to ensure safety of participants and is outlined next. All study procedures and protocols will be reviewed by all relevant Institutional Review boards prior to any data collection and at any time changes are made to study procedures or protocols. Dr. Nayak, (the PI) will monitor study implementation regularly through periodic observations at the study site, at least weekly meetings with the research staff, and monthly meetings with clinic staff or more frequently as needed. She will monitor specific study procedures, including informed consent procedures, maximizing confidentiality of data collected, referrals for substance use and mental health care, and proactively address possible adverse events by ongoing training and supervision of research staff. Dr. Nayak is a licensed clinical psychologist in California and has over 19 years of clinical and research experience in various settings and cultures. Her experience and qualifications as a mental health professional will help her identify and respond to any serious adverse event (SAE) expediently, and to plan for as many unanticipated problems as possible. Dr. Nayak will also

consult with the county mental health and substance abuse counselors to address any adverse situations. We have already connected behavioral health service networks within the Sonoma County public health system and within La Clinica De La Raza and will seek their assistance to put together a DSM board to help minimize adverse events and to provide needed assistance to participants who may need substance use and mental health services.

A research assistant will be on site at each site and maintain communication with WIC site staff when not on site in order to be alerted, as quickly as possible, to any adverse events that may occur between data collection times. During data collection periods, Dr. Nayak will meet with the RAs at least twice a week and maintain daily contact with the RAs via telephone, email and text messaging. All consent forms will include contact information for the PI and the chairperson of the Public Health Institute (PHI) IRB and will be provided to participants in printed form (printouts of relevant screens of the computerized study program – see storyboards for consent form screens). Since the proposed study design includes two follow-ups and participants will be contacted between follow up periods to help reduce attrition, we will use these re-contact opportunities, with participant consent, to assess need for additional intervention due to increased alcohol consumption or mental health problems in the time periods between study follow ups and provide again the WIC referral information as needed.

All adverse events and unanticipated problems will be reported to the CPHS and the Public Health Institute IRBs. Serious adverse events and unanticipated problems will be reported within 48 hours to the IRBS and the NIAAA project officer, who will also receive the annual reports to the IRBs that summarize all adverse study events.

7. Benefits

7. Benefits: **(*All project types*)**
Are the benefits adequately described? It should not include compensation. ☒ Yes ☐ No

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, please state such.

Potential benefits of the proposed research to human subjects and others

The proposed study seeks to reduce excessive alcohol consumption among non-pregnant women of child bearing age as a primary prevention approach to reduce prenatal alcohol use. It is expected to provide important information relevant to public health efforts to reduce Fetal Alcohol Spectrum Disorders and to improve the health of mothers and their infants. The study includes a specific focus on cost-effective methods for screening and brief intervention (e-SBI) and on factors that affect the efficacy of e-SBI. Thus, the proposed study will impact not only public health efforts to reduce drinking in women of childbearing age women, but the larger body of science on the prevention of alcohol-related harm.

Because procedures to adapt e-SBI for use with non-pregnant women involves the input of WIC staff and local experts in maternal and child health, the proposed study will increase networking and collective action among professionals invested in improving women's health. We have already connected with the bay area perinatal advocates and integrated their input into our study implementation and planned dissemination of findings.

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

Importance of the knowledge to be gained

There is an urgent need for cost-effective tools for delivering SBI to meet challenges to increase health care access for the implementation of the Affordable Care Act (ACA) in a weak economy with dwindling health care resources. The proposed study will addresses barriers to recommended screening and brief intervention and to the prevention of drinking during pregnancy with a novel electronic SBI to reduce drinking in women before they become pregnant. It will also test if drink size assessment alone can reduce drinking, providing data on possible cost effective interventions. Thus, the proposed study is of significance for the prevention of Fetal Alcohol Spectrum Disorders and for improved maternal and child health. Scientific knowledge on what may reduce or enhance e-SBI efficacy will also impact public health prevention efforts beyond that for childbearing age women and help further refine cost-effective strategies to reduce alcohol-related harm.

8. Administrative Safeguards: **(*All project types*)**

a. Are administrative safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☒ Yes ☐ No

b. Has the individual(s) responsible for the security of this research data submitted a letter or statement that the organization is meeting the CPHS data requirements? ☒ Yes ☐ No

The following requirements apply to all researchers, their contractors, and subcontractors with access to Personally Identifiable Data (PID).

PID is defined as any data containing one or more of the 18 Health Insurance Portability and Accountability Act (HIPAA) Identifiers.

If the researcher demonstrates that they are unable to comply with any of the requirements below, they may request an exception from these requirements. The researchers should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

8. Administrative Safeguards

a) Describe the procedures for training all research staff, who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security and privacy

Research Assistants (RA) will be trained in the use of the computerized study program, including the e-SBI and computerized assessments, all study documentation and follow up procedures, and requirements for ensuring confidentiality. A study protocol and procedure manual which details privacy and security of personal identifiable information will be completed in the 2-month-preparatory period of the study. Staff will complete the NIH human subjects training and a responsible conduct of research training online and also sign a confidentiality statement related to use, security and privacy of personal identifying information. Indeed, all ARG staff sign data standards forms for the storage, transfer and integrity of research data.

b)Describe procedures, either background check or thorough reference check, for vetting staff, who will have access to PID.

Research assistants for this project have not been hired yet. The hiring process at our organization includes background checks and thorough reference checks. Thus, all research staff who have access to PID will have undergone all necessary checks and required training in research with human subjects.

c) Indicate whether you have obtained and submitted to CPHS a statement from the state agency or department you are receiving data from. That statement should include that the release of the desired data is legal and that the entity is willing to release the desired data to you, the researcher.

The present study does not involve release of data from the participating agency to us. However, we have requested initial review letters from the sites interested into participating in our study and expect to submit these letters by May 22, 2015. We have also requested an initial review letter from the State WIC program and expect to submit their letter on May 29th, 2015 prior to the June 5 meeting of the CPHS.

d) Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity (unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS?

Identifying information from participants will be stored separately from the study data in two separate electronic files: The first will list the WIC ID number and a study ID which is entered into the computerized study program at each assessment point to begin the program, the second file will list the study ID, participants name and contact information. Both these electronic files will be zipped, encrypted, and password protected and stored on an encrypted external hard drive and backed up using secure VPN access to network drives at our organization, remaining in an encrypted form. The external hard drive used to store identifying information requires a physical key in addition to electronic passwords to be accessed. The physical key and the external hard drive will be locked in separate rooms at the study sites, each of which have controlled access areas and alarm monitoring.

Files with identifying information will be accessed by research staff only by connecting the hard drive to a secure, study computer which has hard drive encryption and multiple layers of password-protection (boot up, log-in, file access). Information will be accessed by research staff by connecting the external hard drive to a study laptop which will also be encrypted and thus password protected. However, no identifying information will be stored on the study laptop which will be removed from the site each day.

As an additional protection for identifying information provided by participants, we will apply to the NIH for a Federal Certificate of Confidentiality for our study.

e) Indicate whether information will not be published that could possibly be used to identify an individual subject.

Only group data will be published. No information that can identify an individual subject will be presented at any venue or published in any form.

f) Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

Not applicable as the present study is not requesting from the participating agencies.

g)Indicate if access to data limited only to those with a need to know for purposes of implementing or evaluating the research.

Access to the data collected for this study will be limited to research staff.

h)If applicable, justify why unique identifiers, other than social security numbers, cannot be used.

Does not apply.

i)Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

We will not report data on any groups with small cell sizes, e.g. women aged 43, and will combine data for cells with small numbers into larger groups (e.g. age 40 and older) where indicated

j)If the data set is to be linked with any other data sets, identify all data sets and each of the variables to be linked, with justification for each linkage. If there is an extensive list, include the list as an attachment, in the Attachment Section.

The study data will not be linked with any other data set.

k) If a third party is being used to perform data matching, provided evidence of the third parties' ability to protect PID, including third parties' ability to comply with all the CPHS data security standards

No third party will access or analyze the data collected in this study.

l) Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

We will provide CPHS with a letter certifying that personal identifying information has been destroyed once the study has concluded.

m) Include a certification from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.A letter or statement assuring these standards are met from this individual on organizational letterhead may be included as an attachments in the Attachment Section.

A letter from Jim Simpson, General Counsel at the Public Health Institute is included, to certify that CPHS Data Security Standards are met

9. Physical Safeguards: ***(All project types)***
Are the physical safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☒ Yes ☐ No ☐ N/A

9. Physical Safeguards

a)Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room , desk, or office.

All PID will be secured in locked rooms with controlled access. Paper forms of PID, consent forms for the testing of the software will be scanned into electronic files within 24 hours. Paper consent forms will be secured in a locked cabinet in a locked office at the study sites until scanned. The electronic version of the consent forms will be placed in a single file and saved on the encrypted external drive that is manually and digitally secured. Once scanned, the paper consent forms will be destroyed by cross-cut shredding.

b) State whether data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

PID will be destroyed once the study has concluded.

c) If samples are to be retained, will they have personal identifies or be de-identified?

Data collected for the study via the computerized study program is de-identified,

d) Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

All PID in paper form will be destroyed using cross cut shredding. See text in section 9a above

e) Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

We will not receive or send any faxes with PID.

f) Indicate whether mailings of PID are sealed and secured from inappropriate viewing; mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

No personal identifiable information will be mailed.

g)State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will never be left unattended in cars or other unsecured locations.

No PID in any form (electronic or paper) will ever be left unattended in any unsecured location. PID will never be saved on the laptops used by the RAs and all PID will be retained at the study site (WIC sites) in secured, controlled accessed areas only.

h)Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Both the Santa Rosa WIC and La Clinica De la Raza Fruitvale WIC sites, where the PID will be stored have controlled access procedures and 24 hour guard/ monitored alarm service

Our organization, the Alcohol Research Group (ARG), has security systems in place which monitor access via a FOB, an electronic chip assigned to all ARG staff. ARG visitors must register at the reception area. Access to the building is monitored by security cameras and a security service vigils the facility 24 hours a day.

i)Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Only encrypted PID will be stored for this study on the external hard drive at the study site and backed up to

the network at ARG.
All ARG servers all locked in a server closet and are only accessible by the IT department staff.

j) Indicate whether identifiers will be stored separately from analysis data.
All personal information will be stored separately from the study data.

k) State whether all disks with PID will be destroyed.
All electronic files with PID will be destroyed at the conclusion of the study.

10. Electronic Safeguards: ***(All project types)***
Are the electronic safeguards for data security being met or is there justification for not meeting specific safeguards or providing an alternative safeguard? ☒ Yes ☐ No ☐ N/A

10. Electronic Safeguards
a)State whether all computer access be protected through the use of encryption, passwords, and other protections.
Access to all ARG systems is protected through the use of encryption, strong passwords, and protections against intrusions via anti-virus and malware programs.
All systems that are used to work with the PID data will be using a special hard drive that will house the data in a 192-bit NIST certified AES Encryption method. The encryption method requires, as an additional security feature, the use of a removable hardware key which will be stored away to prevent unauthorized access.

b. Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software.
The use of the 192-bit NIST certified AES encrypted hard drive is mandatory. Hence PID will only be stored on devices that uses FIPS 140-2 compliant software

c. Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software
The use of the 192-bit NIST certified AES encrypted hard drive is mandatory. Laptops will not store PID. However all study laptops will have full disc encryption that uses FIPS 140-2 compliant software

d.Note if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup tapes) are encrypted with software which is FIPS 140-2 compliant.
The use of the 192-bit NIST certified AES encrypted hard drive is mandatory to work and house PID data. Hence PID will only be stored on devices that have full disk eare encrypted with FIPS 140-2 compliant software.

e. Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.
All systems used for the study will have security patches applied in a reasonable time frame as per organizational standards.

f)Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.
ARG is committed to maintain a high security standard and has very strong password controls. All passwords must be ten characters long (minimum), must contain alpha-numeric and at least one special character (e.g. !@#$%^&*). In addition to this, passwords expire after 90 days and must be changed prior to expiration time.

g)Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews?
All study systems will have the screensaver feature turned on in order to automatically lock the computer after five minutes of inactivity and require that users enter credentials to log back in. In addition, ARG has a SonicWall firewall

router that filters network traffic and prevents unauthorized access. All systems are protected by an anti-virus program which runs weekly scans to prevent malicious code from running.

h)Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

The use of the 192-bit NIST certified AES encrypted hard drive is mandatory in our systems. Thus all transmissions of electronic PID will use secure networks only (e.g. file transfer using vpn access to back up to ARG network drives) and therefore will be encrypted with FIPS 140-2 compliant software.

i)Note if PID in an electronic form will be accessible to the internet.

At no time will the PID data be sent via the internet and hence will not be accessible to the internet.

j)When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used

The following methods will be used to dispose of electronic PID:

The "nuke method" which reformats the drive multiple times by filling it with 1s and 0s.

Hard drives will be removed, tagged and degaussed. Any recorded media will also be tagged and degaussed. Degaussing uses strong magnets to rip-off any electronic data residing in the device, e.g., the hard drive and recorder.

11. Conflict of Interest: ***(All project types)***

Are there any financial or other relationships of the researcher or institution that could be perceived as as a conflict of interest described?

☐ Yes ☒ No
☐ N/A

11. Conflict of Interest

Describe any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings.

Financial relationships to be disclosed include but are not limited to the following:

Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.

Receipt or expectation of payment of any sort in connections with papers, symposia, consulting, editing, etc. from the source of funding.

The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.

Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

NO

I certify that all members of the study team have answered the financial interests question and only those individuals listed in the box above have disclosed any financial interest related to this study.

YES

12. Informed Consent: **(*Common Rule projects only*)** ☒ Yes ☐ No
Is a description of the consent procedure included ☐ N/A
or a waiver consent requested?

12. Informed Consent

Provide a description of procedures to be used in obtaining and documenting the prior informed consent of participants. Further CPHS instructions and consent format may be found on the CPHS website link: http://www.oshpd.ca.gov/Boards/CPHS/index.html.

Non-English versions of consent/assent forms or scripts must be submitted as attachments in the Attachment section , along with the curriculum vitae of the translators(s) and/or proof of certification of the translation firm. CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. In general, Spanish translation should use formal language.

CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, provide information as to how all of the criteria below will be satisfied.

Consent for the testing of the computerized study program will be obtained using paper forms. The paper forms of this consent will be converted to electronic password-protected files stored separate from the study data. Paper forms will be destroyed after being converted to electronic form (e.g. scanning), within 24 hours of completion of the paper form.

Consent for the main study (screening and trial) will be obtained electronically and as part of the study computerized program. Details regarding consent procedures are provided in sections 2 (procedures) and 6 (reducing risks).

The English versions of both consent forms are attached. We will translate the consent forms into Spanish once all study materials, including the consent forms are finalized and approved by the IRB. The translator expected to work with us is a native Spanish speaker and has experience with translation as well as public health work. Her resume is attached with the application for review.

13. Assent Background**: (*Common Rule projects only*)** ☐ Yes ☐ No
Is a description of the informed assent procedure (for ☒ N/A
individuals age 7 to 17) included or a waiver of assent
requested?

13. Assent Background

Provide a description of procedures to be used in obtaining and documenting the prior assent of participants. Further CPHS instructions and assent format may be found on the CPHS website link: http://www.oshpd.ca.gov/Boards/CPHS/index.html.

Does not apply as the study will not include participants less than 18 years of age. A dummy file is attached.

While the intent of informed assent is the same as that of informed consent, the informed assent must be written at a level that is understandable to potential participants who are children between the age of 7-17 years of age. Different informed assent forms may be needed if the study involves children of significantly different ages. The same headings must be used. Because some children cannot read through as long a form as an adult, assent forms may be shortened to facilitate reading and understanding by children. However, all of the required elements of the informed consent must still be adequately addressed. The CPHS website link to the format and additional instructions is : http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf#Untitled (53).

14. Health Insurance Portability and Accountability Act:

(*Common Rule and Information Practices Act projects only*)

If the data being requested is covered by HIPAA, is there a HIPAA Authorization, HIPAA waiver request or the approval of another IRB attached?

☐ Yes ☒ No
☐ N/A

14. Health Insurance Portability Accountability Act (HIPAA)

To determine if data for this project is covered by HIPAA, respond to the four questions below.

1. Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

Yes **No**

2. Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

Yes **No**

3. If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?

Yes **No**

4. Will the study involve other HIPAA criteria not listed above?

Yes **No**

If you answered "YES" to any of the questions above, you are subject to HIPAA and must complete a HIPAA authorization or waiver request with your protocol.

Use table below ONLY when requesting waiver/alteration of HIPAA authorization.
(the table is for attachments only)

Text not included in online application as no space to enter text on the relevant screen

HIPPA applies only when healthcare providers release protected health information. We are not asking the WIC sites to provide us with any client data. Personal information, such as the WIC ID, while protected health information, will be provided voluntarily by participants who provide informed consent. Thus the data collected by our study, being provided by individuals themselves, does not fall under the purview of HIPAA.

15. Assurance of Consistency between Grant Application and CPHS Protocol: **(*Common Rule projects only*)**

a. If the project is funded by a grant, is the grant summary that addresses the questions in this section attached?
☒ Yes ☐ No
☐ N/A

b. Are the page numbers or sections of the grant and protocol included?
☒ Yes ☐ No
☐ N/A

15. Assurance of Consistency between Grant Application and CPHS Protocol

Is this project funded by a grant?

Yes No

If 'Yes' is checked, please attach only the sections of the grant application, in Attachments, that address the questions below. List the page(s) in the grant application that confirm the consistency with the protocol. Also include that section, such as Subject Population, in the Protocol Information that confirms the consistency with the grant application. This section does not apply to contracts.

a)The title of the project in the grant application and the research protocol are the same. If not explain why.

Yes

b)The specific aims of the project in the grant application and the research protocol are the same. If not, explain why. Please include the page number(s) where this information may be found on both documents.

Yes. Specific aim 3 in this application is reworded slightly to make it more understandable for the general public. Specific aims in the grant application are on page 39 and in the purpose section of the research protocol.

c)The research design/methods are the same in the grant application and the research protocol. If not, explain why. Please include the page number(s) were this information may be found on both documents.

Minor differences exist between the grant application and the research protocol. The number of participants has increased from 150 in one site to 200 in two sites. This is because our grant application was written with a letter of support from the Contra Costa County WIC program, proposing a single study site. This program withdrew its support for the funded study at the end of March 2015 due to administrative and reorganization issues that would make their participation in the study difficult. Other changes in the methods are related to changes in referrals for alcohol problems and depression being done via site staff to being done by the computerized program. This is consistent with the program being a staff-free tool for low resource settings and reduces risks of stigma for participants.

The relevant information is in the methodology and risks section of the grant application (page 45, 53 and 53) and under Subject population and Risks (item d) sections of the protocol.

d)The inclusion criteria are the same in the grant application and the research protocol. If not, explain why. Please include the page number(s) were this information may be found on both documents.

Inclusion criteria are the same. However, we clarify in the research protocol that women who become pregnant during the course of the study will be excluded at follow up. This is because the intervention provided is for non-pregnant women.

The relevant information is in the methodology section of the grant application (pages 46) and under screening procedures of the protocol.

e)The human subjects protections, including vulnerable populations, are the same in the grant application and the research protocol. If not, explain why. Please include the page number(s) were this information may be found on both documents.

Minor differences exist between the grant application and the research protocol, mostly due to changes in how referrals are made for participants who report alcohol-related problems and depression as explained in item c) above. The relevant information is on pages 53 and 54 of the grant application and the Risks (item d) of the protocol.

16. Attachments: **(*All project types)***

Required Documents: **(*All project types*)**

- ☐ New Project Checklist
- ☐ CV or resume of Principal Investigator (PI) and Co-PI
- ☐ Data Security Letter from staff of the organization who is responsible for the security of the research data
- ☐ Budget
- ☐ Cover Letter

Other Possible Items: **(*Please check all that apply*)**

- ☐ Checklist for Research Involving Minors
- ☐ Checklist for Research Involving Pregnant Women and Fetuses
- ☐ Checklist for Neonates
- ☐ Checklist for Research Involving Prisoners
- ☐ Informed Consent Form (attach in section 12)
- ☐ Informed Assent Form (attach in section 13)
- ☐ Grant application
- ☐ CV for translator
- ☐ Surveys and questionnaires
- ☐ Recruitment material

☐ Other (Please specify): _____

I. Translations: (*Common Rule projects only*)

Are there or will there be any translations? ☒ Yes ☐ No

Specify the language(s) Spanish ☐ N/A

II. Obligations: (*All project types)*

Have the PI and Responsible Official checked this section? ☒ Yes ☐ No