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Title: Program Sustainability Action Planning Training Project

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1.0 Introduction – Background and Rationale

Background

The emergence of dissemination and implementation (D&I) science has driven a rapid increase in studies of how new scientific discoveries are translated and developed into evidence-based programs and policies. However, D&I science has paid much less attention to what happens to programs once they have been implemented. Public health programs can only deliver benefits if they reach maturity and sustain activities over time. In order to achieve the full benefit of significant investment in public health research and program development, we need to understand the factors related to sustainability and develop tools and trainings that support strategic long-term program sustainability. The goal of this proposed study is to increase the capacity for sustainability among evidence-based tobacco control (TC) programs.

Rationale

Sustainability as an important next step in dissemination and implementation (D&I) research.

Demonstrating that an intervention is effectively implemented, (the initial process of embedding interventions within settings[12]), is only the first step in impacting the health and wellness of a target population. In order for the population to reap the benefits of an implemented evidence-based intervention, it must be sustained over time. In recognition of this, several recent D&I papers have called explicitly for sustainability research as an essential next step in the field.[10,11,13–21] Program sustainability—the extent that interventions can continue to be delivered over time and institutionalized within settings[12]—is a complex process, often fraught with challenges.[16,21–23] Research consistently indicates that even effectively implemented interventions risk failure when funding ends[10,20,24] or when planning and training stops.[25] In fact, it is estimated that up to 40% of programs fail within two years of losing funding.[26] Implementing a program and then failing to sustain it can have disastrous consequences for the community though loss of trust and waste of valuable community resources.[27] Though there is growing interest in the study of program sustainability, there is little agreement on how to best sustain initiatives over time.[23,28] This is due, in large part, to the historical lack of sustainability assessment tools that are both reliable and widely disseminated[16,29] and an essential absence of an evidence-based action planning process for sustainability.

Importance of sustaining evidence-based TC for public health.

As of 2013, 42.1 million– or 1 in 5— adults in the US smoke, which leads to an estimated 480,000 preventable deaths per year due to tobacco use. Approximately 61,000 of those deaths occur from secondhand smoke exposure. According to the Center for Disease Control and Promotion (CDC), if smoking continues at its current rate, more than 5 million of today's youth will die prematurely, and the economic cost of smoking will rise to more than $300 billion per year.[30]

Tobacco use has long been identified as a major preventable cause of death and disease in the US. There is also little debate that TC expenditure directly impacts tobacco use rates in the US. Between 1985 and 2003, US adult smoking prevalence declined from 29.5% to 18.6%. This sharp decline directly correlated with state TC program funding rates.[1] Farrelly et al. estimates, "If, starting in 1995, all states had funded their TC programs at the minimum or optimal levels recommended by the CDC, there would have been 2.2 million to 7.1 million fewer smokers by 2003."[1] Given the established evidence for the state TC model and the work left to do in this field, it is vital that these programs continue in all 50 states, both to improve quality of life and reduce

the massive healthcare costs incurred by smoking-related illness.[1] Failing to sustain evidence-based TC initiatives will likely lead to stagnation in smoking cessation rates and an increase in new smokers.[1]

The need for evidence-based sustainability training and technical assistance. Empirical evidence has established that program sustainability can be improved through training and technical assistance;[11,31–33] however, to date, no evidence-based program sustainability training curricula exists. Thus, systematic methods are needed to empirically develop, test, and disseminate sustainability training to improve institutionalization of evidence-based programs. While there is a growing body of research on the factors affecting sustainability,[11,15,20–23,34] virtually no empirical work has been done to translate the components of program sustainability capacity into practical guides and tools for practitioner utilization.[11,28] Our work with over 50 public health programs indicates that managers, evaluators, and practitioners need assistance in using sustainability assessment results to inform sustainability planning priorities, along with a clear process for completing a written sustainability plan that is easy to implement.

Importance of utilizing an action-oriented approach. Literature indicates that the best practice for impacting long-term behavior and institutional change is a hands-on, action-oriented, in-person[35–37] training program. A study that involved action planning training with coalition groups working on substance abuse initiatives in Tennessee found positive changes in sustainability readiness (increased infrastructure capacity) post training,[11] and a meta-review of health behavior change outcomes found that intervention amount, duration, and penetration all impact level of behavior change.[38,39]

Research also highlights the importance of creating an action plan to move sustainability progress forward. Creating a sustainability plan has predicted both program survival and post-launch funding,[40] and obtaining future funding facilitated the institutionalization process of a new intervention.[41] Additionally, plan specificity and attitude toward intervention predicted plan adherence,[42] and perceived self-efficacy, policy support, and level of institutionalization predicted sustainment of plan initiatives.[25]

Innovation

This study makes important contributions to D&I science and is innovative because it:

1. *Develops the first ever evidence-based Program Sustainability Action Planning Model and Training Curriculum.* By establishing an evidence-based method for action planning and technical assistance surrounding program sustainability, we are supporting state TC programs and other evidence-based public health initiatives to sustain their positive impact in a tumultuous funding climate. In addition, this work will advance the field of study of action planning and technical assistance in general which can contribute to aspects of the D&I field beyond sustainability.

2. Links closely with practice at an opportune time. As part of the DP15-1509, National State-Based TC Program Funding Announcement set forth by the CDC, all 2015 awarded applicants (includes all states and territories) are "required to develop a sustainability plan to ensure sustainability and maintaining a state based TC program" and "provide measures of execution of all activities as outlined in the sustainability plan."[2] Our development of the Program Sustainability Action Planning Training and broad dissemination will assist states in fulfilling this requirement and establishing their capacity to continue sustainability planning over time.

3. Further advances D&I science related to establishing validated measures for sustainability. The study will also provide further clarity on the challenges, benchmarks, and programmatic factors that contribute to sustainability (versus implementation) of an intervention. We will also use the data collected to explore the predictive validity of the Program Sustainability Assessment Tool, which will enable programs to better plan for and improve the sustainability of effective programs.

4. Provides broad dissemination of training materials and results. The curriculum and lessons from the training program will be systematically disseminated (at no cost) to several key audiences (e.g., trainers in federal and state agencies, staff in public health agencies). Since our training program focuses on capacity for sustainability, our methods and approaches will be applicable to numerous other public health issues.

1.0 Objectives

The overall goal of this proposed study is to increase the capacity for sustainability among evidence-based tobacco control (TC) programs. Although all 50 states have implemented evidence-based TC programs and policies, states vary in their abilities to support and sustain these programs over time. Most states still do not meet the CDC recommended level for funding their TC program allowing for tobacco use to remain the leading cause of preventable disease and death in the US.[1] Also, as part of the 2015 National State-Based Tobacco Control Program Funding Announcement released by the CDC,[2] all awarded state applicants are "required to develop a sustainability plan" and "provide measures of execution of all activities as outlined in the sustainability plan". There are currently no available resources specifically designed to help states meet this requirement making this project imperative for states to effectively meet this important funding requisite.

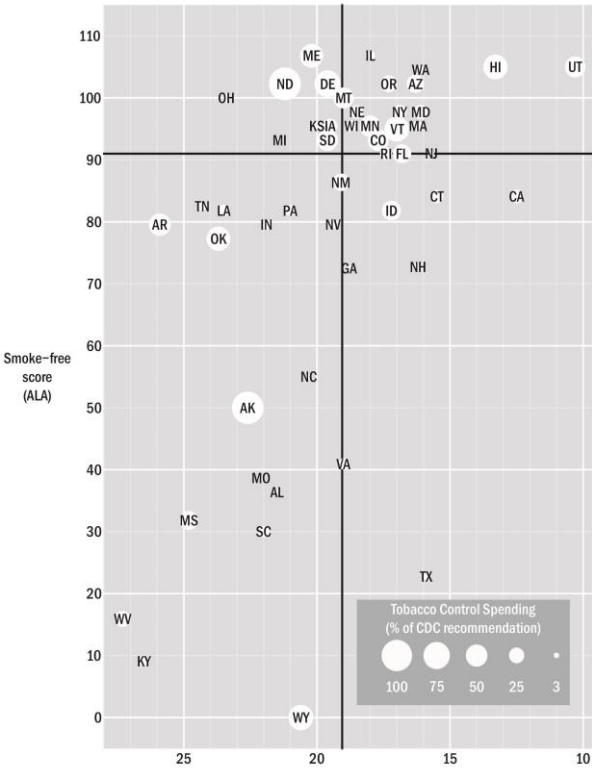
- Phase 1 (Aim 1) focuses on refining and finalizing our evidence-based Program Sustainability Action Planning Model and Training Curriculum and deliver to 12 states. The Program Sustainability Action Planning Training will incorporate experiential learning methods[3–6] and includes: action planning workshops, development of action plans with measurable objectives to foster institutional changes, and technical assistance.
- Phase 2 (Aim 2) will use a randomized effectiveness trial to assess the Program Sustainability Action Planning Training in 24 states (12 intervention, 12 comparison). Evaluation of our training program is centered on the theory of change.[7,8]
- Phase 3 (Aim 3) focuses on responding to study results by making any needed revisions and conduct widespread dissemination of our Program Sustainability Action Planning Model and Training Curriculum starting with the 12 comparison states.

3.0 Selection of Participants – Eligibility Criteria

Recruitment. A total of 24 state TC programs will be recruited to participate in this study. We believe this number is feasible for three main reasons: (1) this training will be in high demand because of the CDC's requirement for all state TC programs to complete a sustainability plan; (2) our strong relationships and past success in evaluating state level TC programs; (3) our project consultant's 20+ years working directly with state level tobacco programs (Eischen).

State selection. We will recruit 24 states, and then randomly assign each state into intervention and comparison conditions. To ensure that both the intervention and comparison groups are equally diverse in terms of organizational factors relevant to tobacco control, we will stratify states using the following three criteria: (1) tobacco control policy progress, (2) smoking rates, and (3) funding for TC program. Tobacco control policy progress is operationalized as the American Lung Association's (ALA) 2015 Smoke-free Score for each state.[88–90] The ALA "grades" each state annually according to the comprehensiveness of its smoke-free policies (higher scores indicate more comprehensive smoke-free policies). 2013 adult smoking rates are used for smoking rates[90] and funding is measured as the actual amount spent on tobacco control as a percentage of the CDC-recommended amount of spending for FY2015.[88,91] Together, these three indicators characterize states' needs (smoking rates), inputs (funding), and environments (policy). States will also be chosen based on willingness to participate and receipt of prior sustainability training. Figure 3 is divided into quadrants by the median smoking rate and median Smoke-free Score. The size of the circles within each quadrant represents the varying levels of funding. The quadrants delineate the primary selection guidelines. Six states from each quadrant representing varying levels of funding will be randomly assigned to either the intervention or comparison group. This process will guard against selecting a disproportionate number of well- or poorly-funded programs for each group. Furthermore, it will ensure both the intervention and comparison groups are evenly varied in terms of needs and policy environments. All participants in this study are aged 18 years or older. States agreeing to participate in the study will learn of their group assignment after completing the PSAT.

Figure 3. Selection criteria for intervention and comparison groups



4.0 Participant Registration

We will work with the Office on Smoking and Health (OSH) at the CDC to identify a list of state TC program managers to contact during study recruitment/registration. We will contact all identified program managers and invite them to participate in the study, as well as provide project fact sheets, outlining benefits and responsibilities of being a part of the study. Once we divide states into intervention or comparison group, we will work with each state program manager to identify a sustainability workgroup consisting of 5-12 members actively involved in TC initiatives in the state. In our experience, we have found that the desired organizational outcome (institutionalization) is best achieved if an integrated workgroup comprised of internal state health department staff (i.e., the program coordinator and TC program director); external stakeholders (i.e., TC coalition members or national TC advocacy groups); and policy makers (especially if there is a TC champion in the state) complete the PSAT and actively participate throughout the 6-step action planning process. Therefore, the composition of each state program's sustainability workgroup will not be randomized.

Participants receive a consent letter (Appendix D, attached) that details participation in the study. Participants are able to review this letter privately and for several days. To register, participants email the research project manager identified in the letter. Participants are able to ask questions at all times using phone and email contact information for the research team located at Washington University in St. Louis.

5.1 Treatment Plan

Phase 1 (Aim 1)

<u>Delivery of Program Sustainability Action Planning Training (intervention protocol).</u>
The Program Sustainability Action Planning Training will be designed to assist states in completing each of the 6 steps in the action planning process and consists of three components (1) pre-workshop preparation, (2) an in-person two day workshop, and (3) ongoing technical assistance and support. Each component will be defined by experiential learning and participation by multiple stakeholders. A sustainability workgroup will be defined for each state consisting of 5-12 members who are actively involved in TC initiatives in the state. To ensure training fidelity, delivery of all training components will be overseen by Dr. Sarah Moreland-Russell, Principal Investigator and Ms. Rebecca Vitale, Project Manager.

Preparing for the workshop. Approximately two months before scheduled workshop, we will work with the state tobacco control program manager to identify the list of TC stakeholders who will be involved in workgroup based on our standardized workgroup selection criteria.[31] Once a list is determined, we will work with the program manager to plan a time to conduct an "Introduction to Sustainability" webinar. This webinar educates listeners on the Program Sustainability Framework (8 domains), defines the parameters one should use when completing PSAT items (i.e., define the "program"), explains how to complete the PSAT online, and provides a time for state-specific Q & A. Prior to the webinar, we will ask the program manager and all stakeholders to complete an *optional* Qualtrics survey, assessing general state tobacco control program sustainability perceptions and individual demographics (age, gender, race, per NIH reporting requirements). Personally identifiable information will not be collected. The pre-

workshop webinar is important for two reasons: (1) it familiarizes all workgroup members with the components of sustainability as outlined in our framework, and (2) introduces the PSAT and steps for completing the PSAT online. The webinar instructs users to answer N/A to PSAT items they are unable to accurately assess. The pre-workshop webinar will last 45 minutes and provide a forum for participants to ask questions about the project. The PSAT will be administered online to all workgroup members and results will be aggregated into a report that will be disseminated to the participants prior to the start of the in person workshop. There will also be follow-up correspondence, discussing state-level results of the PSAT, as well as recommendations for action planning next steps and a summary of resources.

Workshop Day 1. The workshops will take place in each state at the state health department (unless a more convenient site is determined). Trainers will follow an instructor manual and will provide an interactive workbook for completing the main goals for each day. This workbook will prompt users throughout the training to document reactions, ideas, and plans that arise in the workshop. The main goals for Day 1 will include defining the program and reviewing assessment results. Activities for Day 1 will include clarifying the program's mission and vision and specifying the population it currently serves; reviewing the current activities and services that the program is implementing; and clarifying any program and organizational capacities that will be necessary to sustain the activities. PSAT scores will identify sustainability areas that need attention. These goals align with Steps 1-2 of the Program Sustainability Action Planning Model.

Workshop Day 2. The main goal for Day 2 is to develop an action plan. Activities for Day 2 include outlining action plan components including: (1) specific, measureable, attainable, realistic, and time-sensitive (SMART) objectives; (2) specific action steps (activities) for achieving objectives; (3) a timeline for completion of each objective; (4) persons responsible for completing each objective; (5) a clear definition of outcomes and measures for successful completion of each objective and overall plan. The workbook will include activity handouts encouraging discussion around different areas of program sustainability. Handouts will also include templates for action planning and materials for tracking technical assistance interactions. These goals align with Step 3 of the Program Sustainability Action Planning Model.

Technical Assistance and Support. Following the in person two-day workshop, the state TC program will be responsible for executing the action plan and tracking its progress in achieving plan objectives (Steps 4-6 in action planning model). Technical assistance is an essential step in the proposed action planning process and will be focused on building each state program's capacity for quality implementation of the action plan.[92,93] Technical assistance built on best practice indicators[17,92–100] will include state-specific quarterly plan review and feedback, assistance in troubleshooting problems with step completion, sharing insights on plan successes from other similar states, and facilitating connections between similarly-focused states. The research team will remain "on call" for states who need assistance beyond the planned quarterly calls. States will also have access to our website https://sustaintool.org, which contains a wealth of information on general action plan execution and domain-specific resources to support plan completion and execution. The website is updated quarterly with new resources and materials. States will be encouraged to retake the PSAT at 12 months and repeat the action planning cycle to revise their action plan based on PSAT results and environmental changes, using the indicators and process provided in the original training cycle.

Comparison state protocol

Comparison state programs will participate in the PSAT assessment, record abstraction, and a key informant interview and survey with state program managers at three time points. Before taking the PSAT, we will work with the state tobacco control program manager to identify the list of TC stakeholders who will be involved in workgroup based on our standardized workgroup selection criteria.[31] Once a list is determined, we will work with the program manager to plan a time to conduct an "Introduction to Sustainability" webinar. This webinar is identical to the webinar issued to the intervention group, because state programs will be informed of their group selection after completing the PSAT. The webinar educates listeners on the Program Sustainability Framework (8 domains), defines the parameters one should use when completing PSAT items (i.e., define the "program"), explains how to complete the PSAT online, and provides a time for state-specific Q & A. Prior to the webinar, we will ask the program manager and all stakeholders to complete an *optional* Qualtrics survey, assessing general state tobacco control program sustainability perceptions and individual demographics (age, gender, race, per NIH reporting requirements). Personally identifiable information will not be collected. The pre-workshop webinar is important for two reasons: (1) it familiarizes all workgroup members with the components of sustainability as outlined in our framework, and (2) introduces the PSAT and steps for completing the PSAT online. The webinar instructs users to answer N/A to PSAT items they are unable to accurately assess. The pre-workshop webinar generally lasts 45 minutes. Comparison states will receive a detailed sustainability assessment report outlining the state's PSAT scores. There will also be follow-up correspondence, discussing state-level aggregated results of the PSAT, as well as recommendations for action planning next steps. At this point, we will provide a brief packet with resources about program sustainability. However, comparison states will not receive any other component of the training until year four of this project, when they we disseminate the finalized curriculum materials. Some comparison states might independently implement sustainability plans over the course of the grant. We will track implementation and account for it in analyses.

Phase 2 (Aim 2)

(Aim 2): Demonstrate change in sustainability outcomes in states who received the Program Sustainability Action Planning training compared to states who did not.

The overall goal for the Program Sustainability Action Planning Training and subsequent dissemination activities is to increase capacity for sustainability of evidence-based state TC programs through the institutionalization of the program. To determine the extent of reaching this goal, we will design a randomized effectiveness trial to document differences in organizational and programmatic measures and Program Sustainability Assessment Tool scores between intervention and comparison states. We will rely on three sources of data for this study: 1) state-level program records for measures of predictors of sustainability and institutionalization,[9,11] 2) PSAT scores and 3) a key informant interview and survey with state program managers. While we anticipate that our study will impact behavioral risk factors for tobacco-related diseases (*e.g.,* rates of smoking and initiation), the dependent variable for our study involves measures of program institutionalization and sustainability.

C.6.a. Data collection methods

Pre-Introduction to Sustainability Webinar Survey

All participants will receive an optional Qualtrics survey via email, prior to participating in the "Introduction to Sustainability" webinar. Participants will be asked program sustainability perception questions, as well as demographic questions (age, gender, race, per NIH reporting requirements). Personally identifiable information, such as the participant's name, will not be collected.

Program Sustainability Assessment Tool (PSAT)

The PSAT has established reliability and face validity for effectively measuring program capacity for sustainability.[43] The PSAT contains 40 questions (5 items per 8 domains) and is measured on a 1-7 scale where 1 indicates "To little or no extent" and 7 indicates "To a very great extent". Users also have the option to choose N/A (Not able to answer), and are encouraged to do so if they are not familiar with that aspect of the program. The PSAT is directly linked to the eight domains outlined in the sustainability framework. Since this framework will be used to guide the action planning for each state, the scores from the PSAT will be important in assessing programmatic challenges and strengths related to sustainability. The sample for our survey is the workgroup defined by the program manager in each of the 24 participating states. We anticipate that 5-12 people in each state will complete the survey. PSAT scores are aggregated across participants for each state so that each state will have an overall PSAT score. Power calculations indicate that surveying workgroups in 24 states (12 intervention, 12 comparison) at three time points- intervention states at baseline and 12 and 24 months post training and comparison states at baseline and 12 and 24 months after baseline collection- will sufficiently capture group differences (Figure 4).

The survey will be conducted online using established methods for Web-based surveys.[102] To enhance the survey response, we will employ the well-established method developed by Dillman.[103] First, all members of the sample will receive a personalized, advanced notice email. This helps to identify the purpose of the survey and establish its legitimacy. Second, approximately one week after the advance email is sent, all members of the workgroup receive the survey link. In all cases, the replies to the surveys will be anonymous. Third, approximately one week after completion of the PSAT, a follow-up email will be sent to all members of the sample. It will thank those who have already responded and request a response from those who have not yet responded. Finally, once data collection is closed, the workgroup members will receive a detailed sustainability report that includes their responses and an aggregated score for the program. For intervention states, this report will serve in the assessment and planning phases. All correspondence will come from WU and the TCN (an important professional association for our sample). The CDC has also agreed to allow us to participate on the OSH Program Service Branch calls to make CDC program officers aware of their state's participation and for promotion of our study. We have had previous success with online administration of surveys including the PSAT. Response rate for PSAT administration across the six TC states was 86% (123 out of 143). In another study, in which we administered an email survey among all 50 state TC managers in three waves, with an overall response rate of 97%.[51,78] In addition, we have years of experience and building partnerships with state TC programs and CDC-OSH.

Program record abstraction

A review and abstraction of state level TC program public records will be performed for all 24 states at three time points- baseline and at the annual CDC progress reporting time (June) in years

2 and 3. This will help in evaluating the impact of the training intervention on the capacity for sustainability and institutionalization of the TC program within the organization.

Step 1: Identifying relevant records and measures. Relevant state-level TC program records will be identified within the 24 selected states from various sources. First, all state tobacco programs are required by CDC (DP15-1509 funding requirements[2]) to submit an annual progress report. We will begin by using our consultants and empirical literature to identify relevant state-level programmatic measures documented in these annual progress reports. We have also reviewed the DP15-1509 funding requirements for relevance and have outlined the connection between state reporting requirements and established predictors of sustainability and outcomes in Appendix C. This will increase our likelihood of retrieving all relevant information and provide empirical evidence with which to substantiate the responses in the PSAT and identify and address any potential bias therein. In addition, for those metrics not included in the report, we will review state health agency websites and publically available state-level government documentation. Dr. Brownson has extensive experience in collecting this type of information and has incorporated similar strategies in three other studies.

Step 2: Data abstraction. TC program records will be reviewed and data will be abstracted by two trained evaluators using standardized methods and data collection tools created by the research team. The development and use of a standardized instrument for the review and abstraction will improve inter-rater reliability and will provide quantitative data for monitoring trends and intervention effects.

Step 3: Establishing reliability and validity. Data collected via record review and abstraction are subject to bias that may result from rater subjectivity.[104] In order to determine the agreement between the two evaluators, a baseline reliability evaluation will be conducted early in the process to calculate inter-rater reliability. In order to determine validity of self-reported data from the PSAT, agreement between self-reported and record-based information will be assessed. Both inter-rater reliability and validity of self-reported data will be checked at baseline and two other time points.

Key Informant Interview and Survey

In order to collect additional organizational metrics, a key informant interview and survey will be conducted with state program managers. These will be performed for all 24 states at three time points- baseline and in June during years 2 and 3. This will help in evaluating the impact of the training intervention on the capacity for sustainability and institutionalization of the TC program within the organization.

Step 1: Identifying relevant measures. Relevant state-level sustainability metrics will be identified within the 24 selected states from various sources, including CDC Best Practices, ALA State of Tobacco Control, empirical literature, and consultation of our advisory group.

Step 2: Key Informant Interview and Survey. TC program managers will be contacted to complete a phone interview and survey. The interview and survey will only collect organizational metrics not collected in reporting records, and no personal information will be collected. We will record phone interviews to ensure comprehensive analysis by trained abstracters. Prior to the interview, program managers will be provided a copy of the questions to be asked from a standard script created by the research team. Each question is formatted in multiple choice, e,g,, "How long has the program been in existence?" [1: Less than 1 year; 2: 1-3 years; 3: 3-5 years; 4:5-10 years; 5: 10 or more years; 6: Don't know]. Using this method, program managers will provide unambiguous answers to data points not collected by record abstraction.

Step 3: Establishing reliability and validity. Data collected via interview/survey and abstraction are subject to bias that may result from rater subjectivity.[104] In order to determine the agreement between the two evaluators, a baseline reliability evaluation will be conducted early in the process to calculate inter-rater reliability. In order to determine validity of self-reported data from the PSAT, agreement between self-reported, record-based information, and interview/survey information will be assessed. Both inter-rater reliability and validity of self-reported data will be checked at baseline and two other time points.

Phase 3 (Aim 3):

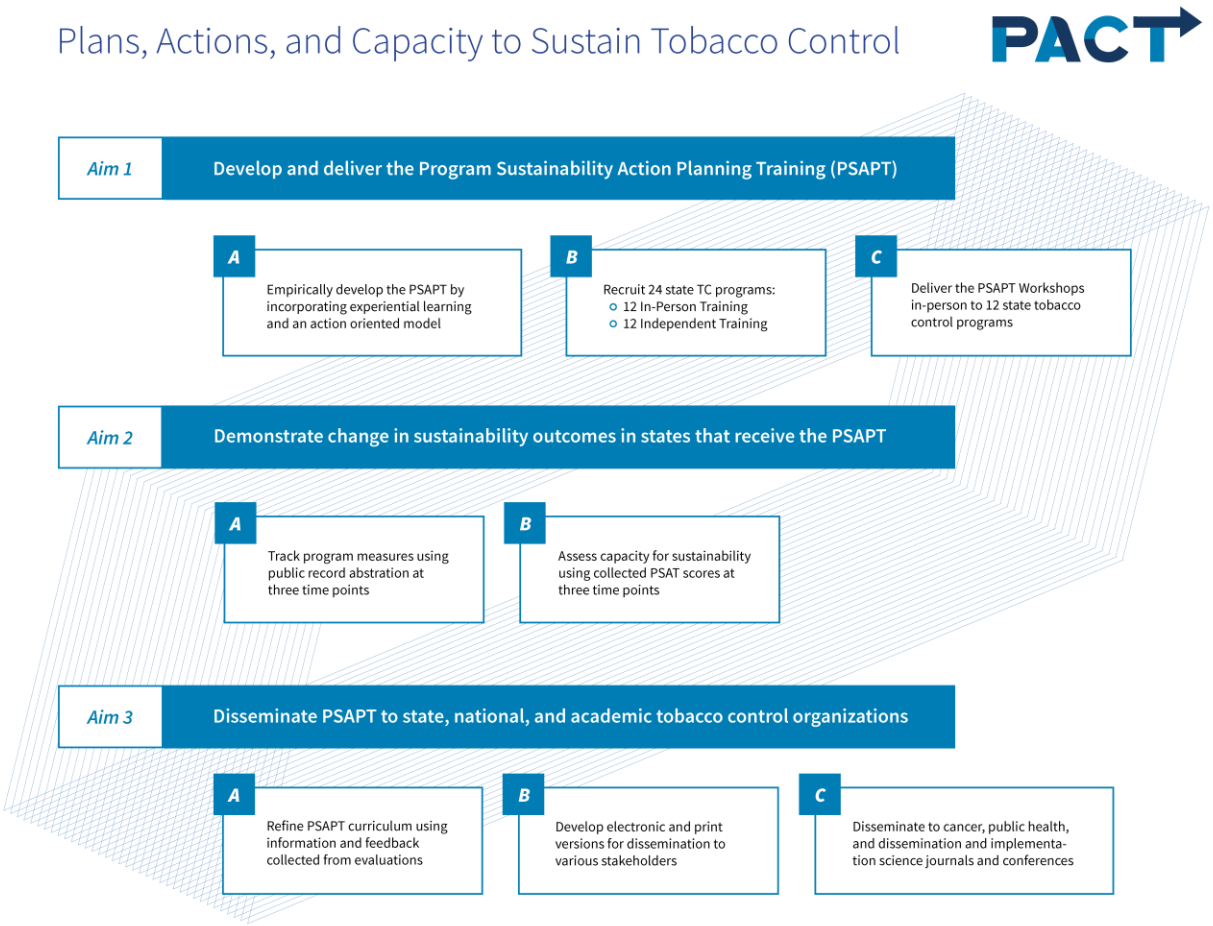
C.7. (Aim 3): Actively disseminate The Program Sustainability Action Planning Model and Training Curriculum materials and study results to support future adoption.

No treatment with intervention or comparison groups will take place during this phase.

5.2 Administration

Not applicable.

5.3 Schema



5.4 Dose Modification

Not applicable.

5.5 Duration of Therapy

Not applicable

5.6 Supportive Care

Not applicable

6.0 Response Assessment

Not applicable

7.0 Study Parameters

Not applicable

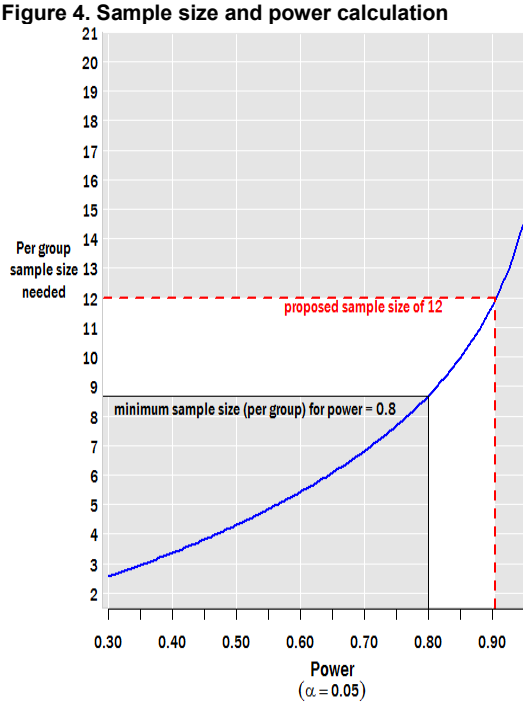
8.0 Drug Formulation and Procurement

Not applicable

9.0 Statistical Considerations

C.6.d Statistical power

Figure 4. Sample size and power calculation



To estimate the sample size needed for the study, an a priori power analysis was performed using data from a natural experiment. The data consists of Pre and Post PSAT averages from previous work with five tobacco control programs that received action planning and training, and five programs that did not receive action planning or training for which pre- and post-PSAT scores are available. To determine effect size, t-tests of differences-in-means were conducted for the two groups using the changes in PSAT scores between the Pre and Post PSAT data. The standardized differences and t-statistics yielded an effect size of 1.25, which is a large effect size according to Cohen's criteria.[107] Using R statistical environment with packages from Del Re[108] and Champely,[109] the effect size with power = 0.8 and $\alpha = 0.05$ project the necessary sample size to be approximately 9 (programs) per group. Since these calculations are based on a natural experiment, which we note occurred over a period of time that also saw changes to the recommended action planning,[2] we are careful not to overstate the anticipated power and therefore conservatively propose a sample size one-third larger than calculated, 12 per group as shown in Figure 4. This sample is also sufficient to measure the main goal of the study, to discern whether the training, and accompanying PSAT tool, significantly increase institutionalization of state TC programs.[108–110]

C.6.e. Data analyses. Descriptive statistics will be calculated (e.g., frequencies and measures of central tendency and dispersion), for both the intervention and comparison group at each of the three data collection time points to assess baseline averages and changes. Multiple comparisons across groups and times will be drawn for independent and dependent variables. All continuous measures will be examined for non-normality and all relationships will be examined for linearity where applicable. Strategies for addressing issues encountered will be applied as necessary such as different functional forms, category scaling, and robust error calculations. In addition, the dose reception and delivery, and participant measures from Aim 1 (C.5.d). will be used to calculate rates of adoption and implementation of training recommendations (intervention states) and other potential actions taken (comparison states, C.5.e).

To incorporate the influence of idiosyncratic characteristics of the state programs, longitudinal regression analysis will be used to model the outcome for each of the dependent variables. This analysis is modeled in Equation 1.

$$\beta_0 + \beta_1 PSAT_{i\,t=0} + \beta_2 G_i + \beta_3 D_{it} + \beta_4 (G_{it} * D_{it}) + B_{5-k} X_{it} = Y_{it}$$

Equation 1

where i = state, t = time 1 or 2, $PSAT_{i\,t=0}$ = baseline PSAT score, G_i = group (intervention or comparison), D_{it} = dose variable, $(G_{it} * D_{it})$ = an interaction between the group and dose terms, X_{it} = a vector of programmatic, organizational, community and funder variables, and Y_{it} = the

outcome variable. This analysis will ultimately be used to test Hypothesis 1, that the impact of the training is nonzero and positive.

$$H_o: \hat{\beta}_{intervention} = 0 \qquad H_a: \hat{\beta}_{intervention} > 0$$

Hypothesis 1

The multivariate approach allows us to account for the numerous influences found in programmatic, organizational, community, and funder attributes. Data collection at different time points also allows for measuring changes in these variables, and the influence these changes have on institutionalization outcomes. In addition, the level of adoption and implementation of action plans both from the training (intervention states) and from other initiatives (comparison states) will vary across programs and time. Varying levels of action plan implementation across states must be acknowledged. Multivariate longitudinal analyses also allow us to control for differing degrees of dosage reception and delivery. We have successfully used similar dose variables. [111,112]

10.0 Recordkeeping

The Principal Investigator, Sarah Moreland-Russell, will be responsible for monitoring the data safety and quality of the overall study. This is a minimal risk study that does not warrant a formal Data Safety Monitoring Board.

Program Sustainability Assessment Tool (PSAT). The PSAT is a 40-item measure of a program's sustainability capacity which requires 10-15 minutes to complete. Individuals selected by state TC program managers will be invited to complete the PSAT online via our secure website https://sustaintool.org/. Data collected through the website is automatically de-identified by the website and aggregated at the state level. E-mail addresses are collected on the site, but solely for website management, technical assistance, and user access. See Appendix A for full copy.

Workshop Data Collection Form. Several process measures will be collected to assess the effectiveness of the training and support delivered. All measures will be collected via survey at the completion of each training component or tracked by review of programmatic records (i.e., action plan, meeting minutes). Quantitative data collected for this aim will be analyzed using descriptive statistics. Qualitative analysis of programmatic records will be conducted following procedures outlined. See Appendix B for full copy.

Dosage delivered is the number of units of an intervention delivered or provided.[101] For this study, this measure will be defined by the number of hours of training and technical assistance provided to each state.

Dosage received is the extent to which participants engage with or use the materials provided.[101] This will be measured by whether or not the action plan is completed and implemented, whether the workgroup utilizes the resources and materials provided, and the extent to which the action plan is implemented.

Participant reactions will be measured by the extent to which the participants felt that the objectives of the training and technical assistance were achieved, satisfaction with the training and technical assistance and perceived usefulness of the training provided.

Data abstraction. State level TC program records will be reviewed and data will be abstracted by two trained evaluators using standardized methods and data collection tools created by the research team. Examples of variables of interest include: implementation of action plan, amount and source of funding allocated for the implementation of tobacco control programs, size of the program and organization, and number of staff dedicated to support programmatic activity. Funding-related information will be collected from annual progress reports of state health departments, annual reports, and funding opportunities of funding agencies relevant to tobacco control. Abstraction will include only records that are publically available and only programmatic and organizational information will be recorded. No individual identifying information will be recorded.

Furthermore, the Prevention Research Center has developed a safety monitoring plan to address: 1) training staff on data sensitivity and protocols for safeguarding confidentiality; 2) storing and processing data in a secured, centralized location; 3) securing any hardcopy data in locked files when not in use; 4) removing names, addresses, and other direct identifiers from hardcopy and computer-readable data when they are no longer necessary for respondent tracking and then using encrypted codes for subsequent identification of participants; 5) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed; 6) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis; 7) ensuring that the research team members and others with direct contact with participants and/or access to identifiable data complete human research certification (e.g., CITI, and other human research training programs); 8) including human research concerns as a standard agenda item for regular project meetings; 9) incorporating responsibility for the human research protection process into the Project Manager's job description; and 10) regular review of research data to ensure validity. All data will be stored on a section of the Washington University in St. Louis password protected server protected by the university's firewalls. The only people who will have access to the raw survey data are the study staff and faculty based at the Washington University in St. Louis. Each has taken the CITI training and will be approved by the Washington University Institutional Review Board for this specific study.

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12.0 Personnel

There are no laboratory or ancillary laboratory instructions to report for this study. However, we have included below a list of all personnel working on the study.

Principal Investigator: Sarah Moreland-Russell, PhD, MPH*
Co-Investigators: Ross Brownson, PhD*; Douglas Luke, PhD†
Statistician: Todd Combs, PhD†
Research Manager: Rebecca Vitale, MPH*
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12.0 Informed Consent

Please see separate informed consent letter document (Appendix C)

13. Additional Elements

There are no known risks from being in this study, and participants will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.

Participation comes at no additional cost to the participant. Participation is entirely voluntary and participants can withdraw from the study at any time simply by indicating that they do not wish to continue. Should participants withdraw from the study, they are not penalized for benefits for which they otherwise qualify. This study anticipates a maximum of 288 participants, with a maximum of 12 participants at each state tobacco control program site.

Appendices

Appendix A. Program Sustainability Assessment Tool (PSAT) Survey

Program Sustainability Assessment Tool

What is program sustainability capacity?
We define program sustainability capacity as *the ability to maintain programming and its benefits over time*.

Why is program sustainability capacity important?
Programs at all levels and settings struggle with their sustainability capacity. Unfortunately, when programs are forced to shut down, hard won improvements in public health, clinical care, or social service outcomes can dissolve. To maintain these benefits to society, stakeholders must understand all of the factors that contribute to program sustainability. With knowledge of these critical factors, stakeholders can build program *capacity* for sustainability and position their efforts for long term success.

What is the purpose of this tool?
This tool will enable you to assess your program's current capacity for sustainability across a range of specific organizational and contextual factors. Your responses will identify sustainability strengths and challenges. You can then use results to guide sustainability action planning for your program.

Helpful definitions
This tool has been designed for use with a wide variety of programs, both large and small, across different settings. Given this flexibility, it is important for you to think through how you are defining your program, organization, and community before starting the assessment.
Below are a few definitions of terms that are frequently used throughout the tool.

Program refers to the set of formal organized activities that you want to sustain over time. Such activities could occur at the local, state, national, or international level and in a variety of settings.

Organization encompasses all the parent organizations or agencies in which the program is housed. Depending on your program, the organization may refer to a national, state, or local department, a nonprofit organization, a hospital, etc.

Community refers to the stakeholders who may benefit from or who may guide the program. This could include local residents, organizational leaders, decision-makers, etc. Community does not refer to a specific town or neighborhood.

The name of the program or set of activities I am assessing is:

_____

In the following questions, you will rate your program across a range of specific factors that affect sustainability. Please respond to as many items as possible. If you truly feel you are not able to answer an item, you may select "NA." **For each statement, circle the number that best indicates the extent to which your program has or does the following things.**

Environmental Support: Having a supportive internal and external climate for your program

1. Champions exist who strongly support the program.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program has strong champions with the ability to garner resources.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. The program has leadership support from within the larger organization.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

NA 4. The program has leadership support from outside of the organization. 1 2 3 4 5 6 7 NA

5. The program has strong public support.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Funding Stability: Establishing a consistent financial base for your program

1. The program exists in a supportive state economic climate.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program implements policies to help ensure sustained funding.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. The program is funded through a variety of sources.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. The program has a combination of stable and flexible funding.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program has sustained funding.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Partnerships: Cultivating connections between your program and its stakeholders

1. Diverse community organizations are invested in the success of the program.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program communicates with community leaders.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. Community leaders are involved with the program.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. Community members are passionately committed to the program.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The community is engaged in the development of the program goals.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Organizational Capacity: Having the internal support and resources needed to effectively manage your program and its activities

1. The program is well integrated into the operations of the organization.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. Organizational systems are in place to support the various program needs.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. Leadership effectively articulates the vision of the program to external partners.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. Leadership efficiently manages staff and other resources.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program has adequate staff to complete the program's goals.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Program Evaluation: Assessing your program to inform planning and document results

1. The program has the capacity for quality program evaluation.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program reports short term and intermediate outcomes.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. Evaluation results inform program planning and implementation.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. Program evaluation results are used to demonstrate successes to funders and other key stakeholders.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program provides strong evidence to the public that the program works.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Program Adaptation: Taking actions that adapt your program to ensure its ongoing effectiveness

1. The program periodically reviews the evidence base.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program adapts strategies as needed.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. The program adapts to new science.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. The program proactively adapts to changes in the environment.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program makes decision about which components are ineffective and should not continue.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Communications: Strategic communication with stakeholders and the public about your program

1. The program has communication strategies to secure and maintain public support.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. Program staff communicate the need for the program to the public.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. The program is marketed in a way that generates interest.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. The program increases community awareness of the issue.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program demonstrates its value to the public.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Strategic Planning: Using processes that guide your programs direction, goals, and strategies

1. The program plans for future resource needs.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

2. The program has a long-term financial plan.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

3. The program has a sustainability plan.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

4. The program's goals are understood by all stakeholders.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

5. The program clearly outlines roles and responsibilities for all stakeholders.

Likert [1: To little or no extent; 2; 3; 4; 5; 6; 7: To a very great extent; or Not able to answer]

Appendix B. Data Collection Form for Workshop

I. DOSAGE DELIVERED:
number of units of an intervention delivered or provided

1. # Stakeholders to complete PSAT
2. # Stakeholders to attend training
3. # Stakeholders to attend TA calls
4. # hours of training
5. # hours of TA

II. DOSAGE RECEIVED:
extent to which participants engage with or use materials or recommended resources.

Service-Related Questions related to Comprehension- required for properly completing tools
1. After viewing the Introduction to Sustainability Webinar, I now understand the concept of program sustainability completely (5 point Likert scale strongly agree- strongly disagree).

2. After attending/viewing the Action Planning Workshop, I now understand the process of Program Sustainability Action Planning completely (5 point Likert scale strongly agree- strongly disagree).

3. The handouts provided helped me to understand the Action Planning Workshop material (5 point Likert scale strongly agree- strongly disagree).

Action Plan Implementation-Related Questions (Implementation- "measures the extent to which users engaged with or used")
1. My program created a program sustainability action plan based on the results of the Program Sustainability Assessment Tool and Action Planning Training (Y/N).

2. My program implemented the activities outlined in our program sustainability Action Plan (Y/N).

3. Please indicate the percentage of your sustainability plan your program has implemented (i.e., If you met 3 out 4 objectives, you would select 75%).

_____ 10% or less _____ 25% _____ 50% _____ 75% _____ 90% or more
4. Please estimate the amount of time per month your sustainability plan was discussed among staff.

_____ Less than 1 hour per month _____ 1-3 hours _____ 3-5 hours _____ 5-7 hours _____ 7-9 hours _____ 10+

5. Please estimate the amount of time per month your program staff focused on implementing your sustainability plan steps.

_____ Less than 1 hour per month _____ 1-3 hours _____ 3-5 hours _____ 5-7 hours _____ 7-9 hours _____ 10+

III. PARTICIPANT REACTION

Service Delivery: PSAT and Report-Related Questions (Relevance, Satisfaction)

1. I found the Program Sustainability Assessment Tool to be informative (5 point Likert scale strongly agree- strongly disagree).

2. The Program Sustainability Assessment Tool and Report helped me to think about program sustainability in ways I hadn't considered before (5 point Likert scale strongly agree- strongly disagree).

3. My program's future planning was impacted positively by the process of completing the Program Sustainability Assessment Tool (5 point Likert scale strongly agree- strongly disagree).

4. Planning for my program's sustainability was made easier by completing the Program Sustainability Assessment Tool (5 point Likert scale strongly agree- strongly disagree).

Service Delivery: Action Planning Training-Related Questions (Relevance, Satisfaction)

1. Objectives of the Action Planning Training were useful for my work (5 point Likert scale strongly agree- strongly disagree).

2. Objectives of the Action Planning Training were clearly articulated (5 point Likert scale strongly agree- strongly disagree).

3. Objectives of the training were achieved during the Action Planning Training (5 point Likert scale strongly agree- strongly disagree).

4. Overall, how would you rate the quality of the facilitator's presentation for the Action Planning Training? (5 point Likert scale excellent- poor).

5. The length of the Action Planning Training was: (3 point Likert scale too long- too short).

6. The Action Planning Training made planning for my program's sustainability easier. (5 point Likert scale strongly agree- strongly disagree).

7. The Action Planning Training was beneficial for my program. (5 point Likert scale strongly agree- strongly disagree).

8. The Action Planning Training was directly relevant to my program. (5 point Likert scale strongly agree- strongly disagree).

9. Overall, how satisfied were you with the Action Planning Training? (5 point Likert scale very satisfied to - very dissatisfied).

Service Delivery: Technical Assistance-Related Questions (Relevance, Satisfaction)

1. The technical assistance provided following the Action Planning Training was beneficial for my program. (5 point Likert scale strongly agree- strongly disagree).

2. The technical assistance provided following the Action Planning Training was directly relevant to my program. (5 point Likert scale strongly agree- strongly disagree).

3. The technical assistance provided following the Action Planning Training made planning for my program's sustainability easier. (5 point Likert scale strongly agree- strongly disagree).

4. Overall, how satisfied were you with the technical assistance provided following the Action Planning Training? (5 point Likert scale very satisfied to - very dissatisfied).

Appendix C. Sample Consent Letter

INFORMED CONSENT DOCUMENT

Project Title: Program Sustainability Action Planning Training Project

Principal Investigator: Sarah Moreland-Russell

Research Team Contact: Rebecca Vitale (314) 935-8025

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you were identified as an important or relevant tobacco control program stakeholder in your state.

The purpose of this research study is to test education materials to see if they can help improve state-level tobacco control initiatives across the United States.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, we would like you to indicate your intent to enroll to the research team member identified at the bottom of this document.

If you do not wish to participate, please indicate this to the research team member identified at the bottom of this document. We will not contact you again.

For state employees who are not program managers: Although your program manager will know who participates in the study, **you do not have to participate** and your position and evaluations by your employer will not be affected by your choice. Your program manager might changes to the way your state tobacco control program functions after the study. If this occurs, it will be done separate from this research project and you will continue to do your job as normal.

Your state program will either be in the "intervention group" or the "control group". The intervention group will do some additional education activities.

All states:

We will ask you to attend a webinar during work hours introducing you to the study. Following this, we will ask you to complete an electronic survey tool through http://www.sustaintool.org, in which you will rate various aspects of your state-level tobacco control program. The webinar will take approximately one hour to complete, while the survey will take approximately twenty minutes to complete. On the survey, you are free to choose "Not Applicable" for any question you choose. This survey will be repeated again 12 months after the study starts and a third time 24 months after the study starts. Program managers will complete a survey through Qualtrics providing information about their program. Program managers will also complete an audio-recordedphone interview with the research team for information about their program.

Intervention States:

The WUSTL research team will come to your office to deliver in-person workshops. The workshop includes a discussion of the survey results as well as a personalized training to establish action plans in fulfillment of CDC sustainability planning guidelines. You will also complete a short questionnaire rating your experience in the workshops.

Workshop Day 1:

The main goals for Day 1 will include defining the program and reviewing survey results. We will clarify the program's mission and vision and specify the population it currently serves. We will review the current activities and services that the program is implementing and clarify any program and organizational capacities that will be necessary to sustain the activities.

Workshop Day 2:

The main goal for Day 2 is to develop an action plan. We will outline action plan components including: (1) specific, measureable, attainable, realistic, and time-sensitive objectives;

(2) specific action steps (activities) for achieving objectives;

(3) a timeline for completion of each objective;

(4) persons responsible for completing each objective;

(5) a clear definition of outcomes and measures for successful completion of each objective and overall plan.

Handouts will be provided including an action plan template and spreadsheets that allow for easy tracking and analysis of action plan outcomes.

Following the workshops, you will receive a list of resources relevant to your program's needs. Your program will be able to work with the WUSTL research team for technical assistance towards your action plans.

Will you save my research data to use in future research studies?

As part of this study, we are obtaining survey data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding how to best improve tobacco control programs. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

The use of your data for the purposes described above is optional. Please let the WU research team know whether you agree to this future use.

Audio/Video Recording or Photographs

One aspect of this study involves making audio recordings. Only interviews with program managers will be recorded. Interactions with participants that are not program managers will not be recorded by the research team. The research team will record audio from interviews with program managers to ensure accurate transcription of answers collected over the phone. Because of this, audio recording is not optional for program managers. Only members of the research team at Washington University will have access to these recordings, and they will not be released outside of the research team in any way. The recordings will be destroyed at the conclusion of the study.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 288 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for a total of 24 months.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of what we will learn.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health National Cancer Institute (NCI) is funding this research study. This means that the Washington University is receiving payments from NCI to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NCI for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institutes of Health and National Cancer Institute
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will automatically de-identify your survey responses. This means that any information you input into our survey is not connected to your name, or you personally, and is instead aggregated at the state level. Email addresses are collected on the site, but this is solely for website management, technical assistance and user access. Your email address is not connected with your responses. All collected data are secured using passwords and encryption. Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was

collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Rebecca Vitale, (314) 935-8025**.** If you feel that you have been harmed in any way by your participation in this study, please contact Rebecca Vitale, (314) 935-8025.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.