Smartphone Help for DWI Offenders and Their Families: A B-SMART App

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Study Protocol and Statistical Analysis Plan

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STUDY PROTOCOL

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3. RESEARCH STRATEGY

3A. SIGNIFICANCE

Our objective is to maintain the cessation of intoxicated driving afforded by the Ignition Interlock Device (IID) by mobilizing the DWI offender's social network, *focusing on CFMs,* and enhancing their involvement through the use of smartphone technology. This study will be the first to use smartphone technology to extend and make permanent the cessation of intoxicated driving, providing an intervention that uses easily-accessible and diffusible technology.

3A.1. DWI Interventions and Outcomes

Nochajski and Stasiewicz[24] found that deterrence sanctions employed soon after the offense (e.g., fines, license suspension) may have a deterrent effect for repeat offense. IIDs have been shown to be effective while installed in offenders' cars; however, once removed, re-arrest rates rise to levels comparable to offenders who do not have IIDs installed.[7,25-28] Evidence for the efficacy of therapeutic interventions for DWI offenders has improved over time.[24] Cognitive-behavioral skills training[29] and brief intervention modes[30] have shown moderate effects for DWI offenders. Interventions that engage and retain the offender in treatment may produce beneficial results.[24,31] Notably, family-based approaches which accomplish this are the basis of the planned smartphone app.

Preliminary Studies: DWI Research and Treatment. Drs. Woodall and Westerberg have extensive experience conducting DWI-related research, including randomized trials of the efficacy of MADD Victim Impact Panels on DWI Recidivism,[12] an incarceration/ treatment program for first-time DWI offenders,[13-19] and Responsible Beverage Service training.[16,20-23] They have developed extensive research experience with DWI offenders, including successful recruitment, assessment, tracking, and data analysis. Dr. McCrady directed an outpatient treatment program that served DWI offenders for 10 years and has clinical experience that complements the other investigators' research experience.

3A.2. Family-Involved Treatment

One limitation of DWI treatment interventions is the exclusive focus on the offender. Treatments that address the social environment should result in better maintenance of change by decreasing environmental cues for drinking and providing positive incentives for desirable behaviors.[34] Research has found that family-involved treatment enhances positive AUD outcomes[9,35,36] and family-based contingency management improves adherence to aftercare[37] and medication.[38] Efficacious treatments include interventions for family members alone;[33] contingency management where family members learn to provide desirable outcomes contingent on treatment goals;[37] 12-20 session protocols of behavioral couple therapy (BCT);[39] brief BCT of 1-6 sessions;[40-42] and single session applications of the BCT model to any CFM that motivates persons undergoing detoxification to continue treatment.[41] Results across this literature suggest three core treatment elements: (a) increasing family support and reinforcement for behavior change, (b) increasing positive exchanges in the family, and (c) improving communication.[16] The proposed *B-SMART* intervention incorporates these three major elements.

Preliminary Studies: Family-involved Research. Dr. McCrady, Co-Investigator, has conducted research on conjoint and family-involved treatment for individuals for AUDs for more than 40 years. This research has found consistent support for the efficacy of couples approaches[32] in reducing drinking and, in some studies, enhancing relationship stability and satisfaction.[4,9,24,33] She currently is developing a brief family-involved treatment (B-FIT) based on these 3 principles.

3A.3. Smartphone Technology in Health Communication Interventions

Smartphone applications (apps) are changing healthcare[43] in a number of areas, including health education and clinical practice,[44] data collection,[45] sexual health education,[46] weight management,[47] diabetes,[48,49] smoking cessation,[50-52] substance abuse,[53] and sun protection.[54] To date, there are few apps related to substance abuse available.[55] Mobile apps on smartphones have not been tested extensively for disease prevention, but have for monitoring behavior.[56,57] Cell phone use is widespread. Recent Pew Internet research indicates that 77% of adults in the United States are smartphone owners.[58] Smartphones usually accompany users are usually turned on. Thus, mobile apps can deliver advice/reminders and content to the families of DWI offenders at all times. Little research has been conducted on use of smartphones for DWI offense issues in family settings. Some DWI-related smartphone apps are available: *R-U-Buzzed* estimates BAC and warns intoxicated users not to drive[59]; *Stumble Safely* plots safe walking routes home for intoxicated customers; *SafeRide* calls cabs for intoxicated bar customers. However, no empirical evaluations of these DWI-related smartphone apps have been reported, and all are targeted to the offender only. Smartphone apps for DWI offenders or their family members have not been reported in the research literature or popular press.

Smartphone apps may be useful, convenient, and easily diffusible tools that may extend and strengthen the impact of families on long-term outcomes for DWI offenders.

3A.4. Interlock Ignition Device (IID) Research

With the advent of the technology to support the development of IIDs in 1970, these devices have become more sophisticated technologically, allowing digital photography of the driver, WiFi connection to device providers and court systems that allow immediate data transmission of lockout events, and GPS monitoring of driving and breath-testing events.[68] They have also become more widespread in use, with estimates of 300,000 in use among DWI offenders.[69] All 50 U.S. states have some type of IID law, with 25 U.S. states having mandatory IID laws for all DWI offenses.[5] All 50 U.S. states have some type of Ignition Interlock law, with 25 U.S. states having mandatory Ignition Interlock laws for all DWI offenses.[5] Research on the effectiveness of IIDs has shown: 1) IID's reduce the incidence of DWI recidivism while installed in the offender's vehicle, but not once the IID is removed[70] and 2) the frequency of a DWI offender being prevented from starting a vehicle because of a lockout event (the IID sensing the presence of alcohol and disallowing the vehicle to start) predicts DWI recidivism – the more frequent the lockout events, the more likely an offender will have a subsequent DWI arrest. These findings have led researchers to consider ways to extend the effectiveness of IIDs beyond their installation period, including implementing health promotion and treatment programs tied to IID use while in place in offenders' vehicles.[71,72] Most recently, Voas and colleagues[73] have shown that requiring alcohol treatment of DWI offenders who have frequent IID lockout events resulted in a one-third reduction in DWI recidivism.[68] has recommended increased attention to programs that integrate health promotion interventions while the offender has an IID installed in their vehicle. To date however, no research has examined the impact of family-based treatment on reducing IID lockout events and subsequent DWI recidivism or the provision of family-based treatment via smartphone apps to achieve lockout event reduction and subsequent DWI recidivism. The current investigation will examine this important possibility.

Preliminary Studies: Web-based and Smartphone Interventions, and Adolescent Risk Behavior Research. Drs. Woodall, Starling, and colleagues have collaborated on the development and randomized trial testing of seven web-based interventions focusing on adolescent smoking,[60] dietary change in multicultural rural adults,[61] risky drinking among college students,[62] web-based responsible beverage service training,[63] prevention of drug use and risky sexual behavior among adolescents,[64,65] and HPV vaccine uptake among young adolescent girls.[66] In mobile computing app development, Drs. Woodall and colleagues have developed and evaluated: 1) A web-based smoking cessation program for young adults, *Real e Quit Mobile*, that includes short counseling messages, a tool to list reasons and benefits of quitting and create plans for coping with craving and relapse, short informational documents, testimonials about quitting, and a screen for setting a quit date improved quitting behavior (27% of smokers reported 30-day point-prevalence abstinence and 24%, continuous abstinence at 12-weeks)[52]; and 2) a mobile app with sun protection advice for the adult population, called *Solar Cell*[54] in a nationwide trial improved self-efficacy for sun protection (p=0.022), increased shade use (+7%, p=0.034), decreased reliance on sunscreen (-6%, p=0.48), and decreased participants' time in the sun (+15%, p=010).[67] The proposed project will leverage the research team's extensive experience in developing and testing web and mobile applications in adolescent and family settings.

3A.5. Summary of Significance

DWI continues to be a major source of injuries and fatalities. To date, DWI interventions have focused almost exclusively on the DWI offender, with little regard for the offender's social environment. Approaches that combine policy-level interventions such as the IID with interventions that target the DWI offender's social environment (e.g., family-focused interventions) are likely to show strong efficacy. We will integrate an effective family-focused brief therapy (B-FIT) with the accessibility of the smartphone to extend the effectiveness of IID, as assessed by IID lockout events, after the device is removed from the vehicle.

3B. INNOVATION

3B.1. Innovation of the Proposed SBIR Research

Innovation in the proposed Phase II SBIR research derives from the application of an existing conceptual model about maintaining behavior change to a new population and enhancing that application through smartphone technology:

- Efforts to decrease repeat-DWI generally have used either external controls or therapeutic approaches. External controls in general, and the IID in particular, are incomplete approaches; controlled research

combining external controls with therapeutic approaches is lacking, making this research innovative.
- Interventions have not considered the social context in which DWI offenders live. The proposed research will extend the reach of the IID and therapeutic intervention into the offender's *family* environment, another unique aspect of the proposed research.
- Smartphone apps are in the early stages of being tested as means to initiate and maintain changes in health behaviors; applications to the DWI offender population and their families are rare and untested.

3B.2. Commercial Potential

KB has a successful history of collaborating to commercialize a web-based alcohol responsible beverage service training program (i.e., *WayToServe*®).[19] We envision taking a similar approach to market *B-SMART mobile web app* as we did with *WayToServe*®. A licensing partnership with Wedge Communications LLC, has resulted in over 60,000 purchases of the *WayToServe*® training in its seven years of commercialization. We anticipate that during Phase III commercialization, Wedge will market and distribute *B-SMART* to multiple target markets for bundling with devices and services including IID manufacturers, DWI schools, and car insurance companies. *B-SMART* will also be promoted to community social services agencies, mental health clinics, and government agencies responsible for implementing alcohol education and treatment programs for DWI offenders and families. For example, state alcohol beverage control agencies, state departments of transportation, and the National Highway Traffic Safety Administration are heavily involved in high-risk population alcohol prevention programs.[74-77] In addition, there are nearly 8,100 substance abuse treatment services organizations in the U.S.[73] *B-SMART* will be promoted directly to device users through social media advertising.[78] Finally, IID providers may support the adoption of *B-SMART* as a way to extend the IID's period of effectiveness, and we will reach out to IID providers (e.g., courts) for possible commercial collaboration. See the detailed Commercialization Plan.

One of the most marketable characteristics of *B-SMART* is that through early intervention with first-time offenders, it has the potential of being an affordable option to reduce the economic and societal costs incurred by drunk driving. We anticipate that *B-SMART* will be an attractive tool to court systems and state agencies in all 50 states that have some IID law, the 25 states with mandatory IID laws, and the more than 30 states that mandate alcohol education and/or treatment following a DWI.[79] *B-SMART* could enhance existing programs because it offers important skills training *to CFM* on a widely used platform.

A recent review of current smartphone apps found sobriety testing and drink tracking apps[80-82] and safe ride locator (e.g., to call a cab) apps but no apps providing skills training and communication guidelines to support interactions between family members and DWI offenders. To our knowledge, there are currently five apps in the Android Play Store and one app in the Apple Store for users of IID. These apps provide resources on state programs, overcoming reciprocity obstacles, and maintenance of the device. The information provided is more technical and targeted toward the offender than the information presented *in B-SMART*. *B-SMART* will be the first smartphone app designed to improve family members' ability to support changes in drinking and driving and improve family relationships and communication as a way to reduce repeat DWI offenses. The innovation of the program, its potential impact on DWI re-arrest, and its strong commercial potential indicate that *B-SMART* would be an important and easily adoptable tool for families of DWI offenders.

3C. APPROACH

3C.1. Progress on SBIR Phase I Research

All milestones and deliverables were achieved in the Phase I research funded in September of 2014 and completed with a no cost extension in September 2016. We completed focus groups and usability testing, developed an app prototype, convened the Expert Advisory Board, and created a specifications document.

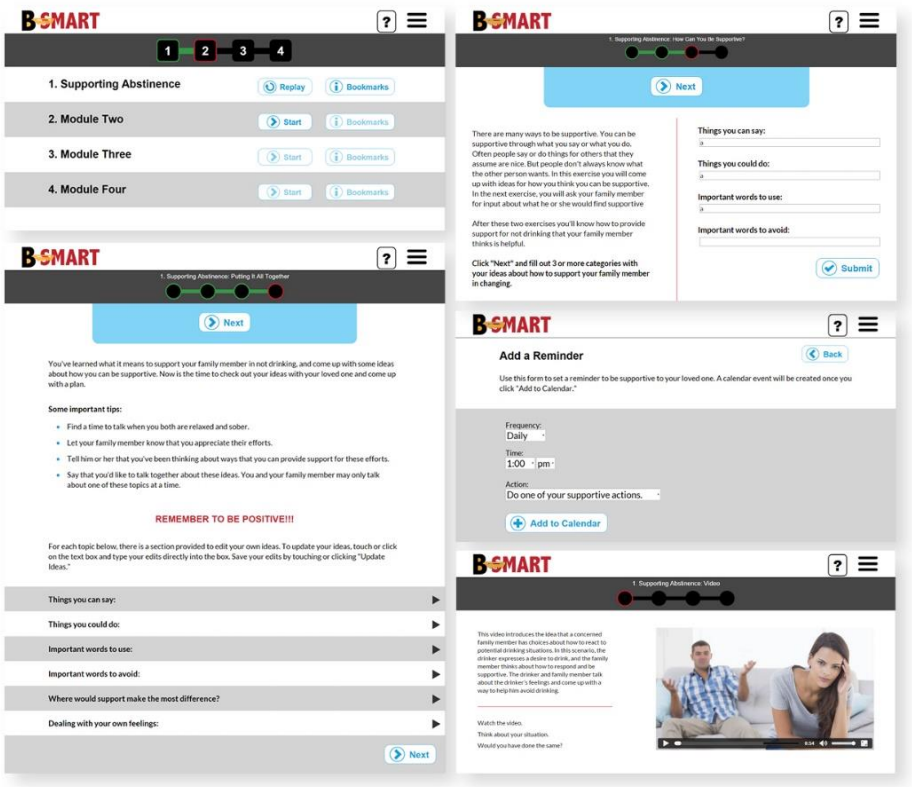
3C.1.1. Milestone 1: Expert Advisory Board. An Expert Advisory Board (EAB) included Dr. Paul Marques, an expert in DWI treatment interventions; Dr. Paul Stasiewicz, an expert in traffic safety, alcohol, and DWI epidemiology and policy in New Mexico; and Dr. Reid Hester, expert in development of alcohol-related digital interventions. The EAB met on a quarterly basis during the Phase I project period to aid in the development of formative interview questions, review interview results, evaluate the *B-SMART mobile web app* beta version, and finally assess the results of the usability tests and determine feasibility for future development. The EAB provided key input at all phases of this investigation, found the *B-SMART* module 1 to be compelling and likely useful to target users (Concerned Family Members of DWI offenders and the offenders themselves), and strongly supported developing a full version of the *B-SMART* in this Phase II project.

3C.1.2. Milestone 2: DWI Advisory Board. A DWI Advisory Board (DWI-AB) met quarterly during the project period to review 1) the translation of B-FIT to *B-SMART* content, 2) summaries of DWI offender

and CFM interviews, 3) the beta version of the first module of *B-SMART mobile web app*, 4) summaries of the DWI offender and CFM interviewees' reactions to the beta *B-SMART* module, and 5) the specifications document for future production. The members of the DWI-AB were: Ms. Linda Atkinson, Director of the New Mexico DWI Resource Center, Ms. Carol Trotter, Director of the Albuquerque Metropolitan Counseling Intake program, Ms. Julie Walsh, Director of Walsh Counseling in Albuquerque, Mr. Tom Starke of Impact DWI in Santa Fe, NM, and Jill Ingraham, Director of rehabilitative services for Metropolitan Courts of Albuquerque. The DWI-AB was unanimous in its support for a Phase II project for full production and testing of the *B-SMART*.

3C.1.3. Milestone 3: Concerned Family Member and DWI Offender Development Interviews. Development interviews were conducted with CFM (n=6) and DWI offenders (n=6). Five participants were Anglo and 7 were Hispanic, with 6 males and 6 females comprising the sample. Participants were recruited on a voluntary and informed consent basis from local DWI counseling and court programs and were compensated for their time. Research staff posed a series of EAB-approved questions to each interviewee, and the interviews were audio recorded. The following consistent themes emerged from the interviews with DWI offenders. 1) They expressed frustration about the IID, including financial burden, embarrassment and social isolation, and heavy time investment; they were typically cautious about exposing their family to these challenges. 2) There was general distrust and perhaps misinformation about the interlock program and device. 3) All thought the proposed app was a good idea; they liked the idea of being linked with their family member via the app. 4) They expressed the importance of supportive behaviors (e.g., reminders about consequences; positive encouragement and affirmations; reflecting on goals/the future; discussing triggers; planning ways to avoid driving after drinking or not to drink at all; and shared activities such as walks/exercise) and unsupportive behaviors (e.g. family members engaging in heavy drinking themselves). 5) More specific ideas for app content included a BAC calculator/countdown; pop-up reminders about consequences, goals, and positive encouragement; and utilization of GPS services to connect easily to public transportation or their family member. Key takeaways from interviews with CFM included the following. 1) Overall, they had very good awareness about the DWI offenders' challenges with the IID (as outlined above) and how those challenges affected the whole family. 2) All thought the app sounded promising and offered many specific ideas for content including a tip or fact of the day; inspirational anecdotes; incentives; check-in questions (e.g., "do you feel like drinking right now?") with easy access for contacting social supports; information on local non-alcoholic activities/events; reminders about consequences and progress; access to transportation services; and a social scheduling module. 3) They largely agreed with what the DWI offenders identified as supportive and unsupportive behaviors but noted that other family members are less insightful (a reason to potentially connect multiple people via the app). There appeared to be marked differences in responses between family members whose loved ones were now in control of their drinking compared to those who were still problem drinkers, with the former expressing more optimism and indicating that families have a range of perspectives and needs. As specified above, these themes were reviewed by both the EAB and DWI-AB and were used by research staff and web app production staff to structure and produce the first beta module of the *B-SMART* prototype.

FIGURE 1: Phase I Prototype Creation



3C.1.4. Milestone 4: Prototype Creation. A prototype of the *B-SMART mobile web app* with one module was completed for Phase I (see **Figure 1**). In addition to the module titled *Supporting Abstinence*, the prototype also includes the following pages: login; module explorer; bookmarks; and information about the research

study. The programmed *Supporting Abstinence* module is highly interactive with six successive events, including a video as well as activities. The module begins with a video modeling a discussion between an offender and CFM. Supportive communication and behaviors (e.g., suggesting an alternative activity to do together) are demonstrated. The next activity, *What is Support?,* provides a series of statements and users have to swipe the statement to the right if they think it is supportive and to the left if they think it is unsupportive. Feedback is provided after each statement is swiped. The following event allows users to consider what behaviors are supportive in their relationship. There are two columns on this activity page. On the left, there is a description of ways to be supportive. On the right side, the user types in her/his own answers to ways she/he can be supportive. Categories of supportive actions are “Things you can say”, “Things you can do”, “Important words to use”, and “Important words to avoid”. The program saves this information in the user’s bookmarks and on-screen in the next activity. Finally, a page entitled *Putting it All Together* summarizes the lessons from the module and gives users the opportunity to edit their responses after seeing additional suggestions of supportive behavior. The module was built for users to experience linearly. They must view each page and activity in sequential order. Once they have completed it, they may navigate through the module. The prototype was built for CFM to access individually via a login, without their DWI offender. The *B-SMART* prototype was built on a full stack website using HTML/JavaScript as its main interface. Animations are performed using GreenSock Animation Platform, CSS3, and animated GIFs. Front-end JavaScript framework is Angular. Look and feel of the program was designed and developed using CSS 3.0 with HTML5. Login and network activity is managed by PHP, including creation of user calendar events. A backend tracking mechanism is utilized.

3C.1.5. Milestone 5: Usability and Navigability Tests. Multimedia usability and navigability tests were conducted by having participants browse through the *B-SMART* beta mobile web app and provide feedback about the module while browsing (all comments were audio recorded). At the conclusion of browsing the module, participants rated their experience on the Bangor System Usability Scale (SUS).[83] CFMs of convicted DWI offenders (n= 32) in Bernalillo and Santa Fe counties in New Mexico were recruited for the usability tests and compensated for their time. Mean age was 37.2 years (range = 20-63). Ethnicity of participants was 56% Hispanic/Latino, 38% non-Hispanic, while racial makeup of the sample was 76% Anglo/Hispanic, 6% Native American, 3% Asian, 3% multiple response, 9% no category applicable, and 3% prefer not to answer. The usability ratings reflected an average overall SUS rating of 44.2 (sd=4.78, scale range: 10-50) (**Table 1**), with 87% of participants rating the *B-SMART* module 40 or above, meeting the milestone set a priori in Phase I. Further, the results indicate that users found the *B-SMART* module easy to use, informative, and very positive. A summary of this developmental research for the *B-SMART* beta mobile web app was presented at the annual conference of the Research Society on Alcoholism.[84]

TABLE 1: SUS RESULTS FROM PHASE I USABILITY TESTING

Item (1 = strongly disagree; 5 = strongly agree)	Mean	Std Dev
I think that I would like to use this mobile application frequently	4.1	0.83
I found the product unnecessarily complex	1.6	0.83
I thought the product was easy to use	4.6	0.62
I think that I would need the support of a technical person to be able to use this application	1.3	0.78
I found the various functions in the product were well integrated	4.1	1.02
I thought there was too much inconsistency In this mobile application	1.5	0.76
I imagine that most people would learn to use this mobile application very quickly	4.6	0.66
I found the mobile application very awkward to use	1.8	1.04
I felt very confident using the mobile application	4.4	0.75
I needed to learn a lot of things before I could get going with this mobile application	1.3	0.93
Total Score	44.2	4.78
Overall, I would rate the user-friendliness of this mobile application as: 1 = worst imaginable; 7 = best imaginable	5.7	0.53

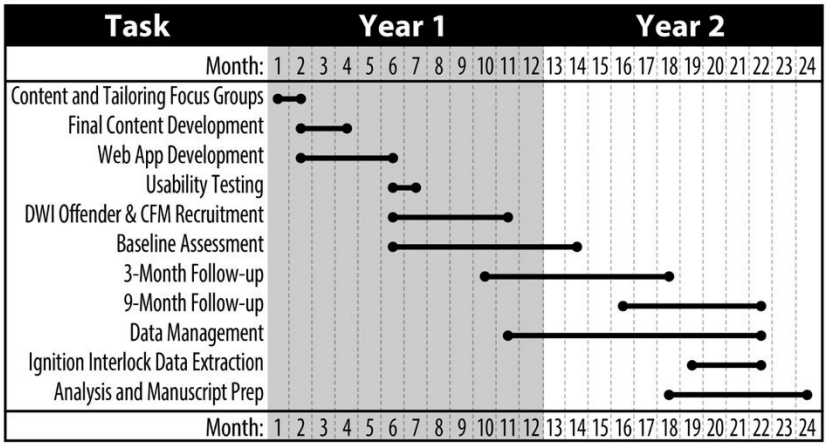
3C.1.6. Importance of Phase I Findings. Results from Phase I demonstrate: 1) the potential impact of a smartphone app utilizing a therapeutic family-based approach to reduce DWI (i.e., B-FIT) is strong and extensive; 2) KB has the ability to create a prototype of the *B-SMART mobile web app*; and 3) focus group participants and usability testers approved of the *B-SMART* design and concept. The EAB advised the research team that the Phase I research results indicate it is feasible to develop a full-scale *B-SMART mobile web app* and that the team should conduct Phase II research to evaluate the effectiveness of *B-SMART* with DWI offenders and CFMs.

3C.2. Overview of SBIR Phase II Research

A two-phase project is proposed for the Phase II research. The overall goal of the proposed project is to systematically develop, produce, and test a smartphone application that will aid concerned family members (CFMs) of DWI offenders and the DWI offenders themselves in extending and reinforcing the drinking and driving abstinence introduced by the IID. The target population is first-time DWI offenders and their CFMs, defined as a spouse or close relative living with the DWI offender. In the development phase (Months 1-7), investigators and staff from Klein Buendel (KB) and U. of New Mexico (UNM), the consultants, and KB media

developers will iteratively design and program the *B-SMART mobile web app*. A web app functions similar to a mobile app on a smartphone or tablet computer. However, rather than a stand-alone program running on the local mobile device, a mobile web app runs through the phone's/computer's web browser, controlled by an external web server. Mobile web apps can be mobile device responsive and also run on personal laptop/desktop computers, ensuring cross-platform compatibility. There are several advantages to this approach. 1) User experience of a mobile web app is similar to a stand-alone mobile app, but content can be updated more quickly than in stand-alone mobile apps that need to be downloaded to install updated versions. 2) Mobile web app programming avoids the need to program for multiple operating systems (e.g., iOS or Android for smartphones/tablet computers and iOS and Windows for personal computers), a more time and effort efficient approach. 3) Mobile web app use can be better tracked from the web server than a stand-alone mobile app, leading to superior tests of the relationship between app use and alcohol-related outcomes. This development phase also will include formative focus groups to finalize content and final usability testing sessions of *B-SMART* with DWI offenders and their CFM in both English and Spanish in New Mexico.

FIGURE 2: Study Timeline



The second phase of the project (Months 8-24) will involve implementation and evaluation of *B-SMART* in a randomized controlled efficacy trial, with baseline, 3-month, and 9-month posttest assessments. Participants will be recruited from the Santa Fe County DWI first-time offenders program, in cooperation with the Santa Fe Magistrate Court (see letter of support in Section 9G). See **Figure 2** for the overall project timeline.

FIGURE 3: Inclusion and Exclusion Criteria for First-time DWI Offenders and CFM

DWI Offenders	Concerned Family Members
Inclusion criteria	
Males and Females	Males and Females
21 Years and older	21 Years and older
First-time Offender with IID installed in vehicle	Spouse, Parent, or immediate family relative of Offender
Have a smartphone, tablet computer or personal computer with Internet access	Have a smartphone, tablet computer or personal computer with Internet access
Consent to Participate	Consent to Participate
Ability to read and speak English or Spanish	Ability to read and speak English or Spanish
Exclusion criteria	
Other Family Members already enrolled in the project	
Second or above DWI conviction	

3C.3. Target Population

The project has two relevant, linked target populations: 1) CFM of DWI offenders and 2) the first-time DWI offenders themselves. The CFM is the primary user of the *B-SMART mobile web app* and content will be tailored toward them, with supporting information provided for the DWI offender. Participants in both the web app development phase (Months 1-7) and the randomized efficacy trial phase of the project (Months 7-24) will be recruited from the Santa Fe County DWI Program, the county-wide program that manages probation and sentencing programs and requirements for all DWI offenders in Santa Fe County, New Mexico. In New Mexico, Santa Fe County had the fourth-highest ranked number of first time DWI offenders (360) in 2015 and 313 first time convictions in 2016. Participants in the development phase will not be eligible for the randomized trial phase of the project. **Figure 3** displays the inclusion and exclusion criteria for participation in either phase of the investigation.

3C.4. Expert Advisory Board (EAB)

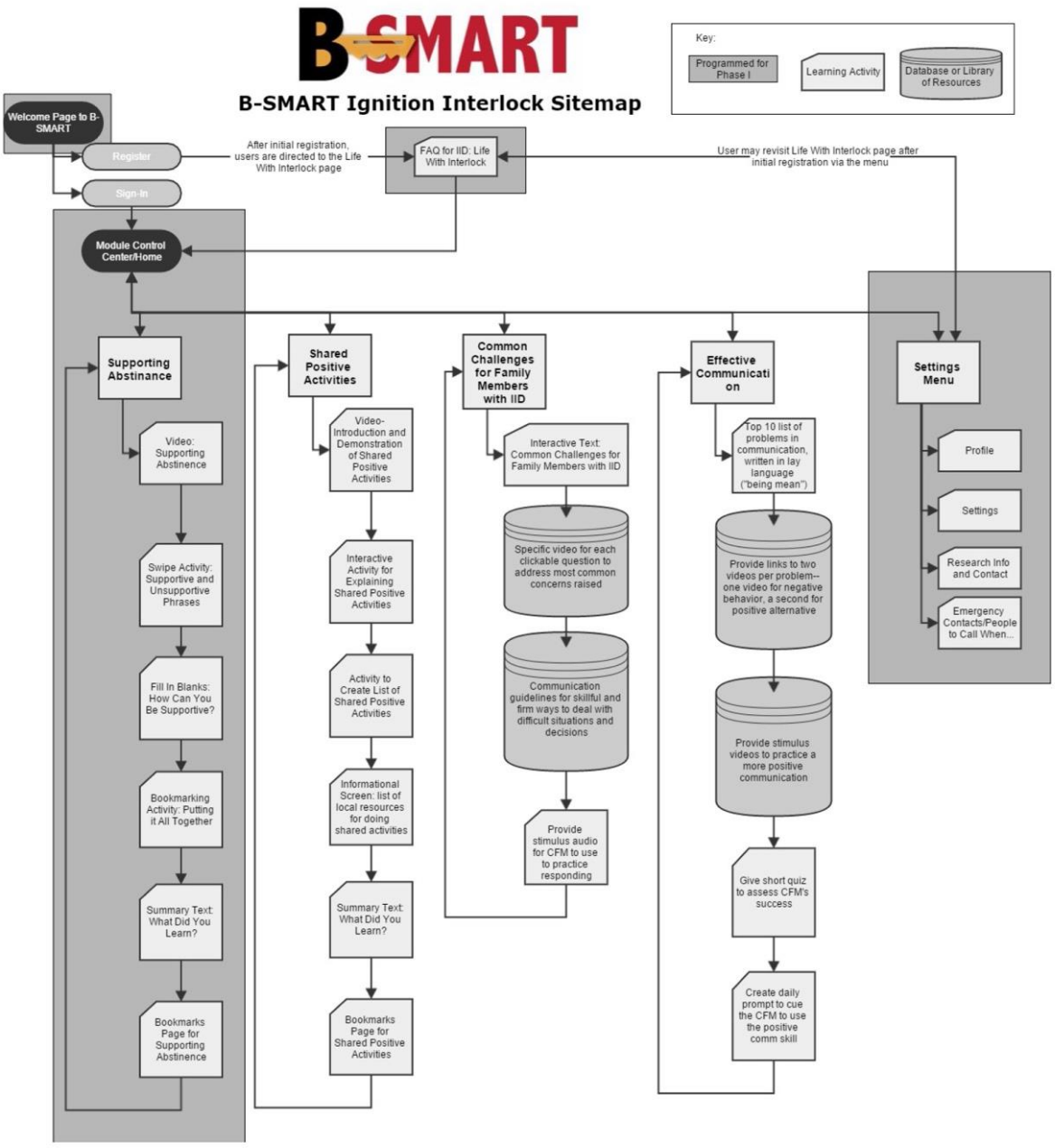
Dr. McCrady, who developed the B-FIT program that is the basis of our smartphone app, will convene an EAB of DWI and Family Intervention experts, and Investigators. The EAB includes experts in DWI policy research, IID research, and traffic safety: Dr. Paul Marques of the Pacific Institute for Research and Evaluation (PIRE); an expert in DWI treatment interventions and IID research, Dr. Paul Stasiewicz of the Research Institute on Addictions, an expert on evidence-based approaches to alcohol treatment and drunk driving, Dr. Reid Hester, an expert in brief motivational interviewing, DWI intervention research, and digital intervention development and testing, Dr. Beth Epstein, a co-author with Dr. McCrady on brief interventions for couples in treatment, and Mr. Thomas Starke, an expert in traffic safety, alcohol and DWI epidemiology and IID policy in New Mexico. Similar to Phase I of this project, the EAB will meet bi-monthly during the project and review the translation of B-FIT to *B-SMART* content, review summaries of DWI offender and CFM focus groups, and

usability data for the final *B-SMART mobile web app*. The EAB will review and approve the final version of *B-SMART*. The EAB will also review plans for, and monitor the progress of the randomized trial of the *B-SMART mobile web app* and review trial outcomes and advise the team the efficacy of *B-SMART*.

3C.5. Iterative Final Production of *B-SMART Mobile Web App* (Specific Aims 1 & 3; Months 1-7)

3C.5.1. The *B-SMART Mobile Web App* Intervention. Based on results of usability testing in Phase I, the research team, with the EAB's input, proposed the flow (**Figure 4**) of the *B-SMART mobile web app* to be developed in Phase II. In the fully developed app, there will be four modules: 1) Supporting Abstinence (already developed in Phase I), 2) Shared Positive Activities, 3) Common Challenges for Family Members with IID, and 4) Effective Communication. Within each module there will be a series of learning activities, including presentation text, interactive engagement, and videos. The content of the modules will be written primarily for CFMs in order to improve communication, provide resources on how to support their family member, and promote positive shared experiences to support the DWI offender's abstinence. CFMs will be able to share content with the DWI offender. When appropriate, we will encourage the CFM to invite the DWI offender to participate in the activities together for shared learning. Working with KB's instructional designer and utilizing the design of the Phase I prototype, the team will create a fully-functional mobile web app with a learning-centric structure with content, activities, tools and exercises that are tailored for CFMs to maximize effective navigation for the user but allow a user to toggle settings to navigate all content. *B-SMART* will also be useful and functional for the first-time DWI offender and will be designed to be easily navigable and informative for both the CFM and offender. While our Phase I research developed these specifications, they will be validated in final form by the iterative development research for Phase II. Additional

FIGURE 4: Proposed Flow for *B-SMART* Web App



features to be programmed will be considered during the formative research, based on feedback from participants. All app content will be available in both English and Spanish, based on user language preference. The Spanish translation/back-translation verification process will be managed by Project Coordinator Ms. Jeannyfer Reither (KB), a native Spanish speaker, and assisted by Project Research Scientist Mr. Leonel Diaz (UNM), a native Spanish speaker. A professional translator will also be utilized for back-translation.

3C.5.2. Iterative Development Approach. As with all effective digital designs, smartphone applications must be carefully and systematically designed, employing feedback and reviews from the intended target group (in this case, DWI offenders and their CFMs) in a series of repeated development cycles. We will employ a series of systematic app development steps used in prior smartphone application and website projects: 1) initial focus groups to review the proposed program flow and content (n=32); 2) usability testing sessions with CFM (n=16) and DWI offenders (n=16) of a beta version (near final) of *B-SMART* to ensure usability and navigability, and 3) review of the final version of *B-SMART* by EAB members. We project app development to occur in Months 1-7.

3C.5.3. Final Content and Tailoring Focus Groups. Focus groups will be used to frame the content in the *B-SMART mobile web app*. Four focus groups (2 of DWI offenders, 1 each in English and in Spanish; 2 of CFM, 1 each in English and Spanish) will be conducted. Although the app will be designed for CFMs, input from DWI offenders will be crucial to learn what they believe would be helpful for them. Participants will be recruited from the Santa Fe County DWI program (see Letter of Support) in Month 2 of Phase I and paid $50 for 2 hours of participation. Focus group discussions will be led by English and Spanish speaking research staff trained in focus group facilitation techniques who will follow a protocol to lead discussions about the use of B-FIT content in the *B-SMART* smartphone app. Topics will include: how the CFM would share information with the DWI offender; what type of content the DWI offender would expect to see; examples of positive shared activities; obstacles to scheduling positive shared activities and how to overcome them; examples of how CFMs can be most supportive of the offender to reduce recidivism; typical difficulties in effective communication in couples in conflict; and examples of how to use specific skills to overcome these difficulties. Discussions will be audiotaped, transcribed, and analyzed using procedures developed in previous work by the research team. Analysis of all focus group discussions will be accomplished via InVivo NUDIST content and theme analysis software to identify consistent and recurrent content themes in response to focus group questions. These results will be summarized in focus group reports distributed to the research team, EAB, and KB media developers and used to make final decisions about app design, instructional design, and final content.

3C.5.4. Mobile Web App Programming and Production Procedures. Production of the *B-SMART mobile web app* will be completed by KB's media developers following well-established agile iterative production steps. Broad goals and specific instructional/behavioral objectives and content will be developed by investigators and staff. Messages and graphic design elements will be reviewed from Phase I research and previous digital programs and screen scripts created. Interface design ideas will be prepared in written form, combined with scripts into flowcharts/storyboards, and reviewed by investigators and EAB before authoring *B-SMART*. An overall look and feel of the app and graphics and functions of components will be based on the Phase I development, and also this initial review and usability testing (see following section). Each component of the mobile web app will be thoroughly tested for platform stability and code errors prior to being exported to the Web server. Language, graphics, and video depictions that have "timeless" features will be used. KB's production team includes a graphic designer, junior- and senior-level multimedia programmers, and an instructional designer. These production steps were implemented successfully in the production of the first module of *B-SMART* as a prototype in Phase I.

3C.5.5. Hardware/Software Requirements and Region Connectivity. *B-SMART* will be served to smartphones, tablet computers, and personal laptop/desktop computers from KB's state of the art web server (see description in KB's Resources page). The content will be authored utilizing a Responsive Web Design approach that optimizes user experience across platforms and screen sizes, using HTML5, CSS, JavaScript, and Microsoft dotNet platform (using C# language). Microsoft SQL databases will track use. KB's media developers will maintain the mobile web app, monitor app usage, manage the SQL database storing use data, and provide technical support to CFMs and DWI offenders (by email and toll-free phone number). *B-SMART* will be programmed to run on common web browsers on iOS and Android smartphones and tablet computers and on iOS devices and Windows personal computers. A recent review[85] found that 91% of New Mexicans have access to wired Internet service and 99% of New Mexicans have access to mobile broadband service. While broadband speeds in New Mexico are not always optimal (75% of New Mexicans have broadband speeds of 25 megabits per second or greater), access to the Internet, particularly from mobile broadband service (the focus of this project) is widely available. As such, the connectivity requirements for the proposed project are in place in New

Mexico.

3C.5.6. Iterative Usability Testing with Concerned Family Members (Specific Aim 2). Led by Ms. Berteletti, iterative usability testing will be conducted with CFMs (n=32), employing an established protocol to test the navigability and usability of the newly-programmed modules (i.e., those not programmed in Phase I: Shared Positive Activities; Common Challenges; and Effective Communication). During individual in-person sessions with research staff, participants will be instructed to navigate through sections of *B-SMART* and provide their verbal reactions as they do so. Staff will prompt with questions, asking what the participants might change about activities and how they might use the app with their DWI offender. At the completion of each session, participants will complete the 10-item Bangor System Usability Scale (SUS).[83] CFM ratings of the *B-SMART* beta module in Phase I on the SUS averaged 44.2 out of a possible 50 scale points, indicating good usability. The target score for indicating usability in Phase II will be 40 or above, as is suggested as being acceptable. In addition to the SUS measure, the Instructional Designer at KB will create a summary report listing usability problems experienced and their severity. The research team and KB media developers will make necessary changes to address these problems before launch in the randomized controlled trial (see 3C.6). All usability sessions will be video recorded and transcribed. Both qualitative and quantitative (SUS scale) summaries will be provided to Investigators and the EAB for review. All usability testing sessions will be held in New Mexico and will last approximately one hour. Spanish and English speakers will both be recruited. Participants will be compensated $50.00 for their time.

3C.5.7. Summary of Development Phase. Our team will use its accumulated experience and expertise in developing technology interventions, including mobile technology, to design a highly functional and effective *B-SMART mobile web app*, continuing the production started in Phase I. Systematic, iterative development and testing will ensure that the app addresses the specific needs of CFMs and DWI offenders to provide therapeutic approaches, that are generally only provided to families during in-person sessions, to reduce recurrence of drunk driving.

3C.6. Randomized Trial Evaluating *B-SMART* (Specific Aim 4; Months 8-24)

3C.6.1. Experimental Design. The *B-SMART mobile web app* will be evaluated in a randomized pretest-posttest controlled design. In months 6-11, first time DWI offenders and CFMs will be recruited for participation in the trial. First-time DWI offenders and their CFMs will be randomized together to the intervention (*B-SMART*) (n=150) or a usual and customary (UC) IID information condition comparison group (n=150) following baseline assessment. Assessment via web-based surveys will be conducted with the DWI offenders and CFMs at baseline, 3-month follow-up, and 9-month follow-up post randomization. Also, information on frequency of alcohol-positive IID tests (termed "lockout events) will be acquired by the project from the Santa Fe County and Municipal DWI Program at the 9-month assessment point (posttest only) for each DWI offender. Thus, the proposed efficacy trial (see **Figure 5**) will be a 2 (level of treatment – app intervention vs. UC information) x 3 (level of time – baseline vs. 3-month follow-up vs. 9-month follow-up) mixed factorial design. Baseline and follow-up data collection will be conducted via online surveys and a customized web portal and include DWI offender and CFM alcohol frequency and use measures and measures of family communication and functioning (see 3C.7). Participants will fill out a locator form with contact information and collateral contact information to locate them for assessment at the 3-month and 9-month follow-ups. We have employed these locator procedures in prior trials, keeping average loss across 9 months at 15%-20%. Cumulative IID lockout event data will be collected for all DWI offenders from the Santa Fe County DWI Program at the 9-month assessment point.

FIGURE 5: Randomized Efficacy Trial Design

Time	Experimental Group (randomized)	
	***B-SMART* Intervention Group** N=150 DWI Offenders & CFM	**Usual & Customary Information Group** N=150 DWI Offenders & CFM
Baseline	study cohort assessment	study cohort assessment
Web App Intervention	YES	NO
3-month Follow-up Post-test	study cohort assessment	study cohort assessment
9-month Follow-up Post-test & IID Data Collection	study cohort assessment	study cohort assessment

3C.6.2. Recruiting and Consenting Procedures. Potential participants will be contacted for recruitment and consenting at monthly Santa Fe County DWI Program meetings held for each DWI offender at the beginning of her/his probation period. CFMs of first-time DWI offenders will be contacted via email and a web recruitment portal designed exclusively for the project and followed up with a recruitment phone call.

Participants will only be enrolled in the trial if **both** the DWI offender and CFM consent to participate. Our previous work in Phase I of the project found a strong willingness to participate in the project among both DWI offenders and CFMs based on their interest in better family functioning and the unique convenience of a *B-SMART mobile web app* that could be beneficial to their experiences with the IID.

3C.6.3. Implementation of *B-SMART Mobile Web App*. *B-SMART* will be implemented with first-time DWI offenders and CFM randomized to the intervention in months 7-11. Following the baseline survey, a link will be presented to the participants where the *B-SMART mobile web app* can be accessed through their web browsers on their smartphones, tablet computers, or personal laptop/desktop computers. This link will also be sent to their email addresses and by text message to their mobile phones. A customized backend SQL database will track participants' progress through the mobile web app. Unique identifying user codes will be assigned to all first-time DWI offenders and their CFM by the research staff; participants will select their own password under the user profile section of the web app. The User ID and password will be used to access *B-SMART* and mark the usage data in the SQL database (see description of Server-side Process Measures in Section 3C.7.3). In case users forget their password, they will provide a unique answer to a standard personal question (e.g., what is your mother's first name), and using this information, the mobile web app database will return the forgotten password. If users forget both their User ID and password, they can call or email a technical assistance hotline staffed by KB media developers.

Orientation to *B-SMART* will be primarily self-explanatory, which we will confirm in usability testing (see 3C.5.6). In our past research, nearly all adults were adept at using a web browser across devices, so we are confident that *B-SMART* and its use will take little explanation. To ensure use, we will: 1) design the mobile web app to be inherently interesting and enjoyable through our iterative development procedures incorporating user input (see C3.5.2); 2) make the user navigation simple and easy to browse so modules can be viewed quickly; 3) create a mobile web app that can be completed in no more than 120 minutes to avoid boredom that provokes drop out; 4) program the mobile web app so its interface is optimized on a variety of technology platforms (smartphone, tablet computer, or personal computer) to accommodate the preferences of any user; and 5) engineer low and high bandwidth versions of the mobile web app that automatically adjust to the user's bandwidth access. While connectivity data in 3C.5.5 indicates sufficient broadband and cell coverage in New Mexico for the *B-SMART mobile web app*, this programming feature will allow the use of *B-SMART* even in limited connectivity situations. Reminders to use *B-SMART* (or read the IID Information pamphlet in UC group, see 3C.6.3) will be sent to participants every 5 days for two weeks after randomization. If the either the mobile web app (or the web pamphlet in the UC group) still is not accessed, research staff will contact participants by telephone and encourage them to use it.

3C.6.4. Usual and Customary IID Information. Participants randomized to the usual and customary care (UC) group will receive a website with a pamphlet on the IID installed in their vehicle and the manufacturer information provided about the IID in PDF format, in both English and Spanish. This constitutes a UC group, as such pamphlets are widely distributed to DWI offenders who have IIDs installed in their vehicles. Thus, providing this pamphlet represents a standard information provision for first-time DWI offenders and their CFMs.

3C.6.5. Sample Size Determination. The sample size for the randomized trial in the Phase II research is designed to provide sufficient information for Phase III commercialization. The sample size assumes the counts of interlocks are Poisson distributed. We have assumed 4 interlocks over 9 months in the control arm or a rate of 0.44 per month for each DWI offender. In the *B-SMART mobile web app* group, we have assumed a reduction of 40% from 0.44, resulting in a rate of 0.27 per month. The null hypothesis is that the ratio of these two rates is 1.0 versus 0.6. Assuming a Type I error of 0.05 (2-sided), 90% power, sample size is only 27 DWI offenders per group. However, if the rate is higher up to 1 per month, the sample size required declines since the percent reductions yield wider absolute differences in the rates. We also are keen to know the reductions achievable with the *B-SMART* group, so we evaluated the sample size with regards to other effect sizes. A Cochrane meta-analysis[7] reported the impact of IIDs to reduce risk by 64%, but with a confidence interval that ranged from 76% to 37%. In the proposed trial, we have two treatment groups and may see less impact than that in the meta-analysis. Thus, a sample size of 119 DWI offenders per group will allow for 90% power with a comparison of 0.44 to 0.36 or approximately a 20% reduction in interlocks. We will adjust for an expected 15% attrition and this sample size also has sufficient sample size to evaluate the impact in various gender and ethnic subgroups. Thus, we propose to randomize 150 DWI offenders and 150 CFMs to each arm of the trial.

3C.7. Outcome Measures

3C.7.1. Measure of Primary Outcome Variable: IID Lockout Events. The primary outcome

measure will be frequency of IID lockout events from baseline to 9-month follow-up post-randomization, collected from the Santa Fe DWI program database for each first-time DWI offender participant. Marques, Voas and colleagues[86-89] have demonstrated in a series of investigations that frequency of lockout events strongly predicts DWI recidivism over time, and as such, IID lockout events are an important and useful proxy measure for DWI recidivism. Given the length of time necessary to accumulate DWI recidivism data (average length of time varies across locales and can be between 2 and 8 years), IID lockout events provide a direct and accessible measure of DWI recidivism within the two-year project timeline.

3C.7.2. Measures of Secondary Outcome Variables and Mediators. Alcohol use by the DWI offender, a secondary outcome, will be assessed at baseline, 3-month follow-up, and 9-month follow-up with versions of the Form 90[90,91] adapted for online assessment for the CFMs (Form 90-ACS) and first-time DWI offenders (Form 90-AF). The Form 90 measures produce detailed quantity and frequency measure of alcohol use for the first-time offender that are validated by the CFM reports. Family functioning will be assessed at baseline, 3-month follow-up, and 9-month follow-up, as potential mediators of *B-SMART* effects, with DWI offenders and CFMs with three measures: (1) Family Environment Scale – Cohesion and Conflict subscales[92] assesses offender and CFM perceptions of positive and negative family functioning; the two subscales selected are strongly associated with treatment outcome; (2) Family Communication Scale from FACES-IV[93] assesses perception of quality of communication in the family; (3) Pleasant Events Schedule (adapted)[94] assesses shared positive activities within a family. These three measures are also being used in the B-FIT study, allowing for comparison of outcomes across the two studies.

3C.7.3. Ancillary Measures. CASAA Demographics Form: This form collects participant identification data and demographic information (e.g., age, education, sex, and ethnicity) about DWI offenders and CFMs. Items will be added to describe the relationship between the offender and CFM and the frequency of contact between them. System Usability Scale:[78,79] This scale consists of ten Likert strongly agree to disagree items (Cronbach's alpha=.90) that asks the respondent to rate the technology product being reviewed (Example items: I think that I would like to use this product frequently; I found the product very awkward to use; I felt very confident using the product). Participants also provide a final overall rating of the product along a 7-point worst imaginable to best imaginable dimension.

3C.7.4. Server-side Process Measures of *Mobile Web App* Performance and Use. KB's programmers will create custom programs to track the implementation and use of the *B-SMART mobile web app*, as we have done for other technology-based and mobile interventions[52,67,95]). The mobile web app will be hosted on KB's secure web server. Users will register and use a password to access the *B-SMART mobile web app* and this password will be used to track use, keeping data about users private. KB utilizes Microsoft SQL server for data collection of users; click-stream (pages visited), time on *B-SMART*, and number of individual visits.

3C.8. Outcome Analysis Plan

The trial is intended to evaluate the following hypotheses:

H1: First-time DWI offenders in the intervention group (*B-SMART mobile web app*) will have significantly fewer IID lockout events than participants in the control group (UC information condition).
H2: Lower rates of IID lockout events will be mediated by improvements in Family Functioning, Family Communication, and Shared Positive Family Events in the intervention (*B-SMART mobile web app)* condition compared to the UC information condition.

We will also analyze moderation of the effect of *B-SMART* by demographics and mediation of IID lockout events by *B-SMART* use in the intervention group.

Three levels of analysis are planned: (1) hypothesis testing using Poisson regression testing the differences in lockout events between the two intervention groups, (2) analysis of possible covariates (e.g., sex, ethnicity, and age of DWI offenders and CFMs), added to the Poisson regression and (3) other exploratory analyses.

3C.8.1. Preliminary Analysis of Baseline Data. Descriptive data at baseline, with comparisons by treatment group, will be examined to check distributional characteristics and assess any concerns for imbalances that might be considered as covariates in analyses. The potential meaning of non-normality will be examined, i.e., excessive skewness potentially identifying key subgroups. These analyses will be at the level of the individual DWI offenders and CFMs responses and be conducted within 3 months of completion of recruitment. If there is excessive skewness on the IID lockout rates, negative binomial regression will be used.

3C.8.2. Planned Analysis for Hypothesis 1. The second major analysis will focus on impact of the *B-SMART mobile web app* on primary (IID lockout events) and secondary (DWI offender's alcohol consumption) outcomes, and be completed within 1 month of the end of the posttest data collection in Year 2. The effect of *B-SMART* on IID lockout events in Hypothesis 1 will be tested primarily using PROC GENMOD with a Poisson link via SAS Version 9.4, which includes capabilities to test these Poisson models with missing data, account for the temporal design, and include information by participant. Participants will be treated as a random effect and treatment as a fixed effect, at p=0.05 (2-sided). Analyses of primary outcomes will not be released before completion of the intervention. Since CFM and DWI offender can be clustered within the same family, hierarchical models with participants nested within families will be considered.

The secondary outcome of quantity and frequency of alcohol consumption by DWI offenders will be compared in several ways. Quantity and frequency will be evaluated using Poisson models, as well as a composite variable based on total alcohol consumption (the product of the two variables), using negative binomial regression models, unless a Poisson model is sufficient.

Since date of IID lockout events will collected and alcohol consumption is measured at all three assessments, we will examine the time by treatment interaction in the analyses of Hypothesis 1 to assess the question of the durability of the effects of B-SMART over time. For example, we will evaluate time to first lockout using a Kaplan Meier approach and the times to subsequent lockouts.

3C.8.3. Mediation Analysis for Hypothesis 2. To address the predicted mediation effects of family function on improving the effect of the *B-SMART mobile web app* in Hypothesis 2, we will assess a formal effect on predicting fewer IID lockout events. Mediation will be tested by applying regression techniques from Judd and Kenny[96] and elaborated by MacKinnon,[97] with significance of mediation determined via interval estimation using bootstrapping.[98,99] Ratio of indirect to total effects will estimate the proportion of the effect mediated. The primary mediational analysis will rely on temporal order of assessments by examining the effect of *B-SMART* on change in the mediators from baseline to 3-month follow-up and in turn their association with changes in the IID lockout events from baseline to the 9-month follow-up and from 3- to 9-month follow-up.

3C.8.4. Ancillary Analysis of Moderators. Potential moderators (see 3C.7.3) will be tested at p=.05 (2-tailed) unadjusted for multiple tests. For Hypothesis 1, they will be added as interactions by condition in a manner similar to regression testing for effect modification. Gender is included to probe differences by sex of DWI offenders and CFMs. For Hypothesis 2, we will explore if improvements in IID lockout events produced by increases in family function by different participant groups (sex, ethnicity, age, etc.), using moderated mediational analyses.[98] Moderation effects must be large to be detected, so these are ancillary tests.

3C.8.5. Ancillary Analysis of the *B-SMART Mobile Web App* Exposure. The same mediational analysis techniques described in 3C.8.4 will be used to explore the relationship of exposure to the *B-SMART mobile web app* and pre-post changes in IID lockout events. Summed scores on exposure will be calculated from the SQL database (e.g., time on app, number of visits to the app, etc.) to assess intervention exposure.

3C.9. Strengths and Limitations to Approach

The research has several strengths. A scientifically-rigorous pretest-posttest randomized controlled design is used. Randomization will equalize participants across conditions. Established recruitment protocols and measures will be used and IID lockout events will be measured from court records, an objective assessment. The *B-SMART mobile web app* is built on our B-FIT theory- and evidence-based family intervention. Data collection will be automated (i.e., court records and online survey) so project staff are blind to condition. We minimized potential problems. Participation will be confidential to minimize selection bias. Valid, easy-to-administer, and low-cost self-report measures of mediators will be used to control social desirability biases and any bias is equalized by randomization.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	B-SMART: A randomized trial of a smartphone app for DWI Offenders and their Families	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

B-SMART: A randomized trial of a smartphone app for DWI Offenders and their Families

1.2. Is this study exempt from Federal Regulations * ○ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- Secondary Prevention
- Driving Under the Influence
- Accident Prevention
- Alcoholic Intoxication
- Alcohol Drinking

2.2. Eligibility Criteria

The project has two relevant, linked target populations: 1) concerned family members (CFM) of driving while intoxicated (DWI) offenders and 2) the first-time DWI offenders themselves. The inclusion/exclusion criteria for these populations are as follows.

DWI Offender:
- male or female
- 21 years or older
- first-time DWI offender with IID installed in vehicle
- enrolled in Santa Fe County DWI Program
- have a smartphone, tablet computer, or personal computer with Internet access
- consent to participate
- able to read and speak English or Spanish

Concerned Family Member (CFM):
- male or female
- 21 years or older
- spouse, parent, or immediate family member of first-time DWI offender with IID installed in vehicle and enrolled in Santa Fe County DWI Program
- have a smartphone, tablet computer, or personal computer with Internet access
- consent to participate
- able to read and speak English or Spanish

Exclusion Criteria:
- other family members already enrolled in the project
- second or above DWI conviction

2.3. Age Limits	Min Age: 21 Years		Max Age: 85 Years
2.4. Inclusion of Women, Minorities, and Children	2.4_BSMART.pdf		
2.5. Recruitment and Retention Plan	2.5_BSMART.pdf		
2.6. Recruitment Status	Not yet recruiting		
2.7. Study Timeline	2.7_BSMART.pdf		
2.8. Enrollment of First Subject	06/01/2019	Anticipated	

2.4. INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

Inclusion of Women and Minorities

Potential participants will not be excluded based on ethnic group or race. We will attempt to recruit participants at similar rates to the 2014 New Mexico DWI Offender Characteristics and Recidivism Report. According to the Report, the race/ethnicity of the DWI offender population in New Mexico from 2003 through 2013 were as follows: 49% Hispanic, 28% White, 20% American Indian/Alaska Natives, and 3% African American. The gender of the DWI offender population was 72% male and 28% female. The Targeted Enrollment Table represents a composite of these numbers.

During the recruitment process, the UNM project coordinator will screen for participants using IRB-approved protocols for screening based on gender, race, and ethnicity. If the project coordinator finds that we are over-recruiting a particular gender or racial or ethnic group, we will place them on a waiting list until we have recruited an adequate number of targeted participants

Inclusion of Children

Children under 18 will be ineligible for participation. Children under 18 will not be enrolled in the proposed project because this app is aimed at adults. We are limiting age to no younger then 21 years old because DWI offenders under age 21 fall under a different set of laws and court programs than offender 21 or older. To keep things simple, we will also limit the age of CFMs to 21 years or older. Age will be self-reported by the participants.

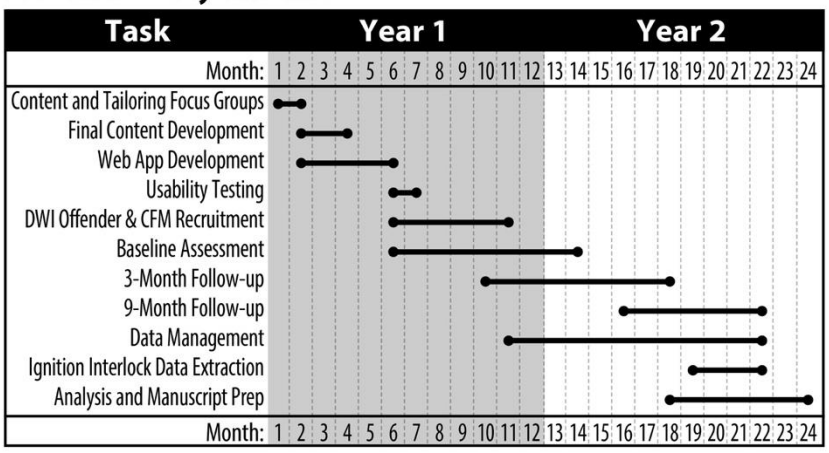
Human Subjects oversight will be conducted by the Western Institutional Review Board (WIRB; DHHS IRB Reg. No. 00000533). The IRBs will approve all consenting procedures (including recruitment advertisements, posters, recruitment letters and consent forms), intervention protocols, survey instruments and data collection protocols, and data management procedures prior to study implementation and prior to the recruitment of any participants.

The investigative team has extensive experience from previous community-based trials and as a result already have a rich inventory of recruiting materials and protocols to be used for this study, including materials and protocol used to recruit DWI offenders and CFMs to the Phase I research. We will recruit 300 eligible DWI offenders and 300 eligible CFMs to complete the baseline assessment and be randomized. That way, at least 255 DWI offenders and 255 CFMs will complete the 9-month follow-up (85% retention).

Potential participants will be contacted for recruitment and consenting at monthly Santa Fe County DWI program meetings held for each DWI offender at the beginning of her/his probation period. CFMs of first-time DWI offenders will be contacted via email and a web recruitment portal designed exclusively for the project and followed up with a recruitment phone call. Participants will only be enrolled in the trial if both the DWI offender and CFM consent to participate. Our previous work in Phase I of the project found a strong willingness to participate in the project among both DWI offenders and CFM based on their interest in better family functioning and the unique convenience of a *B-SMART mobile web app* that could be beneficial to their experiences with the IID. In New Mexico, Santa Fe County had the fourth-highest ranked number of first time DWI offenders (360) in 2015 and 313 first time convictions in 2016.

The Project Coordinator will track participants and report on progress in recruiting women and ethnic/racial minorities. The study data team will provide detailed reports describing overall recruitment, as well as with strategies for recruiting women and ethnic/racial minorities. To retain participants, participants will fill out a locator form with contact information (name, address, telephone numbers [landline and cell], and email address) and collateral contact information (i.e., a person close to them who can reach them if they do not respond to follow-up communication from the study) to locate them for assessment at the 3-month and 9-month follow-ups. Prior to the posttests, study staff will text and email the participants to remind them of the upcoming posttest survey. Once invitations are issued for the follow-up surveys, reminders to complete the follow-up survey will be sent by email and text at 5-day intervals for two weeks. To reach persistent non-responders, staff will send printed/PDF copies of posttests by mail (with a stamped return envelope) and email. Although participants can withdraw at any time, steps will be used to minimize dropouts to ensure high internal validity. Participant progression will be tracked. Staff will use behavioral reinforcement strategies known to be effective in the behavior change literature and be trained to develop rapport with participants by communicating expectations for participants and staff. We will compare dropouts to those retained to determine if there is any potential bias. We have employed these retention procedures in prior trials, keeping average loss across 9 months at 15%-20%.

FIGURE 2: Study Timeline



Inclusion Enrollment Reports

Entry#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	New Mexico

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ❍ Yes ● No

Enrollment Location Type* : ● Domestic ❍ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): New Mexico

Comments: 32/Focus Group; 32/Usability testing; 600/Randomized Control Trial

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	37	96	0	0	133
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	6	14	0	0	20
White	52	134	91	234	511
More than One Race	0	0	0	0	0
Total	95	244	91	234	664

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	3.1._Protection_of_Human_Subjects20180401.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	❍ Yes ● No ❍ N/A
If yes, describe the single IRB plan	
3.3. Data and Safety Monitoring Plan	3.3._Data_and_Safety_Monitoring_Plan_draft_20180401.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	❍ Yes ● No
3.5. Overall structure of the study team	3.5_structure.pdf

3. PROTECTION OF HUMAN SUBJECTS

3.1. RISKS TO HUMAN SUBJECTS

3.1.A. Human Subjects Involvement, Characteristics, and Design. This proposed Phase II SBIR project will develop a full-scale, fully programmed *B-SMART mobile web app* that aims to enhance the maintenance of behavior change among DWI offenders by mobilizing the DWI offender's social network and enhancing that involvement via smartphone technology. We will complete the development of the *B-SMART mobile web app,* test its usability, translate the complete app to Spanish, and test the impact of the app on alcohol-related outcomes and family function outcomes.

The two target populations consist of first-time DWI offenders and their concerned family members (CFM - defined as a spouse or close relative living with the DWI offender). All participants will be recruited from the Santa Fe County DWI Program, a county-wide program that manages probation and sentencing programs and requirements for all DWI offenders in Santa Fe County, New Mexico.

Inclusion criteria for DWI offenders are: (a) over 21 years of age; (b) first-time offender with an Ignition Interlock Device (IID) installed in their vehicle, (c) have a smartphone, tablet computer, or personal computer with internet access, (d) able to read and speak in English or Spanish, and (e) consent to participate. Inclusion criteria for CFMs are: (a) over 21 years of age; (b) parent, spouse, or immediate family member of a participating DWI offender, (c) have a smartphone, tablet computer, or personal computer with internet access, (d) able to read and speak in English or Spanish, and (e) consent to participate. Participants in the development phase will not be eligible for the randomized trial phase of the project.

The collaborating site is the University of New Mexico (FWA No. 00003255).

3.1.B. Study Procedures, Materials, and Potential Risks.

Study Procedures:

Focus Groups Participants (n=32). Four focus groups will be conducted. Two focus groups will be held with DWI offenders (one in English and one in Spanish). In addition, two focus groups with CFMs will be held (one ins English and one in Spanish). Although the app is designed for CFMs, input from DWI offenders will be crucial to learn what they believe would be helpful for them. Focus group discussions will be led by English and Spanish speaking research staff trained in focus group facilitation techniques who will follow a protocol to lead discussions about the use of B-FIT content in smartphone applications. Topics include: how the CFM would share information with the DWI offender; what type of content the DWI offender would expect to see; examples of positive shared activities; and examples of how CFMs can be most supportive of the offender to reduce reoffending.

Discussions will be audio taped, transcribed and analyzed using procedures developed in previous work by the research team. Analysis of all focus group discussions will be accomplished via InVivo NUDIST content and theme analysis software to identify consistent and recurrent content themes in response to focus group questions. These results will be summarized in focus group results reports distributed to research team members and the EAB. These results will be used to make final decisions about smartphone application design, structure, navigability, and approach.

Usability Testing Participants (n=32). One round of iterative usability testing will be conducted with CFMs on an individual basis to validate the design approach and identify usability problems. During individual in-person sessions with research staff, participants will be instructed to navigate through sections of the app and provide their verbal reactions as they do so. Staff will prompt with questions, asking what the participants might change about activities and how they might use the app with their DWI offender. At the completion of the usability session, participants will complete the Bangor System Usability Scale (SUS). In addition to the SUS measure, the Instructional Designer at KB will create a summary report listing usability problems experienced and their severity. The research team and KB media developers will make necessary changes to address these problems before launch in the RCT. All usability sessions will be video recorded and transcribed. Both qualitative and quantitative (Bangor scale) summaries will be provided to Investigators and the EAB for review. All usability testing sessions will be held in New Mexico and will last approximately one hour. Spanish and English speakers will both be recruited.

Randomized Controlled Trial Participants (n=300). First-time DWI offenders and their CFM will be randomized to the intervention (*B-SMART mobile web app*) (n=150) or a usual and customary (UC) IID Information condition comparison group (n=150) following the baseline assessment. Assessments, conducted via web-based surveys, will be conducted with first-time the DWI offenders and CFMs at baseline, 3-month follow-up, and 9-month follow-up post randomization. Also, information on frequency of alcohol-positive IID tests (termed "lockout events) will be acquired by the project from the Santa Fe County and Municipal DWI Program at the 9-month assessment point (posttest only) for each DWI offender. Baseline and follow-up data collection will be conducted via online surveys and a customized web portal and include DWI offender and CFM alcohol frequency and use measures, and measures of family communication and functioning. Participants will fill out a locator form with contact information and collateral contact information to locate them for assessment at the 3-month and 9-month follow-ups.

Study Materials: Data from the focus groups, usability testing, surveys, and randomized trial will be collected in the form of handwritten notes, audio tapes, computer files, transcriptions, and questionnaires. Discussions will be recorded, transcribed, and analyzed using Atlas.ti© software. Data will be gathered from surveys used in the randomized trial. Data will be obtained specifically for research purposes and will be kept confidential with access limited to the Investigators and specific project staff. All data will be kept in locked files.

Potential Risks: Potential risks are minimal, mainly social or psychological. Focus group participants may be hesitant or uncomfortable responding to questions about the challenges of having an IID, concerns about family members' feelings about the IID, and ways that family members could be helpful in supporting the DWI offender to not drink and drive. Usability test participants may not feel comfortable responding to questions about their opinions on appeal, ease of understanding, navigation, and functionality of the *B-SMART* mobile app. There are no anticipated risks from completing the self-report questionnaires. If signs of minor stress or fatigue are apparent, participants will be given time to take a break from completing the questionnaires. For the randomized trial, surveys will be completed online, at the participants own pace.

Participants' responses will not be shared with anyone except project staff. Responses to survey questions will be coded to protect confidentiality. All participants will be allowed to withdraw at any time if they are uncomfortable with the discussions. Although half of the potential participants are involved with the criminal justice system as a result of having a DWI, that involvement is overseen by other entities and is not a part of the research project.

3.2. ADEQUACY OF PROTECTION AGAINST RISKS

3.2.A. Informed Consent and Assent.

Human Subjects oversight will be conducted by the Western Institutional Review Board (WIRB; DHHS IRB Reg. No. IRB0000053; FWA No. 00003715) and the University of New Mexico's Institutional Review Board DHHS IRB Reg. No. IRB0000431; FWA No. 00004690). All consenting procedures will be IRB-approved. The IRB(s) will review and approve subject materials (including recruitment letters, consent forms, survey instruments) and data management procedures prior to study implementation. Potential participants will be informed of the study purposes and procedures, given opportunities to ask questions and have them answered, and provide informed consent according to IRB-approved guidelines.

Focus group and usability test participants will be consented in-person and will sign an IRB-approved consent form. For the randomized trial, DWI offenders recruited to the study will be consented in-person and will be administered by a UNM Project Coordinator. Project staff will provide participants with copies of their signed IRB-approved consent forms. For the randomized trial, CFMs will be consented online and will have an option to save or print the IRB-approved consent. Participants will only be enrolled in the trial if both the DWI offender and CFM consent to participate. Consent forms will be either Spanish or English, dependent on the participants' language.

The IRB-approved consent forms will describe the purpose of the project, risks and benefits, and selection criteria. Participation will be voluntary, with the right to stop participating at any time. No clinical data will be captured. All data coding, data entry, analysis, and reporting activities will be conducted by KB. Participants will be informed that they have a right to withdraw from the study at any time. No additional data will be collected from participants who decide to withdraw; however, the information collected prior to withdrawal will remain in the study. IRB-approved surveys and discussions will be carried out under the supervision of senior project staff.

3.2.B. Protection Against Risk.

Although we are working with participants who have been convicted of DWI and mandated to treatment, their participation in this research study has absolutely no bearing on the requirements they need to fulfill obligations with the court. To minimize the risk of coercion to participate, we will make it clear both verbally and in the consent form that participation in the study will not help nor hinder their standing with the courts. Although participants in this study are not prisoners, they are involved in the criminal justice system insofar as they have been convicted for DWI. We will make it very plain that data collected as part of the research study will not be available to the courts and will have no bearing on their DWI status with the courts. Because they are not prisoners they will not require special protections, but we still need to be mindful that simply being involved in the criminal justice system makes them more vulnerable than a group not involved in the criminal justice system.

To minimize potential psychological risk, all focus group and usability testing facilitators will establish ground rules for discussion that includes an open, non-evaluative exchange of comments and ideas. All surveys and data collection forms will be approved by an IRB and employed under the supervision of senior project staff. Participants will be told that they do not have to answer any questions which make them uncomfortable and can terminate their participation at any time they wish.

Notes, surveys, audiotapes, and data will be accessible only by research personnel. No clinical data will be

captured. The data collected on this project will be obtained with the "use of educational tests, survey questions, [and] interview procedures."

Data forms will be labeled only with participant identification number. Participant names and study identification numbers will be recorded and stored separately from the research data files. Focus group participants will be asked to use first names only during focus groups. Data will be de-identified before being submitted for analysis. All notes and printed data collection forms and questionnaires will be stored in locked cabinets; all electronic data files will be stored on UNM's and/or KB's secure network servers behind computer firewalls, with routine backup. All identifiers will be stored in secure files and behind computer firewalls and results will be shared in aggregate form only. All human subjects participating in this project will be adults who are 18 years and older.

All focus group and usability testing research data collected by research staff (e.g., focus groups scales, demographic and locator forms, etc.) will be logged in and taken back to the CASAA research offices in a briefcase or similar closed storage medium for transport - loose papers or papers in open folders will not be allowed. After returning to the research office, all hard copy materials (consent forms, demographic and locator forms, usability scales) will be logged in and stored in a locked file cabinet, within a locked office, in a locked suite. Once information from the focus groups is transcribed, the transcriptions will also be placed within the locked file cabinet. There is a risk that data could be accessed by someone other than project staff. While hard copies of materials will be placed within a locked filing cabinet, inside a locked office, digital audio recordings will be uploaded to a secure server located within UNM-CASAA and transcribed. The UNM-CASAA server is located in a locked room, on the second floor of the CASAA building, which is burglar alarmed. Access to the server in the locked room is gained through the IT Manager's office. Only four staff members (having a need to have access to the server) have keys to that locked room. Electronic access to files and data are provided by the IT Manager on a need to know basis, meaning staff can only access that part of the server on which their project-specific files and data reside. The server is protected by IT protocols and a firewall from outside access and attacks. The only outside access is through a secure virtual private network (VPN). The VPN requires a shared key that is known only by the IT manager. The original focus group digital audio recordings will be deleted from the recording device once the recording is uploaded to the previously mentioned server.

To minimize the risk to participant data privacy and protection through the internet in the randomized trial, KB programmers will monitor and maintain all programs and databases and use an established protocol for participant cyber safety and security. KB is HIPAA complaint and maintains vigorous technical safeguards which are built into KB's IT system to protect information and to control access to it. All participant information will be protected using 128-bit SSL encryption. All Internet information must travel through KB's CISCO ASA 5505 firewall using ASA software version 9.0(2) encrypted 3DES-AES. Traffic then moves to KB's web server. This server is a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V Operating System. The virtual web server uses Windows 2008 IIS Web server software. User click stream data is collected using Webtrends and is saved to our SQL server. Enrollment data is transferred to our SQL server (Windows Server 2008) which uses MS SQL server 2008 R2 database software. This machine is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V OS and has no access to the Internet. When a participant is directed to take a survey, their computer is linked to a third server in our system which is also a Dell Power Edge T-310 with 32 GB of RAM, 1.5 TB available disk space on a RAID 5 redundant drive system using Windows Hyper-V OS. This server runs Question Pro Survey software. Data from each survey is collected and saved to the SQL server mentioned above. All network traffic is sent from the CISCO firewall to a Syslog server using Manage Engine Firewall Analyzer 7 software. Login and network activity is required and monitored by Windows servers to an event viewer. Servers are kept in a locked room on site. All files are secured locally using MS NTFS. All traffic between servers and PCs on the LAN are digitally signed communications. Each local machine has a built-in operating system firewall. Data from the Question Pro surveys are exported for data analysis by local machines which are also behind KB's firewall. Access to this exported data by outside sources is done using File Transfer Protocol (FTP) protected by Secure Socket Layer (SSL). SQL databases are protected by the built-in security of MS Active Directory. Data is backed up using a Quantum SuperLoader 3 tape library using LT04 tapes that contain 800 GB/1.6 TB of info (depending on compression used). The device holds 16 tapes. The backup software used by KB is Symantec Back-up Exec. 2012. Daily backups are incremental and tapes are recycled weekly. Weekly backups are done every Friday and are recycled every 6 weeks. Monthly backups are done on the last Friday of each month and are full backups of all data. These monthly tapes are stored in a secure offsite facility and are never recycled.

With regards to app security on personal devices, Apple (e.g., iOS programmed apps) completes a full security review of any app installed on a phone including beta/testing apps through their App Transport Security (ATS). KB App programming will include all key developer-related features to ensure ATS security. Google Play (Android programming) does not conduct a similar security check; however, KB has extensive experience with developing and marketing both iOS and Android programmed apps using an established

protocol (SSL/TLS: Secure Sockets Layer/Transport Security Layer) and has never experienced a data breach. All usability testers will be informed that information being sent to and from their device will remain encrypted and password protected, and at any time they are allowed to opt-out and uninstall the app.

3.3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO PARTICIPANTS AND OTHERS

Potential benefits for all participants will be the knowledge that one has helped in development of an innovative method of maintaining the cessation of intoxicated driving. Participants may benefit by knowing that they are instrumental in developing the content that will help others.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify the participant. At most, the website will include a summary of the results. This website can be searched at any time.

3.4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

We are proposing two innovations with potential to enhance maintenance of changes in drinking that begin with the DWI conviction and installation of the IID by extending the reach of treatment into the offender's world through family-involved treatment and smartphone technology to reinforce treatment interventions. We believe these interventions have the potential to provide efficient means to decrease an important public health consequence of risky drinking and will add substantial original knowledge to the DWI field.

This study will be the first to use smartphone technology to extend and make permanent the cessation of intoxicated driving, providing an intervention that uses easily-accessible and diffusible technology.

3.3. DATA AND SAFETY MONITORING PLAN

A data safety and monitoring plan will be implemented for this project, following well-established procedures within KB and UNM. We will not set up an independent Data Safety and Monitoring Board because this trial is very low risk; does not include use of therapeutics; and physical risks are not anticipated. The progress of the research will be monitored monthly by the PI, Co-Investigators, Project Coordinator, and Project Biostatistician, who will meet bi-weekly to discuss the activities in the project, participant recruitment, and data collection. Any issues that the research scientist has identified will also be discussed at that time.

The study investigators have extensive experience in clinical trials organization and management, including data safety monitoring for single site and multisite trials. Relevant study staff will also be trained in monitoring and documenting adverse events.

Critical events will be reviewed by the investigators to ensure that project methods have not been intrusive or disruptive. Annual reports on data safety and monitoring are submitted to the IRBs. Compliance with data collection protocols will be monitored throughout data collection by the Investigators and Project Coordinator. The data management staff at KB will examine the quality of data input throughout the data collection period following standard quality control and assurance procedures (e.g., double entry of hard-copy coded data; detection and estimates of keystroke errors, identification of systematic mistakes in coding or responses; range checks). Analyses of the data will be performed by Dr. Cutter and Ms. Liu at the conclusion of the data collection period to assess distributional assumptions and the success of randomization. By having the Project Coordinator, Project Biostatistician and data management staff monitor the data, the PI's conflict of interest is reduced. The PI and Project Coordinator are responsible for reporting all adverse events to the IRBs. Only Grade 1 events are expected on this trial. Thus, adverse events will be reported annually, as required by DHHS. This report will be reviewed by the IRBs. Any action taken by the IRB or project investigators resulting in a temporary or permanent suspension of the trial will be communicated immediately by the PI to the NIH program officer.

All study staff will be required to report serious adverse events within 24 hours of their occurrence, regardless of their relevance to the study. The PI will be required to provide a report of all serious adverse events to the IRB within 24 hours of the reporting.

An annual report will be submitted to the IRB. This report will include all progress report categories.

The governance structure for the research team is designed to take advantage of the expertise of each investigator, consultant, and staff person, while minimizing overlap. The PI, Dr. Gill Woodall, is responsible for governance of the overall study and he will chair a Steering Committee comprised of the Co-Investigators (Drs. McCrady, Starling, and Westerberg and Ms. Berteletti), Biostatistical Advisor (Dr. Cutter), and Project Coordinator. The Steering Committee will communicate with NIH and IRBs. This Committee will meet weekly to make design and administration decisions, plan activities, track progress across sites, trouble-shoot problems, maintain consistency in actions, and implement quality controls. Major decisions concerning the project will be made within the Steering Committee with the ultimate decision-making responsibility residing with Dr. Woodall.

Four subcommittees will supervise important parts of the project. Dr. Woodall will chair the Recruitment Committee that will recruit the participating DWI Offenders and CFMs. Dr. Starling will be on this committee. Drs. Woodall and McCrady will co-chair the Intervention Development Committee and will be assisted by Dr. Westerberg, Ms. Berteletti, and the KB media developers. Drs. Starling and Woodall will Co-Chair the Data Collection Committee and survey the DWI Offenders and CFMs and obtain the cumulative IID lockout event data for the DWI offenders from the Santa Fe County DWI Program at the 9-month assessment point. Dr. Cutter, Project Biostatistician, will assist in the development of the procedures for the surveys and lockout event collection. This committee will work to ensure that all data collection procedures have detailed protocols. The Analysis Subcommittee, co-chaired by Dr. Cutter and Dr. Woodall with Drs. McCrady, Starling, and Westerberg and Ms. Berteletti as members, will plan and conduct all data management and analysis procedures. This subcommittee will develop a detailed data analysis plan and supervise work by KB's Biostatistical Manager to prepare all databases for analysis. The subcommittees will meet on a weekly, biweekly or monthly basis as needed depending on the project tasks and activities. Ad hoc committees will be formed to address specialized tasks as necessary. Dr. Woodall will supervise project activities at KB; Dr. Starling will supervise project activities at UNM; and Dr. Cutter will supervise project activities at Pythagoras, Inc.

The Project Coordinator at KB, Ms. Jeannyfer Reither, will assist Dr. Woodall with all aspects of the project. Ms. Reither will coordinate the relationships among the investigators and project staff, sit on the Steering Committee, and oversee the conduct of the study protocols. Ms. Liu (Biostatistical Manager) and Mr. Kramer (Data Assistant) will perform data management and Ms. Liu will assist Dr. Cutter with day-to-day data analysis tasks. Ms. Liu and Mr. Kramer will create data entry programs for printed forms. Dr. Woodall and Ms. Reither will work with the IRBs to obtain approval of all forms and procedures. Dr. Cutter, Ms. Liu, and Mr. Kramer will work together to ensure successful transfer of database files and performance of all analyses.

With investigators collaborating from two organizations, high quality communication among project staff and investigators will be maintained by using telephone, fax, email, web-assisted conference call technology, and Wrike, KB's new, robust, real-time, cloud-based work management software. We successfully conducted the Phase I research on the *B-SMART mobile web app* with investigators from these same institutions and Dr. Woodall has successfully conducted other multi-institution trials using these same communication methods. Regular meetings of the Steering Committee and subcommittees will take place using telephone and web conferencing technology. All investigators and staff will meet in person at KB three times each project year. Telephone and email will be used for day-to-day communication, as needed. With Wrike, the team is able to organize the important components of a project and break large deliverables into manageable pieces, attach files, communicate quickly, and assign tasks with due dates. It allows for live editing and file management to facilitate efficient collaboration amongst users. KB staff are equipped with full licenses to use all features of Wrike and investigators outside of KB will be provided with a collaborator license. Having project-related files, deliverables, and tasks in a centralized location greatly improves communication among investigators and research staff. Wrike practices industry-standard network protection procedures, including network segregation, firewall and router technologies, intrusion detection systems, log aggression and alert mechanisms. TLS technology protects information accessed in Wrike using both server authentication and data encryption. This is equivalent to network security methods used in banking and leading e-commerce sites. KB's IT manager oversees Wrike security and activity.

Conflicts will be handled through frank discussions within the Steering Committee and subcommittees. All sides of an issue or sources of the conflict will be discussed and a final decision will be rendered through group consensus when possible. Conflict arising from differences in interpersonal style will be handled by the PI, respecting the privacy of those involved. If conflict cannot be resolved within the research team, Dr. Valerie Myers, a Senior Scientist at KB who is a clinical psychologist and not a member of the research team, will serve as an outside mediator, meeting with both sides in the dispute and recommending ways to resolve it. If the conflict still cannot be resolved, a mediator from Mountain States Employer Council will be hired to mediate the dispute. This Council provides business advice and services to small businesses. KB has been a member of this Council for 11 years and regularly uses its business services. At that point, the research team will agree to make the mediator's decision binding. We have used these same management procedures to conduct successfully community-based research in previous multi-institutional projects.

Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	B-SMART Mobile Web App	The B-SMART mobile web app will contain four modules: 1) Supporting Abstinence, 2) Shared Positive Activities, 3) Common Challenges for Family Members with IID, and 4) Effective Communication. Within each module there will be a series of learning activities, including presentation text, interactive engagement, and videos. All app content will be available in both English and Spanish, based on user language preference.
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Usual and Customary Ignition Interlock Device Information	Participants randomized to the usual and customary care (UC) group will receive a website with a pamphlet on the IID installed in their vehicle and the manufacturer information provided about the IID in PDF format, in both English and Spanish. This constitutes a UC group, as such pamphlets are widely available to DWI offenders who have IIDs installed in their vehicles. Thus, providing this pamphlet represents a standard information provision for first-time DWI offenders and their CFMs.

4.2.d. Study Phase: Phase 3

Is this an NIH-defined Phase III Clinical Trial? ● Yes ○ No

4.2.e. Intervention Model: Parallel

4.2.f. Masking: ○ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation: Randomized

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Ignition Interlock Device Lockout Events	9-month follow-up posttest	The primary outcome measure will be frequency of IID lockout events from baseline to 9-month follow-up post-randomization, collected from the Santa Fe DWI Program database for each first-time DWI offender participant.
Secondary	Alcohol Use	Baseline, 3-month follow-up posttest, and 9-month follow-up posttest	Alcohol use by the DWI offender will be assessed with versions of the Form 90 adapted for online assessment for the CFMs (Form 90-ACS) and first-time DWI offenders (Form 90-AF). The Form 90 measures produce detailed quantity and frequency measure of alcohol use for the first-time offender.
Other	Family Functioning Scales	Baseline, 3-month follow-up posttest, and 9-month follow-up posttest	Family functioning will be assessed as a potential mediator of B-SMART effects, with DWI offenders and CFMs with three scales: (1) Family Environment Scale - Cohesion and Conflict subscales assesses offender and CFM perceptions of positive and negative family functioning; the two subscales selected are strongly associated with treatment outcome; (2) Family Communication Scale from FACES-IV assesses perception of quality of communication in the family; (3) Pleasant Events Schedule (adapted) assesses shared positive activities within a family.

Other	System Usability Scale	3-month follow-up posttest and 9-month follow-up posttest	The System Usability Scale consists of ten Likert strongly agree to disagree items that asks the respondent to rate the technology product being reviewed (Example items: I think that I would like to use this product frequently; I found the product very awkward to use; I felt very confident using the product). Participants also provide a final overall rating of the product along a 7-point worst imaginable to best imaginable dimension. This measure will be assessed with DWI offenders and CFMs in the intervention group.
Other	B-Smart Mobile Web App Use	3-month follow-up posttest and 9-month follow-up posttest	A custom program on the KB web server will track use of the B-SMART mobile web app. Users will register and use a password to access B-SMART and this password will be used to track use, keeping data about users private. Click-stream (pages visited), time spent on the B-SMART mobile web app, and number of individual visits to the mobile web app will be recorded.
Other	Demographic Characteristics	Baseline	The CASAA demographics form will collect information on participants' age, education, sex, and ethnicity.

4.4. Statistical Design and Power — 4.4_bsmart.pdf

4.5. Subject Participation Duration — 9 months

4.6. Will the study use an FDA-regulated intervention? — ❍ Yes ● No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.7. Dissemination Plan — 4.7_bsmart.pdf

Sample Size Determination

The sample size for the randomized trial in the Phase II research is designed to provide sufficient information for Phase III commercialization. The sample size assumes the counts of interlocks are Poisson distributed. We have assumed 4 interlocks over 9 months in the control arm or a rate of 0.44 per month for each DWI offender. In the *B-SMART mobile web app* group, we have assumed a reduction of 40% from 0.44, resulting in a rate of 0.27 per month. The null hypothesis is that the ratio of these two rates is 1.0 versus 0.6. Assuming a Type I error of 0.05 (2-sided), 90% power, sample size is only 27 DWI offenders per group. However, if the rate is higher up to 1 per month, the sample size required declines since the percent reductions yield wider absolute differences in the rates. We also are keen to know the reductions achievable with the *B-SMART* group, so we evaluated the sample size with regards to other effect sizes. In a Cochrane meta-analysis reported the impact of IIDs to reduce risk by 64%, but with a confidence interval that ranged from 76% to 37%. In the proposed trial, we have two treatment groups and may see less impact than that in the meta-analysis. Thus, a sample size of 119 DWI offenders per group will allow for 90% power with a comparison of 0.44 to 0.36 or approximately a 20% reduction in interlocks. We will adjust for an expected 15% attrition and this sample size also has sufficient sample size to evaluate the impact in various gender and ethnic subgroups. Thus, we propose to randomize 150 DWI offenders and 150 CFMs to each arm of the trial.

Outcome Analysis Plan

The trial is intended to evaluate the following hypotheses:

H1: First-time DWI offenders in the intervention group (*B-SMART mobile web app*) will have significantly fewer IID lockout events than participants in the control group (UC information condition).

H2: Lower rates of IID lockout events will be mediated by improvements in Family Functioning, Family Communication, and Shared Positive Family Events in the intervention (*B-SMART mobile web app)* condition compared to the UC information condition.

We will also analyze moderation of the effect of *B-SMART* by demographics and mediation of IID lockout events by *B-SMART* use in the intervention group.

Three levels of analysis are planned: (1) hypothesis testing using Poisson regression testing the differences in lockout events between the two intervention groups, (2) analysis of possible covariates (e.g., sex, ethnicity, and age of DWI offenders and CFMs), added to the Poisson regression and (3) other exploratory analyses.

Preliminary Analysis of Baseline Data. Descriptive data at baseline, with comparisons by treatment group, will be examined to check distributional characteristics and assess any concerns for imbalances that might be considered as covariates in analyses. The potential meaning of non-normality will be examined, i.e., excessive skewness potentially identifying key subgroups. These analyses will be at the level of the individual DWI offenders and CFMs responses and be conducted within 3 months of completion of recruitment. If there is excessive skewness on the IID lockout rates, negative binomial regression will be used.

Planned Analysis for Hypothesis 1. The second major analysis will focus on impact of the *B-SMART mobile web app* on primary (IID lockout events) and secondary (DWI offender's alcohol consumption) outcomes, and be completed within 1 month of the end of the posttest data collection in Year 2. The effect of *B-SMART* on IID lockout events in Hypothesis 1 will be tested primarily using PROC GENMOD with a Poisson link via SAS Version 9.4, which includes capabilities to test these Poisson models with missing data, account for the temporal design, and include information by participant. Participants will be treated as a random effect and treatment as a fixed effect, at p=0.05 (2-sided). Analyses of primary outcomes will not be released before completion of the intervention. Since CFM and DWI offender can be clustered within the same family, hierarchical models with participants nested within families will be considered.

The secondary outcome of quantity and frequency of alcohol consumption by DWI offenders will be compared in several ways. Quantity and frequency will be evaluated using Poisson models, as well as a

composite variable based on total alcohol consumption (the product of the two variables), using negative binomial regression models, unless a Poisson model is sufficient.

Since date of IID lockout events will collected and alcohol consumption is measured at all three assessments, we will examine the time by treatment interaction in the analyses of Hypothesis 1 to assess the question of the durability of the effects of B-SMART over time. For example, we will evaluate time to first lockout using a Kaplan Meier approach and the times to subsequent lockouts.

Mediation Analysis for Hypothesis 2. To address the predicted mediation effects of family function on improving the effect of the *B-SMART mobile web app* in Hypothesis 2, we will assess a formal effect on predicting fewer IID lockout events. Mediation will be tested by applying regression techniques from Judd and Kenny and elaborated by MacKinnon, with significance of mediation determined via interval estimation using bootstrapping. Ratio of indirect to total effects will estimate the proportion of the effect mediated. The primary mediational analysis will rely on temporal order of the posttests by examining the effect of *B-SMART* on change in the mediators from baseline to 3-month follow-up and in turn their association with changes in the IID lockout events from baseline to the 9-month follow-up and from 3- to 9-month follow-up.

Ancillary Analysis of Moderators. Potential moderators (see 3C.7.3) will be tested at p=.05 (2-tailed) unadjusted for multiple tests. For Hypothesis 1, they will be added as interactions by condition in a manner similar to regression testing for effect modification. Gender is included to probe differences by sex of student and employee. For Hypothesis 2, we will explore if improvements in IID lockout events produced by increases in family function by different participant groups (gender, ethnicity, etc.), using moderated mediational analyses. Moderation effects must be large to be detected, so these are ancillary tests.

Ancillary Analysis of the *B-SMART Mobile Web App* Exposure. The same mediational analysis techniques described in 3C.8.4 will be used to explore the relationship of exposure to the *B-SMART mobile web app* and pre-post changes in IID lockout events. Summed scores on exposure will be calculated from the SQL database (e.g., time on app, number of visits to the app, etc.) to assess intervention exposure.

A description of this study will be made available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify participants. At most, the website will include a summary of the results. This website can be searched at any time. The PI will ensure that the project is registered and results are submitted to ClinicalTrials.gov according to specific timelines as outlined in the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11). All informed consent documents will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov as outlined in the policy.

To ensure compliance, the PI and Project Coordinators will review the Final Rule Webinar Series and Protocol Registration and Results System (PRS User's Guide) and confirm understanding of knowledge and procedures with the Klein Buendel, Inc. (KB) Compliance Officer. KB (applicant organization) has a Quality Control procedure in place for registering all required data into ClinicalTrials.gov. The PI will be the responsible party for ensuring all documents are uploaded based on Final Rule policy. The KB Compliance Officer will independently monitor the timeliness of the uploads and will provide direct communication with the Multiple PIs if a procedure is out of compliance. A formal internal policy is in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

The *B-SMART mobile web app* will be disseminated commercially as described in the Commercialization Plan. The Commercialization Plan addresses five different potential markets for commercialization of *B-SMART*: 1) DWI Offenders with Court-mandated Ignition Interlock Devices, an estimated 300,000 users; 2) Ignition Interlock Device Manufacturing Companies, eight different companies currently in the market; 3) DWI Schools – almost 3700 schools typically working under the auspices of court systems currently exist in the U.S.; 4) Magistrate and DWI Courts – which oversee and supervise the remediary and probation activities of offenders and sentence offenders to Ignition Interlock Device use; and 5) Automobile Insurance Associations, Companies, Agents and Brokers – whose business practices and policies are greatly affected by DWI convictions. These five separate markets hold great potential for the commercialization of *B-SMART*.

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

REFERENCES

1. National Center for Statistics and Analysis. *2015 Motor Vehicle Crashes: Overview*. Washington, DC: National Highway Traffic Safety Administration;2016. DOT HS 812 318.
2. Brown TG, Dongier M, Ouimet MC, et al. Brief motivational interviewing for DWI recidivists who abuse alcohol and are not participating in DWI intervention: a randomized controlled trial. *Alcoholism: Clinical and Experimental Research*. 2010;34(2):292-301.
3. Bjerre B, Laurell H. The Swedish alcohol ignition interlock programme. Paper presented at: International Conference on Alcohol, Drugs and Traffic Safety; 2000 2000; Stockholm, Sweden.
4. Woodall WG, Buller DB, Saba L, et al. Effect of emailed messages on return use of a nutrition education website and subsequent changes in dietary behavior. *Journal of Medical Internet Research*. 2007;9(3):e27. doi: 10.2196/jmir.9.3.e27
5. State ignition interlock laws. National Conference of State Legislators Web site. Available at: http://www.ncsl.org/issues-research/transport/state-ignition-interlock-laws.aspx. Published 2012. Updated December 2016. Accessed April 4, 2018.
6. Coben JH, Larkin GL. Effectiveness of ignition interlock devices in reducing drunk driving recidivism. *American Journal of Preventive Medicine*. 1999;16(1):81-87.
7. Willis C, Lybrand S, Bellamy N. Alcohol ignition interlock programmes for reducing drink driving recidivism. *Cochrane Database of Systematic Reviews*. 2004;18(4):CD004168.
8. Litt MD, Kadden RM, Kabela-Cormier E, Petry NM. Changing network support for drinking: Network Support Project two-year follow-up. *Journal of Consulting and Clinical Psychology*. 2009;77(2):229.
9. McCrady BS, Epstein EE, Cook S, Jensen N, Hildebrandt T. A randomized trial of individual and couple behavioral alcohol treatment for women. *Journal of Consulting and Clinical Psychology*. 2009;77(2):243.
10. Brendryen H, Kraft P. Happy ending: a randomized controlled trial of a digital multi-media smoking cessation intervention. *Addiction*. 2008;103(3):478-484.
11. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *American Journal of Preventive Medicine*. 2009;36(2):165-173.
12. Woodall WG, Delaney H, Rogers E, Wheeler DR. A randomized trial of victim impact panels DWI deterrence effectiveness. Poster presented at the annual conference of the Research Society on Alcoholism; Denver, CO.
13. Woodall WG, Starling R, Saltz R, Buller DB. A randomized trial of a DWI intervention program for first offenders: Intervention outcomes and interactions with anti-social personality disorder among a primarily American Indian sample. *Alcoholism: Clinical and Experimental Research*. 2007;31:1-14.
14. Gruenewald PJ, Johnson FW, Treno AJ. Outlets, drinking and driving: a multilevel analysis of availability. *Journal of Studies on Alcohol and Drugs*. 2002;63(4):460.
15. McCrady BS, Epstein EE, Hirsch LS. Maintaining change after conjoint behavioral alcohol treatment for men: outcomes at 6 months. *Addiction*. 1999;94(9):1381-1396.
16. McCrady BS, Stout R, Noel, Abrams, Nelson. Effectiveness of three types of spouse-involved behavioral alcoholism treatment. *British Journal of Addiction*. 1991;86(11):1415-1424.
17. Holder HD, Treno AJ. Media advocacy in community prevention: news as a means to advance policy change. *Addiction*. 1997;92(6s1):189-200.
18. McCrady BS, Epstein EE, Kahler CW. Alcoholics anonymous and relapse prevention as maintenance strategies after conjoint behavioral alcohol treatment for men: 18-month outcomes. *Journal of Consulting and Clinical Psychology*. 2004;72(5):870-877.
19. Woodall WG, Starling R, Saltz RF, Buller DB, Stangetta P. Results of a randomized trial of Web-based retail onsite responsible beverage service training: WayToServe. *Journal of Studies on Alcohol and Drugs*. 2018. In press.
20. Dresser J, Starling R, Woodall WG, Stanghetta P, May PA. Field trial of alcohol-server training for prevention of fetal alcohol syndrome. *Journal of Studies on Alcohol and Drugs*. 2011;72(3):490.
21. Ker K, Chinnock P. Interventions in the alcohol server setting for preventing injuries (Review). *Cochrane Database of Systematic Reviews*. 2008;16(3): CD005244.
22. Saltz RF, Woodall WG, Wheeler DR. Does gender matter when serving obviously-intoxicated patrons? Paper presented at: Scientific Meeting of The Research Society on Alcoholism2001; Montreal, Canada.
23. Lacey JH, Ferguson SA, Kelley-Baker T, Rider RP. Low-manpower checkpoints: can they provide effective DUI enforcement in small communities? *Traffic Injury Prevention*. 2006;7(3):213-218.

24. Nochajski TH, Stasiewicz PR. Relapse to driving under the influence (DUI): a review. *Clinical Psychology Review*. 2006;26(2):179-195.
25. Beck KH, Rauch WJ, Baker EA, Williams AF. Effects of ignition interlock license restrictions on drivers with multiple alcohol offenses: a randomized trial in Maryland. *American Journal of Public Health*. 1999;89(11):1696-1700.
26. Frank JF, Raub R, Lucke RE, Wark RI. Illinois ignition interlock evaluation. Paper presented at 16th International Conference on Alcohol, Drugs and Traffic Safety; Montreal, Canada: 2002.
27. Vezina L. The Quebec alcohol ignition interlock program: impact on recidivism and crashes. 2002.
28. Voas RB, Marques PR, Tippetts AS, Beirness DJ. The Alberta interlock program: the evaluation of a province-wide program on dui recidivism. *Addiction*. 1999;94(12):1849-1859.
29. Donovan DM, Salzberg PM, Chaney EF, Queisser HR, Marlatt GA. Prevention skills for alcohol-impaired drivers. *Alcohol, Drugs and Driving*. 1990;6:169-188.
30. Wells-Parker ES, Bangert-Drowns R, McMillen R, Williams M. Final results from a meta-analysis of remedial interventions with drink/drive offenders. *Addiction*. 1995;90(7):907-926.
31. Dill PL, Wells-Parker E. Court-mandated treatment for convicted drinking drivers. *Alcohol Research & Health: The Journal of the National Institute on Alcohol Abuse and Alcoholism*. 2006;29(1):41.
32. McCrady BS, Epstein EE. *Overcoming Alcohol Problems: A Couples-Focused Program Workbook*. Oxford University Press, USA; 2008.
33. Manuel JK, Austin JL, Miller WR, et al. Community reinforcement and family training: a pilot comparison of group and self-directed delivery. *Journal of Substance Abuse Treatment*. 2012;43(1):129-136.
34. Moos RH. Theory-based processes that promote the remission of substance use disorders. *Clinical Psychology Review*. 2007;27(5):537-551.
35. Fals-Stewart W, Birchler GR, O'Farrell TJ. Behavioral couples therapy for male substance-abusing patients: effects on relationship adjustment and drug-using behavior. *Journal of Consulting and Clinical Psychology*. 1996;64(5):959.
36. Santisteban DA, Perez-Vidal A, Coatsworth JD, et al. Efficacy of brief strategic family therapy in modifying Hispanic adolescent behavior problems and substance use. *Journal of Family Psychology*. 2003;17(1):121.
37. Ossip-Klein DJ, Rychtarik RG, O'Farrell TJ. Behavioral contracts between alcoholics and family members: improving aftercare participation and maintaining sobriety after inpatient alcoholism treatment. *Treating alcohol problems: Marital and Family Interventions*. 1993:281-304.
38. Azrin NH, Sisson RW, Meyers R, Godley M. Alcoholism treatment by disulfiram and community reinforcement therapy. *Journal of Behavior Therapy and Experimental Psychiatry*. 1982;13(2):105-112.
39. Powers MB, Vedel E, Emmelkamp PM. Behavioral couples therapy (BCT) for alcohol and drug use disorders: a meta-analysis. *Clinical Psychology Review*. 2008;28(6):952-962.
40. Fals-Stewart W, Lam WKK. Brief behavioral couples therapy for drug abuse: a randomized clinical trial examining clinical efficacy and cost-effectiveness. *Families, Systems, & Health*. 2008;26(4):377.
41. O'Farrell TJ, Murphy M, Alter J, Fals-Stewart W. Brief family treatment intervention to promote continuing care among alcohol-dependent patients in inpatient detoxification: a randomized pilot study. *Journal of Substance Abuse Treatment*. 2008;34(3):363-369.
42. Zweben A, Pearlman S, Li S. A comparison of brief advice and conjoint therapy in the treatment of alcohol abuse: yhe results of the marital systems study. *British Journal of Addiction*. 1988;83(8):899-916.
43. Boulos MN, Wheeler S, Tavares C, Jones R. How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. *Biomedical Engineering*. 2011;10:24.
44. Lindquist AM, Johansson PE, Petersson GÝI, Saveman BI, Nilsson GC. The use of the Personal Digital Assistant (PDA) among personnel and students in health care: a review. *Journal of Medical Internet Research*. 2008;10(4):e31. doi: doi: 10.2196/jmir.1038
45. Blaya JA, Fraser HSF, Holt B. E-health technologies show promise in developing countries. *Health Affairs*. 2010;29(2):244-251.
46. Lim MS, Hocking JS, Hellard ME, Aitken CK. SMS STI: a review of the uses of mobile phone text messaging in sexual health. *International Journal of STD & AIDS*. 2008;19(5):287-290.

47. Fukuoka Y, Kamitani E, Bonnet K, Lindgren T. Real-time social support through a mobile virtual community to improve healthy behavior in overweight and sedentary adults: a focus group analysis. *Journal of Medical Internet Research*. 2011;13(3):e49. doi: 10.2196/jmir.1770
48. Chomutare T, Fernandez-Luque L, ...rsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. *Journal of Medical Internet Research*. 2011;13(3): e65. doi: 10.2196/jmir.1874.
49. Mougiakakou SG, Kouris I, Iliopoulou D, Vazeou A, Koutsouris D. Mobile technology to empower people with diabetes mellitus: design and development of a mobile application. Paper presented at: Information Technology and Applications in Biomedicine, 2009. ITAB 2009. 9th International Conference on; 4-7 Nov. 2009 2009.
50. Smokefree smartphone applications: about the NCI QuitPal app. Smokefree.gov Web site. Available at: http://smokefree.gov/apps-quitpal. Published 2013. Accessed April 2, 2018.
51. McClernon FJ. Development of a smartphone-based virtual sensor for detecting smoking behavior. 2013.
52. Buller DB, Borland R, Bettinghaus EP, Shane JH, Zimmerman MA. Randomized trial of a smartphone mobile application compared to text messaging to support smoking cessation. *Telemedicine Journal and eHealth*. 2014;20(3):206-214.PMC3934597
53. Litvin EB, Abrantes AM, Brown RA. Computer and mobile technology-based interventions for substance use disorders: an organizing framework. *Addictive Behaviors*. 2013;38(3):1747-1756.
54. Buller DB, Berwick M, Shane J, Kane I, Lantz K, Buller MK. User-centered development of a smart phone mobile application delivering personalized real-time advice on sun protection. *Translational Behavioral Medicine*. 2013;3(3):326-334.PMC3771005
55. West JH, Hall PC, Hanson CL, Barnes MD, Giraud-Carrier C, Barrett J. There's an app for that: content analysis of paid health and fitness apps. *Journal of Medical Internet Research*. 2012;14(3):e72. doi: 10.2196/jmir.1977.
56. Sposaro F, Tyson G. iFall: an Android application for fall monitoring and response. *Engineering in Medicine and Biology Society, 2009. EMBC 2009. Annual International Conference of the IEEE*: IEEE; 2009:6119-6122.
57. Tsai CC, Lee G, Raab F, et al. Usability and feasibility of PmEB: a mobile phone application for monitoring real time caloric balance. *Mobile Networks and Applications*. 2007;12(2-3):173-184.
58. Rainie L, Perrin A. 10 facts about smartphones as the iPhone turns 10. *FactTank*. June 28, 2017. http://www.pewresearch.org/fact-tank/2017/06/28/10-facts-about-smartphones/. Accessed April 4, 2018.
59. Topher. Smartphone apps look to reduce DUI arrests. *Check Points*. Vol 2015: Total DUI Web site; 2013. Available at: http://www.totaldui.com/blog/smartphone-apps-look-to-reduce-dui-arrests/.
60. Buller DB, Borland R, Woodall WG, et al. Randomized trials on Consider This, a tailored, internet-delivered smoking prevention program for adolescents. *Health Education & Behavior*. 2008;35(2):260-281.PMC4380290
61. Buller DB, Woodall WG, Zimmerman DE, et al. Randomized trial on the 5 A Day, the Rio Grande Way website, a web-based program to improve fruit and vegetable consumption in rural communities. *Journal of Health Communication*. 2008;13(3):230-249.PMC4376106
62. Woodall W, Zimmerman D, Stapel L, et al. Systematic development of a website to reduce risky college alcohol consumption. Paper presented at: Society for Prevention Research Annual Meeting; May 30 - June 1 2007; Washington, D.C.
63. Woodall GW, Saltz R, Buller D, Starling R, Stanghetta P. Results of a randomized trial of web-based responsible beverage service training: WayToServe.org. Paper presented at: Poster presented at the annual meeting of the Society for Prevention Research2012; Washington, DC.
64. Woodall WG, Starling R, Buller D, Donohew L, Zimmerman R, Helme D. DA018575: Web-based substance abuse and STD/HIV prevention. Application funded by the national institute on drug abuse. 2009. Available at: http://projectreporter.nih.gov/project_info_description.cfm?aid=7914379&icde=23322944&ddparam=&ddvalue=&ddsub=&cr=8&csb=default&cs=ASC. Accessed April 3, 2018.
65. Fost N. Parents as decision makers for children. *Primary care*. 1986;13(2):285-293.
66. Woodall WG, Starling R, Wheeler C, Bryan A, Buller D. AI084081: Web enhanced adoption of HPV vaccine in minority communities. 2009. Available at: http://projectreporter.nih.gov/project_info_description.cfm?aid=7763578&icde=23322944&ddparam=&ddvalue=&ddsub=&cr=7&csb=default&cs=ASC. Accessed March 31, 2018.

67. Buller DB, Berwick M, Lantz K, et al. Smartphone mobile application delivering personalized, real-time sun protection advice: a randomized clinical trial. *JAMA Dermatology*. 2015 May;151(5):497-504. PMC4431912
68. Voas RB. Enhancing the use of vehicle alcohol interlocks with emerging technology. *Alcohol Research : Current Reviews*. 2014;36(1):81-89.
69. Roth R. Survey of Currently Installed Interlocks in the U.S. Available at: http://rotherinterlock.org/2012surveyofcurrentlyinstalledinterlocksintheus.pdf. 2012. Accessed April 4, 2018.
70. Elder RW, Voas R, Beirness D, et al. Effectiveness of ignition interlocks for preventing alcohol-impaired driving and alcohol-related crashes: a Community Guide systematic review. *American Journal of Preventive Medicine*. 2011;40(3):362-376.
71. Timken DS, Nandi A, Marques P. *Interlock Enhancement Counseling: Enhancing Motivation For Responsible Driving - A Provider's Guide*. Boulder, CO: Center for Impaired Driving Research and Evaluation; 2012.
72. Marques P, Voas R. Are we near a limit or can we get more safety from vehicle alcohol interlocks? *Addiction*. 2013;108(4):657-658.
73. Voas RB, Tippetts AS, Bergen G, Grosz M, Marques P. Mandating treatment based on interlock performance: evidence for effectiveness. *Alcoholism: Clinical and Experimental Research*. 2016;40(9):1953-1960. doi: 10.1111/acer.13149
74. The National Highway Traffic Safety Administration. The role of alcohol beverage control agencies in the enforcement and adjudication of alcohol laws. Available at: http://www.nllea.org/documents/RoleofABCsNHTSA.pdf. 2005. Accessed April 3 ,2018.
75. The Wisconsin Department of Transportation. Drive sober smartphone app. Google Play App Market Web site. Available at: https://play.google.com/store/apps/details?id=air.com.goelement.widot&hl=en. Published 2013. Accessed April 3, 2018.
76. MADD. Fifth Anniversary Report to the Nation. Available at: http://www.talklikemadd.org/books/statereport/index.html#/1/. Published 2011. Accessed April 4, 2018.
77. National Highway Traffic Safety A, Transportation USDo. Digest of impaired driving and selected beverage control laws. Twenty-sixth edition. Current as of June 1, 2011. Available at: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=15&ved=0CFkQFjAEOAo&url=http%3A%2F%2Fwww.nhtsa.gov%2Fstaticfiles%2Fnti%2Fpdf%2F811673.pdf&ei=Utj_Ub6ZD7e64APUt4DQBw&usg=AFQjCNGN8fc9R207_b9HZw848PF9g_yYZA. Accessed April 4, 2018.
78. Center for Behavioral Health Statistics, National Survey of Substance Abuse Treatment Services. Table 2.2. Facility operation and primary focus of facility: 2007-2011: number and percent distribution. Substance Abuse and Mental Health Services Administration Website. Available at: http://www.samhsa.gov/data/DASIS/2k11nssats/NSSATS2011Tbl2.2.htm. Accessed April 2, 2018.
79. State-by-state DUI penalties. FindLaw Web site. Available at: http://dui.findlaw.com/dui-laws-resources/state-by-state-dui-penalties.html. Accessed April 4, 2018.
80. *iTunes* [computer program]. Apple, Inc.; 2013.
81. Google play app store: "Sobriety testing" search results. Google Play Web site. Available at: https://play.google.com/store/search?q=sobriety%20testing&c=apps. Published 2013. Accessed April 2, 2018.
82. Google play app store: "Drink tracker" search results. Google Play Web site. Available at: https://play.google.com/store/search?q=Drink%20tracker&c=apps. Published 2013. Accessed April 2, 2018.
83. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. *International Journal of Human-Computer Interaction*. 2008;24(6):574-594.
84. McCrady BS, Woodall WG, Starling R, Westerberg V, Griffith J, Burris S. Usability test of a smartphone web app for DWI offender families: the B-SMART app. Annual Conference of the Research Society on Alcoholism; New Orleans, LA.
85. broadbandnow. Broadband Service in New Mexico. Available at: http://broadbandnow.com/New-Mexico. Published 2015. Accessed March 31, 2018.
86. Marques PR, Tippetts AS, Voas RB, Beirness DJ. Predicting repeat DUI offenses with the alcohol interlock recorder. *Accident Analysis and Prevention*. 2001;33(5):609-619.

87. Marques PR, Tippetts AS, Voas RB. The alcohol interlock: an underutilized resource for predicting and controlling drunk drivers. *Traffic Injury Prevention*. 2003;4(3):188-194.
88. Marques PR, Tippetts AS, Voas RB. Comparative and joint prediction of DUI recidivism from alcohol ignition interlock and driver records. *Journal of Studies on Alcohol*. 2003;64(1):83-92.
89. Voas RB, Tippetts S, Grasz M. Recidivism following interlock: any evidence of change? Paper presented at: 20th International Council on Alcohol, Drugs and Traffic Safety (ICADTS)2013; Brisbane, Queensland, Australia.
90. Tonigan JS, Miller WR, Brown JM. The reliability of Form 90: an instrument for assessing alcohol treatment outcome. *Journal of Studies on Alcohol*. 1997;58(4):358-364.
91. Grant KA, Tonigan JS, Miller WR. Comparison of three alcohol consumption measures: a concurrent validity study. *Journal of Studies on Alcohol*. 1995;56(2):168-172.
92. Moos R, Moos B. *Family Environmental Scale Manual and Sampler Set: Development, Applications and Research*. 4 ed. Palo Alto, CA: Mind Garden; 2009.
93. Olson D. FACES IV and the Circumplex Model: validation study [published online ahead of print Jan]. *Journal of Marital and Family Therapy*. 2011;37(1):64-80. doi: 10.1111/j.1752-0606.2009.00175.x
94. MacPhillamy DJ, Lewinsohn PM. The pleasant events schedule: studies on reliability, validity, and scale intercorrelation. *Journal of Consulting and Clinical Psychology*. 1982;50(3):363-380.
95. Hall JR, Ax BJ, Frank CA, et al. Challenges to producing and implementing the Consider This web-based smoking prevention and cessation program. *The Electronic Journal of Communication*. 2001;11(3 and 4).
96. Judd C, Kenny D. Process analysis: estimating mediation in treatment evaluations. *Eval Rev*. 1981;5:602-619.
97. MacKinnon D. *Introduction to Statistical Mediation Analysis*. New York: Erlbaum; 2008.
98. Edwards JR, Lambert LS. Methods for integrating moderation and mediation: a general analytical framework using moderated path analysis. *Psychological Methods*. 2007;12(1):1-22.
99. MacKinnon DP, Lockwood CM, Williams J. Confidence limits for the indirect effect: distribution of the product and resampling methods. *Multivariate Behav Res*. 2004;39(1):99.
100. Things are looking app. *The Economist*: The Economist Newspaper Limited; 2016:2.
101. research2guidance. mHealth App Developer Economics 2016: The Current Status and Trends of the mHealth App Market. Published October 2016.
102. Federal Bureau of Investigations. Crime in the United States, 2010: Table 29, Estimated Number of Arrests. FBI Uniform Crime Reports. Federal Bureau of Investigation Web site. Available at: www.fbi.gov/about-us/cjis/ucr/crime-in-the-u.s/2010/crime-inthe-u.s.-2010/tables/10tbl29.xls. Published 2012. Accessed April 4, 2018.
103. Mothers Against Drunk Driving. *Ignition Interlock Institutes: Promoting the Use of Interlocks and Improvements to Interlock Programs*. Washington, D.C.: National Highway Traffic Safety Administration;2013, July. DOT HS 811 815.
104. Mayer R. *Ignition Interlocks - A Toolkit for Program Administrators, Policymakers, and Stakeholder*. Washington, D.C.: National Highway Traffic Safety Administration;2014, February. DOT HS 811 883.
105. State laws mandating interlocks for all DUI offenders save lives. *IIHS News*. March 29, 2018. http://www.iihs.org/iihs/news/desktopnews/state-laws-mandating-interlocks-for-all-dui-offenders-save-lives. Accessed April 4, 2018.
106. Casanova TD, Wanlaar WGM, Robertson RD. 2016 Annual Ignition Interlock Survey: United States. Published May 2017.
107. Fielder K, Brittle C, Stafford S. *Case Studies of Ignition Interlock Programs*. Washington, D.C.: National Highway Traffic Safety Administration;2012. DOT HS 811 594.
108. Ignition interlock devices manufacturers in the United States. Manta Web site. Available at: https://www.manta.com/mb_35_E12B67Y4_000/ignition_interlock_devices_manufacturers. Accessed April 5, 2018.
109. North American ignition interlock devices market revenue to expand at a CAGR of 5.6% between 2015 and 2021, driven by stringent NHTSA regulations [press release]. Persistence Market Research, February 11.Available at: https://www.persistencemarketresearch.com/mediarelease/north-america-ignition-interlock-devices-market.asp. Accessed April 4, 2018.
110. The high cost of a DUI. BACtrack Web site. Available at: https://www.bactrack.com/blogs/expert-center/35042565-the-high-cost-of-a-dui. Accessed April 4, 2018.
111. Where to find DUI classes online. Find Law Web site. Available at: http://dui.findlaw.com/dui-cases/where-to-find-dui-classes-online.html. Accessed April 4, 2018.

112. *Substance Abuse and Mental Health Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2016. Data on Substance Abuse Treatment Facilities*. Rockville, MD: Substance Abuse and Mental Health Services Administration;2017. HHS Publication No. (SMA) 17-5039.
113. AAA. DUI/drug courts. DUI Justice Link. AAA Web site. Accessed April 4, 2018.
114. The 10 largest auto insurance companies. Nerd Wallet Web site. Available at: https://www.nerdwallet.com/blog/insurance/car-insurance-basics/largest-auto-insurance-companies/. Published 2018. Accessed April 5, 2018.
115. Statista. Number of agents, brokers and service employees in the insurance industry in the United States from (in thousands). Statista Web site. Available at: https://www.statista.com/statistics/194232/number-of-us-insurance-brokers-and-service-employees/. Accessed April 5, 2018.
116. Higgins A. Will an interlock breathalyzer earn me an insurance discount? Net Quote Web site. Available at: https://www.netquote.com/auto-insurance/interlock-breathalyzer. Accessed April 4, 2018.
117. Ignition interlock devices may help get you cheap SR22 insurance. Cheap Insurance Web site. Available at: http://www.cheapinsurance.com/ignition-interlock-devices-may-help-get-cheap-sr22-insurance/. Published 2017. Accessed April 5, 2018.
118. Dev R. Patent protection of mobile [smartphone] applications - Android, Apple, Microsoft & Blackberry apps. *Rahul Dev's Website*.
119. Hindy J. 15 best Android fitness apps and workout apps. *Android Authority*. April 1, 2018. https://www.androidauthority.com/best-android-fitness-apps-and-workout-apps-567999/ Accessed April 4, 2018.
120. Duffy J. The 25 best fitness apps of 2017. *PC Mag UK*. December 28, 2016. http://uk.pcmag.com/apps/42450/guide/the-25-best-fitness-apps-of-2017 Accessed April 4, 2018.

STATISTICAL ANALYSIS PLAN

Sample Size Determination

The sample size for the randomized trial in the Phase II research is designed to provide sufficient information for Phase III commercialization. The sample size assumes the counts of interlocks are Poisson distributed. We have assumed 4 interlocks over 9 months in the control arm or a rate of 0.44 per month for each DWI offender. In the *B-SMART mobile web app* group, we have assumed a reduction of 40% from 0.44, resulting in a rate of 0.27 per month. The null hypothesis is that the ratio of these two rates is 1.0 versus 0.6. Assuming a Type I error of 0.05 (2-sided), 90% power, sample size is only 27 DWI offenders per group. However, if the rate is higher up to 1 per month, the sample size required declines since the percent reductions yield wider absolute differences in the rates. We also are keen to know the reductions achievable with the *B-SMART* group, so we evaluated the sample size with regards to other effect sizes. In a Cochrane meta-analysis reported the impact of IIDs to reduce risk by 64%, but with a confidence interval that ranged from 76% to 37%. In the proposed trial, we have two treatment groups and may see less impact than that in the meta-analysis. Thus, a sample size of 119 DWI offenders per group will allow for 90% power with a comparison of 0.44 to 0.36 or approximately a 20% reduction in interlocks. We will adjust for an expected 15% attrition and this sample size also has sufficient sample size to evaluate the impact in various gender and ethnic subgroups. Thus, we propose to randomize 150 DWI offenders and 150 CFMs to each arm of the trial.

Outcome Analysis Plan

The trial is intended to evaluate the following hypotheses:

H1: First-time DWI offenders in the intervention group (*B-SMART mobile web app*) will have significantly fewer IID lockout events than participants in the control group (UC information condition).

H2: Lower rates of IID lockout events will be mediated by improvements in Family Functioning, Family Communication, and Shared Positive Family Events in the intervention (*B-SMART mobile web app)* condition compared to the UC information condition.

We will also analyze the moderation of the effect of *B-SMART* by demographics and mediation of IID lockout events by *B-SMART* use in the intervention group.

Three levels of analysis are planned: (1) hypothesis testing using Poisson regression testing the differences in lockout events between the two intervention groups, (2) analysis of possible covariates (e.g., sex, ethnicity, and age of DWI offenders and CFMs), added to the Poisson regression and (3) other exploratory analyses.

Preliminary Analysis of Baseline Data. Descriptive data at baseline, with comparisons by treatment group, will be examined to check distributional characteristics and assess any concerns for imbalances that might be considered as covariates in analyses. The potential meaning of non-normality will be examined, i.e., excessive skewness potentially identifying key subgroups. These analyses will be at the level of the individual DWI offenders and CFMs responses and be conducted within 3 months of completion of recruitment. If there is excessive skewness on the IID lockout rates, negative binomial regression will be used.

Planned Analysis for Hypothesis 1. The second major analysis will focus on impact of the *B-SMART mobile web app* on primary (IID lockout events) and secondary (DWI offender's alcohol consumption) outcomes and be completed within 1 month of the end of the posttest data collection in Year 2. The effect of *B-SMART* on IID lockout events in Hypothesis 1 will be tested primarily using PROC GENMOD with a Poisson link via SAS Version 9.4, which includes capabilities to test these Poisson models with missing data, account for the temporal design, and include information by participant. Participants will be treated as a random effect and treatment as a fixed effect, at p=0.05 (2-sided). Analyses of primary outcomes will not be released before completion of the intervention. Since CFM and DWI offender can be clustered within the same family, hierarchical models with participants nested within families will be considered.

The secondary outcome of quantity and frequency of alcohol consumption by DWI offenders will be compared in several ways. Quantity and frequency will be evaluated using Poisson models, as well as a composite variable based on total alcohol consumption (the product of the two variables), using negative binomial regression models, unless a Poisson model is sufficient.

Since date of IID lockout events will collected and alcohol consumption is measured at all three assessments, we will examine the time by treatment interaction in the analyses of Hypothesis 1 to assess the

question of the durability of the effects of B-SMART over time. For example, we will evaluate time to first lockout using a Kaplan Meier approach and the times to subsequent lockouts.

Mediation Analysis for Hypothesis 2. To address the predicted mediation effects of family function on improving the effect of the *B-SMART mobile web app* in Hypothesis 2, we will assess a formal effect on predicting fewer IID lockout events. Mediation will be tested by applying regression techniques from Judd and Kenny and elaborated by MacKinnon, with significance of mediation determined via interval estimation using bootstrapping. Ratio of indirect to total effects will estimate the proportion of the effect mediated. The primary mediational analysis will rely on temporal order of the posttests by examining the effect of *B-SMART* on change in the mediators from baseline to 3-month follow-up and in turn their association with changes in the IID lockout events from baseline to the 9-month follow-up and from 3- to 9-month follow-up.

Ancillary Analysis of Moderators. Potential moderators (see 3C.7.3) will be tested at p=.05 (2-tailed) unadjusted for multiple tests. For Hypothesis 1, they will be added as interactions by condition in a manner similar to regression testing for effect modification. Gender is included to probe differences by sex of student and employee. For Hypothesis 2, we will explore if improvements in IID lockout events produced by increases in family function by different participant groups (gender, ethnicity, etc.), using moderated mediational analyses. Moderation effects must be large to be detected, so these are ancillary tests.

Ancillary Analysis of the *B-SMART Mobile Web App* Exposure. The same mediational analysis techniques described in 3C.8.4 will be used to explore the relationship of exposure to the *B-SMART mobile web app* and pre-post changes in IID lockout events. Summed scores on exposure will be calculated from the SQL database (e.g., time on app, number of visits to the app, etc.) to assess intervention exposure.