OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION

Organizational DUNS*: 0788206480000

Legal Name*: REAL PREVENTION, LLC
Department:
Division:
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 070134007

Person to be contacted on matters involving this application

Prefix: First Name*: Ann Middle Name: Last Name*: Bolser Suffix:
Position/Title: CFO/Business Manager
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 07013-4007
Phone Number*: 814-360-0203 Fax Number: 877-631-0766 Email: ann@real-prevention.com

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 46-2906812

7. TYPE OF APPLICANT* R: Small Business

Other (Specify):
Small Business Organization Type ❍Women Owned ❍Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍Resubmission
❍ Renewal ❍Continuation ❍Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍B. Decrease Award ❍C. Increase Duration
❍ D. Decrease Duration ❍E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Feasibility of a mobile parent-based intervention to reduce alcohol use by high school seniors

12. PROPOSED PROJECT
Start Date* Ending Date*
04/01/2019 03/31/2021

13. CONGRESSIONAL DISTRICTS OF APPLICANT
NJ-009

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Michael Middle Name: Last Name*: Hecht Suffix:
Position/Title: President
Organization Name*: REAL PREVENTION, LLC
Department:
Division:
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 070130000
Phone Number*: 814-360-1893 Fax Number: Email*: hechtpsu@gmail.com

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$1,479,836.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$1,479,836.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ❍ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
❍ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: Dr. First Name*: Michael Middle Name: Last Name*: Hecht Suffix:
Position/Title*: President
Organization Name*: REAL Prevention LLC
Department:
Division:
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 07013-4007
Phone Number*: 814-360-1893 Fax Number: 877-631-0766 Email*: michael@real-prevention.com

Signature of Authorized Representative*
Michael Hecht

Date Signed*
08/31/2018

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:Cover_Letter_PBIm_Phase_2.pdf

424 R&R and PHS-398 Specific
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OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: REAL Prevention LLC
Duns Number: 0788206480000
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 07013-4007
Project/Performance Site Congressional District*: NJ-009

Project/Performance Site Location 1

❍I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: GfK Custom Research, LLC
DUNS Number:
Street1*: 1230 Midas Way, Suite 100
Street2:
City*: Sunnyvale
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94085-4068
Project/Performance Site Congressional District*:

Project/Performance Site Location 2

❍I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Klein Buendel, Inc.
DUNS Number: 1179360420000
Street1*: 1667 Cole Boulevard, Suite 225
Street2:
City*: Golden
County:
State*: CO: Colorado
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 80401-3313
Project/Performance Site Congressional District*:

Project/Performance Site Location 3

❍I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Rutgers, The State University of New Jersey
DUNS Number: 0787958800000
Street1*: 4 Huntington Street
Street2:
City*: New Brusnwick
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 08901-1071
Project/Performance Site Congressional District*: NJ-006

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _1 __ 2 __ 3 __ 4 __ 5 __ 6 __ 7 __ 8 If

NO, is the IRB review Pending? ❍ **Yes** ● **No**

IRB Approval Date: 03-27-2015

Human Subject Assurance Number 00022919

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Project_Summary_-_PBIm_P2_final_8-30-2018.pdf
8. Project Narrative*	Project_Narrative_-_PBIm_P2_final.pdf
9. Bibliography & References Cited	PN_References_final_8.27.18.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources_PBM_9-18.pdf
11.Equipment	
12. Other Attachments	SBC_000406995.pdf

The goal of this Phase II SBIR is to provide an efficient, engaging, and effective means to enhance parents' ability to reduce prevalence of alcohol use and consequences, and other substance use through the development and evaluation of Parenting Now (PN). PN is a brief, interactive, self-paced, and digital curriculum for parents of high-school-aged adolescents, a frequently neglected population created from the evidence-based Parent Handbook,[1-3] available in hard copy and DVD for college-bound youth only. The curriculum is needed because most parent-based prevention interventions target children or young adolescents, neglecting older adolescents, despite that fact that alcohol use increases in frequency and risk through mid-adolescence. Also, unlike other evidence-based parenting curricula, PN is brief, requires only the parents, does not require training, and can be used "on the go" through any digital device. This provides a market niche for the proposed project that addresses this curriculum gap through the innovative use of both technology and prevention science. During the successful Phase I, formative research was conducted to identify parent needs and interests, and a curriculum prototype was developed that demonstrated strong usability and feasibility. During Phase II, we work with Klein Buendel to refine and complete digital programing. The fully developed PN will have core and optional modules based on Phase I findings. This format will allow us to personalize or target parents based on their communication style and allows parents to customize their experience by choosing or clicking through the optional content. Personalization and customization are two essential engagement strategies for digital prevention interventions.[4] Following development, a randomized clinical trial will be conducted through GfK Global. GfK will recruit a nationally representative sample of parent-adolescent dyads who will be randomly assigned to treatment or active control. Parents will complete either PN or be directed to the publicly available SAMSHA parenting materials as an active control condition. Parents also will complete an immediate posttest evaluating their intervention experience. Youth will complete a pretest, immediate posttest and follow-up posttests at 1 and 6 months to assess effects. A theoretical model of moderation and mediation also will be evaluated with alcohol use and consequences as the primary outcome and other substance use as secondary outcomes. Results will guide preparation of PN for the market including immediate dissemination through D.A.R.E. America's new high school program as well as REAL Prevention's other community-based partners such as 4-H and Planned Parenthood.

This Phase II SBIR will evaluate an interactive, self-paced, digital parenting intervention, Parenting Now, to prevent youth alcohol use and prepare it for dissemination to youth community organizations and schools. Parenting Now is adapted from the evidence-based Parent Handbook and has the potential for wide impact on youth substance use through implementation in D.A.R.E., and REAL Prevention's other partners while advancing our understanding of digital prevention strategies.

Facilities & Other Resources

REAL Prevention

Project Offices/Physical space: REAL Prevention headquarters is located at 130 Pearl Brook Road, Clifton, NJ 07013 with a satellite office in Orange County, CA. Realprevention1@gmail.com or visit http://www.real-prevention.com

Computers: Five desktop PCs and Macintosh computers with Intel Core 2 Duo Processors (2.53 GHz or faster) with 8 GB RAM memory are designated for company use and research. Computers are loaded with the latest user interface (e.g., OSX 10.8.5 Mountain Lion for Macs and Windows7 for PCs) and word processing software (MS Office Professional 2010 or later) as well as advanced quantitative (SPSS, SAS 9.3, Mplus version 6 statistical software) and qualitative (NVIVO 9) programming. The RP offices additionally house 6 printer/scanners, 2 tablets, advanced clerical accounting software, 5 digital audio recorders for interviewing, 5 video cameras, conference call equipment, and 1 fax machine/copier. RP offices are video- and audio-conference ready. Each staff person has a telephone with voice mail.

Software: As noted, RP offices are housed with equipment for essential prevention tasks including 6 digital audio recording equipment for recoding interviews, transcription software (MS Word, NVIVO 9), data analysis, (NVIVO 9 for qualitative and SAS9.3, SPSS, Mplus for quantitative analysis).

Internet service: RP offices are equipped with fast speed wireless Internet service.

Access to Library Information Services (LIS): Through Pennsylvania State University and Chapman University affiliations, RP staff access an extensive set of library resources. This affords RP research staff access to more than 4.9 million volumes, 5.2 million microforms, and 58,000 serial subscriptions. At University Park, the Libraries include 9 subject libraries in Pattee and Paterno library and 6 additional subject libraries at branch locations. Access to holdings is obtained through a computerized catalog (CAT), part of the library information access system (LIAS). LIAS is a dynamic, integrated information system that provides electronic access to a great variety of subject area materials and the latest electronic, up to date published, peer- reviewed journal information. A growing collection of over 350 databases, including 8000 journals with full-text articles is available to researchers and can be accessed from the libraries' home page.

General and Financial Accounting Fiscal oversight is provided by the members of the LLC. Our long-established relationship with local banks and our record of sound fiscal management have made increases in lines of credit possible as required by the contract work load. Prevention Strategies uses generally accepted for-profit accounting principles and is audited annually by a professional public accounting firm.

Turrisi Facilities

Dr. Turrisi's lab space is located in Prevention Research Center, consisting of a suite of 11 offices and a large conference meeting room. It has 12 workstations, networked computers and fully functioning office equipment (e.g., fax and copy machines, networked printers). It also contains 9 iMac desktops with 4.0 gigs of RAM, along with 3 Dell PCs with sufficient storage and memory for most analytic functions. The lab also contains 2- laser jet and 4-color jet networked printers, as well as networked access to a large format plotter that can print outstanding presentation-quality posters. These machines together are used to support the various grant projects for office, data entry, or data analytic purposes. Statistical analyses will be performed on PCs and on the networked computer system of the College of Health and Human Development at Penn State University. These machines maintain statistical packages (e.g., SPSS, SAS, MPLUS, LISREL, SUDAN, EQS and more), which will readily accommodate all analyses.

The Prevention Research Center for the Promotion of Human Development (PRC) was established in 1997 in the College of Health and Human Development, and focuses on longitudinal, developmental research on risk. Research examines how communities can work together with families, schools, community groups (social service, youth groups, the faith community), and industry to promote healthy lifestyles for children, youth, and

families. Researchers also conduct clinical trials of innovative models to promote competence and prevent maladaptive outcomes for children, families, and communities. The Center provides research seminars on prevention science for faculty and graduate students. It also supports faculty fellowships and conferences. The Center is funded by a combination of College Funds, permanent endowment, and active research grants. Dr. Mark Greenberg, Bennett Chair of Prevention Research and Professor of Human Development and Family Studies, is the Founding Director of the PRC and Dr. Edward Smith is currently the Interim Director.

The PRC currently has 20 funded grants totaling over $5,000,000 during the current year. A total of 20 faculty members, 16 full-time Ph.D.-level research associates, and 2 post-doctoral fellows are associated with the Prevention Research Center. Within the portfolio of PRC grants are NIAAA grants funded to Dr. Mallett (Achieve) Turrisi (PACT, SkinWatch) and NIDA grants funded to Drs. Greenberg (PROSPER), Bierman (Multisite Prevention of Conduct Disorders: FAST Track), Smith (Adoption of Drug Abuse Prevention Training: ADAPT, Drug and HIV Prevention Among Youth in South Africa: HealthWise). NIH grants funded through the PRC include ones by Bierman (NICHD Head Start/REDI, FAST Track), Foster (NIMH – Economic Analysis of the FAST Track Intervention), Greenberg (PROSPER), and Feinberg (Co-Parenting). In addition, the Center provides evaluation and technical assistance to two Safe Schools/Healthy Students Grants (OJJDP/DOE/CMHS), and has contracts with The Center for Mental Health Services (SAMHSA) on issues concerning effective programming and policy. Other grants currently at the Center come from the state of Pennsylvania, The Poole Trust, The Kellogg Foundation, The Knight Foundation, The William Penn Foundation, and The Greater Harrisburg Foundation.

The Prevention Research Center is the locus of research, technical assistance, and program development in prevention science at Penn State. The Center aims to promote the well-being of children and youth and to reduce the prevalence of high-risk behaviors and poor outcomes for children, families, and communities. Center faculty (1) conduct longitudinal, developmental research on risk and protective factors and their relation to well-being and maladaptation; (2) conduct research to better understand how communities can work together with families, schools, community groups (social service, youth groups, the faith community) and industry to promote healthy lifestyles for children, youth and families; (3) collaborate with Pennsylvania communities to design, implement, and evaluate preventive interventions; (4) conduct clinical trials of innovative models to promote competence and prevent maladaptive outcomes for children, adolescents, families and communities; (5) coordinate prevention research activities within the College of Health and Human Development and promote prevention research throughout the Penn State system; (6) provide policy relevant information on best practices in prevention to federal, state, and local governments; and (7) provide assistance to communities on the development, implementation, and evaluation of prevention programming.

Ray Facilities at Rutgers University

Rutgers, The State University of New Jersey, School of Public Health is a statewide, multi-institutional, multi-campus scholarly community dedicated to improving the health of diverse populations in New Jersey and elsewhere through collaborative research, teaching and service.

Rutgers Biomedical and Health Sciences

The New Jersey Medical and Health Sciences Education Restructuring Act, signed into law on August 22, 2012, and effective July 1, 2013, transferred most schools of the University of Medicine and Dentistry of New Jersey (UMDNJ) to Rutgers, The State University of New Jersey, to form Rutgers Biomedical and Health Sciences (RBHS). The resulting integration builds on the rich histories, talent, and expertise of both institutions. RBHS includes schools from UMDNJ, including the Rutgers School of Public Health (SPH), which will be the home institution of the Principal Investigator. RBHS has at its disposal all of the UMDNJ resources previously available, along with all of the resources afforded by Rutgers University- a large, comprehensive research institution and member of the Association of American Universities. This new integrated structure facilitates research collaborations and enhances access to resources. RBHS is now New Jersey's largest and most influential constellation of academic institutions devoted to education and research across the full spectrum of health professions. Based primarily on the Newark and New Brunswick campuses, top faculty in first-rate facilities train healthcare scientists and practitioners at multiple lo-cations throughout the state. All RBHS units have access to the abundant resources of the broader Rutgers University, to promote innovative research, education, and service.

Rutgers School of Public Health
The Rutgers School of Public Health (SPH) seeks to improve health and prevent disease in diverse populations in New Jersey and around the world through educating students to become well-qualified and effective public health leaders, researchers and practitioners; conducting research to advance public health science and policies; and providing service programs that promote population and individual health. SPH is a statewide, multi-institutional, multi-campus scholarly community with over 49,000 square feet of research, training, administrative and academic space. Faculty research is facilitated through a range of School and University support services, including state-of-the art computer and library resources and access to Rutgers' Office of Research and Sponsored Programs, Office of Grant and Contract Accounting, and Institutional Review Board.

Computing and Data Storage Facilities
Computer: First-rate computing facilities are available to all investigators and project staff. All computers to be used for this project are loaded with appropriate software (e.g., Microsoft Office, SAS, SPSS, SUDAAN, Stata, Atlas.ti) and are connected to the Internet and larger computing and network systems at Rutgers. Computers are supported and maintained by dedicated onsite computer services staff. All investigators and project staff have access to Academic Systems and Technology (AST), a division of the department of Information Services and Technology (IST), which provides quality information technology resources in support of the academic units. Resources include large scale campus hosts and public computer laboratories, university-wide networking facilities and a professional staff with skills spanning academic computing disciplines and information services delivery. Rutgers is committed to excellence in academic and research computing and has an outstanding research computing infrastructure. The University is equipped with a SunFire 6900 scientific multiple cpu server with 24 dual-core, 1.2 GHz ultrasparc IV cpus dedicated to clinical and basic science research applications. To address storage needs, a Sun Storage Area Network (SAN) with 8 Terabytes of available data storage space is available to all researchers. High performance scientific applications on the scientific server include SAS v9 (statistics) and R (statistics). A systems administrative core support group within AST provides hardware infrastructure support and account administration. The computer network at Rutgers complies with HIPAA and other regulations and is extremely proactive about network and system security.

Additionally, the Department of Biostatistics at the Rutgers School of Public Health has five powerful Unix/Linux servers each with at least two Intel Xeon 8-core CPUs, 64 to 256GB memory, and 14 to 32 TB disk storage spaces. There is access to excellent cluster-based computing facilities within the department. Various application software packages and a comprehensive program development environment provide users with the means to analyze large scientific databases and run intensive parallel computations. The department also has a SAS tape library for routine backups. The library can store up to 72 TB data. The data is incrementally backed up daily and fully backed up weekly to ensure fully recovery of at least 6 months' data.

Rutgers Biostatistics and Epidemiology Services Center (RUBIES)
RUBIES is a Center within RBHS that provides basic data analysis and management, epidemiology, and biostatistics services to investigators throughout Rutgers University. RUBIES is composed of faculty members from the SPH Departments of Biostatistics and Epidemiology and the School of Arts and Sciences Department of Statistics and Biostatistics. Services are provided on a fee-for-service basis and may include a wide range of statistical services including data analysis and interpretation including the production of statistical summaries, tables and graphs; statistical programming; design of observational or experimental studies; design and analysis of biomedical studies; comprehensive data management; and technical report preparation.

Office*:* Faculty members have dedicated office space provided by SPH on either the campus in Piscataway, NJ or Newark, NJ. Dr. Lu has dedicated office space on the Piscataway, NJ campus at 683 Hoes Lane W. Office spaces are fully furnished to include a desk, chair, filing cabinet, bookshelf, task chairs, and desktop computer. The desktop computer will be hardwired for high-speed access and access to the Internet through the SPH network. The office space is equipped with a fax machine, copier and scanner equipment, audio-taping and transcription equipment, telephone equipment with voice mail, and conference call capabilities, as well as administrative and research support. In addition, her desktop computer will be hardwired for high-speed access and access to the Internet through the SPH network.

Library*:* Rutgers, a member of the Association of American Universities, is a major research institution, and

has a premiere research library composed of 30 libraries and centers to serve the educational and research needs of more than 50,000 students, faculty, and staff on three campuses. Rutgers offers access to comprehensive health, medical and social science collections, including online access to hundreds of journals and other publications. The Rutgers University libraries allow for access to major bibliographic databases such as OVID, MEDLINE, PsychINFO, PubMed, Web of Science as well as many other searchable databases. The library's Scholarly Communication Center (SCC) pursues cooperative efforts with other institutions to facilitate access to remote resources in support of research at the University. The SCC provides bibliographic access to text and data centers, and maintains reciprocal agreements for data sharing and acquisition, including data sets from the Inter-University Consortium for Political and Social Research (ICPSR). The library also provides training and support to Rutgers affiliated students, faculty, and staff on use of the citation management tool EndNote X8 – which permits research teams of up to 100 members to share a project-based or topical library of citations and associated full-text articles' faculty, students, and staff also have access to a specialized collection in the Robert Wood Johnson Library of the Health Sciences with 15,600 clinical and social science monographs and bound journals and 600 journal subscriptions.

Rutgers Institutional Review Board: The Rutgers University Institutional Review Board (Rutgers IRB) offers training to supplement research compliance and human research protection requirements. Open consultation hours are also offered by the Rutgers IRB. Investigators may meet with Rutgers IRB professionals to discuss regulatory, policy, and procedural questions. Mandatory, web-based training on good clinical practices, human subjects' protection, HIPAA policies, and research with minors and animals (if applicable) is required for any individual involved with research at Rutgers University.

Klein Buendel, Inc. (KB)

KB researchers and staff partner with federal and state-level agencies, research institutions, and professional organizations to develop and evaluate innovative health education products which utilize cutting-edge technology employed by children and adults in schools, worksites, clinics, homes, coalitions, and communities in print format, online, and in group trainings. KB staff has been involved in the development, implementation, and evaluation of numerous evidence-based studies and program dissemination efforts on skin cancer prevention, mental health, nutrition, physical activity, vaccination uptake, tobacco prevention and cessation programs, and responsible substance use. KB's research evaluation experience includes qualitative and quantitative evaluation, including conducting focus groups, in-depth interviews, usability tests, paper-based and online surveys, and randomized trials. **Funding partners** have included numerous DHHS Institutes and Centers (e.g., NCI, CDC, NIAAA, NIDDK, NHLBI, NIA, NIMH, NICHD, NIDA and NIMHD), USDA, Colorado Department of Public Health and Environment, and Colorado Department of Education. **Research partners** have included Kaiser Permanente, Chronic Disease Directors, The Cooper Institute, Fred Hutchinson Cancer Research Center, Produce for Better Health Foundation, San Diego State University, Pennington Biomedical Research Institute, Pacific Institute for Research and Evaluation, Claremont Graduate University, Eastern Tennessee State University, University of New Mexico, Oregon Research Institute, University of Miami, and many others. **Clients** have included the New York State Cancer Coalition, University of Southern California, University of Georgia, University of Colorado, University of South Carolina, Rush University, Memorial Sloan-Kettering Cancer Center, Moffitt Cancer Center, The University of Pennsylvania, Centura Health, and other organizations. KB's core values are passion for the work we do, innovation, respect, significance, diversity, and balance. Our vision for the future is to design, evaluate and disseminate evidence-based products and programs into the marketplace to promote health, prevent disease, improve quality of life, and reduce health care costs for all Americans.

Computer

All KB staff have complete workstations and are networked over a Windows 10 operating system, with at least 8GB of RAM for each workstation. All computers have full Internet communication capabilities via a 50 megabyte Fiber connection, including FTP and VPN. The research and administration departments have Windows workstations that have Intel Core processors. Most of KB's graphic design and multimedia production department has both Windows and Macintosh workstations for cross-platform programming. All production computers run at speeds of 3.2 GHZ or more, with several containing dual and quad processors to increase speed.

All production workstations are fully configured with current versions of standard desktop publishing and multimedia software utilizing Adobe Creative Cloud. In addition, KB utilizes Microsoft Visual Studio Pro for its .NET programming needs. KB also maintains several older computers with various processing speeds, operating systems and web browsers for testing purposes. KB uses MS Office 2016 including Word, Excel, Access and PowerPoint. KB's data management staff use SAS for statistical analysis and Atlas.ti 5.2 for qualitative data analysis. In addition, KB utilizes the Inquisite Web Survey System and QuestionPro for the creation, management and data capture of pre- and post-tests as needed. Financial management is accomplished with the AccuFund 5.05 accounting system.

KB has two high-resolution networked laser printers, including one black and white printer and one color printer. All printers have the ability to duplex and print paper as large as 11 inches x 17 inches.

KB maintains an Xtranet for project management which includes message boards, to-do lists, file storage and scheduling. This Xtranet is utilized by both internal project staff and external clients for centralized two-way communication.

KB's server farm has five Dell PowerEdge servers with two 3.2 Ghz Xeon processors, two with 32 gigabytes of RAM and two with 128 gigabytes, and three 1 Terabyte hard drives that operate off a hardware RAID5 system, connected to a local area network (LAN) running the Windows 2008 or 2012 operating system, and to the Internet through a 50 megabyte fiber connection. KB programmers monitor and maintain all programs and databases, working with data management staff. Sensitive information is protected by a hardware firewall (SonicWall TZ600) and each server has its own native Windows security software. All KB servers are connected via 1 Gigabit high-speed switched network, ensuring high-speed transfer between machines. All networked computers are protected from viruses by Sunbelt Vipre Business. A nightly backup of each computer provides protection against the loss of data.

Office

KB leases 10,231 square feet of office/research space, and an additional 382.5 square feet of storage space in Golden, CO, which includes offices, two conference rooms, audio/editing suite and common space for printers, fax machines and copier.

Scientific Environment

Through NIH, CDC, USDA and other funding sources, KB has developed multiple evidence-based interactive multimedia programs including: SunZapp, an NCI-funded smartphone app currently available on app marketplaces that uses geospatial UV data to help individuals make informed real-time decisions on sun exposure and vitamin D; Real Health commercial stock art service for people and organizations that serve under-represented populations disproportionally facing health disparities (realhealthphotos.com); Colorado Quit Mobile tobacco cessation smartphone app created in conjunction with the The BACCHUS Initiatives of NASPA and CDPHE that is also available on app marketplaces; MomZing, a web-enabled television software program developed for mothers to exercise with their babies and young children; the Live Fit on Campus and 5 A Day at Work nutrition and physical activity programs; Tobacco Control Partners, Consider This, TEAM, and the Real e-Quit tobacco programs. Other technology-based programs include the NCI-funded Sunny Days, Healthy Ways interactive programs, a series of computer games to teach children about sun safety; Nutrition Fun, a series of games designed for the Centers for Disease Control and Prevention website; the Balancing InTake and Expenditure (BITE) web program to support public health practitioners with collaborating on effective energy balance programs; and U-Consider This, a University of New Mexico-sponsored college binge drinking prevention website. KB also collaborated with the University of New Mexico on a web-based responsible beverage service training, WayToServe, that is currently available in both English and Spanish and is employed in several states with more coming. In addition, KB has multimedia programs underway including developing and evaluating an online retail marijuana vendor training for medical and recreational marijuana licensed dispensaries, developing a smartphone app for DUI offenders and their families, a smartphone app to promote physical activity among Latino women, web programs to promote HPV vaccination among both girls and boys, a social media-based intervention to curb indoor tanning practices, the FIT-4-Health pediatric weight loss program, the STEP for LIFE web-enabled interactive activity program for older adults in independent living facilities, a tablet-driven multimedia program to prevent male dating violence in

conjunction with Brown University, a multimedia program to help youth afflicted with sickle cell disease, development of a smartphone app for physical activity maintenance among African-American men, a smartphone app for better food, sleep, and physical activity choices among college students, and the College Bystander interactive web-based program to teach bystander safety.

In addition, KB scientists conduct research on numerous studies that do not have an emphasis on technology. Examples include programs in the area of skin cancer such as the Go Sun Smart workplace-based sun safety program, the Sun Safe Schools policy study, the Sun Safety Ink! study aimed at dispensing sun safety advice among tattoo parlors, and the Norms and the Built Environment shade structure study, which compared shade structure use in Australia and the U.S. In the area of mental health, KB has pilot tested DOSE, a trial exploring the use of exercise to treat major depressive disorder in adolescents. In the area of physical activity, KB conducted a retrospective observational analysis of the processes of dissemination of the Active Living Every Day program. Additional KB projects have included the development of an evidence-based nutrition and physical activity-focused school gardening curriculum and a project to determine the efficacy of Conversations About Cancer, a play and talkback screening program designed to aid more effective communication on topics related to cancer.

RESEARCH APPROACHES	
Dissemination	
Policy adoption	
Social marketing	
Social networking	
Targeting audiences	
Theoretical models	
MAJOR TOPIC AREAS	
Sun safety	
Nutrition	
Obesity and weight management	
Diabetes management	
Bystander safety	
Physical activity	
Responsible Substance Use	
Tobacco control	
Mental health	
Health risk appraisals	
Media literacy	
RESEARCH CAPABILITIES	
Program evaluation	GIS data analysis
Community-based trials	Data management
Usability testing	Process analysis
Survey research	Focus groups
Key informant interviews	Content analysis
Statistical analysis	Cognitive interviews

Commercialization

KB has significant experience in 1) creating programs and products with strong commercial potential, 2) developing lasting commercial partnerships for dissemination and outreach, 3) creating and disseminating marketing and multimedia collateral to generate and sustain interest in KB products and programs, and 4) working with outside organizations to protect and/or license products.

To date, KB has worked with its intellectual property law firm to protect and/or license eight distinct products. We have six registered trademarks and eight active copyright applications. For example, we have successfully licensed Way to Serve, a responsible beverage server and retailer training program, to Wedge Communication

LLC, a technology transfer firm that currently sells an average of 750 units per month. This product has grown to include training programs for the states of New Mexico, Texas, Oregon, and Washington. A Spanish language program has also been implemented in New Mexico and Texas. Additionally, KB has recently partnered with EmicHealth (HPC) to market and distribute products such as MomZing, SunZapp, Real E Quit Mobile, and Sunny Days Healthy Ways.

Products	Ownership Agreement	Co-Owners/ Inventors	TM/C/P Status	Marketing Status	Marketing Company
Sunny Days Healthy Ways	n/a	None	C; TM	In market	HPC
WayToServe	Yes	UNM, PIRE	C; TM	Licensed and in market	WEDGE
sunZapp	n/a	None	C; TM	In market	HPC
Real Health Photos	n/a	None	C; TM	In market	KB
Momzing	Yes	UH	C; TM	In market	HPC
Grow Eat Thrive	n/a	None	C	In market	HPC
Healthy Detours	n/a	None	In process	Under review	
TrainToTend	n/a	None	TM	Agreement in process	KB

Dissemination and outreach are often the specific aims of our research projects. To accomplish this, we use the public relations, marketing, and multimedia skills of our staff who have a wealth of audio, video, graphic design, mobile and internet-based experience. Our staff also has experience with media relations, community relations, event planning, and market research. For community outreach and education, we have internal multimedia authoring and programming capabilities to develop and host our own website (i.e., Kleinbuendel.com), over 30 websites for our research partners and clients, a blog, and multiple webinars. We have Facebook and Twitter platforms and intersect with other social media outlets for promotion, outreach and education. We have a long history of working with large employers, professional associations, city and county governments, health care companies, private foundations, community coalitions and others on problems related to technology and health communication and in a collaborative capacity for program and product dissemination. For example, KB has worked with The Bacchus Network to provide online health risk assessments and smoking cessation programs to college-age populations, and KB's Go Sun Smart workplace-based sun safety program has been disseminated to over 400 ski areas throughout North America.

Collaboration and Communication

KB is confident in its ability to manage complex multi-site projects. KB is currently leading numerous multi-site projects in partnership with investigators from throughout the U.S. and Australia. Communication among investigators and project staff is conducted face-to-face, by telephone, email, and via video conferencing, with an emphasis on maintaining high efficiency (i.e., high effectiveness and low cost). Project activities are managed on Wrike, a robust and real-time cloud-based work management software. 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. The use of Wrike and teleconferencing limit the teams' need to meet face-to-face, controlling travel costs.

Administrative Support Staff

KB investigators are supported by administrative personnel with extensive pre-and post-award management experience. Ms. Pamela Stevens, Finance Director and Certified Research Administrator, oversees all financial activities. Prior to coming to KB, she provided financial and grants management oversight to the Center for Nicotine and Smoking Cessation Research at Duke University. Ms. Stevens and her accounting staff are all

highly versed in budget oversight, adherence to FAR, OMB, and DHHS regulations, federal grant and contract compliance, and employee benefits management. Proper controls are in place to monitor person hours, purchasing requests and travel orders. Post-award research administration and human subjects/IRB-related tasks are managed by Ms. Laura McLaughlin, Compliance Coordinator. KB has extensive experience working with Institutional Review Boards for the protection of human subjects and currently works with the Quorum Institutional Review Board in Seattle, WA and Western Institutional Review Board in Puyallup, WA. Ms. Miranda Reilly, Grant Manager, provides pre-award support to KB scientists. Additional support is provided by Ms. Jill Johnson, Office Manager, who has over 25 years of office management experience, and Mr. Chris Jakan, KB's Information Technology Manager who is certified in Microsoft, Cisco and Novell (Netware 5) as a Certified Novell Engineer and a Microsoft Certified Systems Engineer. Support is also provided for library resource management and manuscript preparation and submission.

Data Management Team

The KB Biostatistical Team includes support from Dr. Gary Cutter, Expert Vendor for Biostatistics from Pythagoras, Inc. Dr. Gary Cutter provides expertise on the data collection and management procedures, as well as advises on the experimental design, execution of a data safety and monitoring plan, and development of a data analyses plan, with input from Investigators. Ms. Lucia Liu, M.S., Biostatistical Manager, oversees all of the day-to-day in-house data management and analysis tasks. Dr. Cutter and Ms. Liu are supported by Daniel Kramer, Data Coordinator.

RESEARCH, DATA MANAGEMENT AND SURVEY SYSTEM INTEGRATION
• Data collection, management and statistical analysis • Data safety and monitoring • Real-time and HIPAA-compliant data capture • Database development and integration • Content management systems • Online and in-person surveys • Project management and fulfillment

KB has well established data management procedures for the secure storage, preparation and analysis of data. Depending on the project, data collection manuals are prepared, containing procedures for administering surveys, responding to questions, recruitment and consent of participants, the supervision of data collection staff, and submitting completed forms for processing. Online surveys are programmed using Inquisite or QuestionPro online survey software. Direct entry of data in the online surveys eliminates third-party data entry errors. Written surveys are formatted with visual cues to lead respondents from one question to another to reduce error. To reduce data entry error, forms have built in value ranges and require specific types of data where possible. Data management systems are stored on KB's local area network (LAN). SAS software is used to monitor timeliness and quality of data submission and produce data expectation reports, data queries and accrual reports. Responses are stored on computer files and master data files created for processing and analysis by the Data Management Staff. Data editing and quality assurance procedures include both manual and computerized audits. All computer records on the KB LAN are backed-up on a daily basis on secure servers. See diagram at the end of this document.

Creative/Multimedia Department

MULTIMEDIA AND PRINT-BASED CAPABILITIES	
• Web design, programming and hosting • Video production and editing • 3-D animation • Online and mobile training modules • Reactive content tailoring based on user history • Game and activity development • Interactive television development • User interface and user experience design	• Graphic design for print media (e.g., brochures, technical reports, posters, newsletters, curricula) • Logo/branding/identity/online advertising • Creative concept development and prototyping • eCommerce systems • Database design • Instructional design • Photography and photo editing • Project management and fulfillment

• Mobile/tablet/smartphone application (app) development • CSS3 Javascript and HTML5 development • Streaming and live video casting • Webinars / online seminars	• Research and management of vendors • Focus groups and usability testing • 508 and COPPA compliance

Technical Skills

KB has a full-service, highly experienced in-house graphic design and multimedia department, which provides leading-edge technology solutions and innovative designs geared towards the unique needs of KB's researchers and clients. Multimedia staff research the latest trends in design and computer/mobile technology to guide decisions about the production of health communication media (e.g., delivery platforms, color schemes, flow of text and images, layout and navigation of user interfaces and overall user experience) as well as the most current applications of emerging technologies, in addition to incorporation of tried-and-true approaches that stand the test of time.

Our development team is fluent in all the popular development platforms including Microsoft .NET, PHP, Apple iOS, Google Android, Windows Mobile, JavaScript, ActionScript, JSON, Structured Query Language and HTML5.

Graphic Design Production

The KB multimedia team is highly experienced in the field of design, working with both small research firms as well as with large multi-institute projects. Staff is well versed in both print-based (small and large format) design as well as interactive design. All design is completed in-house by KB using the industry standard software such as Adobe InDesign. To support these layout programs, KB also utilizes the vector illustration program Adobe Illustrator and the raster photo editing program Adobe PhotoShop. All print materials are fully exportable to Adobe Acrobat PDFs. Graphic Design is led by KB's Creative Director, Steve Fullmer.

Animation/Illustration Production

The KB team has expanded its breadth of experience from traditional illustration (paint, watercolor, photography, etc) into the new media. Staff creates and edits complex illustrations in Adobe Illustrator and Adobe Photoshop. Extensive photo manipulation and editing skills are demonstrated across all staff members. In addition, we have moved from Adobe Flash to HTML5 as the cornerstone for interactive web-based programs. Cinema 4D is used for 3-D animation.

Multimedia Production

Most web production is completed in-house using standards-based techniques prescribed by the World Wide Web Consortium (W3C) that utilizes XHTML (Extensible Hypertext Markup Language) to format the content and Cascading Style Sheets (CSS) to control the look and feel of the content. Dynamic components are deployed and programmed using the .Net framework combined with an SQL database. Page development, integration, graphic design and interactive elements are created using industry standard tools, techniques, and approaches. Native custom-written automated data-gathering programs are created as needed with SQL commands and ASP or PHP scripts to provide an extensive tracking analysis for web-based programs. We are capable of both Web-based applications as well as mobile, tablet and Internet-connected TV applications that can be developed for Google Android and/or Apple's iOS development platforms.

Video Production

KB has complete video production workflows for online video creation. In addition, the company has its own lighting equipment, microphone systems, and a teleprompter capable of handling most common location-based filming situations. The post-production suite utilizes a fully -networked editing environment that operates Adobe's professional editing suite allowing KB to edit video and create complex motion graphics. Voice-over narration and soundtracks are recorded in broadcast quality in our professional in-house audio recording and editing suite.

KB-Lync – KB's Customized Study Management Software
KB-Lync is a custom-built study management system developed by KB's programmers. KB regularly employs and tailors KB-Lync to fit the needs of each unique intervention. KB-Lync consists of a recruitment engine that will randomize consented and vetted participants into the appropriate arm of the study, administer surveys and survey screeners on a scheduled basis to participants, and provides randomization and real-time reporting to PIs for the entire course of the study.

Geographic Information System

KB has purchased Geographic Information System (GIS) software for use in projects. KB uses ESRI's ArcGIS mapping and analysis software to create, manage and share geographic data, maps, and models. KB staff is trained at spatial analysis and the utilization of GIS for public health applications.

Information Technologies Security

All participant information will be protected using 128 bit SSL encryption. KB's web encryption certificates are provided by GoDaddy.com. The CSR created by IIS 8 is 2048 bit encrypted for certificate validation by GoDaddy.com.

All Internet information must travel through KB's SonicWall TZ600 firewall using SonicOS Enhanced software version 6.5. Traffic then moves to KB's web server. This server is a Dell Power Edge T-430 with 128 GB of RAM, 6 TB available disk space on a RAID 5 redundant drive system using Windows HyperV Operating System. The virtual web server uses Windows 2012 IIS Web server software. User click stream data is collected using Webtrends, and is saved to KB's SQL server.

Enrollment data is transferred to KB's SQL server (Windows Server 2012) which uses MS SQL server 2012 R2 database software. This machine is also a Dell Power Edge T-430 with 32 GB of RAM, 6 TB available disk space on a RAID 5 redundant drive system using Windows HyperV OS, and has no access to the Internet.

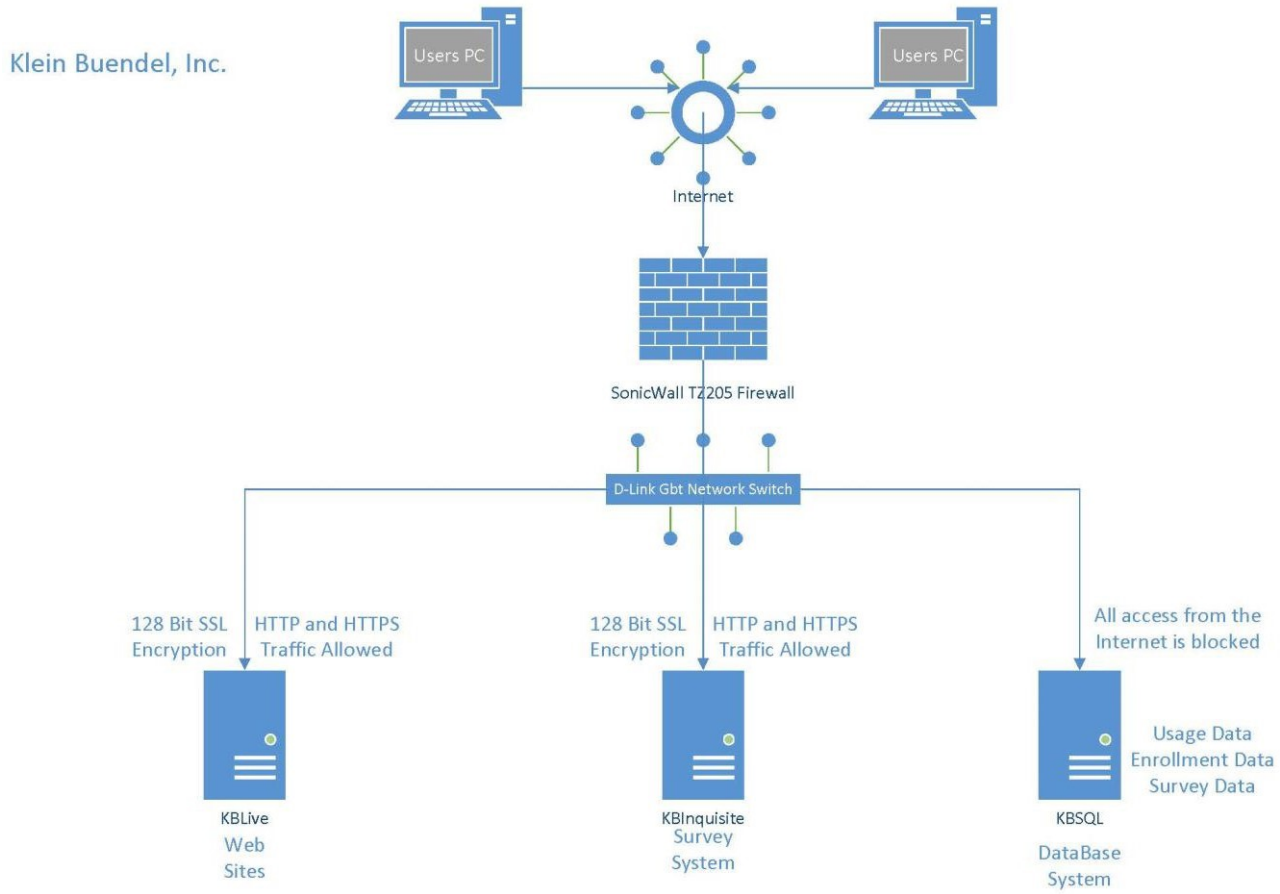
When a participant is directed to take a survey, their computer is linked to a third server in the system which is also a Dell Power Edge T-430 with 128 GB of RAM, 6 TB available disk space on a RAID 5 redundant drive system using Windows HyperV OS. This server runs Windows 2003 Inquisite 9.6 Survey software, as well as QuestionPro survey software (which is hosted on the internet and secured via SSL). Data from each survey is collected and saved to the SQL server mentioned above.

Login and network activity is 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 Inquisite 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 2014. 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.

KB's WAN (wide area network) is provided by 50MB Full Duplex fiber optics. KB's LAN (local area network) is 1GB Full Duplex. KB Wifi access is provided in two ways: Guest use is limited to Internet access only; KB assets server access requires special password entered by KB IT personnel. See below for a simplified diagram of KB's Internet traffic flow:



GfK Custom Research

GfK Custom Research, LLC ("GfK") uniquely maintains the largest, longest-standing, all-online, probability-based panel, known as KnowledgePanel®. Recruited using probability-based sampling, KnowledgePanel overcomes the problems that heretofore had prevented web-based surveys from being accepted by communities of scientists, news media, and public policy experts.

As a probability-based panel, KnowledgePanel respects the principle of random selection of research subjects. (Because KnowledgePanel participants are selected by random chance, and the panel is designed to be representative of the U.S. population, KnowledgePanel avoids the problems of self-selection bias and the recruitment of 'professional respondents' that join one or more volunteer 'opt-in' Internet panels.) As an entirely online panel, KnowledgePanel eliminates mode effects and allows the use of graphics, audio and video clips, and—for a portion of the panel—video recordings of participants' responses to survey questions. As a panel with 50,000+ adults, KnowledgePanel is sufficiently large to allow researchers to target low-incidence populations.

Founded in 1998, the staff of the Government & Academic Research practice of Knowledge Networks (which became part of GfK in 2012) conducts statistical surveys in a variety of fields including public policy, health policy and services, epidemiology, environmental protection, political science, sociology, and social psychology. Researchers in these and other fields have conducted text-based and multimedia surveys, online qualitative research, and collection of physical specimens (such as saliva) using the web-enabled KnowledgePanel.

KnowledgePanel offers:

- Coverage of cell-phone-only households through address-based sampling (ABS), which has also improved panel representation of young adults, racial minorities, Hispanics, low-educated, and low-income households; and coverage of non-Internet households
- Less acculturated Hispanic households based on KnowledgePanel Latino, the web-enabled segment of the KnowledgePanel that covers the Spanish-language dominant portion of the U.S. Hispanic population
- Computer-assisted interviewing capabilities for supporting complex questionnaire designs for economic, social, political, and other research
- Integrated qualitative and quantitative online research
- Panel member profiles that include more than 4,000 variables—refreshed annually—providing detailed information about individual and household demographics, health status, political attitudes and behaviors, media and technology use, sports interests and activities, and retail shopping behavior
- Access to recorded behavioral data (KnowledgePanel Digital) that provides supplemental online activity data for a sample of KnowledgePanel members
- The ability to conduct the survey work in far less time than in an in-person or telephone survey

Furthermore, KnowledgePanel has these attributes:

Statistical validity: The accuracy of any research hinges on the choice of the study sample. The panel is representative of the U.S. population. Members of the panel are randomly recruited by mail and telephone and provided with access to the Internet.

A unique environment: GfK has the advantage of interviewing people in the comfort and privacy of their own homes. Our usual response rates are among the highest in the industry, which maintains the representativeness of the sample. Surveys are addressed to specific members in the household. The panelist can access the questionnaires addressed to them at their convenience.

Multimedia capacity: GfK can easily incorporate graphic images, shelf sets, video and audio; a combination of media that does not exist in other methods. In addition, the KnowledgePanel methodology guarantees consistency of sound and image quality across respondents. Everyone experiences the survey through the same interface.

Self-Administered Web-Based Computer-Assisted Interviewing: The panel's proprietary computer-assisted interviewing system supports conjoint, willingness-to-pay, and other surveys that require precise controls on the display of features and attributes, randomization of sample for specific questions and batteries of questions, etc. The system displays information graphically on probabilities and risks, and it allows respondents to complete complex decision tasks.

KnowledgePanel also has more studies conducted under OMB guidelines and approvals than does any other online panel. Extensive information about past projects conducted using KnowledgePanel and methodological research based on the web-enabled panel may be accessed at www.knowledgenetworks.com/ganp/. Documentation on practices for the protection of the rights of research subjects may be viewed at http://www.knowledgenetworks.com/ganp/irbsupport/.

The key staff responsible for government, academic, and non-profit research each have had long careers in designing and conducting surveys sponsored by the federal government and major universities. Staff have also participated in methodological research on data collection mode effects, nonresponse bias, and panel effects.

The U.S. Small Business Administration

SBIR.gov SBC Registration

SBC Control ID:	SBC_000406995		
Company Name:	REAL PREVENTION LLC		
Address:	765 LONG HILL RD		
City:	GILLETTE		
State:	NJ	**Zip:**	07933-1321
EIN (TIN):	462906812	**DUNS:**	078820648
Company URL:			
Number of Employees:			1
Is this SBC majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms?			No
What percentage (%) of the SBC is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms?			0.00%

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Michael Middle Name Last Name*: Hecht Suffix:

Position/Title*: President
Organization Name*: REAL PREVENTION, LLC
Department:
Division:
Street1*: 130 Pearl Brook Drive
Street2:
City*: Clifton
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 070130000

Phone Number*: 814-360-1893 Fax Number:
E-Mail*: hechtpsu@gmail.com

Credential, e.g., agency login: HechtPI

Project Role*: PD/PI Other Project Role Category:

Degree Type: Ph.D. Degree Year: 1971

Attach Biographical Sketch*: File Name: Hecht_biosketch_-_PBIm_P2.pdf
Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Robert Middle Name J Last Name*: Turrisi Suffix:

Position/Title*: Professor
Organization Name*: The Pennsylvania State University
Department:
Division:
Street1*: PENN STATE UNIVERSITY
Street2: PREVENTION RESEARCH CENTER
City*: UNIVERSITY PARK
County:
State*: PA: Pennsylvania
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 168020000

Phone Number*: (814) 865-7808 Fax Number: (814) 865-0612
E-Mail*: RTURRISI@PSU.EDU

Credential, e.g., agency login: rturrisi

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PHD,BA Degree Year: 1988,1983

Attach Biographical Sketch*: File Name: Turrisi_biosketch_-_PBM_P2.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Anne Middle Name E. Last Name*: Ray Suffix:

Position/Title*: Postdoctoral Associate
Organization Name*: Rutgers, The State University of New Jersey
Department:
Division:
Street1*: Center of Alcohol Studies
Street2: Rutgers University
City*: Piscataway
County:
State*: NJ: New Jersey
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 088520000

Phone Number*: 732.445.2190 Fax Number:
E-Mail*: anne.e.ray@rutgers.edu

Credential, e.g., agency login: ANNERAY

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PHD,MED,BS Degree Year: 2011,2010

Attach Biographical Sketch*: File Name: Ray_biosketch_-_PBM_P2.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ❍ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

❍ Yes ❍ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ❍ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ❍ Yes ❍ No

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	PN_Specific_Aims_RT_Final P2_8-30-18.pdf
3. Research Strategy*	PN_Research_Strategy_RT_Final_P2_8-30-18.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	PN_LOS.pdf
10. Resource Sharing Plan(s)	Resource_Sharing_PBIm_9-18.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Specific Aims

REAL Prevention LLC (RP), a company dedicated to commercializing innovative technologies for delivering evidence-based health promotion practices, proposes this Phase II SBIR to establish the efficacy of Parenting Now©, a digitized adaptation of Turrisi's effective parent-based prevention intervention.[1-3] Once efficacy is established, RP will disseminate the curriculum alongside its other evidence-based products.

Adolescent alcohol and other substance use remains a significant public health concern.[5-8] Unfortunately, evidence-based school programs rarely reach the level of high school and existing parent-based interventions delivered in the community often require an extensive commitment of time and effort by both parent and teen. Moreover, parent-based interventions do not fully utilize technology, which limits their usability in a digital age where people are used to accessing content on the go and at convenient intervals through their devices. Thus, there is a gap in a potential large and profitable market, particularly given that parents expressed need for help in developing these skills.

The Parent Handbook was developed to fill one of these niches.[1-3] The intervention is brief, requires only the parent, and has proven effective in reducing adolescent drinking in a series of RCTs[1-3] and independent replications [12,13,27]. Its main features are its brevity (~20-25 minutes to complete), being self-paced, requiring only parents, and being highly effective in reducing youth alcohol and other substance use/consequences. As a result, the Parent Handbook is one of only two family-based interventions recommended in the 2016 Surgeon General's report on addiction.[9] However, it targets only college-bound youth once they leave high school, and is available in only hard copy/pdf formats. Our successful Phase I project developed a digital prototype that targets parents of all high school students, renamed Parenting Now (PN), that demonstrated excellent usability and feasibility in an independent evaluation and has great potential to fill this prevention need.

This Phase II study seeks to continue this successful line of prevention work by fully building out the digital PN intervention, evaluating its effectiveness, and preparing it for the market dissemination. In this, RP continues to collaborate with Dr. Robert Turrisi (curriculum developer), Dr. Anne Ray (longtime collaborator of Turrisi on several RCTs evaluating the Parent Handbook)[2,10-13] who lead our Phase I research, and Klein Buendel, our technology partners. This team will refine and complete PN based on our Phase I findings examining parents' preferences. These refinements include: 1) PN will have core modules that cover essential topics (e.g., why it is important for parents to talk with their students, improving communication, parent permissiveness toward adolescent drinking, how alcohol works in the body, and the difficulty of making accurate judgments of impairment); 2) Customization through optional topics parents choose to acquire content specific to their interests (e.g., other commonly used substances that adolescents combine with alcohol use, parents' drinking and drug history, the importance of being committed to a healthy lifestyle); and 3) Personalization to the parent's communication style, based on the work of RP President Miller-Day.[14,15] All the refinements are based on the findings of Phase I and add to the innovative features of the PN. For example, having both core modules and optional content will allow the parents to customize or click through the curriculum, a feature of digital information that makes it more engaging.[4] Second, the Parent Handbook and other parenting interventions teach a single communication style, where PN will personalize the skills to match the parent's existing communication style, another feature of engaging technology.[4]

Following the completion of the PN, we will conduct a rigorous RCT that includes using a nationally representative sample through GfK Global and an active control condition (e.g., SAMHSA Parent Education Materials). Following the evaluation (if successful), we will integrate it into RP's dissemination efforts. Our specific aims are:

Specific Aim 1: Evaluate Parenting Now's effects on youth alcohol use and other substance use through a RCT. Our primary outcomes for the analyses are alcohol use and consequences. Our secondary outcomes for the analyses are marijuana use, nicotine use, and their combined use with alcohol. Finally, we will explore differences in all outcomes by sex of the student (as a relevant biological variable).

Specific Aim 2: Examine the process of how PN influences parents' behaviors and how these in turn influence students' behaviors (Figure 1). Our tertiary outcomes for the analyses of mediators are parent communication about alcohol, combined alcohol and other substance use and student factors (e.g., expectancies, norms).

Specific Aim 3: Prepare Parenting Now for market dissemination.

Ultimately, the digital format facilitates rapid dissemination through RP's partnerships. For example, D.A.R.E. America will add PN to their newly initiated high school curriculum for national and international distribution through the largest network of prevention disseminators (see letter). RP also uses a "direct-to-consumer" marketing strategy. The resulting intervention will have the competitive advantages of being self-paced rather than face-to-face group administered, addressing multiple substances with implications for other health decisions by promoting critical thinking, and being of lower cost to purchase and implement.

SIGNIFICANCE

Project Overview. This proposal seeks Phase II SBIR support to provide an efficient, engaging, and effective intervention, Parenting Now (PN), to enhance parents' ability to reduce prevalence of alcohol use and consequences, and other substance use. It is *efficient* because it more closely corresponds to how parents access information in real time/any time while fitting the activity into their busy schedules through digital means. It will be *engaging* because it provides core modules that parents need based on prevention science and their expressed preferences, as well as optional modules that allow parents to differentially access information that they perceive to be personally relevant. It is *effective* because it adapts the evidence-based Parent Handbook[1-3] originally designed for college students for wide scale dissemination among parents of all high school students through digital delivery.

Alcohol Use in Youth. Underage drinking continues to be a significant public health concern in the U.S.[5,8] and is a priority area for research within NIAAA.[16] Recent data indicate that among youth ages 12-20, about 23% report past month use and nearly 14% report at least one binge episode (5+ drinks) within that same time frame.[17] Results from national epidemiologic studies suggest that use escalates in later adolescence (ages 17-20).[18] In particular, there is a substantial increase in use midway through this stage of development: rates of past 30-day use, 1 or more binge episodes, and heavy use (5+ binge episodes) are 22.7%, 13.1%, and 2.7% among 16-17-year olds. Among 18-20-year olds, these rates jump to 43.8%, 29.1%, and 8.5%, respectively. [18] Among the indicators of riskiest use, binge use more than doubles and heavy drinking more than triples in this age group.[18] This is concerning as alcohol use, particularly risky use, has myriad consequences for adolescents, the people around them, and society as a whole.[5-7] Individual-level consequences are physical, emotional, and social in nature including death from injuries,[19] engagement in risky sexual behavior,[20] increased risk of sexual and physical assault,[21] academic failure,[22] and changes in brain functioning,[23,24] which may last into young adulthood.[25] On a societal level, costs of underage drinking were recently estimated at $24.3 billion.[26]

Why Parents? Research has shown that parents have a potentially powerful role to play in reducing the scope of these problems.[e.g.,1-3,27,28-30] However, parenting interventions, such as Strengthening Families, while impactful, require a great investment in delivery (i.e., implementer, space) and participation (i.e., time). In contrast, the evidence-based, *A Parent Handbook for Talking with College Students about Alcohol*, developed by Dr. Turrisi, is a brief guide for parents derived from his research on both college student decision-making about alcohol use and parent-child communication.[1-3,10,28,31-34] The curriculum spans several conceptual domains. The first domain introduces the problem of underage drinking and related harm to help motivate parents to talk with their teen. The next domain focuses on relationship building and specific strategies that parents can use to improve communication channels with their teen. The final domain is an in-depth discussion of the risks of underage drinking alcohol-related consequences (whom is most at risk, decision making, peer influences, positive and negative reasons why some teens drink, alternatives to drinking, driving under the influence, and riding with an impaired driver). Ultimately, the Parent Handbook provides parents with: 1) skills to improve parenting, reducing barriers to communication; 2) skills to guide teens on choosing friends, peer pressure, and decision making; and 3) information for specific topics to discuss about drinking, DUI, and riding with drinking drivers.

The Parent Handbook is the only evidence-based, "brief" parent intervention that has undergone the rigor of multiple, well-controlled clinical trials, with several independent replications.[12,13,27] As a result, the recent Surgeon General's Report on Alcohol, Drugs, and Health highlights the parent handbook as one of two prevention approaches that met rigorous criteria to be considered "efficacious" for preventing college student drinking and consequences.[9] In addition, the National Institute on Alcohol Abuse and Alcoholism's College AIM Matrix has stated that the handbook is an "effective" intervention to produce changes in attitudes or behaviors related to alcohol use rather than the environments in which alcohol use occurs. The data show that the Parent Handbook not only prevents non-drinking teens' onset of use when they come to college campuses, but it also reduces the drinking of those students who come to college with established high-risk drinking habits.[3] However, the current format has limited efficiency and engagement in that it is accessible only in hard-copy handbook/PDF in a technology-driven age.

Additionally, there is a need to extend the reach of Parent Handbook to a larger population of high-school students that include non-college bound youth. The Parent Handbook research has been limited to parents of teens who are college-bound. However, research suggests that those who do not attend college are at higher risk for alcohol problems later in life.[35,36] Further, non-college bound youth are a large group, with recent data indicating that 34% of high school students do not enroll in college immediately following graduation.[7] Focusing prevention efforts specifically on college-bound or recently college-enrolled youth leaves a substantial portion of the late adolescent population vulnerable to hazardous drinking tendencies and associated harm.

Parenting Now (PN). REAL Prevention LLC (RP) adapted the Parent Handbook to digital format, Parenting Now (PN), and established its feasibility for a broader audience through a successful Phase I SBIR to address these limitations. In Phase II, our team will refine and complete PN based on our Phase I findings examining parents' preferences. These refinements include: 1) PN will have core modules that cover essential topics (e.g., why it is important for parents to talk with their students, improving communication, parent permissiveness toward adolescent drinking, how alcohol works in the body, and the difficulty of making

accurate judgments of impairment); 2) Customization, user-initiated tailoring, is accomplished through offering a menu of optional topics that parents can choose to acquire content specific to their interests (e.g., other commonly used substances that adolescents combine with alcohol use, parents' drinking and drug history, and the importance of being committed to a healthy lifestyle); and 3) Personalization, system-initiated tailoring, is accomplished through adapting content to the parent's communication style, based on the work of RP's Miller-Day.[14,15] Sundar's work demonstrates that both customization and personalization can improve engagement with digital materials, but that they work differently for different people.[4,37] All the refinements are based on the findings of Phase I research and add to the innovation of the PN. We now seek to complete the PN adaptation, test its efficacy in a randomized control trial (RCT), and prepare it for rapid and widespread national and international dissemination via collaboration with D.A.R.E. America and other channels.

Aim 1. Toward this extent, Specific Aim 1 will conduct a RCT to evaluate PN's effects on youth alcohol use and other substance use assessed at 3 waves (baseline, 1 mo., and 6 mo.) using a rigorous study design that includes a nationally-representative sample and an active control condition.

H1: Students in the PN condition will engage in less alcohol use and consequences (primary outcome) than in the control condition.

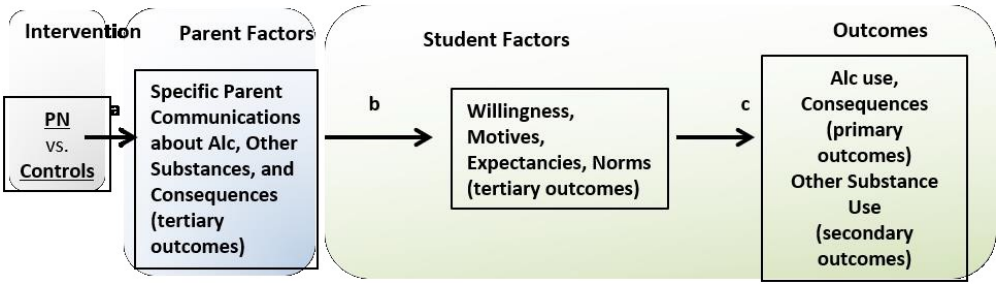
H2: Students in the PN condition will engage in less marijuana use, nicotine use, and their combined use with alcohol (secondary outcome) than in the control condition.

We will also explore differences in all outcomes by student sex (as a relevant biological variable) and sexual orientation and gender identity. Studies have shown that males engage in risky drinking more frequently than females.[e.g.38,39] However, research on sex differences in some domains remains mixed, with some studies finding females having higher rates of risky drinking behaviors (e.g., riding with impaired drivers),[38,40] and others reporting no differences.[41-43] Research has shown that sexual minority teens are more likely to engage in impaired driving, be passengers in cars with impaired drivers, and use drugs than heterosexual youth.[44]

H3: We hypothesize the PN will reduce risky drinking and substance use behaviors for males, females, and sexual minority youth, reducing differences observed in the literature in the PN condition (primary outcome).

Aim2. Specific Aim 2 focuses on examining the process of how PN influences parents' behaviors and how these in turn influence students' behaviors (Figure 1). The model underlying this examination is based on a "unified theoretical model" that emerged from identifying the most influential psychosocial factors in the most influential theories (e.g., Theory of Reasoned Action/Planned Behavior,[45] Social Learning Theory,[46,47] the Health Belief Model,[48,49]) as designated by researchers at the National Institute of Mental Health.[50,51] Turrisi has relied on this framework in prior studies focusing on parenting interventions for substance abuse[52] and we use it here to organize our constructs and provide theoretical justification for intervention features. According to our model, parents in the PN condition will increase their knowledge and skills to improve parenting (initiating conversations, listening, and reducing barriers to communication) and then communicate with their students (about alcohol use and consequences, and combined alcohol and nicotine or marijuana use; tertiary outcome). This communication, in turn, will change students' orientations (e.g., behavioral willingness to use alcohol, motives; expectancies; norms) and subsequent alcohol and substance use behaviors. Our key Aim 2 hypotheses regarding how the PN will affect parents and students are:

Figure 1. Conceptual model



H4: Parents in the PN condition will discuss alcohol use and consequences and combining alcohol with other substances more than controls (tertiary outcome).

H5: Parent communication will in turn influence student factors (e.g., reduced motives and behavioral willingness; tertiary outcome).

Summary of Significance. In summary, the proposed PN intervention is significant because it uses state-of-the-art technology to adapt a novel, evidence-based universal prevention strategy in a flexible, digital format in an underutilized population to address a serious public health concern (alcohol use) among a late adolescent age group whose use is accelerating. It extends the scope of parent interventions by including non-college-bound youth whose career vector includes jobs or military as well as college-bound youth. The digital format provides a more contemporary delivery mechanism that fits the online world and facilitates personalized and customized content. The PN addresses alcohol use and alcohol combined with other substances in an at-risk target population (i.e., high school youth), through an evidence-based approach that is adapted for a broader audience (parents of all high school students) and utilizes technology to effectively implement prevention.

INNOVATION. While parent interventions exist, including the Parent Handbook upon which PN is based, the current project is unique from past research by Turrisi and others in several important ways.
First, PN will be the only digitized, "brief" parent intervention that is evidence-based. While others use DVD or CD-ROM formats, none fully capitalizes on digital media. The PN digital format will make it more efficient for parents who are constantly on-the-go and increasingly tech savvy. Parents will be able to access the information from their computers or tablets, making the content easily accessible and readily available. The digital format also allows increased interactivity to promote retention and application of material.[53]
Second, the Parent Handbook approach is limited in scope and has yet to be tested with parents of a broad adolescent population of all high school-aged students. The focus of the original Parent Handbook approach on parents of college students ignores the 34% of graduating high school students who enter the workforce, military, or other vectors[7] and ignores younger adolescents. By adapting the content and shifting the timing of delivery to parents of all high school students, PN can delay alcohol onset or levels of use and related harm among the broader late adolescent population.
Third, the brief PN intervention will be more engaging than the Parent Handbook because it is personalized and customized,[4] utilizing the most current prevention science and digital pedagogy. Engagement is a key to effective family prevention interventions. Factors limiting the reach of other parenting interventions is the amount of effort involved and the required presence of both parent and child. By personalizing and customizing PN and delivering it to parents only, engagement is maximized.
Fourth, we are evaluating effectiveness by recruiting a nationally representative sample, which will significantly increase the generalizability of the findings. Again, no other published studies examining the effectiveness of brief parent interventions have examined prevention efforts using national-level samples. Having this level of rigor in evaluation is unique and innovative.
Fifth, from a practical standpoint, the PN will be tested using a sustainable platform. Like other digitized formats, there will be some costs for hosting and maintenance, but unlike other family-based interventions, there will be no long-term large expenses associated with having to train/supervise staff for implementing the PN. It simply needs to be provided to parents via the web.
Last, the unique partnership between RP and D.A.R.E. America offers a path to national and international dissemination that is typically difficult to obtain. D.A.R.E., which is in 70% of the U.S. school districts, currently has a limited high school program and the new PN will be the basis for a significant expansion. RP's relationship with 4-H clubs provides a second outlet.

PHASE I PROGRESS REPORT
The objectives of the Phase I research were to: 1) Conduct research to inform the adaptation of Parent Handbook content for parents of all high school students; 2) Adapt PN to a mobilized website format for parents of all high school students; and 3) Conduct an independent usability study of the PN curriculum. All 3 objectives were very successfully accomplished. We discuss these in turn.
Objective #1: Conduct research to inform the adaptation of PN content for parents of all high school students.
Parent Survey. Parents were surveyed to measure how they discussed alcohol use with their older teens and gauge their interest in the PN program. A total of 278 parents of 16 to 20-year-old teens were recruited through (1) a Facebook announcement, (2) the D.A.R.E. program, (3) a Qualtrics survey panel, (4) military organizations, and (4) Chapman University completed the survey (75% female, 25% male) with the following ethnic breakdown: 76% White, 17% Black or African-American, 5% Hispanic or Latino, 1% Asian, and 1% Other. The age distribution of the children was: children aged 16 (24%), 17 (29%), 18 (28%), 19 (24%), and 20 (17%). Our sample reported that 72% of the students planned to attend college following graduation (72%), which was similar to national data based on Bureau of Labor statistics (i.e., 67% actually attending). Screening on parent-child communication styles based on Miller's work[14,15] revealed: 81% reported a partnership communication style with their teen (e.g., open exchange of ideas, joint problem solving); 8% reported a forceful directive communication style with their teen (e.g., strict rules; punishment should rules be broken); and 7% reported an avoidant communication style with their teen (e.g., infrequent and brief communication).

Communication themes that emerged: 1) All communication style parents gathered and shared information from the web or television; 2) Partnership parents discussed the effect of alcohol on decision-making, addiction, sexual risk, social pressure and drinking, the effect of alcohol on the body, refusal strategies, keeping your drink "safe", alternative activities to drinking, and having a safety plan; 3) Forceful parents discussed moderation of use, telling the teen to pace him or herself if drinking alcohol, and telling them to eat food when drinking alcohol; and 4) Forceful and Avoidant parents offered rewards for non-use.

Regarding interest in the PN concept: 1) Interest in the overall PN program was very positive with an overall mean rating of 3.47 (SD = .65) on a 4-point scale (high scores are positive); and 2) Ratings on scales measuring the core modules were all above 4.29 (1-5 scale, with 5 as positive).

Open-ended Parent Interviews. Of the 278 parents surveyed, 32 (28 female, 4 male) parents participated in follow-up interviews. Communication themes that emerged were: 1) Parents discussed effects of alcohol on

decision-making, addiction, and sexual risk; social pressure and drinking; the body; refusal strategies; keeping your drink safe; alternative activities; having a safety plan; discussing family history; hosting parties; legal issues; other drugs including nicotine and marijuana; and friends' problems; and 2) Conversations in their households about alcohol are linked in some way to a parent or other family member who has a problem with alcohol addiction.

Objective #2: Adapt PN to a mobilized website format for parents of non-college bound youth.

The content, format, and features of the PN curriculum[26,54,55] were adapted in collaboration with Klein Buendel's (KB) Creative Team to maximize interactivity and engagement. This process was aided by Dr. Turrisi, Parent Handbook developer and project consultant as well as the expert panel consisting of Dr. Jerod Stapleton (web-based health interventions), Dr. Caitlin Abar (parent-teen communication and adolescent alcohol prevention), and Mr. Andrew Wiss (mobile technology).

Parenting Now! (PN) Talking with High School Students about Alcohol. The curriculum prototype was based on Turrisi's Parent Handbook's original curriculum[1-3] and formative research. The goal of Phase I was to develop the prototype of the first two of the three "core" modules. Module one is an introduction to PN and provides a rationale for why parents should be talking with older teens about alcohol use (completed in Phase I). Module two provides instruction on general communication skills and best practices in communicating with late adolescents about alcohol (completed in Phase I). Module three covers an in-depth discussion of the risks of underage drinking alcohol-related consequences (whom is most at risk, decision making, peer influences, and positive and negative reasons why some teens drink, alternatives to drinking, impaired driving, and riding with an impaired driver) (Scheduled to be produced in Phase II).

Personalization (completed in Phase I). Three adapted versions of core module two were developed based on Miller's work[14,15] and our Phase I findings; each adapted for one of the following parent-adolescent communication styles: Partner parent, Forceful parent and Avoidant parent. Partner parent communication is characterized by communication that is open, bidirectional, and expressive, has shared decision-making, and provides explanations. Forceful parent communication is characterized by an emphasis on parental authority, tends to be unidirectional from parent to child and is focused on gaining compliance. Avoidant parent communication is characterized by communication that is avoidant of sensitive topics and conflict, and a belief that the parent does not influence her/his adolescent.

Optional Content (prototype developed in Phase I and scheduled to be completed in Phase II). A prototype of the "optional content" module was developed in Phase I. The purpose is to provide material to parents with specific interests. These include: Other drugs including nicotine and marijuana, Facts you don't know, Myths busted, Binge drinking 101, Recognizing if your child has a problem, Hosting underage parties, Legal issues related to underage drinking, What can I do?, Alternatives to drinking, Where is your Teen Headed? (College, Military, Workforce), and Cases for Discussion (news stories, video links and discussion questions related to cases of alcohol misuse in the three contexts of college, military, and workplace).

Objective #3: Conduct an independent usability study of the PN curriculum.

An independent usability test was conducted by Dr. Douglas Evans to assess the three most common usability metrics:[56] (1) Efficiency or the degree to which the product is enabling the tasks to be performed in a quick, effective, and economical manner, or is hindering performance; (2) Effectiveness or the accuracy and completeness with which specified users achieve specific goals in a particular environment; and (3) Satisfaction or the degree to which a product is making the user satisfied.

Dr. Evans conducted 10 in-depth interviews with a convenience sample of parent participants recruited from a list provided by Dr. Miller-Day from earlier recruitment efforts as well as his own social network. The interviews were all conducted on the Zoom meeting platform. Dr. Evans and each participant went through the 2 modules of PN content and completed all screens and activities within the prototype training. After each of the two core modules in the prototype, Dr. Evans paused and asked a series of open-ended questions. A summary of themes that emerged are as follows:

- Module 1: Parents felt it started well, provided information that parents need to know, and introduced the overall topic of talking to teens about alcohol well. Most participants liked how it was structured, and at least parts of how it looked and functioned. They found it interesting and generally liked that it explained the research behind why it's important to have these conversations and why having them makes a difference.
- Module 2: The majority of participants felt it provided a lot of valuable information, useful tips, conversation starters, and topical suggestions around communicating with teens about alcohol. Overall, they felt that the basis in research was sound. However, some participants (n = 3) noted that specific studies should be cited (adding links) to back up the frequent claim that "studies show."
- Modules were understandable, easy to use and navigate.
- Video example was realistic and reinforced earlier content. One suggestion was to include more short videos.

After each interview was completed, participants completed a brief additional questionnaire with close-ended usability questions (including the System Usability Scale, SUS) and received a $25 incentive payment. The Overall SUS mean was 4.8, with the means for the 10 SUS items ranging from 4.56 to 5.00, with 5 the highest/most positive rating. Thus, the independent usability study findings were very positive.[56]

Summary of Phase I and Readiness for Phase II. The objectives were all successfully accomplished.

First, we verified parents of all communication styles use the web to gather information for conversations supporting the efficiency of the digital format of the PN that we are refining and completing in Phase II.
Second, our findings revealed not all parents addressed the same topics, which supported the development of core modules (so all parents have the most critical elements), as well as optional modules (so that parents with specific interests will seek information on those topics). This is the basis for the customization approach incorporated into PN in Phase II production.
Third, we observed differences in the communication styles. This is highly suggestive that the personalization approach in PN will be engaging in Phase II.
Fourth, we developed a prototype of 2 of the 3 core modules (as was planned in Phase I) and content for the optional models (as was planned in Phase I). Parents expressed a great deal of interest in PN, found the materials to be interesting, and PN proved very usable in an independent usability trial (e.g., high SUS ratings as well as other data). The independent evaluation and comments from the expert panel also support the usability of the prototype.
In sum, the Phase I confirmed the feasibility of the digital PN intervention and provided, the information needed to develop the full intervention that, we believe, should make a significant impact on youth substance use and contribution to prevention intervention design. We believe we are prepared to advance to Phase II.

APPROACH
The overall aims of this Phase II SBIR are to (1) evaluate the PN intervention for delivery, (2) examine the processes through which PN influences parent, and (3) finalize programming (if needed) and prepare support materials. A timeline of the study procedures and tasks can be found in the Human Subjects forms. To achieve these aims, we established three objectives for Phase II research that provide benchmarks of progress:
Objective 1: Refine and complete development of PN based on Phase I findings.
Objective 2: Conduct a group randomized trial to evaluate outcomes of the PN curriculum.
Objective 3: Finalize PN programming (if needed) and prepare support materials for the market.

Research Team. The proposed study represents a powerful collaboration among RP, Dr. Turrisi (co-I/consultant; Penn State University), Dr. Anne Ray (Rutgers University), Dr. Michael Russell (Penn State University), and Klein Buendel, Inc. for digital technology development. The project is led by PI Dr. Hecht (RP). He has decades of experience with health interventions targeting adolescent/emerging adult populations. RP is a small business focused on the development and commercialization of technology-based health interventions. Drs. Hecht and Miller-Day, the principals, are internationally known for their contributions to prevention science resulting in numerous awards for theoretical and scientific contributions as well as for their prevention videos (see biosketches). The potential impact of an effective, easily implemented D.A.R.E. America curriculum delivered via their national and international network of highly trained Law Enforcement Officers is significant. Dr. Turrisi is internationally known for his work on college drinking prevention as well as other public health issues. Turrisi is a social/developmental psychologist and has built a strong reputation in the field through 30 years of systematic theory-driven research on the implementation of efficacious parent interventions to reduce college student and adolescent drinking and consequences. Turrisi has developed and tested the parent intervention: *A parent handbook for talking with college students about alcohol*. This parent intervention is currently a model prevention resource at NIAAA's College Intervention Matrix and has been evaluated in the most recent Surgeon General's Report as one of two "effective" interventions for college students. Results from Turrisi's NIAAA funded RCTs have provided evidence that parent interventions can be effective as a stand-alone intervention approach or as an important part of comprehensive prevention efforts. Dr. Ray, co-I, will take the lead in refining and completing the digital PN for community implementation, a process she has experience conducting on several NIH-funded projects, including a media literacy digital drug-prevention program for 4-H youth and a tablet-based HPV vaccination promotion intervention for Planned Parenthood clientele. Dr. Ray is also familiar with the Parent Handbook curriculum, as she has collaborated with consultant Turrisi on efforts to evaluate the Parent Handbook, as well as to implement it on several U.S. campuses. Dr. Michael Russell will serve as project methodologist. Russell is one of the core research and training faculty in the Penn State University Methodology Center and has a strong research record with respect to innovative methods for evaluating intensive longitudinal data, RCTs, and conducting complex latent modeling analyses. Russell has worked closely with Turrisi on several projects of the magnitude of the proposed study. He will be primarily responsible for measurement and data analyses and will assist in the dissemination of findings via manuscript and report preparation.

The technology developer, Klein Buendel, Inc. (KB), established in 2002, is a health communication and media development firm that offers experience in the development of interactive, digital health promotion programs, including efforts focused specifically on reducing risky substance use. The KB team will be led by Dr. David Buller, an internationally-known researcher who has contributed to community-based health communication interventions in skin cancer prevention, tobacco control, and substance use prevention. Drs. Buller, Hecht, and Turrisi have strong relationships as colleagues, NIH reviewers, and collaborators for over 15 years. A primary area of Dr. Buller's research is developing effective technology-based interventions to promote disease prevention. These interventions have been delivered over several technology platforms, including

websites, smart phones, and tablet computers. For example, Dr. Buller was PI on the development and evaluation of web-based and mobile interventions to prevent uptake of smoking by adolescents[91] and help young adult smokers quit[92] (R01CA107444), and assist with sun protection for skin cancer prevention[93] (through an SBIR contract from the National Cancer Institute; HHSN261200900025C). Dr. Buller was a co-I on the development and evaluation of a successful online training in responsible beverage service, *Way To Serve*®, to reduce alcohol-related problems,[94] funded by NIAAA (R01AA014982). This program was commercialized by KB through a license agreement and has sold nearly 75,000 units generating over $2 million in sales. Dr. Buller is a co-I on an SBIR project to produce an effective Spanish version of *Way To Serve*®, with support from the National Institute on Minority Health and Health Disparities (NIMHD; R44MD010405). He is currently leading an SBIR project funded by the National Institute on Drug Abuse (R44DA038933) to produce and test a responsible marijuana vendor training for recreational marijuana sales, *Train To Tend*®. Dr. Buller also collaborated on projects to prevent problems associated with substance use in nightclubs using a mobile digital platform (R01AA022331) and translate a family-based intervention for preventing substance use, *Family Matters*, into digital technology (R01AA020977) with NIAAA funding. He is the PI on a randomized trial to demonstrate the utility of using digital platforms for national scale-up of a successful occupational sun protection program, *Sun Safe Workplaces*,[95] with funds from NCI's Cancer Moonshot initiative (R01CA210259). For the proposed project, Dr. Buller will supervise the media developers at KB to create the technology platform for delivering the parent intervention and contribute his expertise and experience with the design of technology-based intervention. KB multimedia developers and graphic designers have developed, tested, and evaluated evidence-based interactive computer-based media for numerous R01, R34, SBIR, and STTR projects and subcontracts. The PN digital platform will be produced by multimedia staff, led by Mr. Steve Fullmer, Creative Team Director and collaborating with study investigators. Beyond projects on substance abuse prevention, KB media developers have produced online training in hospice care for prison staff (National Institute on Aging funding; R42AG049570), mobile apps to promote physical activity by Latina woman (NIMHD funding; R43MD009652) and maintenance of physical activity by African American men (NIMHD funded; R42MD010304), HPV vaccination of culturally-diverse adolescent boys (NCI funded; R01CA210125), and online nutrition education for weight control in pediatric populations (NIDDK funded; R42DK51244).

Dr. Mansfield (Sr. Vice President) will serve as the project manager at GfK, serve as the liaison between GfK and RP and ensure that the goals and objectives of the project that involve GfK are met. Turrisi has worked with members of the research team and GfK on several national studies. The first examined patterns of alcohol use and consequences in non-college-attending adults.[57] In the U.S., abusive drinking patterns are highest among individuals ages 21-25. Although there is a wealth of data on college samples, there is a paucity of research on their non-college counterparts because representative data are extremely difficult to obtain for this hard to reach population of youth. GfK acquired a nationally representative sample of non-college adults (n = 400) and implemented a web-survey on drinking tendencies and constructs from the unified theoretical model. The second was a NCI funded prevention RCT examining indoor tanning initiation (a melanoma risk factor) among female teens[58,59] (ages 12-18).[60] The study collected data on 570 nationally representative teens at baseline, randomized 443 (78%) to intervention arms, and retained 388 (88%) at 12 months. Dr. Buller and KB media developers also have experience working with GfK to recruit national samples for RCTs and implement a smart phone mobile app for skin cancer prevention[93] with NCI funding and health communication messages with tailored visual images with NIMHD funding.

Objective 1: Complete development of PN based on Phase I findings

Content. The refinement and completion of PN will cover three specific areas (core, optional/customization and personalization), all guided by feedback from the Phase I study.

1) Core modules - Each of these are closely based on the content of the Parent Handbook. The *first* module provides an introduction to the problem of substance use generally and an overview of the problems, various basic facts, and instructions on how to use the digitized PN to help motivate them to talk with their teen. The *second* module focuses on specific skill building strategies that parents can use to improve communication channels with their teen and how to roll with resistance. The *third* module is an in-depth discussion of underage drinking, physiological and psychological effects, mixing alcohol with other drugs, motives for why students drink and don't drink, warning signs, risky binge-type drinking, impaired driving, riding with impaired drivers, alcohol and sexual assault, and how to communicate about parents' past experiences.

2) Optional modules (customization) - The purpose of the optional modules is to provide users with control over content based on their specific interests. In Phase I, we developed content for the following: Other drugs including nicotine and marijuana, Facts you don't know, Myths busted, Binge drinking 101, Recognizing if your child has a problem, Hosting underage parties, Legal issues related to underage drinking, What can I do?, Alternatives to drinking, Where is your Teen Headed? (College, Military, Workforce), and Cases for Discussion (news stories, video links and discussion questions related to cases of alcohol misuse in the three contexts of college, military, and workplace).

3) Personalization - The curriculum will be personalized by framing both core and optional content based on parent-child communication style (i.e., partner, forceful), as determined by a brief question set at the

beginning of PN. More specifically, parents will receive similar content, regardless of style, but the way that content is communicated will differ. For example, when presenting alternatives to drinking, content for partner style parents, it will be formatted around "how, what and why" questions they can use to engage their student in coming up with solutions together. Forceful parents will be given direct instruction guidance around consequences of risky drinking and directing them to alternative activities. A second example relates to framing content specific to the importance of having a collaborative, mutual conversation, which is not necessarily the natural orientation for forceful parents. Forceful parents receive this message: "Conversations will be most effective when your teens have the sense that they are collaborating with you and that you both have mutual interests." whereas partner parents receive the following: "Communication is most effective when you both have a feeling of collaboration and mutual interest."

Design Features and Programming. The PN curriculum will adhere to a VODEPS pedagogy – (V) visually engage the learner, (O) provide an overview of the level content, (D) define terms and learning objectives, (E) demonstrate and provide examples, (P) practice skills, and (S) summarize the level. PN is a mobile web app. A mobile web app functions similar to a native app on a smart phone or tablet computer. However, a mobile web app runs through the phone's/computer's web browser controlled by an external web server rather than running on the local device. There are several advantages to this approach: 1) Mobile web apps can be mobile device responsive to ensure cross-platform compatibility. 2) User experience is similar to a native mobile app, but content can be updated much more quickly than native apps that need to download/install a revised version. 3) Mobile web apps avoid the need to program for multiple operating systems (e.g., iOS or Android for smartphones/tablet computers), speeding development. 4) Use of mobile web app can be better tracked from the web servers than from a native app, leading to better evaluation of relationships between curriculum completion and substance abuse outcomes.

Production of PN will be completed by KB's media developers following well-established agile iterative production steps. The mobile web app will run on common web browsers on iOS and Android smartphones and tablet computers and on iOS and Windows personal computers. It will be built on a full stack website, using HTML/JSX, CSS3, and JavaScript for its main interface. Animations are performed using the GreenSock Animation Platform, ReactTransitionGroup, React Motion, and CSS3. The Front-end JavaScript framework used is React.js with React Router v4. Front-end JavaScript framework will be Angular. Look and feel of the training will be designed and developed using CSS 3.0 with HTML5. Login and network activity will be managed by PHP. A backend tracking program will record user progress. The client-side application was developed in a local environment. It includes interactive activities, and voiceover narration detailing instructions for participants. The formats of the pages for PN vary to maintain interest and engagement. Page formats include text-based pop-up animation, video pages, and swiping/clicking activities. Page formats are determined by the content or purpose of each page. 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.

KB will refine and complete the digital programming of PN in consultation with the research team. Investigators have developed goals and specific instructional/behavioral objectives and content for the PN in Phase I. During Phase II, KB will iteratively share content with all members of the team who will review and provide feedback for any remaining revisions. We used a combination of emails, telecommunications, Zoom teleconferencing, and in-person meetings in Phase I (meeting weekly and more often as needed). We will utilize this same approach in Phase II. This process will continue until all necessary improvements are made. Following completion of the digital programming for the remaining modules, we will conduct a usability study that mirrors the approach we used in Phase 1. The functionality of the PN program will be tested by KB on a small group of parents (~n = 5-7). Edits will be made based on these findings and then tested again on another small group of parents (~n = 5-7). Based on our experience on the development time in Phase I, we anticipate this process to be completed in 6 months.

Limitations and Alternative Methods for Objective 1. Face-to-face delivery and/or a longer curriculum may be more effective in reducing substance use. Future research should compare modalities, but the current design facilitates delivery with minimal training and increased consistency, maximizing usability with varied groups. A native mobile app could be produced but it is more expensive and can take longer to produce for multiple device operating systems, is more challenging to update, and its use cannot be as easily monitored as a web app.

Milestones/Deliverables for Objective 1. The benchmark for Objective 1 is when all of the above steps are accomplished and PN is revised to specifications and fully operational with a high degree of usability as expressed in SUS scores above the 68 standard.[56]

Objective 2: Conduct a randomized clinical trial to evaluate outcomes of the PN curriculum.

Randomized Trial Design. The design is a two-arm RCT (PN vs. active control) with 3 waves of data collection: pre-intervention baseline, short-term follow-up (1-month), and longer-term follow-up (6-month). The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks). Youth will complete assessments of all the variables in

Figure 1 at three times. Parent participants will complete a 1-month post-intervention survey to assess fidelity and reactions to PN. Our primary outcomes for the analyses are alcohol use and consequences. Our secondary outcomes for the analyses are marijuana use, nicotine use, and their combined use with alcohol. Our tertiary outcomes for the analyses of mediators are parent communication about alcohol, combined alcohol and other substance use and student factors (e.g., expectancies, norms).

Power analysis. See Design and Power Analyses Section (file) of the new Clinical Information form package.

Inclusion criteria. English-speaking adolescent, aged 16-17, attending high school, and one English-speaking parent (or parental figure), with both having access to the internet. Exclusion criteria: Parents/teens who participated in the Phase I research and any formative research for Phase II will be ineligible for the trial.

Table 1. Randomized Control Trial Study Design

Condition	N	Target	T1	Intervention	T2 – 1 mo	T3 – 6 mo
Active Control	200	Teens	O_{pre}		O_{posts}	O_{posts}
		Parents		X_{SAMHSA}	O_{posts}	
Treatment	200	Teens	O_{pre}		O_{posts}	O_{posts}
		Parents		X_{PN}	O_{posts}	

Participant Recruitment and Procedures. GfK will be responsible for recruiting from their panels. To maximize the diversity of the sample, dyads will be recruited from the GfK KnowledgePanel. This panel closely approximates U.S. Census figures. We will use GfK's tested and nationally-vetted procedures that have consistently resulted in nationally representative samples that are free of sample bias. GfK panels use dual frame recruiting (address-based and random digit dialing; RDD) and statistical sampling to select potential panel members from the general U.S. population. All U.S. households and the members of those households have a known, calculated probability for being selected to join GfK panels. Using known probability information ensures that GfK panel samples are statistically representative across the multiple socio-demographic population characteristics published and updated monthly by the U.S. Census Bureau. Thus, GfK panels use the same principles used in high-quality RDD telephone surveys. Therefore, GfK recruitment and survey collection procedures can minimize: 1) coverage bias, and 2) self-selection bias through use of random sampling techniques. In addition, GfK panels report an excellent record of reducing non-response bias in its panels, with response averages ranging from 50-90% (compare this to 25-50% reported response averages for RDD surveys). A study comparing GfK panels to seven of the largest national panels demonstrated that they came closest to known and standard benchmarks (e.g., Census data, etc.), both overall and in many individual categories. In some instances, the GfK panels were more accurate than the high quality RDD telephone studies. The GfK panels have been used in numerous federally funded projects as well as 100's of peer-reviewed papers and articles in the health and social science fields.[61-63] It has also been utilized for the University of Michigan's CS Mott Children's Hospital National Poll on Children's Health and offered to researchers involved in NSF's Time-Sharing Experiments for the Social Sciences (TESS) projects.

Dyads who meet inclusion criteria will be invited to participate in the study via email before the school year begins. Parent participants will receive a description of the research, a consent form, and contact information for questions or to decline participation. Parents who log on will be directed to a screen describing the research. They will be presented with the parental consent statement and asked to both verify they are the legal guardian and indicate their permission for their teens' participation by typing their name. Once we have received permission from a legally authorized guardian, teens will be sent a link to a teen consent form. Teens who complete their consent will be routed to the survey (see Appendix B). No teen will be given access to study materials without permission of their guardian. Guardians will not be informed of teen's decisions to not participate in the study. Participants who do not respond will receive a series of email reminders (up to 7). Using this approach, we have obtained participation rates of approximately 65-80% across a wide range of topics in our previously funded studies with no evidence of selection bias for individuals who choose to participate versus those that do not on demographic and background characteristics.[1-3] Finally, alcohol or other drug use is not required for inclusion in the study. Thus, there is no concern about this population falsely reporting use to be considered for inclusion in the study.

As noted above, teens who complete their consent will be routed to an online survey. After the baseline assessment, parents will be randomized equally to 1 of 2 groups. Parents in the treatment condition will receive a link to KB's secure server to access PN and complete a brief question set assessing their parent communication style. Parents in the control condition will receive a link to that server to access publicly available SAMHSA alcohol prevention materials for parents. Both conditions take the same length of time to navigate. Parents in both conditions will be instructed to access the materials and discuss the information with their teens during the next month. Thus, the proposed research will have a strong active control condition for which to examine differences in effects increasing the rigor of the study. The link to the website will contain instructions on how to register and use the site. Parents who do not register with the website will receive reminders every 5 days for three weeks; after three weeks, study staff will contact parents by telephone and encourage them to register. RP staff will provide technical assistance if parents have problems using the website. In our previous studies, we have had parental compliance rates with web surveys, parenting materials

from the Parent Handbook, parent-ratings of the Parent Handbook and so on, that have reliably exceeded 88%.[1-3] We anticipate no problems regarding use of the PN in the proposed research.

Teen participants in both the treatment and control groups will receive a follow-up survey (~15 minutes to complete) at 1 and 6 months post-baseline, which will allow us to examine any changes in the proposed mediator variables. Parents randomized to the PN condition will complete a brief question set at the beginning of the PN intervention that assesses parenting communication style and allows for personalization. Parents also receive an immediate posttest to measure fidelity and reactions to PN. Baseline, 1- and 6-month follow-up surveys will each take approximately 25-30 minutes to complete.

Randomization. GfK starts with estimates for survey completion rate, incidence (confirmation of teen's age and consent), and the number of subgroups. These estimates are used to determine the estimated number of eligible parents who have children of study age. GfK then selects the sample of parents from their panels. Parents are then screened for eligibility and consented. Parents that provide consent are assigned numbers based on a random number table sequence and then randomly assigned to one of the study arms.

Data Collection and Measurement. As noted above, self-report surveys programmed and facilitated by GfK will be completed online, at up to 3 timepoints: baseline and 1- and 6-months post intervention (Table 2). In addition, program analytics will be examined to help ensure fidelity to the intervention, and to be included as covariates in all analyses.

Self-Report. Table 2 describes the self-report measures to be assessed, consistent with our conceptual model depicted in Figure 1, including primary, secondary, and tertiary outcomes. As indicated above, both teens and parents will complete online surveys through GfK. This self-report methodology is consistent with major national epidemiological surveys of teen substance use,[64-66] as well as Turrisi's prior work in this area,[1-3,12,13,27,67] and is demonstrated to be valid.[68] Participants will be made aware of the importance of the data, the confidential nature of their responses, and that the research team will follow appropriate procedures to secure their privacy.

Table 2. Measures Reflective of Theoretical Model in Figure 1

Construct	Target	Time	alpha
Primary Outcomes			
Alcohol Use (Daily Drinking, HED, Quantity/Frequency, Peak)[66,69]	Teen	T1-T3	>.70-.90
Alcohol-related Consequences (e.g., Riding with a drunk driver)[66]	Teen	T1-T3	>.75-.85
Secondary Outcomes			
Marijuana Use[66]	Teen	T1-T3	>.70-.90
Nicotine Use (e.g., Cigarette Use; E-cigarette Use; Smokeless Tobacco)[66]	Teen	T1-T3	>.70-.90
Combined Substance Use	Teen	T1-T3	>.70
Tertiary Outcomes (Mediators)			
Parent Communication[70,71]	Parent,Teen	T2	>.75
Alcohol Motives/Expectancies/Willingness/Norms[41,72,73]	Teen	T2	>.70 - >.85
Moderators			
Background Demographics (Birth Sex, Gender Identity, Sexual Orientation, Age, Race / Ethnicity)	Teen	T1	–

PN Program Analytics. Program analytics (i.e., log data) to be collected include total time spent accessing PN, time spent on each module and activities within modules, and number of activities and modules completed. These data will be captured through HTML5 programming and downloaded into Excel. From this data, we will be able to examine the depth of parents' immersion in the program and distinguish between users who quickly moved through the program versus those with a deeper level of engagement as well as assess accuracy and use them to assess effects of program exposure (i.e., dose).

Fidelity of PN Use. We will assess fidelity in several ways. First, we will use the program analytics described above to verify access to PN. Second, we will use practices to ensure that all parents carefully read the PN at least once. We will ask parents to rate each section of the PN in terms of how readable, useful, and interesting they were. Past studies on the Parent Handbook have shown that ratings tend to be uniformly positive, with means on 4-point scales ranging from 3.07 to 3.71 (SDs ranged from .55 to .94).[1,3] Third, parents will be asked if they had discussed specific topics covered in the PN using 4-point scales ranging from (1) not at all to (4) a great deal. Past studies on the Parent Handbook have shown >70% of parents report they had discussed all topics.[3] In our past studies, we have asked parents to underline segments of the Parent Handbook that resonate for them and make comments in the margins of the materials, and found that >70% return the materials with markings and comments throughout (almost all comments being uniformly positive).[1,2] In the current study, we will have an option where parents can click on an icon to add a comment on any section of the PN modules. We will encourage them to do so, letting them know that it will help us understand content they particularly like or feel needs to be refined. Based on our previous work, we anticipate >70% of the parents will read the PN thoroughly, rate the content positively, and communicate the content with their teens.

In our previous work we generally get more mothers (80%) than fathers (20%) to participate. When we have examined the response rates and backgrounds of our families in our previously funded research, we have observed no significant demographic or general attitude biases when we compared parents who agreed to participate in our studies with those who were unwilling to do so.

Participant retention and plans to increase retention. Our retention goals are to have a final sample representative of the U.S. population, free of sample bias, and of sufficient power to address our study aims (see Attrition and Statistical Power sections below). This has been our experience in two large-scale national sample studies with GfK.[57,60] As indicated, GfK's panels tend to outperform other large national panels on known and standard benchmarks (e.g., Census data). GfK's panels typically observe a 2% monthly panel attrition rate that is not-study specific, study-specific retention rates of 80% for short-term follow-ups (1-3 months) and 70% retention in longer-term follow-ups (6-12 months). In Turrisi's recent national RCT study with GfK, he observed a 78% participation rate for teens similar to the proposed study and retained 88% at 12 months.[58,59] Our procedures make every attempt to reduce attrition by keeping respondent contact information current and using methods we have employed in our past work. First, in the initial baseline survey, participants will list and provide contact information for two individuals they DO NOT live with whom we may contact in the event we are unable to locate participants with our contact information, as well as a cell phone number at which they can receive text message reminders. Second, at the beginning of each post-assessment, participants will be contacted by email and asked to update their own contact information and that of the two individuals they indicated as contact individuals in the previous assessment. If they do not respond, we will follow-up by phone. Finally, we will provide sufficient incentives and multiple contacts (up to 7 email reminders) that help with high retention. Using these procedures for the 400 parent-student dyads at baseline, we anticipate the 2% monthly non-study specific attrition will result n's of 320 and 280 dyads at the 1- and 6-month follow-ups.

Attrition analyses. We will first examine if the attrition is random by forming a dummy variable that indicates completion or drop-out at each assessment. The dummy variable will be correlated with key variables in the study (e.g., Group, drinking outcomes). In the past, we have observed nonsignificant correlations suggesting that the attrition has been random and then used the most advanced multiple imputation techniques to impute missing data. We then analyze all cases with the imputed data.[2] Although we have not observed differential attrition by condition, we recognize the potential. We will reduce this possibility by providing the controls with an online link to the intervention at the completion of the 6-month assessment. Thus, all conditions will be identical except for the timing of intervention. However, if we should observe non-trivial correlations (e.g., > .2) between the dummy variable reflecting completers vs. drop-outs, we will include the dummy coded variable as a covariate in subsequent analyses and attempt to interpret significant effects.

Data Analysis

We first discuss general issues and then turn to analyses specific to the aims of the proposed research.

Missing Data. In general, missing data is infrequent and not problematic, but occasions may arise where this must be formally addressed. Data can be missing at random (MAR), missing completely at random (MCAR) or missing in a systematic way. To gain perspective on the nature of the missingness for a given variable, we will create a dummy variable coded for each respondent: 1 = missing value on the variable or 0 = not missing. We will test for associations between this variable and others in the models. We also will apply Little's multivariate test for MCAR. Missing data also can result from attrition. We will differentiate these two sources of missingness and explore for each. We will use Full Information Maximum Likelihood (FIML) and multiple imputation (MI) or systematically model missing data bias, depending on the data and the models.

Assumption Violations. We will use bootstrapping to derive asymmetrical confidence intervals or robust methods[74-76] to address assumption violations. Mplus offers algorithms for both. In general, we will be sensitive to assumption violations and explore data cautiously.

Outliers. We will apply standard methods for outlier detection (e.g., analysis of leverage statistics, residuals, and dfBetas) and also use graphical approaches.

Multiple Items, Variables, and Contrasts. For all of our multi-item measures, we will evaluate the coefficient alphas and factor structures to ensure they are consistent with their psychometric histories. We will examine the intercorrelations and the results of exploratory or confirmatory factor analyses to guide choices about combining indices or latent constructs. When we conduct multiple significance tests, we will compare the robustness of our conclusions both with and without statistical corrections for multiple tests using the strategy discussed in Jaccard & Guilamo-Ramos.[77] In general, we will use a Holm adjusted modified Bonferroni method[78] or the False Discovery Rate (FDR) method[79] for controlling experiment-wise error, both of which are more powerful than Bonferroni methods.

Specification Error. We will be sensitive to issues of specification error, being careful to explore a wide range of model diagnostics to protect against gross model misspecification.

Measurement Error. Where possible, we will adopt strategies that explicitly model measurement error (e.g., use multiple indicators in SEM). For single indicator models, measurement error can be modeled by fixing error variances of measures at a priori specified values that map onto the reliability of these measures suggested by previous research.[80] If it is a multi-item measure, we can create multiple indicators using split-half methods.[81] In cases where we cannot formally model measurement error influences, we will take care to recognize biasing effects of measurement error when interpreting the results of statistical analyses.

Covariates. In our modeling efforts, there may be confounds with some of our core explanatory variables. These confounds will be addressed by statistically controlling for them as covariates in our estimating equations. The choice of covariates is non-trivial, and one must be careful not to engage in atheoretical

partialling. Our approach will be to control if: (1) it is thought to be a source of spuriousness, and/or (2) it is correlated with the key variable(s) in the model but is thought to have an independent effect on the criterion. We will carefully consider the role of variables and explore models as is theoretically appropriate.

Traditional SEM Analyses. Many of our analyses will use structural equation modeling (SEM). A useful computer program for analyzing complex SEM is Mplus.[82,83] It offers bootstrapping, robust standard errors, and numerical strategies to deal with mixtures of categorical and continuous endogenous variables. The models tested will generally be statistically over-identified. We will evaluate model fit using both global indices (chi square, the Bollen-Stine bootstrapped chi square, GFI, CFI, standardized RMR, RMSEA, and p-value for the test of close fit) and focused indices of fit diagnostic of specific points of ill fit (standardized residuals for predicted minus observed variances and covariances, modification indices, the presence of offending estimates, etc.). We will compare results of traditional modeling (maximum likelihood) with those from robust standard errors and bootstrapping. We will have increased confidence in coefficients in results across analytic methods. In the face of poor fit, we will examine diagnostics for revising the model that, first and foremost, are conceptually meaningful. Analytic strategies for interaction effects in complex SEM models are somewhat controversial. Mplus offers a quasi-maximum likelihood method that has desirable properties when data are multivariately normally distributed.[84] Marsh et al.[85] suggest a simple strategy for non-normal data, but which should be supplemented with limited simulation analysis to ensure one is not led astray by relaxed model constraints. Turrisi is skilled at the analysis of interactions in structural equation models and has co-authored several books on the topic. The strategies in Mplus and suggested by Marsh et al.[85] will be pursued as well as limited information estimation approaches using traditional regression models.

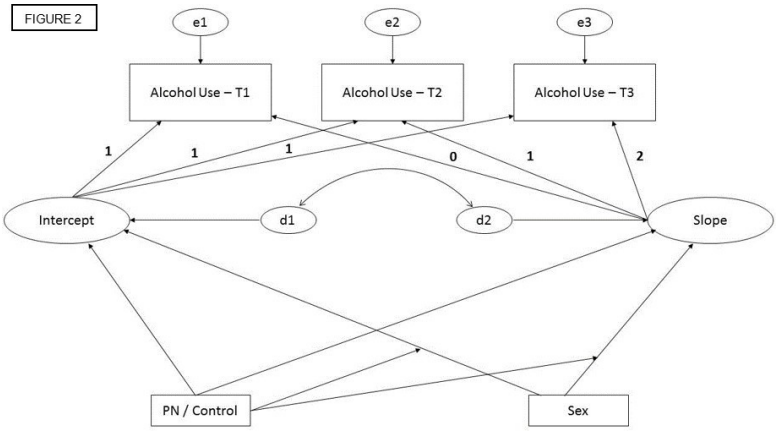
Randomization Bias. We will assess differences at baseline between the groups (PN vs. controls) on major demographic and background variables (e.g., sex, age, education), and if necessary, add these as covariates to the analyses. In our past studies, we have not found significant differences between the groups on these variables when our sample sizes are at the numbers we have proposed (>75 per cell).

Specific issues and approaches for the analyses of the Specific Aims.

Aim 1: Evaluate the efficacy of PN intervention. The primary focus of the analyses will document differences on our primary outcomes (alcohol use and alcohol-related harms) and secondary outcomes (marijuana use, nicotine use, and their combined use with alcohol) between the groups (PN/Control) using a mixed measures analysis of variance. A 2 X 3 (groups X time) MANCOVA will test the impact of the PN intervention on our outcome variables contrasting baseline tendencies against follow-up assessments (3 waves: baseline, 1 mo., and 6 mo.). For Aim 1 (analysis of efficacy), we will conduct an intent-to-treat analysis that will include all individuals who have been randomized to a condition. We will also examine differences in all outcomes by sex of the student (as a relevant biological variable), sexual orientation, and gender identity adding these as covariates to the analyses. We will be sensitive to inflated experiment-wise error rates and control these with modified Bonferroni methods.

Aim 2: Examine mediators. The second aim examines mediation paths in Figure 1 using SEM. We will follow the recommendations of MacKinnon[86] (joint significance). For example, we will examine the relationship between the effects of the PN on predictors at the immediate post-PN assessment (1 mo. follow-up) and their subsequent effects on outcomes at the 6 month follow-up. The models will be statistically over-identified. We will examine global fit indices and focused indices of fit diagnostic of specific points of ill fit in the model (e.g., standardized residuals for predicted minus observed variances and covariances, and modification indices). We will use robust standard errors and bootstrapping. In the face of poor model fit, we will examine diagnostics that are conceptually meaningful and will significantly improve model fit.

FIGURE 2

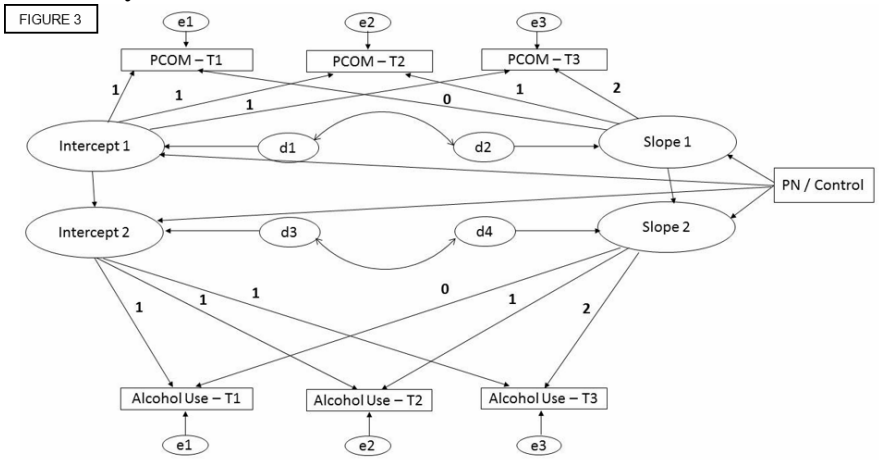


A more sophisticated analysis of efficacy focuses on "growth trajectories" and how these vary by intervention groups. In general, there are two analytic approaches to growth curves, one based on SEM[87] and the other based on the framework of Hierarchical Linear Modeling.[87] We will use the SEM framework to illustrate the basic logic using developmental changes in student alcohol use as an example. This same approach will be used to examine other outcomes. Figure 2 presents a simplified path model illustrating the logic of the approach. In Figure 2, alcohol use is represented by a latent construct at each time point ("T") in the design (T1, T2, T3). We initially discuss the approach assuming a linear trajectory over time, but consider non-linear trajectories shortly. For the variable of interest, a latent intercept variable and a latent slope variable are parameterized, with latent variances of those variables reflecting individual differences in the line that describes growth (either the slope or the intercept) and latent means reflecting the average intercept and slopes, respectively. Paths from the latent variables to the observed measures are fixed at strategically-selected

constants so that the latent intercept reflects the observed measure at baseline and the latent slope reflects the slope of the line describing the trajectory. Individual differences in the slope can be modeled by including time-invariant variables in the model with causal arrows extending to the latent slope variable. This is illustrated in Figure 2 by PN/Control, sex, and the interaction of the two. The statistical machinery for this is well developed and described.[87-89] We will be sensitive to testing, where possible, matters of metric equivalence across time (in the form of equal factor loadings over time [see 88]). We expect to observe metric equivalence but will be sensitive to the need to test this assumption. We suspect that some of the trajectories will be non-linear. One strategy for modeling non-linear trajectories is to use polynomial regression methods that define latent linear quadratic variables, but this often yields difficult to interpret parameter estimates. Our preference is to use spline regression where spline knots are identified and slopes are evaluated between knots. This is incorporated into growth curves and involves representing slopes defined by knots as a latent variable.

Multiple Trajectories that Covary. The analyses can be extended to identify multiple trajectories that covary over time and by group (PN/Controls; Figure 3). For example, the analytic approach would examine the changes over time in parental communication (PCOM) associated with the changes over time in alcohol use and include the effects of time-invariant covariate of PN (vs. controls). This growth curve can be expanded to include other constructs (e.g., parent communication). The focus is on trajectories of change over time rather than single variables. These analyses have not been done in any previous research examining brief PN efficacy or mediation processes in alcohol use but have been used in other risky behavioral areas with good effect.[13] This also can be modified for lagged effects and complex structural dynamics typically discussed in traditional panel analysis. It is possible to parameterize a growth curve model in traditional panel analysis terms like it is possible to parameterize traditional panel analysis in growth curve model terms. The mathematical details can be rather complex, and our experience is that typical social science readers are more comfortable with one framework or the other, depending on the research question. Our point is that for questions that pursue the analysis of the relationship between multiple trajectories, fairly complex causal dynamics and error structures can be modeled.

FIGURE 3



Limitations/Alternative Strategies for Aim 2. An alternative would be to recruit a school district or an adequate number of schools, randomly assigning schools to condition. This would not, however, produce a nationwide sample and would be costly in recruitment and tracking. Administration under these conditions is not, however, directly analogous to eventual dissemination. We accept this tradeoff for the advantages of a representative, national sample.

Indicators of Success/Benchmarks. One indicator of success will be if we hit initial, 1- and 6-month recruitment and retention targets. Secondarily, we expect a high degree of fidelity (i.e., 80% accessing all required material and at least one optional section). The next indicator would be short term effects on mediators on the 1-month follow up. Finally, and most importantly, will be significant effects on behavioral outcomes with a successful test of the conceptual model in Figure 1.

Objective 3: Finalize programming (if needed) and prepare materials for dissemination. We have budgeted for changes to PN based on the overall findings of the study. This may include any technological obstacles we face along with preparing for distribution across platforms and formats. Next, we will integrate PN into the RP website and Facebook sites for dissemination purposes. Finally, we will coordinate with D.A.R.E to integrate PN into its dissemination materials. It is anticipated that we will roll out PN at the annual D.A.R.E International Training Conference. We will also meet with our 4-H collaborators to discuss adoption in their Health Living program. We also will reach out to our other current partners, the Merck foundation, with whom we are expanding the reach of our HPV vaccination intervention and Planned Parenthood, through whom the intervention is currently disseminated. No funds will be used for marketing. This is discussed in further detail in the Commercialization Plan.

Overall Phase II Limitations. We accept that the methodology used is not directly representative of how PN will be ultimately implemented and this will require some adaptation to our community partners. Adaptation occurs in each instance of collaboration. For example, we branded (logos, terminology) our media literacy intervention as REAL messages for D.A.R.E. and as REAL messages for 4-H clubs. It also is possible GfK will be unsuccessful in recruitment and retention, although their record indicates otherwise. Finally, the duration of Phase II funding limits the length of follow up (e.g., no 1-year follow-up posttest) and the number of treatment conditions (i.e., no comparison to handbook version).

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	Feasibility of a mobile parent-based intervention to reduce alcohol use by high school seniors	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002
Expiration Date:03/31/2020

1.1. Study Title *

Feasibility of a mobile parent-based intervention to reduce alcohol use by high school seniors

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

- High school students (ages 16-17)who may be at risk for alcohol, marijuana and nicotine use and abuse, and whose parent/guardian is willing to participate in the proposed study as part of a parent/student dyad.

2.2. Eligibility Criteria

High school students ages 16-17 with their parents/guardians; English fluency; Internet access; at least one parent/guardian fluent in English and with Internet access.

2.3. Age Limits	Min Age: 16 Years	Max Age: 17Years
2.4. Inclusion of Women, Minorities, and Children	Inclusion_of_Women_and_Children_-_PBI_9-18.pdf	
2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan_PBM_9-18.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Timeline_PBIm_PBM_9-18.pdf	
2.8. Enrollment of First Subject	10/01/2019	Anticipated

Inclusion of Women, Minorities, and Children

1. Inclusion of Women

Planned Distribution. The proposed study will involve high school students and their parent/guardian; we expect the data from approximately 50% of female students and expect that 60% of the mothers will be the parent/guardian in these student-parent dyads.

Rationale. We are developing a parent-based alcohol intervention for all high school students. The proposed study will focus on high school students and their parents. Turrisi and Ray have found in past studies of parenting interventions that mothers are more likely to be the consenting/participating parent. Sex of the teen will be examined as a moderator of intervention effects. We will examine sex differences as part of our evaluation.

Recruitment. The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks) drawn from their GfK KnowledgePanel.

Inclusion/Exclusion. Male and female high school students ages 16-17 and their mothers or fathers (or male/female guardian); the student and parent must be fluent in English and have access to a computer and Internet.

2. Inclusion of Minorities

Planned Distribution. Racial/ethnic minorities will be included in this study and participate at rates that approximate similar to national Census population estimates. See the Enrollment Report for expected distributions by ethnicity/race.

Rationale. The goal of the study is to develop an intervention that can be used in schools across the U.S. This requires an effectiveness study conducted on a population that is representative of the U.S.

Recruitment. The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks) drawn from their GfK KnowledgePanel.

Inclusion/Exclusion. Male and female high school students ages 16-17 and their mothers or fathers (or male/female guardian); the student and parent must be fluent in English. This will under-represent certain groups of Hispanics who are monolingual Spanish or prefer Spanish language delivery. Future research will address this subgroup.

2. Inclusion of Children

Planned Distribution. The proposed study will focus on high school students (16-17 years old) and their parents.

Rationale. We are developing a parent-based alcohol intervention for all high school students.

Research Team Expertise. The research team has significant experience as PIs on large-scale funded research projects involving children, teens, young adults and their parents. Team members have been publishing and collaborating together for nearly two decades to improve brief interventions and implement prevention efforts for families. Hecht, Turrisi, and Ray worked together on the Phase I study; Hecht and Ray have worked together on two Phase II NIH/SBIR projects, one of which involved drug prevention; Turrisi and Ray have worked together on several R01 studies of parent-based alcohol prevention.

Recruitment and Retention Plan

Recruitment

The sample will be recruited in Year 1. Parent-teen dyads will be invited to participate and complete baseline assessment during the fall semester and parents will receive the Parenting Now or active control materials shortly afterwards. This will allow an examination of the impact of the PN on alcohol use, and associated consequences and sustained effects across the 6-month follow-up period.

We will use GfK Custom Research (formerly known as Knowledge Networks)'s tested and nationally vetted procedures that have consistently resulted in nationally representative samples free of sample bias. GfK panels use dual frame recruiting (address-based and random digit dialing; RDD) and statistical sampling to select potential panel members from the general U.S. population. All U.S. households and the members within have a known, calculated probability for being selected to join GfK panels. Using known probability information ensures that GfK panel samples are statistically representative across the multiple socio-demographic population characteristics published and updated monthly by the U.S. Census Bureau. Thus, GfK panels use the same principles used in high-quality RDD telephone surveys. Therefore, GfK recruitment and survey collection procedures are able to minimize 1) coverage bias, and 2) self-selection bias through use of random sampling techniques. In addition, GfK panels report an excellent record of reducing non-response bias in its panels, with response averages ranging from 50-90% (compare this to 25-50% reported response averages for RDD surveys).

Dyads from the GfK panels who meet inclusion criteria will be invited to participate in the study via email. Parent participants will receive a description of the research and contact information for questions or to decline participation. Parents who log on will be directed to a screen describing the research. They will be presented with the parental permission statement and asked to both verify they are the legal guardian, and indicate their permission for their teens' participation by typing their name. Once we have received permission from a legally authorized guardian, teens will be sent a link to a teen consent form. Teens who complete their consent will be routed to the survey. No teen will be given access to study materials without permission of their guardian. Guardians will not be informed of teen's decisions to not participate in the study. Participants who do not respond will receive a series of email reminders (up to 7). Using these approaches, we have obtained participation rates of 65–80% across a wide range of topics in our previously funded studies, with no evidence of selection bias for individuals who choose to participate vs. those who do not on demographic and background characteristics. In Turrisi's recent national RCT study with GfK, he observed a 78% participation rate for teens similar to those who will be recruited for the proposed study and retained 88% at 12 months.[58,59]

Finally, alcohol, marijuana or nicotine use is not required for inclusion in the study. Thus, there is no concern about this population falsely reporting use to be considered for inclusion in the study.

Exclusion criteria. Exclusion criteria include: non-high school students; high school students whose parent/guardian does not agree to participate in this study; no computer and/or Internet access.

Retention Plan

Our retention goals are to have a final sample representative of the U.S. population, free of sample bias, and of sufficient power to address our study aims (see *Attrition and Statistical Power* section). This has been our experience in Turrisi's large-scale national sample studies with GfK.[see 57,60] As indicated, GfK's panels tend to outperform other large national panels on known and standard benchmarks (e.g., Census data), both overall and in many individual categories. GfK's panels typically observe retention rates of 80% for short-term follow-ups (1-3 months) and 70% retention in longer-term follow-ups (6-12 months).

Our retention plans include incentives, reminder messages (texts, emails), multiple phone numbers, and contact information for close family and friends. First, teens will each be offered a minimum of $45 for completion of all assessments. Parents will receive a minimum of $25 for participating in the intervention and completing one assessment. To increase participation and retention at later waves, students and parents will be offered small bonuses of $5 for assessments 1 and 2 (youth) and intervention and assessment (parent) completed within five days. Second, in the initial baseline survey, participants will list and provide contact information for two individuals they DO NOT live with whom we may contact in the event we are unable to locate participants with our contact information, as well as a cell phone number at which they can receive text message reminders. Third, at the beginning of each post-assessment, participants will be contacted by email and asked to update their own contact information and that of the two individuals they indicated as contact individuals in the previous assessment. If they

do not respond, we will follow-up by phone. Finally, we will use multiple contacts (up to 7 email or text reminders) that help with high retention. Using these procedures for the 400 parent-student dyads at baseline, we anticipate retaining minimally 80% of the participants across the 12-month follow-up (n = 320 dyads).

	Phase II, Year 1 Timeline											
Month	1	2	3	4	5	6	7	8	9	10	11	12
Finalize PN	x	x	x	x	x	x						
Recruitment (GfK)							x					
Training	x	x						x				
Pretest						x						
Treatment/Active Control									x			
Posttest #1										x		
Data Cleaning											x	x
Report Writing											x	x

	Phase II, Year 2 Timeline											
Month	13	14	15	16	17	18	19	20	21	22	23	24
Posttest 2			x									
Data Cleaning				x	x						x	x
Merge Data Souces					x	x						
Data Analysis						x	x	x				
Report writing									x	x		
Dissemination Plan											x	x

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	National/all states

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): National/all states

Comments:

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	1	0	2	2	5
Asian	8	8	2	2	20
Native Hawaiian or Other Pacific Islander	0	1	1	1	3
Black or African American	20	20	5	5	50
White	100	100	45	45	290
More than One Race	5	5	11	11	32
Total	134	134	66	66	400

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	Protection_of_Human_Subjects_PN_P2_8-24-2018_final.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	DSMPlan_PBIm_9-18.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	Structure_of_Team_PN_9-18.pdf

Protection of Human Subjects

1. Risk to the Subjects

Human Subjects Involvement and Characteristics: Participants recruited to the research study total 400 parent-teen dyads. The teens (aged approximately 16-17) will be current high school students.

Inclusion criteria: Teens who are currently in high school, along with a parent (or parental figure). Dyads will be fluent in English and have smartphone, tablet or computer Internet access. Alcohol use is not required for inclusion in the study. There are also no other exclusion criteria for recruitment other than not meeting inclusion criteria. Teens will be incentivized (amount in brackets) to individually complete a total of 3 assessments including baseline (incentive of $10 plus $5 bonus for early return), 1-month follow-up ($15 plus $5 bonus for early return), and 6-month follow-up ($20). Parents will participate in the Parenting Now intervention or an active control intervention ($15 incentive) and complete 1-month follow-up assessment of the intervention ($15 incentive). Each assessment will take no longer than 25-30 minutes to complete. All assessment procedures proposed in the current study have been used in previous research without adverse incident.

Sources of Material: Research material will consist of self-report responses to web surveys. At baseline, all youth will be asked about alcohol, marijuana, and nicotine use, combined substance use, willingness to use alcohol, alcohol motives, alcohol expectancies, norms about alcohol use, parenting behaviors and basic demographics. Parents will be asked to rate their perceptions of the interventions (interest, usability, etc.). All measures will be completed confidentially and will be collected only for research purposes. Data will not be shared between parents and teens.

Potential risks: The potential psychological risks to human subjects are expected to be minimal and are primarily related to the sensitivity of some of the measures. Items include thoughts, feelings, and substance use that may be private. It is important to note that measures are not diagnostic in nature and will not assess risk of harm to self (i.e., suicidal thoughts). In addition, participants are asked to report on behaviors that may be illegal in some states, such as drinking under the legal drinking age. Answers to these questions could pose a risk if the information were known and linked to identifiable individuals. Although it is our responsibility to point out the potential for these risks, we must emphasize that we have not observed any indications of these risks materializing in any of our previous research using the same procedures we will employ in the proposed study.

2. Adequacy of Protection Against Risks

Recruitment and Informed Consent:
The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks). It will be drawn from the GfK KnowledgePanel that closely approximates U.S. Census figures. These will allow us to enroll a nationally representative sample into the study. The sample will be recruited in Year 1. Parent-teen dyads will be invited to participate and complete baseline assessment during fall semester and parents will be provided access to PN or the active control shortly afterwards. This will allow an examination of the impact of the PN on youth alcohol and other substance use and sustained effects across the 6-month follow-up period.

We will use GfK's tested and nationally vetted procedures that have consistently resulted in nationally representative samples that are free of sample bias. GfK panels use dual frame recruiting (address-based and random digit dialing; RDD) and statistical sampling to select potential panel members from the general U.S. population. All U.S. households and the members of those households have a known, calculated probability for being selected to join GfK panels. Using known probability information ensures that GfK panel samples are statistically representative across the multiple socio-demographic population characteristics published and updated monthly by the U.S. Census Bureau. Thus, GfK panels use the same principles used in high-quality RDD telephone surveys. This online panel includes households that do not have Internet capability by supplying recruited non-Internet households with Internet access free of charge. Therefore, GfK recruitment and survey collection procedures are able to minimize 1) coverage

bias, and 2) self-selection bias through use of random sampling techniques. In addition, GfK panels report an excellent record of reducing non-response bias in its panels, with response averages ranging from 50-90% (compare this to 25-50% reported response averages for RDD surveys). A study comparing GfK panels to seven of the largest national panels demonstrated that they came closest to known and standard benchmarks (e.g., Census data, etc.), both overall and in many individual categories. In some instances, the GfK panels were more accurate than the high quality RDD telephone studies. The GfK panels have been used in numerous federally funded projects as well as hundreds of peer-reviewed papers and articles in the health and social science fields.[61-63] It has also been utilized for the University of Michigan's CS Mott Children's Hospital National Poll on Children's Health and offered to researchers involved in NSF's Time-Sharing Experiments for the Social Sciences (TESS) projects.

Dyads from the GfK panels who meet inclusion criteria will be invited to participate in the study via email. Parent participants will receive a description of the research and contact information for questions or to decline participation. Parents who log on will be directed to a screen describing the research. They will be presented with the parental permission statement and asked to both verify they are the legal guardian and indicate their permission for their teens' participation by typing their name. Once we have received permission from a legally authorized guardian, teens will be sent a link to a teen consent form. Teens who complete their consent will be routed to the survey. No teen will be given access to study materials without permission of their parent or guardian. Guardians will not be informed of teen's decisions to not participate in the study. Participants who do not respond will receive a series of email reminders (up to 7). Using these approaches, we have obtained participation rates of approximately 65-80% across a wide range of topics in our previously funded studies, with no evidence of selection bias for individuals who choose to participate vs. those that do not on demographic and background characteristics.[1-3] In Turrisi's recent national RCT study with GfK, he observed a 78% participation rate for teens similar to those who would be recruited for the proposed study and retained 88% at 12 months.[58,59]

Intervention Materials and Follow-Up Surveys:
At the 1-month follow-up to the baseline survey teens in both treatment and control conditions which will be surveyed to allow us to examine any changes in proposed mediator variables. After the baseline, dyads will be randomized to the treatment and active control conditions. Parent respondents will receive either PN or the active control (SAMHSA website) link. Parents in both conditions will be instructed to read the materials and discuss the information with their teens during the next month. Both conditions will take the same length of time to navigate, and identical fidelity questions and prompts will be used. Instructions for how to register and use the site will be provided on the home page. Parents who do not register with the website will receive reminders every 5 days for three weeks; after three weeks, study staff will contact parents by telephone and encourage them to register. Implementation of technology interventions can be challenging due to participants forgetting, fatiguing, or believing they have learned all they need. The GfK staff will send periodic reminders to parents to use the website; RP staff will be available to provide technical assistance if parents have problems using the website. In our previous studies, we have had parental compliance rates with e-surveys, hard-copy Parent Handbook, parent-ratings of the Parent Handbook and so on that have reliably exceeded 88%. We anticipate no problems regarding use of the web-PN.

Following the intervention dissemination, teens and parents will be asked to complete an immediate posttest survey (1-month) and teens will complete a second posttest at 6-months following the same procedures as detailed above.

Protection Against Risk: All study participants will be provided with an email address and phone number to contact study staff in the event they have concerns. We have taken steps to protect participants against potential risks posed by their participation in this research. Psychological risks of invasion of privacy or increased awareness or concern about one's behavior as a result of completing the assessments will be addressed as a risk in the consent documents. Participants are encouraged to contact the investigators at any time to discuss any concerns they might have. Drs. Hecht (PI), Turrisi (Co-Investigator) and Ray (Co-Investigator) have substantial experience in the prevention of adolescent risky behaviors and are qualified to provide referrals and address concerns related to psychological distress

arising through participation. In our prior research using these same measures in similar age groups, no adverse effects of participation have been encountered. Some participants do contact us to request referrals or other information, suggesting that our projects become identified as a source of support and assistance rather than a stressor.

3. Potential Benefits of the Proposed Research to the Subjects and Others

The risks of this study are expected to be minimal, if they occur. At the conclusion of the study, all control group participants will be sent the link to the web-based PN. There is potential to also help teens in this group choose behaviors to prevent or reduce alcohol use behaviors, thereby reducing their risk of associated consequences. We feel that the potential benefits, in reduced morbidity and mortality, to the subjects outweigh the risk of potential anxiety from answering the personal questions. Should subjects report or exhibit high levels of anxiety, a referral for psychological support will be made.

4. Importance of the Knowledge to be Gained

The knowledge to be gained by the proposed study is key to the evaluation of the long-term benefit of parent involvement in adolescent singular and comorbid substance use prevention. By evaluating means of parent-teen communication about the harmful effects of using alcohol and alternatives to such behaviors, the applicants believe that it will be possible to determine if PN would be beneficial if brought into widespread use.

Data and Safety Monitoring Plan

The Data Safety and Monitoring Plan includes data monitoring, the monitoring and analysis of adverse events, and the description of adverse events; it is presented in accordance with the Interim Guidelines for Reporting Adverse Events to NIH IRBs (http://ohsr.od.nih.gov/info/) and NIH Policy for Data and Safety Monitoring (http://grants.nih.gov/grants/notice-files/not98-084.html). The PIs will report to RP's IRB (Tanglewood), our DSMB, and NIH/NIAAA. The guidance for reporting adverse events will be followed for any adverse events; for serious adverse events, reporting will include the verbal reporting of the event within 24 hours and providing a written report of the event within 72 hours. Expected, non-serious adverse events will be reported at the time of annual, continuing IRB review of the study.

Potential adverse events resulting from participation:

- Distress answering questions
- Discomfort participating in study activities
- Breach of confidentiality
- Disclosure of crime (i.e. substance use) committed by adolescent
- Iatrogenic effects of the PN curriculum

Risk management protocols in place to deal with adverse events.

All project staff will be trained to recognize adverse events at quarterly training sessions that all staff must attend. Opportunities to report events will occur during monthly staff meetings and as they arise.

Parents of students will be required to sign a parental consent form prior to any involvement by the youth in any phase of the study. The consent will acknowledge the potential for events described above. Students will provide assent prior to participation. Parent consent and youth assent to research activities will be obtained through an online process. Only by agreeing to these procedures can the student access the study.

All team members will follow all IRB, RP, and university guidelines that pertain to the handling the identity of human subjects. Informed consent/assent documents will be kept in a locked cabinet in the PI's (Hecht) office.

Plan for Data Monitoring

Confidentiality and Data Security. De-identified data will be maintained in a study-specific database on Dr. Hecht's computer. Customized data management protocols will be developed to confirm the validity and consistency of the data. Confidentiality will be maintained by storing subject names and associated study identification numbers in a separate computerized file maintained on a CD and stored in a locked file cabinet at GfK. Study data will be accessible only through a password-accessible account, which will be maintained by the GfK supervisor.

All data and other information in this study will be maintained confidentially but will not be anonymous due to the longitudinal nature of participation. To protect against risks posed by a potential loss of confidentiality, we will take the following steps: First, subjects will be assured that they are free to refrain from answering any questions they do not wish to answer. Second, all data will be identified only by a unique personal identifier (PIN), which will be randomly generated for study purposes. Web-based data will be collected using a secure server supporting 128-bit encryption. This level of encryption provides the highest level of protection against hackers, computer break-ins, etc. GfK, with extensive experience with sensitive data collection, have secure servers and will sign a confidentiality agreement. A master list of

names and code numbers will be stored in locked file cabinets under the supervision of the GfK supervisor and will be available only to research staff on this project. Experienced research assistants will be employed. Research assistants will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project will complete the required NIH training in protection of human research participants. All staff will sign confidentiality statements. Data will be retained on computers with restricted and password protected access, without links to the master code list. All data based on this research will be reported in aggregate form. No individual respondents will be identified. Finally, using new NIH policy, we will be automatically granted a Federal Certificate of Confidentiality to address our proposed research. This certificate offers the highest protection available by law for research data. We have previously used these certificates in our work with college student and adolescent drinkers.

All project staff will be required to complete and be current with certifications on the NIDA Clinical Trials Network six-hour training on good clinical practices. The current training includes modules on: IRBs, informed consent, confidentiality and privacy, participant safety and adverse events, quality assurance, the research protocol, documentation and record keeping, research misconduct, roles and responsibilities, recruitment and retention, and investigational new drugs.

Plan for Monitoring and Reporting Adverse Events
As described in the human subjects section, all participants are encouraged to contact project staff to report complaints or adverse events and will be given a telephone number and email address. Instructions for reporting adverse events and complaints, as well as for contacting the investigators, are included in the consent documents and on all contact information provided to participants through the course of the study. Dr. Hecht has conducted research for over 30 years in the area of risky substance use prevention and is highly experienced in dealing with these types of issues. Dr. Ray and Turrisi have similar experience, are competent to handle any adverse events that may arise.

Our measures do not assess individuals at risk of immediately harming themselves (e.g., suicidal ideation); therefore, we will not have to screen the data to potentially intervene with individuals who may be a risk to themselves.

Members of the research team have conducted federally funded research on populations of children and adults over the past 30 years and are competent to handle any adverse events that may arise. The research team has conducted and/or had primary leadership roles on several grant funded clinical studies. Both are experienced and qualified to distinguish serious adverse events.

We will notify the RP IRB, our project officers, and NIH (e.g., NIAAA) within 24-48 hours of any serious adverse event. We will provide an annual report to the NIH (e.g., NIAAA) Project Officer summarizing all adverse events should any arise.

Structure of Team

The project is a collaboration among Dr. Michael Hecht and REAL Prevention LLC (RP), Dr. Robert Turrisi (Penn State University; co-I/consultant), Dr. Anne Ray (Rutgers University;co-I), Dr. Michael Russell (Penn State University; researcher/consultant), Wendy Mansfield/GfK, and David Buller/Klein Buendel. It will be managed by Dr. Hecht, PI, supported by a leadership team consisting of Turrisi, Ray, and Russell. The team will have at least monthly meetings, with the entire team meeting at the beginning of each year as appropriate.

PI Hecht (RP) will oversee all facets of the human subjects research, curriculum design (with Ray and Turrisi), financial management/administration, and supervise:

- Ms. Glenn (Staff Assistant, RP), who will schedule meetings and coordinate project activities. She will be responsible for the project timetable.
- Dr. Miller-Day (researcher, RP) who will consult on personalization of curriculum and report writing.
- Dr. Russell (researcher/consultant) who will be responsible for measurement and data analyses.
- Dr. Turrisi (co-I/consultant) who will participate in all facets of the study.
- Dr. Ray (co-I) who will take the lead on curriculum design and be primarily responsible for coordination with Klein Buendel.
- GfK who will recruit the sample and administer the study.
- DSMB consisting of 3 members.

Dr. Michael Hecht (RP) will serve as Principal Investigator of the overall study. Trained in communication, he has decades of experience with health interventions targeting adolescent/emerging adult populations including serving as PI on 5 NIH R01 projects and 2 NIH Phase II SBIR projects. RP is a small business focused on the development and commercialization of technology-based health interventions. Dr. Hecht is internationally known for the contributions to prevention science focused on narrative and culturally grounded prevention intervention design as well as implementation and dissemination science. Hecht's *keepin' it* REAL substance use prevention intervention, recommended by the Surgeon General in the 2016 report on addictions, reaches over 800,000 students in the U.S. and his digital REAL media curriculum, listed as evidence-based by NREPP, is distributed in 11 states through 4-H and nationally through D.A.R.E. The potential impact of RP's partnership with D.A.R.E. to disseminate an effective, easily implemented curriculum via their national and international network of highly trained Law Enforcement Officers is significant.

Dr. Turrisi (consultant) will serve as Co-Investigator of the overall study. Turrisi is a social/developmental psychologist and has built a strong reputation in the field through 30 years of systematic theory-driven research on the implementation of efficacious Parent-Based Interventions (PBIs) to reduce college student and adolescent drinking and consequences. He is internationally known for his work on college drinking prevention as well as other public health issues. Turrisi has developed and tested the PBI: *A parent handbook for talking with college students about alcohol*. This PBI is currently a model prevention resource at NIAAA's College Intervention Matrix and has been evaluated in the most recent Surgeon General's Report as one of two "effective" interventions for college students. Results from Turrisi's NIAAA funded randomized control trials (RCTs) have provided evidence that PBIs can be effective as a stand-alone intervention approach or as an important part of comprehensive prevention efforts.

Dr. Anne Ray (Rutgers) will serve as co-I and take the lead in refining and completing the digital PN for community implementation, a process she has experience conducting on several NIH-funded projects, including collaboration with Hecht on a media literacy digital drug-prevention program for 4-H youth, and a tablet-based HPV vaccination promotion intervention for Planned Parenthood clientele. She is trained in both counseling psychology and biobehavioral health, with an appointment in the School of Public Health. Dr. Ray was a research scientist at RP before joining Rutgers, and is also familiar with the Parent Handbook curriculum, as she has collaborated with consultant Turrisi on efforts to evaluate the Parent Handbook, as well as to implement it on several U.S. campuses.

Dr. Russell (consultant) will serve as project methodologist. Russell is one of the core research and training faculty in the Penn State University Methodology Center and has a strong research record with respect to innovative methods for evaluating intensive longitudinal data, randomized control trials, and conducting complex latent modeling analyses. Russell will work closely with Hecht, Turrisi, and Ray to develop analytic programs for the data analyses, conduct data analyses and assist in the dissemination of findings via manuscript and report preparation. Russell has worked closely with Turrisi on several projects of the magnitude of the proposed study.

Dr. Michelle Miller-Day (researcher) will consult on personalization of the curriculum and research reports and presentations derived from the evaluation component. Dr. Miller-Day is the developer of the family communication styles that will be used to personalize the curriculum whereby her measure of the styles will be adapted to brief form and then content targeted based on this assessment. Dr. Miller-Day played a key role in developing the Parenting Now Phase I curriculum, including overseeing the qualitative formative research. She has published widely and is recognized for her work on family communication about substances, implementation science, and intervention design. Dr. Miller-Day is the co-developer of the *keepin' it REAL* substance use prevention intervention, recommended by the Surgeon General in the 2016 report on additions, reaches over 800,000 students in the U.S.

Dr. Wendy Mansfield (Sr. Vice President, GfK) will serve as the project manager at GfK and liaison between GfK and Hecht, Ray, and Turrisi to ensure that the goals and objectives of the project that involve GfK are met. Turrisi has worked with GfK on several national studies. The first examined patterns of alcohol use and consequences in non-college-attending adults.[57] In the U.S., abusive drinking patterns are highest among individuals ages 21-25. The second was a NCI funded prevention RCT examining indoor tanning initiation (a melanoma risk factor) among female teens[58,59](ages 12-18).[60]

Dr. David Buller will be the lead technology developer at Klein Buendel (KB). KB has been established since 2002, and offers experience in the development of interactive, digital health promotion programs, including efforts focused specifically on reducing risky substance use. Dr. Buller's primary area of research is developing effective technology-based interventions to promote disease prevention. These interventions have been delivered over several technology platforms, including websites and smart phones. For the proposed project, Dr. Buller will supervise the media developers at Klein Buendel to create the technology platform for delivering the parent intervention and contribute his expertise and experience with the design of technology-based intervention.

Ms. Glenn (Staff Assistant, RP) will serve as staff assistant, coordinating activities, maintaining schedules, and assisting in the completion of Parenting Now. Ms. Glenn has a degree in health communication from Rutgers University and experience working with Hecht and Ray on

digitalized prevention interventions materials development. She is trained in research support, a role she fills on a current Phase II SBIR project where she coordinates implementation and evaluation activities in 11 states. She has experience conducting formative research on a project collaborating with the Coalition of Compulsive Gaming of New Jersey focusing on youth gambling online gaming disorder.

Collectively, Hecht, Turrisi, Ray, Russell, Mansfield and Buller have collaborated on several NIH projects over the past decade. Hecht, Turrisi, Ray and Buller/KB collaborated on the recently completed and successful Phase I project developing the Parenting Now prototype and establishing its usability and feasibility. Hecht and Ray have developed and evaluated two digital interventions with community partners through the Phase I/Phase II SBIR sequence. Turrisi and Ray have worked and published together for over two decades to improve brief interventions and implement prevention efforts for families. Turrisi and Mansfield have worked on prior projects examining impaired driving and community-level intervention efforts and have an ongoing collaboration examining the effects of the Mothers Against Drunk Driving intervention on a national level. Turrisi and Russell have worked on cutting edge analyses of RCTs, latent class and latent transition analyses, and intensive longitudinal analyses (diary, EMA), and trained pre- and post-doctoral students in advanced methods. Together, these deep, meaningful, and productive collaborations will add considerably to the research.

Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

High school students' alcohol, nicotine, and marijuana use are major public health problems. Among the many consequences of these risky behaviors are impaired driving and impaired passenger fatalities as well as increased health risks. Both school administrators and parents have requested parent-based interventions (PBIs)for the general high school population that include content on alcohol, nicotine and marijuana use. In addition, digital materials are needed for the "on-the-go" parent. The proposed research will address this omission, curb the alarming trends noted above, and move the field forward by conducting a randomized controlled trial testing a modified, digital version of the Parent Handbook for the all high school students that includes additional content for parents to have broader discussions about combined alcohol nicotine and marijuana use alone (referred to as Parenting Now).

4.2. Study Design

4.2.a. Narrative Study Description

High school students' alcohol, nicotine and marijuana use are major public health problems. Among the many consequences of these risky behaviors are impaired driving and impaired passenger fatalities plus elevated health risks. These concerns are further magnified by reports about alcohol showing: 1) younger drivers are overrepresented in fatal crashes involving impaired drivers; 2) nearly 1 in 5 nighttime weekend drivers are under the influence of combined alcohol and marijuana or marijuana alone; and 3) although over 1.3 million drivers in the U.S. are arrested for impaired driving annually, they only represent 1% of the estimated 121 million self-reported episodes of impaired driving each year. Despite the evidence that our prior brief parent-based interventions (Parent Handbook) for college students have reduced risky drinking and are currently being used on many campuses, there are no digital PBIs with specific content for reducing combined alcohol, nicotine and marijuana in the general high school student population. The proposed research will attempt to address this omission, curb the alarming trends noted above, and move the field forward by conducting a randomized controlled trial testing a modified version of our PBI that includes content for parents to have broader discussions about alcohol and marijuana (referred to as Parenting Now). The study will use an extremely rigorous design that meets the Society for Prevention Research Criteria for Efficacy, a nationally representative sample to significantly increase its generalizability, and an examination of gender differences. To the extent that the research is successful, it will provide an easy to implement and low-cost alternative that can be widely disseminated to address this important public health problem. For example, D.A.R.E. has agreed to implement Parenting Now as part of its high school curriculum.

Parenting Now will be refined and completed based on our successful Phase I research that identified the need for core and optional modules. The core provide a common base of information. The optional modules allow content to be customized, a feature of engaging and effective digital health promotion. In addition, we will personalize content based on parents

styles of communication about substances. This will produce an efficient, engaging and effective means to ienhance parents? ability to reduce prevalence of alcohol use and consequences, and other substance use.

The design is a two-arm randomized control trial with 3 waves of data collection (Parenting Now v active control). The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks). All dyads will complete assessments of all the variables iat three times: pre-intervention baseline, immediate follow-up (1mo.), and follow-up postest(6-mo.). The sample will be drawn from the GfK KnowledgePanel that closely approximate U.S. census figures (exclusion criterion will lead to under-representation of monolingual Hispanics whose inclusion would make the study cost prohibitive).

4.2.b. Primary Purpose: Prevention

4.2.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Parenting Now Intervention that includes content on alcohol, nicotine, and marijuana	Preventive Parenting Now digital intervention emphasizing parent-teen/ young adult communication on drinking/risks of drinking/risks of alcohol abuse, with the addition of a communication component on the risks of nicotine and marijuana use, with the goal of reducing alcohol, nicotine and marijuana use in college students

4.2.d. Study Phase: Early Phase 1 (or Phase 0)

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

4.2.e. Intervention Model: Other

Two-arm randomized trial

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	Alcohol Use	Project years 1-2	A standard drink definition will be provided: a standard drink consists of 12 oz. beer or wine cooler, 8.5 oz. of malt liquor, 4 oz. of wine, 3.5 oz. fortified wine, or 1.5 oz. of hard liquor. Typical weekly drinking: participants will respond to the Daily Drinking Questionnaire(DDQ; Collins et al., 1985) to indicate number of drinks consumed on each day of a typical week within the past six months. Participants will report maximum number of drinks consumed on an occasion within the past month and number of hours spent drinking on that occasion using the Quantity/ Frequency/Peak questionnaire (QFP; Dimeff et al., 1999; Marlatt et al., 1998). Drunkenness will be assessed by asking how many times in the past month participants have gotten drunk, or very high from alcohol using a 6-point scale: (0) never to (5) 9 or more. Heavy episodic drinking will be measured for females and males separately, asking for number of times they?ve had 4/5, respectively, drinks in a row within two hours.
Secondary	Marijuana Use	Project years 1-2	Frequency of use will be assessed by asking how often participants used marijuana during the past six months using a 7-point scale ranging from (0) never to (6) 40 or more times.
Secondary	Combined Use	Project years 1-2	Frequency of combined use will be assessed for participants indicating marijuana and nicotine use with a single item: During times you used marijuana, how often did you also drink alcohol? using a 6-point scale ranging from (0) never to (5) 40 or more times. For participants that indicate their peak drinking occasion a follow up question will assess whether marijuana or nicotine was also used(yes or no).
Secondary	Consequences of Alcohol Use	Project years 1-3	Alcohol-related consequences (e.g., said or done embarrassing things, blackout) from the past six months will be measured using the established Brief Young Adult Alcohol Consequences Questionnaire (BYAACQ; Read, Kahler, Strong, & Colder, 2006). Response options will again be measured on the same a 7-point scale above.
Secondary	Nicotine Use	Project years 1-2	Frequency of use will be assessed by asking how often participants used nicotine products (tobacco, vaping, snuff) during the past six months using a 7-point scale ranging from (0) never to (6) 40 or more times.

Other	Alcohol Motives (tertiary/other outcome)	Project years 1-2	Using the past six months as a time reference, participants will be asked about their motivations to use alcohol. Twenty items for each substance will assess motives for using alcohol, such as ?to be sociable? and ?to forget about your problems? on a 5-point scale ranging from (1) almost never/ never to (5) almost always/always.
Other	Alcohol Expectancies (tertiary/ other outcome)	Project years 1-2	Alcohol expectancies will be measured using a 7-point scale ranging from (-3) strongly disagree to (3) strongly agree. Items will assess how likely a variety of alcohol-related consequences will be experienced in the next few months. For example, items, be worded specifically for alcohol use, such as ?I will feel badly about myself because of my drinking.?
Other	Alcohol Willingness (tertiary/ other outcome)	Project years 1-2	Response options for willingness items will be on a 7-point scale ranging from (1) strongly disagree to (7) strongly agree. Willingness to use alcohol will be measured to assess participants? willingness to 1) drink once or twice in two hours; 2) drink 3-4 times in two hours; and 3) drink 5+ times in two hours. Willingness to use marijuana and COMBINE will be assessed individually with four items asking their willingness to use marijuana/ COMBINE occasionally, regularly, weekly, and daily.
Other	Alcohol Norms (tertiary/other outcome)	Project years 1-2	Perceived norms of drinking for the past six months will be measured using the DDQ using closest friend as a referent. To assess peer injunctive norms of alcohol use participants will be asked to indicate how acceptable their closest friends would find of a list of situations (e.g., drinking enough alcohol to pass out) using a (1) strongly disapprove to (7) strongly approve scale.
Other	Parental Communication (other/tertiary outcome)	Project years 1-2	Parental communication about alcohol, nicotine, and marijuana use, COMBINE, and alcohol consequences will be assessed separately for parent and teen. Participants will be asked whether their parent discussed these topics (yes/no) with them within the past six months. Items include topics such as ?the importance of not being pressured to drink to fit it? and ?how marijuana works in the body?.

4.4. Statistical Design and Power — PN_Statistical_Design_and_Power final.pdf

4.5. Subject Participation Duration — 2 years

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 — Dissemination_Plan_-_PN_FINAL_REVISED.pdf

Statistical Design and Power

Design: The design is a two-arm randomized control trial with 3 waves of data collection (PN vs. Control). The study will enroll a nationally representative sample of 400 parent-student dyads through GfK Custom Research (formerly known as Knowledge Networks). All dyads will complete assessments of the variables in Figure 1 at three times: pre-intervention baseline, immediate follow-up (1-mo.), and a short-term follow-up (6-mo.).

Power: The sample sizes were chosen based on statistical analytic and theoretical considerations. For Aim 1—examining the efficacy of the PN, we will have final dyad sample n = 400. This translates into our two groups (PN/Control) each having n's of ~200 at the 1- and 6-month follow-ups. Using power estimation procedures described in Cohen,[90] these sample sizes will yield power of greater than 0.80 for small effect sizes (e.g., 5–10% of the outcome variance) in the MANCOVA-based analyses (omnibus tests, interactions, and planned comparisons). In our published papers with similar Ns comparing drinking or marijuana (primary outcomes) for similar parenting-based interventions and controls,[1-3,12,13,27,67] we have detected effect sizes of .05 to .09 for main effects and .05 to .08 for interactions. We will have similar power for comparing consequences of alcohol (secondary outcomes). Thus, with our final Ns we should have sufficient power to evaluate Aim 1.

For Aim 2, we will use structural equation modeling (SEM) to assess paths between the Group (PN vs. Control) and the mediators (parent-child communication, parental monitoring, parental permissiveness) and student factors at follow-ups (e.g., motives, behavioral willingness, norms, expectancies) as described in MacKinnon et al.[86] In terms of determining the proper sample, the use of SEM means that in addition to statistical power, issues of the stability of the covariance matrix, model complexity, and use of asymptotic theory must be taken into account. In terms of power, it is difficult to evaluate the power associated with specific path coefficients in complex SEM models due to the large number of assumptions about population parameters that must be made. A rough approximation can be obtained by applying power analyses for a coefficient in multiple regression analyses in the context of limited information estimation of path models. As an example, for a regression analysis with 5 predictors (e.g., intervention group, parent discussions, student motives, behavioral willingness, sex, and age) where the squared multiple correlation is 0.25 and where one wants to detect a predictor accounting for at least 5% unique variance in the outcome (e.g., alcohol misuse or alcohol-related consequences), the sample size to achieve power of 0.80 is approximately 125. For a logistic regression analysis having a dichotomous outcome (e.g., yes/no to heavy episodic drinking in past 30 days) where the target predictor is a continuous predictor (e.g., motives), with four other predictors in the equation (e.g., group, parent discussions, sex, and age), where the event rate at the mean of all predictors is 0.20 and where the multiple correlation of the predictor with the other predictors is 0.30, the sample size needed to detect an odds ratio of 1.75 expressed in standardized metrics is about 170 and for an odds ratio in standardized metrics of 2.00 is about 110. Our projected completed sample sizes exceed these thresholds. Thus, we should have sufficient power to evaluate Aim 2 for continuous and non-continuous outcomes.

Dissemination Plan

We plan to disseminate results of the project both through publication/presentation and through the commercialization plan. As demonstrated by our biosketches, this is likely to include a wide variety of public health-related disciplines as well as a broad national and international reach.

Publication Plans: We plan at least 3 main publications from this project: 1) on results of the RCT efficacy trial on alcohol use; 2) examination of co-occurring substance use effects; 3) a test of the mediation and moderation model. The project has significant potential to be applied in other public health domains and if efficacious may be a model for public health prevention programs. We also plan on presenting papers at conferences, like the ones we have previously attended such as CADCA, Society for Prevention Research, and D.A.R.E.'s International Training Conference.

Implementation Models: One of the competitive advantages this project will offer, if effective, is a flexible implementation model with effects on youth. During the final step in Phase II we will confer with D.A.R.E. about integrating Parenting Now into their high school curriculum and explore alternative ways to implement the curriculum in schools and community groups not involved with D.A.R.E.

Distribution Plans: REAL Prevention utilizes two strategies for distribution: (1) commercialization through partners, and (2) commercialization through REAL Prevention's direct-to-consumer program. The commercialization through partners is best exemplified through our existing licensing agreement with D.A.R.E. America for our elementary and middle school versions of *keepin' it REAL*. The middle school curriculum *keepin'* it REAL was developed under a series of NIH R01 grants to Penn State University (Hecht PI) and licensed to D.A.R.E. Penn State transferred the IP and license to REAL Prevention, which now owns the copyright. The elementary version was then developed in a separate contract between REAL Prevention and D.A.R.E. for collaborative development and joint copyright ownership. D.A.R.E. markets the curricula to law enforcement and schools, and then pays a royalty to REAL Prevention. Our REAL media curriculum is being implemented by 4-H clubs in 11 states this year with plans for a similar licensing agreement through their Healthy Living program. With this strategy REAL Prevention incurs no marketing and distribution expenses, allowing us to maintain a lean organizational structure. This structure also allows REAL Prevention to focus most of its energy on new product development and evaluation.

The second strategy involves REAL Prevention direct-to-consumer commercialization. Here, schools and community organizations purchase curricula directly from REAL Prevention. To date, this has been a smaller part of our business, but we are positioned to expand rapidly through our newly redesigned website and Facebook page. Publication of the Surgeon General's report and inclusion of Youth Message Development (a predecessor for REAL media and thus REAL media plus) on NEPP along with enhanced marketing through social media have increased sales through the website. Youth organizations and individual consumers purchase access to curricula using this site. System (OS) services include: Point of purchase (i.e., where individual or group licenses can be purchased); Secure login (i.e., user ID and passwords for up to 10 million profiles); Cloud storage for participant data; Database architecture and file management; and analytics for the curriculum to track in-app participation. REAL Prevention hired staff member Erin Messmer specifically to support these efforts.

Delayed Onset Studies

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

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Resource Sharing Plan

REAL Prevention is committed to the open and timely dissemination of research outcomes. Investigators in the proposed activity recognize that promising new methods, technologies, and strategies may arise during the course of the research. The Investigators are aware of and agree to abide by the principles for sharing research resources as described by NIH in "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Research Resources." The proposed research will include data from approximately 400 high school teenagers and their parents. The final dataset will be stripped of identifiers. We will make the data and associated documentation available to users only under a data-sharing agreement that conforms to the REAL Prevention's IRB approved participant informed consent that provides for: (1) a commitment to using the data only for research purposes and to not attempt to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.