Information Collection Request

New

National Diabetes Prevention Program (DPP) Introductory Session Project

Supporting Statement Part A

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- **Goal of the Project:** In this new information collection request, we describe plans to determine the prevalence and types of introductory sessions being offered as a recruitment strategy to increase enrollment in the National Diabetes Prevention Program lifestyle change program (National DPP LCP) (Phase 1: Introductory Session Landscape Assessment) and to evaluate the effectiveness of a behaviorally-focused intervention known as Be Your Best (BYB) Discovery Session compared with other already occurring introductory sessions (Phase 2: Introductory Session Evaluation). The ultimate goal of the Introductory Session Project is to determine whether the BYB Discovery Session is an effective recruitment strategy compared with other existing introductory sessions, and, if so, should be promoted to maximize the National DPP's potential to reduce type 2 diabetes incidence.
- **Intended Use of the Resulting Data:** The Centers for Disease Control and Prevention (CDC) will use this information collection to provide our partners and stakeholders with guidance on whether use of introductory sessions is an effective solution to increase enrollment in the National DPP LCP. Subsequently, the CDC will share the final behaviorally-informed Be Your Best Intervention implementation guide broadly with partners and stakeholders for large-scale dissemination and implementation if it is found to be as effective or more effective than other standard introductory sessions with regards to increasing enrollment in the National DPP LCP.
- **Methods to Be Used to Collect:** Introductory Session Landscape Assessment (Phase 1): we will administer a voluntary web-based survey of up to 1,700 CDC-recognized organizations plus approximately 540 additional class locations offering the National DPP LCP, followed by a hard copy mailed survey to non-respondents. Introductory Session Evaluation (Phase 2): participating class locations (n=132) will administer two hard-copy surveys to assess participant attitudes, perceptions, beliefs, and intentions related to pertinent behavioral barriers to enrollment during the Discovery Session. Up to 2,640 introductory session attendees will be surveyed via a Pre-Session Survey and a Post-Session Survey. We will collect additional data on introductory session implementation and effectiveness from LCP personnel. We will use the following tools to gather this information: the BYB Discovery Session Implementation Fidelity Checklist and the Registration and Attendance Tracking Form, both of which will be designed in Microsoft Excel and distributed using secure FTP upload for LCP personnel to complete electronically.
- **Subpopulation to Be Studied:** All National DPP CDC-recognized organizations and their affiliated class locations (approximately 1,700 plus 540 class locations) will receive the Landscape Survey; participation is voluntary. We will recruit 132 volunteer class locations to participate in the Introductory Session Evaluation; half of whom will be randomized to implement the BYB Discovery Session and half will continue to implement their standard introductory sessions. Respondents to the Landscape Assessment, the Fidelity Checklist, and the Tracking form will consist of National DPP LCP staff including LCP coaches, program managers, and other implementation staff. Respondents to the Surveys will consist of LCP introductory session attendees; their participation is voluntary.
- **How Data Will Be Analyzed**: We will analyze the Landscape Assessment survey data using descriptive and bivariate statistics. For the Introductory Session Evaluation, we will use bivariate analyses (e.g., two sample *t* tests or chi-square measures of association) to examine any differential effects in outcomes (registration and first-session attendance) based on intervention group (BYB vs. standard introductory session); staffing levels;

PART A. JUSTIFICATION

This statement supports a new information collection request (ICR) supporting a two-phase project of the Centers for Disease Control and Prevention's (CDC's) National Diabetes Prevention Program lifestyle change program (National DPP LCP) focused on helping participants adopt healthier behaviors (e.g., improving diet, increasing physical activity, reducing stress) to prevent or delay the development of type 2 diabetes. Specifically, this project's primary purposes are to (1) increase knowledge about one recruitment strategy—"introductory sessions"—for recruiting, engaging, and enrolling participants in the National DPP LCP (Phase 1) and (2) evaluate the effectiveness of the CDC-developed behaviorally-informed[1] introductory session known as the Be Your Best (BYB) Discovery Session compared with other existing introductory sessions (Phase 2).

CDC's Division of Diabetes Translation (DDT) developed the BYB enrollment intervention. The cornerstone of BYB is a behaviorally-focused introductory session known as a *Discovery Session* that relies on a behavioral economics approach and focuses on the social and psychological motivations that influence decision-making, particularly those that may lead to lifestyle or behavior change. This intervention has been packaged as an implementation guide to share with CDC partners and stakeholders.

Many organizations offering a CDC-recognized LCP already offer some type of introductory session as a strategy to recruit and enroll participants into the LCP. Introductory sessions are informational sessions that occur before the start of an LCP year-long class to introduce the National DPP LCP to potential participants. These introductory sessions vary in their approach and delivery, including more structured sessions similar to the BYB Discovery Session and more informal "open house"-like sessions that do not include a structured format. However, to date, there has been no systematic assessment of how many CDC-recognized LCPs offer these introductory sessions, how they are conducted, or how they vary across CDC-recognized organizations, nor has there been an evaluation of the effectiveness of the Be Your Best (BYB) Discovery Session in increasing enrollment in the LCP, compared with other existing introductory sessions.

For Phase 1 of this project, CDC is seeking approval to disseminate a brief Landscape Assessment to all National DPP CDC-recognized organizations (***Attachment 1***) and their affiliate class locations (***Attachment 1aa***). The expected sample size is approximately 1,700 CDC-recognized organizations plus any additional class locations (up to 540 class locations). The overall evaluation objectives of the Introductory Session Landscape Assessment are to increase knowledge of recruitment strategies (specifically introductory sessions) used by CDC-recognized organizations to increase enrollment in LCPs; understand how CDC-recognized organizations are using introductory sessions, including session content and delivery; and inform

[1] Focused on the key factors that influence behavioral change as noted in the research literature.

the subsequent Introductory Session Evaluation that will evaluate the BYB Discovery Session compared with other types of introductory sessions.

For the Phase 2 Introductory Session Evaluation, CDC is seeking approval to disseminate the following data collection tools: (1) Pre-Session Survey (***Attachment 2***), (2) Post-Session Survey (***Attachment 3***), (3) Registration and Attendance Tracking Form (***Attachment 4***), and (4) Discovery Session Implementation Fidelity Checklist (***Attachment 5***). We will recruit up to 132 National DPP LCP class locations to participate in the Phase 2 Introductory Session Evaluation. Participating class locations will administer two hard-copy surveys to up to 2,640 introductory session participants. The primary aim of the Introductory Session Evaluation is to evaluate the effectiveness of the BYB Discovery Session intervention in increasing enrollment in the National DPP LCP compared with already occurring introductory sessions (i.e., standard care), with a secondary aim of better understanding how it is implemented and the context of its implementation.

This ICR is authorized by the Public Health Service Act, Section 301 (42 U.S.C.241) (***Attachment 9***).

A.1 Circumstances Making the Collection of Information Necessary

Prediabetes & Diabetes

Diabetes is the seventh leading cause of death worldwide (World Health Organization, 2018) and the seventh leading cause of death among U.S. adults (CDC, 2017a). Diabetes affects diverse populations; however, racial and ethnic minorities, individuals with low socioeconomic status, and persons living in rural areas experience a disproportionate burden (Beckles & Chou, 2016; Massey, Appel, Buchanan, & Cherrington, 2010). Overall, care for people with diabetes accounts for about one out of every four health care dollars spent. Additionally, Americans with diabetes have health care costs 2.3 times greater than Americans without diabetes (American Diabetes Association, 2018).

Prediabetes, the precursor of type 2 diabetes, is usually a symptomless condition that is characterized by blood sugar levels that are higher than normal but not high enough yet to constitute a type 2 diabetes diagnosis (CDC, 2018b). Almost one in three adult Americans live with prediabetes, although only 10% of the 84 million living with prediabetes are aware of their condition. Left unaddressed, prediabetes can lead to type 2 diabetes, heart disease and stroke (CDC, 2018a). Type 2 diabetes causes undue premature morbidity and mortality, making this information collection important and necessary in efforts to reduce type 2 diabetes prevalence (CDC, 2017b).

Background on the National DPP Lifestyle Change Program

Accumulating evidence, including the DPP randomized controlled trial, demonstrated that lifestyle change interventions are effective in reducing the risk of developing type 2 diabetes among those with prediabetes (Knowler et al., 2002). As a result, CDC established the National DPP (Albright & Gregg, 2013). The National DPP provides a framework for type 2 diabetes prevention efforts in the United States founded on four key pillars: (1) a trained workforce of lifestyle coaches; (2) national quality standards supported by the CDC Diabetes Prevention Recognition Program (DPRP); (3) a network of program delivery organizations sustained through coverage; and (4) participant enrollment in National DPP LCPs and referral from health care providers, insurance providers, and other sources. These pillars link closely to CDC's strategic goals for the National DPP: increase the supply of quality programs, increase demand for the program among people at risk, increase referrals from health care providers, and increase coverage among public and private payers.

A key component of the National DPP is a structured, evidence-based, year-long LCP to prevent or delay the onset of type 2 diabetes in adults with prediabetes or who are at risk of developing type 2 diabetes. The National DPP LCP is founded on the science of the DPP trial and subsequent translation studies, which showed that making realistic behavior changes helped people with prediabetes lose 5% to 7% of their body weight and reduce their risk of developing type 2 diabetes by 58% (Knowler et al., 2002). CDC manages the Diabetes Prevention Recognition Program (DPRP), which is the quality assurance arm of the National DPP. Through the DPRP, CDC recognizes organizations that deliver the LCP and are able to meet national quality standards and achieve the outcomes proven to prevent or delay the onset of type 2 diabetes.

Gaps in Knowledge about Introductory Sessions

Increasing enrollment in the National DPP LCP remains a top priority for DDT. However, there are significant gaps in the literature on how to increase enrollment in the National DPP LCP and similar programs. A PubMed search revealed that only one study has rigorously evaluated introductory sessions, although not for the National DPP LCP specifically (Jiang et al., 2014). There is an opportunity for additional studies evaluating introductory sessions, as an evaluation of a subset of National DPP LCPs conducted by CDC and RTI International found that more than half (54%) of CDC-recognized organizations reported using introductory sessions as a recruitment method (Gruss et al., 2017). In this study of a small number of National DPP LCPs, introductory sessions were not characterized in terms of timing or content; only the presence of introductory sessions was associated with attendance.

Additionally, there is no standardized way for a CDC-recognized organization to conduct an introductory session; other past evaluations conducted by RTI on the National DPP LCP indicated that these sessions are conducted differently across organizations. For example, some

CDC-recognized organizations use past participants as program "champions" to deliver testimonials to increase participant engagement and enrollment; others use small incentives to engage participants; whereas others use a PowerPoint presentation to demonstrate the risks and costs associated with developing type 2 diabetes.

Need for Evidence-Based Strategies to Increase Enrollment in LCPs

RTI's *Evaluation of the National Diabetes Prevention Program* found that 73% of sites reported suboptimal enrollment as a barrier to programmatic success (Gruss et al., 2017). However, as mentioned above, there is very little literature on evidence-based strategies to increase enrollment. Therefore, it is important to examine this area so that CDC disseminates evidence-based strategies that increase enrollment in National DPP LCPs to maximize the program's potential to reduce the incidence of type 2 diabetes.

Understanding Enrollment Barriers and Developing Solutions: Evaluation and Assessment of Strategies for Enrollment (EASE)

Although some enrollment challenges are due to structural barriers (cost, lack of transportation, etc.), others can be addressed by better understanding and intervening on barriers to enrollment that are behaviorally based, such as misperception of risk and lack of urgency. To gain a deeper understanding of the barriers inhibiting enrollment in the LCP and to develop an intervention to address these barriers, CDC initiated the EASE project. This was a multiphase project involving (1) qualitative data to understand enrollment barriers, (2) alignment of enrollment barriers with solutions based on behavioral economics theory, (3) development of a behaviorally focused enrollment intervention incorporating these theory-based solutions, (4) development of evaluation tools to measure mindset changes among individuals exposed to the intervention (BYB Discovery Session), and (5) implementation of the intervention to pilot the behavioral economics-informed evaluation tools and to determine if they are sensitive enough to detect changes in attitudes, perceptions, beliefs, and intentions related to enrollment mindset change (Office of Management and Budget [OMB] Control Number: 0920-1154).

The EASE project revealed several behavioral barriers that might impede an individual's enrollment into0 an LCP. These barriers were identified through stakeholder interviews (≤9 individuals) consisting of current LCP participants, LCP staff, and potential participants who did not enroll in the LCP. These barriers included: not feeling an urgent need to make a lifestyle change; having misperceptions about one's risk of type 2 diabetes and one's ability to change their risk (efficacy); and that the program's commitment costs outweighing the program's future benefits (program burden).

To address these barriers, CDC developed solutions grounded in behavioral economics theory to intervene where most appropriate on a potential participant's journey to enrollment in the LCP. Through discussions with CDC DDT subject matter experts, CDC identified three primary pathways through which an individual may enroll in the LCP: (1) exposure to

recruitment and outreach materials, (2) referrals from their health care provider or friend and family (e.g., word-of-mouth referrals), and (3) participation in an introductory session. Each of these pathways was determined to be subject to the described barriers; together, they comprise multiple opportunities for intervening. The resulting enrollment intervention developed through this process was Be Your Best.

Be Your Best Enrollment Intervention and Formative Tool Testing

As a result of the process described above, CDC's DDT collaborated with its contractors to develop the BYB intervention, which was packaged as an implementation guide to share with CDC partners and stakeholders. The intervention includes one main component that is required for implementation and is the main focus of this information collection request: a behaviorally focused introductory session, known as a Discovery Session.

Discovery Session (required component). This component is a 90-minute introductory session that uses a series of strategies (such as self-affirmation activities) that empower and encourage attendees to enroll in the LCP. This session occurs prior to the first session of an LCP.

Tool Testing Process. For this information collection request, all instruments in Phase 1 and Phase 2 were internally tested with the project team members, which included testing the web surveys and secure FTP sites on different browsers, testing for implausible skip patterns or data entry values, and testing an automated process for downloading and saving data. Furthermore, the Pre-Session Survey (***Attachment 2***) and Post-Session Survey (***Attachment 3***) instruments were previously field tested during a pilot demonstration of the BYB Discovery Session to determine whether they are sensitive enough to detect mindset change (Office of Management and Budget [OMB] Control Number: 0920-1154).

Next Steps

Even though some National DPP LCPs report using introductory sessions as a recruitment method (Gruss et al., 2017), there has been no systematic assessment of how many CDC-recognized LCPs offer introductory sessions, how they are conducted, or how they vary across CDC-recognized organizations, nor has there been an evaluation of their effectiveness in increasing enrollment in the LCP. As a next step in this work to continue to explore the effectiveness of introductory sessions, CDC plans to conduct an Introductory Session Landscape Assessment. This survey will be sent to all National DPP CDC-recognized organizations (approximately 1,700 plus approximately 540 additional class locations). The objectives of this Introductory Session Landscape Assessment are to increase knowledge of recruitment strategies used by CDC-recognized organizations to increase enrollment in LCPs, specifically, use of introductory sessions; understand how CDC-recognized organizations are using introductory sessions, including session content and delivery; determine whether current introductory sessions are associated with increased enrollment; and inform the development of the subsequent

Introductory Session Evaluation which will then evaluate the effectiveness of the BYB Discovery Session compared with other kinds of introductory sessions. The evaluation findings will help CDC decide whether to disseminate the BYB Discovery Session as a recommended introductory session to maximize recruitment into the National DPP LCPs and thereby maximize the National DPP's potential to reduce type 2 diabetes incidence.

A.2 Purposes and Use of the Information Collection

Phase 1. Introductory Session Landscape Assessment

The purposes of Phase 1 are to increase knowledge of recruitment strategies, specifically introductory sessions, used by CDC-recognized organizations to increase enrollment in lifestyle change programs; understand how CDC-recognized organizations are using introductory sessions, including session content and delivery; determine whether current introductory sessions are associated with increased enrollment; and inform the subsequent Introductory Session Evaluation that will evaluate the BYB Discovery Session compared with other types of introductory sessions (Phase 2). In addition to informing Phase 2 of this evaluation, the findings from Phase 1 will be documented in an Introductory Session Landscape Assessment final report for dissemination.

This survey includes all National DPP CDC-recognized organizations and will assess the programmatic characteristics, current recruitment strategies, and introductory session content and delivery of each CDC-recognized organization at both the (1) organizational/programmatic level and (2) class location level in order to efficiently capture the information on the aforementioned variables of interest. We will send each National DPP CDC-recognized organization and its affiliated class locations a link to complete a web-based survey through Voxco. Participants will be allowed 6 weeks to submit data following the receipt of the initial e-mail (***Attachment 1b***). The survey will take no longer than 15 minutes to complete. As we receive responses to the organizational survey, which will be fielded first, we will retrieve contact information for additional class locations to populate the sample for the additional class location–level survey. For CDC-recognized organizations or class locations that do not complete the online survey within 2 weeks of the initial invitation, we will send an email reminder 2 weeks after the initial invitation (***Attachment 1c***), 4 weeks after the initial invitation (***Attachment 1d***), and a final email reminder (***Attachment 1e*)** 6 weeks after the initial email sent. If CDC-recognized organizations do not respond in the 6-week data collection window, they will be mailed a letter requesting their participation (***Attachment 1f***) along with a paper questionnaire. The Landscape Assessment survey for the CDC-recognized organizations and class locations are provided in ***Attachment 1*** and ***Attachment 1aa***, respectively.

The evaluation questions we seek to answer, relevant measures, and data sources, are described in ***Exhibit 1***. The Introductory Session Landscape Assessment will not duplicate data collection efforts of the DPRP program or already-existing data sources (e.g., Area Health

Resource File, AHRF); we will combine data from the Assessment to a limited number of variables from the DPRP registry and the publicly available AHRF to answer the evaluation questions.

Exhibit 1. Introductory Session Landscape Assessment Evaluation Questions, Measures, and Data Sources

Evaluation Question (EQ)	Measures	Data Source(s)
EQ 1: What strategies are used by CDC-recognized organizations to recruit and engage participants into National DPP lifestyle change programs?	• Whether the lifestyle change program classes are offered at the organization's administrative office or at different class locations • Strategies used to recruit participants, including introductory sessions • Whether introductory sessions are offered	Landscape Assessment (***Attachment 1*** and ***Attachment 1aa***)
EQ 2: What proportion of programs (organizations, class locations) offer introductory sessions? • How are sessions being offered? • What is the content of introductory sessions? • What proportion of programs (organizations, class locations) offer introductory sessions solely for recruitment? In contrast, what proportion offer introductory sessions purely to complete enrollment paperwork for those who have already decided to enroll?	• Whether introductory sessions are offered • How introductory sessions are offered • Introductory session content	Landscape Assessment (***Attachment 1*** and ***Attachment 1aa***)

(continued)

Exhibit 1. Introductory Session Landscape Assessment Evaluation Questions, Measures, and Data Sources (continued)

Evaluation Question (EQ)	Measures	Data Source(s)
EQ 3: What are the characteristics of programs that offer introductory sessions compared with programs that do not?	• Whether introductory sessions are offered	Landscape Assessment (***Attachment 1*** and ***Attachment 1aa***)
	• Date of DPRP recognition	DPRP registry data
	• DPRP recognition status	
	• Type of program (e.g., in-person, combination)	
	• Class type (e.g., public, employee, member only, other)	
	• Average class size	
	• Average participant demographics (e.g., percentage female, average age)	
	• Participation in 1705 or other CDC cooperative agreements	
	• Community characteristics (e.g., percentage of persons in poverty)	Area Health Resource File
EQ 4: Can introductory sessions be categorized into different types or categories (for the purpose of studying the comparative effectiveness of implementing the BYB Discovery Session)? What are the different types of introductory sessions?	• Reason(s) for offering introductory sessions	Landscape Assessment (***Attachment 1*** and ***Attachment 1aa***)
	• How introductory sessions are offered	
	• Introductory session content	

(continued)

Exhibit 1. Introductory Session Landscape Assessment Evaluation Questions, Measures, and Data Sources (continued)

Evaluation Question (EQ)	Measures	Data Source(s)
EQ 5: What are characteristics of programs that offer different types of introductory sessions?	• Types of introductory sessions	Landscape Assessment (***Attachment 1*** and ***Attachment 1aa***)
	• Date of DPRP recognition • DPRP recognition status • Type of program (e.g., in person, combination) • Class type (e.g., public, employee, member only, other) • Average class size • Average participant demographics (e.g., percentage female, average age) • Participation in 1705 or other CDC cooperative agreements	DPRP registry data
	• Community characteristics (e.g., percentage of persons in poverty)	Area Health Resource File

Phase 2. Introductory Session Evaluation

The primary aim of the Introductory Session Evaluation is to determine the effectiveness of the BYB Discovery Session intervention in increasing enrollment in the National DPP LCP compared with already occurring introductory sessions (i.e., standard care), with a secondary aim of better understanding how BYB is implemented and the context of its implementation. The Introductory Session Evaluation will build on the Introductory Session Landscape Assessment completed earlier in the project by conducting an evaluation of the BYB Discovery Session intervention, with a comparison group of CDC-recognized organizations offering their naturally-occurring introductory sessions, and a process evaluation that quantitatively documents implementation fidelity and its context. Evaluation questions for the Introductory Session Evaluation are listed in ***Exhibit 2***.

Exhibit 2. Introductory Session Evaluation Questions

Outcome Evaluation Questions	1. Does implementation of the BYB Discovery Session lead to greater participant **registration** in a lifestyle change program than already occurring introductory sessions?[a] a. Are there differential effects in participant registration based on staffing levels, organizational characteristics, and area-level characteristics? b. Are there differential effects in participant registration based on implementation fidelity? c. Are there differential effects in participant registration based on participant attitudes, perceptions, beliefs, and intentions related to pertinent biases to enrollment? 2. Does implementation of the BYB Discovery Session lead to greater participant **first-session attendance** in a lifestyle change program than already occurring introductory sessions? a. Are there differential effects in participant first-session attendance based on staffing levels, organizational characteristics, and area-level characteristics? b. Are there differential effects in participant first-session attendance based on implementation fidelity? c. Are there differential effects in participant first-session attendance based on participant attitudes, perceptions, beliefs, and intentions related to pertinent biases to enrollment? 3. Does implementation of the BYB Discovery Session lead to greater participant changes in attitudes, perceptions, beliefs, and intentions related to pertinent biases to enrollment than already occurring introductory sessions?
Process Evaluation Questions	1. To what extent did class locations overall implement the BYB Discovery Session with **fidelity**?[b] 2. What aspects of the BYB Discovery Session did class locations implement the most? 3. What aspects of the BYB Discovery Session did class locations implement the least? 4. How did differing contexts affect fidelity of the BYB Discovery Sessions?

[a] Registration is an eligible person's formal documentation of intent to attend the first session of a National DPP lifestyle change program. Formal documentation may include filling out paperwork, providing health insurance information, and/or providing contact information. Registration for the lifestyle change program is not a standardized process and will have a different format among different programs.

[b] Fidelity is the extent to which the BYB Discovery Session is implemented as described in the BYB Discovery Session manual. Fidelity is documented by intervention staff and an introductory session observer who indicate in a checklist whether each component was implemented as described in the BYB Discovery Session manual during the specified introductory session.

We will recruit CDC-recognized organizations and individual class locations from among those that complete the Landscape Assessment survey (Phase 1), deliver programs in-person (not virtual), plan to hold an introductory session within the study period, and agree to be contacted for potential participation in the Introductory Session Evaluation. We will categorize eligible class locations into strata based on criteria such as geographic location and organization type. We will randomly select locations for recruitment from each stratum, and randomly assign participating locations within each stratum to either the BYB Discovery Session (i.e., intervention group) or standard care (i.e., comparison group).

We will use four data collection tools to assess the effectiveness of the BYB Discovery Session compared with naturally occurring introductory sessions: (1) participant Pre-Session Survey, (2) participant Post-Session Survey, (3) Registration and Attendance Tracking Form, and (4) BYB Discovery Session Implementation Fidelity Checklist. ***Exhibit 3*** describes the content for each data collection tool to be completed by introductory session attendees (up to 2,640 attendees) as well as how we will administer each tool.

Exhibit 3. Data Collection Tools for Introductory Session Attendees

Tool Name	Content	How it is being administered
Pre-Session Survey **(*Attachment 2*)**	• Perceived behavioral barriers to registering for LCP • Demographics: Race, ethnicity, insurance, gender, and age • Intentions to register for LCP • Perceived likelihood of developing diabetes • Previous enrollment in LCP • Source of referral to introductory session	• CDC contractors will ship blank questionnaires and pre-paid/pre-labeled envelopes to return the completed surveys to all enrolled class locations. • Staff at each class location will administer the pre-survey to introductory session attendees at the beginning of the introductory session and mail back to CDC contractors. • CDC contractors will use Entry Point Plus, a validated system used for central data entry, for data collection and management.

(continued)

Exhibit 3. Data Collection Tools for Introductory Session Attendees (continued)

Tool Name	Content	How it is being administered
Post-Session Survey (***Attachment 3***)	• Perceived likelihood of developing diabetes • Perceived behavioral barriers to registering for LCP • Intention to register for LCP • Importance of Introductory Session • Reasons for signing up • Quality ratings of Introductory Session	• CDC contractors will ship blank questionnaires and pre-paid/pre-labeled envelopes to return the completed surveys to all enrolled class locations. • Staff at each class location will administer the post-survey to introductory session attendees at the end of the introductory session and mail back to CDC contractors. • CDC contractors will use Entry Point Plus, a validated system used for central data entry, for data collection and management.

Exhibit 4 describes the content for each data collection tool that LCP staff will complete at each class location, as well as how we will administer each tool. Only LCP staff at class locations assigned to the BYB Discovery Session (up to 66) will complete the Discovery Session Implementation Fidelity Checklist; LCP staff at all class locations (up to 132) will complete the Registration and Attendance Tracking Form. The primary outcome will be first-session attendance in the lifestyle change program among introductory session participants.

Exhibit 4. Data Collection Tools for LCP Class Locations

Tool Name	Content	How it is being administered
Registration and Attendance Tracking Form (***Attachment 4***)	• Whether introductory session attendee registered for the LCP at any time (during introductory session, after introductory session but before LCP session 1, during session 1) • Whether introductory session attendee registered for the LCP during introductory session • Whether introductory session attendee attended LCP session 1	• CDC contractors will contact LCP staff at enrolled class locations with login information and data collection instructions. • LCP staff at enrolled class locations will download and complete an Excel data collection form off of a secure file transfer site.
Discovery Session Implementation Fidelity Checklist (***Attachment 5***)	• BYB Discovery Session implementation fidelity • Staffing levels	• CDC contractors will contact LCP staff at enrolled class locations with login information and data collection instructions. • LCP staff at enrolled class locations will download and complete an Excel data collection forms off of a secure file transfer site.

To detect an absolute difference of 10 percentage points across the two arms (i.e., BYB Discovery Session, standard care) with alpha = 0.05 and 80% power with an intraclass correlation of 0.05, 1,140 total participants are required in the evaluation. Assuming a minimum of 10 participants per class, the power calculations require a minimum of 114 classes.

A.3 Use of Improved Information Technology (IT) and Burden Reduction

Phase 1. Introductory Session Landscape Assessment

We will administer the Landscape Assessment to approximately 1,700 CDC-recognized organizations (***Attachment 1***), plus an additional 540 class locations (***Attachment 1aa***), via a web-based survey platform, Voxco. This electronic survey platform is accessible via the Internet without downloading or installing specialized software, making it easy and efficient for organizations to complete the survey and for CDC and its contractors to track responses and seamlessly merge into our data analysis software program. Respondents will not be required to

own any computer equipment outside of the minimum needed for web browsing. Respondents also have the option of taking the survey from a web-enabled mobile phone, as the survey is compatible with mobile browsers. Completing the survey online will eliminate the burden of completing a paper survey; only non-respondents, after three email reminder attempts, will be mailed a paper survey. CDC contractors will program the survey with skip patterns to further reduce respondent burden (i.e., respondents will only see items for which they are eligible to respond). We will house all survey data in a secure location created by the contractor.

Phase 2. Introductory Session Evaluation

Phase 2 will be conducted partially using electronic methods. We will provide LCP staff from up to 132 National DPP LCP class locations with electronic versions of the Registration and Attendance Tracking Form (***Attachment 4***) and Discovery Session Implementation Fidelity Checklist (***Attachment 5***) through a secure FTP site, wherein each site has a unique login. These instruments were designed in Microsoft Excel and include the use of drop-down selection menus throughout each data collection tool making it easy and efficient for included LCP staff to complete.

We will disseminate paper Pre-Session (***Attachment 2***) and Post-Session Surveys (***Attachment 3***) for LCP staff to administer to introductory session attendees to ensure data collection is easy and efficient and accurately reflects attendee's perceptions. To reduce burden, we will provide all class locations with prepaid envelopes to return completed Pre-Session and Post-Session Surveys to the contractor, who will manually enter responses into Entry Point Plus (a data capture software program). Across all evaluation tools, we have limited questions to those most relevant to the project's purpose and objectives to reduce burden on respondents.

A.4 Efforts to Identify Duplication and Use of Similar Information

We employed several methods to ensure that this data collection effort would not be a duplication of other current or previous efforts. We conducted a brief literature search examining the use of introductory sessions to increase enrollment in lifestyle change programs such as the National DPP LCP. A PubMed search revealed that only one study has rigorously evaluated introductory sessions, although not for the National DPP LCP specifically (Jiang et al. 2014).

Furthermore, we collaborated closely with other DDT colleagues who have undertaken data collection efforts associated with the National DPP LCP. While previous and current evaluations of the National DPP LCP have assessed whether CDC-recognized organizations offer introductory sessions as a recruitment strategy (Gruss et al. 2017; OMB Control Number: 0920-0909), these evaluations include only a subset of all CDC-recognized organizations currently offering the National DPP LCP. In addition, these evaluations did not collect detailed information on how these introductory sessions were implemented, session content, or whether current introductory sessions use behavioral insight approaches to overcome behavioral barriers

to enrollment as described in section A.1. Thus, this project is the first to systematically assess the prevalence and effectiveness of introductory sessions as a recruitment strategy to increase enrollment in the National DPP LCP.

We also collaborated with staff who oversee CDC's Diabetes Prevention Recognition Program (DPRP), the quality assurance arm of the National DPP. Through the DPRP, CDC recognizes organizations delivering the lifestyle change program that are able to meet national quality standards and achieve the outcomes proven to prevent or delay the onset of type 2 diabetes. CDC-recognized organizations offering the National DPP LCP submit data based on the 2018 standards (OMB Control Number: 0920-0909) in 6-month intervals. We have worked with CDC's DPRP to ensure that data collection tools as part of this information collection request do not include any variables already collected by CDC's DPRP. Furthermore, we will work with National DPP LCP staff to ensure that any individual-level data collected as part of this information collection request will be assigned participant IDs that follow the same naming conventions as specified in the DPRP 2018 standards to reduce burden on National DPP CDC-recognized organizations participating in this project.

We conducted formative research and tool testing to develop the following data collection tools (OMB Control Number: 0920-1154): Pre-Session Survey (***Attachment 2***), Post-Session Survey (***Attachment 3***), and Discovery Session Implementation Fidelity Checklist (***Attachment 5***). As no current standard introductory session exists for the National DPP, this project will be the first to evaluate a behavior economics-informed introductory session, the Be Your Best Discovery Session compared to already-occurring introductory sessions (i.e., standard care) using these tools.

A.5 Impact on Small Businesses or Other Small Entities

Both the Introductory Session Landscape Assessment (Phase 1) and Introductory Session Evaluation (Phase 2) will include CDC-recognized organizations, including healthcare centers, local health departments, recreation centers, wellness centers, pharmacies or other nonprofits which may qualify as small entities. Participation in both Phase 1 and Phase 2 of this project is voluntary. There are no special requirements for small businesses. We will minimize the burden of data collection placed on small businesses by providing printed data collection instruments for distribution (i.e., Pre-Session and Post-Session Surveys), a return envelope with prepaid postage for completed data collection instruments, and instruments that have been streamlined to collect only the most essential information, which can be completed and submitted electronically (e.g., BYB Discovery Session Implementation Fidelity Checklist and the Registration and Attendance Tracking Form). The Introductory Session Evaluation (Phase 2) also has the potential added benefit to organizations in that it may help meet the standards needed to be achieve CDC recognition.

All class locations will receive compensation to accommodate intervention implementation cost.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time information collection request for both Phase 1 and Phase 2 of this project.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. This request fully complies with the regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice (FRN) and Effort to Consult Outside the Agency

Part A: PUBLIC NOTICE

A 60-day Federal Register Notice was published in the *Federal Register* on September 4, 2019, Vol. 84 No. 171, pp. 46536-7 (see Attachment 10). CDC received three public comments, two of these comments were out of scope for this information collection request and were forwarded to the appropriate program office for consideration. The remaining comment was non-substantive and CDC replied with a standard CDC response. Public comments and CDC responses are provided in (Attachment 11).

Part B: CONSULTATION:

CDC has been working with contractors at RTI International and Amico Consulting on the Introductory Session Landscape Assessment (Phase 1) and Introductory Session Evaluation (Phase 2) designs and data collection tools for this information collection request. Additionally, CDC worked with contractors at Abt Associates, FHI 360, and ideas42 under a prior contract on the intervention design of the Be Your Best Discovery Session. Several CDC subject matter experts provided input on the Landscape Assessment and Introductory Session Evaluation designs, Be Your Best implementation guide and data collection instrument content. External consultants are listed in ***Exhibit 5*** and consultants within CDC are listed in Exhibit 6.

Exhibit 5. External Consultants

Individuals Consulted Outside the Agency		
Name	**Organization**	**Contact Information**
Deborah Porterfield	RTI International	Email: dsporterfield.contractor@rti.org Phone: 919-630-0532
Pam Williams	RTI International	Email: pamwilliams@rti.org Phone: 919-316-3936

Individuals Consulted Outside the Agency		
Name	**Organization**	**Contact Information**
Kara Suvada	RTI International	Email: ksuvada@rti.org Phone: (919) 541-8030

Exhibit 5. External Consultants (continued)

Individuals Consulted Outside the Agency		
Name	**Organization**	**Contact Information**
Sara Jacobs	RTI International	Email: sjacobs@rti.org Phone: 770-407-4951
Wendi Elkins	RTI International	Email: welkins@rti.org Phone: 336-905-1203
Sreelatha Meleth	RTI International	Email: smeleth@rti.org Phone: 770-407-4936
Peter Amico	Amico Consulting	Email: peter@amicoconsulting.org Phone: (617) 863-0917
Cynthia Klein, PhD	Abt Associates	Email: cynthia_klein@abtassoc.com Phone: (404) 946-6310
Tara Earl, PhD	Abt Associates	Email: tara_earl@abtassoc.com Phone: (404) 946-6379
Stephanie Frost	Abt Associates	Email: stephanie_frost@abtassoc.com Phone: (404) 946-6379
Rebecca Ledsky	FHI 360	Email: rledsky@fhi360.org Phone: (919) 544-7040
Jess Leifer, MPP	ideas42	Email: jleifer@ideas42.org Phone: (646) 330-5700
Matt Darling, MS	ideas42	Email: matthew@ideas42.org Phone: (646) 330-5700

Exhibit 6. Consultations within CDC

Individuals Consulted within the Agency		
Name	**Organization**	**Contact Information**
Krista Proia	DDT- Translation, Health Education, and Evaluation Branch	Email: isp9@cdc.gov Phone: (404) 498-0961
Robin Soler	DDT- Translation, Health Education, and Evaluation Branch	Email: dqx4@cdc.gov Phone: (770) 488-5103
Andrew Lanza	DDT- Translation, Health Education, and Evaluation Branch	Email: lea0@cdc.gov Phone: (404) 610-1294
Matthew Jackson	DDT – Translation, Health Education, and Evaluation Branch	Email: kpj5@cdc.gov Phone: (404) 429-0417
Renee Skeete	DDT- Translation, Health Education, and Evaluation Branch	Email: ysf5@cdc.gov Phone: (404) 498-6361
Michael Cannon	DDT- Translation, Health Education, and Evaluation Branch	Email: mrc7@cdc.gov Phone: (404) 498-6722
Stephanie Gruss	DDT – Program Implementation Branch	Email: inf6@cdc.gov Phone: (770) 488-8173
Thea Nhim	DDT – Program Implementation Branch	Email: xmh8@cdc.gov Phone: (770) 488-0912

A.9 Explanation of Any Payment or Gift to Respondents

Phase 1. Introductory Session Landscape Assessment

Participation in the Landscape Assessment is voluntary. National DPP LCP staff responding to this survey will not receive a monetary gift or other payment for their participation in this phase of the project.

Phase 2. Introductory Session Evaluation

Introductory and Discovery Session attendees will not receive a monetary gift or other payment for their participation in the Introductory Session, Discovery Session, or completing the Pre-Session Survey or Post-Session Survey.

National DPP LCP program staff delivering either the Introductory Session or BYB Discovery Session will not receive a monetary gift for their participation in the project. CDC-recognized organizations and class locations will receive compensation to accommodate intervention implementation cost. Class locations assigned to implement the BYB Discovery

Session (up to 66 classes) will be compensated up to $1,450 for time and materials, including time for lifestyle coaches to implement the BYB Discovery Session (e.g., time spent attending training webinars on how to implement the session, preparing materials for the session, and delivering the session) and cost of buying materials needed to implement BYB Discovery Session. Those providing introductory sessions as usual (up to 66 classes) will be compensated up to $600, which is to cover the costs for LCP staff to implement their usual introductory session. The compensation is larger for class locations implementing the BYB Discovery Session to account for the additional training and materials needed to implement the new introductory session.

A.10 Protection of the Privacy and Confidentiality of Information Provided to Respondents

A.10.1 Collection of Personally Identifiable Information

Phase 1. Introductory Session Landscape Assessment

The National Center for Chronic Disease Prevention and Health Promotion's Information Security Officer has reviewed the submission and has determined that the Privacy Act does not apply. We will have the names, email addresses, and mailing addresses of the primary point of contact for each CDC-recognized organization delivering the National DPP LCP. All CDC-recognized organizations will receive a link to complete the Phase 1 Landscape Assessment by email. Past evaluations on the National DPP indicated that introductory sessions are not only conducted differently across CDC-recognized organizations, but that some organizations offer the National DPP LCP at multiple class locations and their implementation of introductory sessions also vary. We anticipate that a subset of these CDC-recognized organizations are delivering classes in multiple locations, however contact information for these individual locations are not currently available. Therefore, a survey item included in the Landscape Assessment for CDC-recognized organizations (***Attachment 1***) asks these administrative locations to provide the contact information (i.e., name, email, and phone number) for any affiliated locations where LCP classes are delivered (i.e., class locations) so that we can send a modified version of the Landscape Assessment (***Attachment 1aa***) to those class locations.

Because contact information constitutes personally identifiable information (PII) for respondents to the Landscape Assessment, trained CDC contractors will keep survey responses in a password-protected, secure share drive folder within the contractor's network. CDC contractors will back up databases and project file shares nightly to minimize the risk of losing significant data through hardware or software malfunctions. Only authorized staff will have access to this folder. We will store respondent data in a separate server from PII.

Phase 2. Introductory Session Evaluation

We will not collect any PII for Phase 2. Trained National DPP LCP staff will administer Pre-Session and Post-Session Surveys and will assign attendees a unique user ID. National DPP LCP staff will mail completed Pre-Session and Post-Session surveys to CDC's contractor for this project. National DPP LCP staff will complete the Registration and Attendance Tracking Form and the BYB Discovery Session Implementation Fidelity Checklist (if assigned to the Discovery Session only) and return to CDC's contractor using secure FTP upload. The contractor will enter data from the Pre-Session and Post-Session Surveys into an electronic database and upload the submitted Registration and Attendance Tracking Forms and Discovery Session Fidelity Checklists to a secure folder on a password protected computer.

For both phases of the project CDC will not have direct contact with Introductory Session or BYB Discovery Session attendees or receive any identifiable response data from respondents. Although CDC knows the names of the CDC-recognized organizations and key program staff, CDC will not be able to link specific responses to actual organizations. Any data delivered to CDC from the contractor or reports produced will not include PII or identifiable information.

A.10.2 Privacy Act Statement

See Privacy Narrative (***Attachment 6***). A Privacy Impact Assessment has also been submitted as part of this OMB package.

A.10.3 System of Records Notice (SORN)

A SORN is not required because records are not retrievable by PII.

A.10.4 Privacy Impact Assessment (PIA)

A draft copy of the PIA for the National DPP Introductory Session Evaluation has been provided with this package for OMB's review.

A.10.5 Records Retention and Disposition Schedule

We will retain, store, and dispose of all records in accordance with CDC's Records Control Schedule for Scientific and Research Project Records. We will remove all PII before records are archived. CDC contractors will destroy all records no later than five years after the end of the project.

A.11 Institutional Review Board (IRB) & Justification for Sensitive Questions

Phase 1. Introductory Session Landscape Assessment

The information collection contractor's IRB determined that Phase 1 does not constitute research with human subjects as defined by the U.S. Code of Federal Regulations (45 CFR 46.102). The contractor's IRB determination memorandum is included as ***Attachment 7***.

The Landscape Assessment will collect information about organizational strategies to recruit and engage participants in National DPP LCPs. The survey questions are **not** of a sensitive nature, such as criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, or other matters that are commonly considered private. We are not collecting data on the race or ethnicity or health of survey respondents. Respondents may provide professional judgments and opinions, as well as facts, during data collection. Some of the information relates to strategy effectiveness and could therefore be considered sensitive by a portion of respondents; however, disclosure of this information is unlikely to result in liability or competitive disadvantage to the organization.

Phase 2. Introductory Session Evaluation

The information collection contractor's IRB determined that the Phase 2 evaluation does not constitute research with human subjects as defined by the U.S. Code of Federal Regulations (45 CFR 46.102). The contractor's IRB determination memorandum is included as ***Attachment 8***.

National DPP staff will administer the Pre-Session **(*Attachment 2*)** and Post-Session **(*Attachment 3*)** surveys to introductory session attendees. The surveys will be used to collect information about barriers and facilitators to enrolling in the National DPP LCP, as well as the session's impact on changes in participants (e.g., changes in participant attitudes, perceptions, beliefs, and intentions related to registering in and participating in an LCP). The Pre-Session Survey also contains demographic questions of a somewhat sensitive nature (e.g., related to insurance status, race, and/or ethnicity), however respondents will be informed that they will not be required to answer any questions they do not wish to answer, that their answers will remain anonymous, and that any data collected will not include PII or identifiable information. In addition, we will fully inform introductory session attendees of safeguards put into place to ensure that their identity will not be shared and that information collected will be securely stored by the contractor.

The Registration and Attendance Tracking Form **(*Attachment 4*)** will collect first-session attendance in the LCP among introductory session participants. We will also assess intervention fidelity among class locations implementing the BYB Discovery Session, using the BYB Discovery Session Implementation Fidelity Checklist **(*Attachment 5*)**. The Post-Session Survey, the Registration and Attendance Tracking Form, and the BYB Discovery Session Implementation Fidelity Checklist do not contain questions of a sensitive nature.

A.12 Estimated Annualized Burden Hours and Cost to Respondents

This new OMB approval is being requested for two phases of data collection.

Phase 1. Introductory Session Landscape Assessment

The burden estimates for the Landscape Assessment (***Attachments 1*** and ***1aa***) includes time to complete the tool. The Landscape Assessment is designed to take no longer than 15 minutes to complete. We will ask up to 1,700 CDC-recognized organizations plus approximately 540 additional class locations to complete the survey for a total of up to 2,240 respondents. Response to the Landscape Assessment will be completely voluntary, however annualized burden hours are estimated assuming a 100% response rate. For all information collection for Phase 1, the total estimated burden response is **560 hours**, as shown in ***Exhibit 7***. There are no costs to respondents other than time.

Exhibit 7. Phase 1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (minutes/hour)	Total Burden Hours
LCP Staff	Landscape Assessment	2,240	1	15/60	**560**
Total					**560**

Exhibit 8 shows the annualized cost to respondents during Phase 1 of data collection. We calculated average hourly wage of LCP staff by using previous knowledge of occupations in this role from other National DPP evaluations. We included community health workers, nurse practitioners, dieticians/nutritionists, pharmacists, health educators, and healthcare social workers. We captured average salaries from the Bureau of Labor Statistics and averaged the hourly wages from the different categories of LCP staff divided by the average number of hours worked by someone in the US per year.

Exhibit 8. Phase 1 Annualized Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	Total Burden (in hours)	Average Hourly Wage	Total Cost (Total burden in hours multiplied by respondent hourly wage)
LCP Staff	Landscape Assessment	2,240	560	$40.77	$22,831
Total					$22,831

Bureau of Labor Statistics. Retrieved from https://www.bls.gov/oes/current/oes_nat.htm

Phase 2. Introductory Session Evaluation

Exhibits 9 and ***10*** below describe the burden and costs associated with the information collection estimates of average burden per response for Phase 2 data collection for the following tools: Pre-Session Survey, Post-Session Survey, Registration and Attendance Tracking Form, and Discovery Session Implementation Fidelity Checklist.

The Pre-Session and Post-Session Surveys are designed to take no longer than 10 minutes per survey to complete. We estimate that both surveys will be completed by up to 20 respondents attending introductory/discovery sessions in up to 132 class locations for a total of 2,640 respondents. The Registration and Attendance Tracking Form is designed to take no longer than 15 minutes to complete and will be completed by an individual LCP staff member in up to 132 class locations. The Discovery Session Implementation Fidelity Checklist will only be completed by an individual LCP staff member at one of the 66 LCP locations assigned to deliver the Be Your Best Discovery Session. We estimate that the Discovery Session Implementation Fidelity Checklist will take no longer than 1.5 hours to complete in accordance with the Discovery Session delivery time. Responses to all data collection instruments will be completely voluntary, however annualized burden hours are estimated assuming a 100% response rate. For all Phase 2 information collection, the total estimated burden response is **1,012 hours**, as shown in ***Exhibit 9***.

Exhibit 9. Phase 2 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	Participation Time (minutes/hour)	Burden in Hours
Introductory Session Attendees (Individuals)	Pre-Session Survey	2,640	10/60	**440**
	Post-Session Survey	2,640	10/60	**440**
LCP Staff (Individuals)	Registration and Attendance Tracking Form	132	15/60	**33**
	BYB Discovery Session Implementation Fidelity Checklist	66	90/60	**99**
Total				**1,012**

Exhibit 10 shows the annualized cost to respondents during Phase 2 of data collection. As with Phase 1, we calculated average hourly wage of LCP staff by using previous knowledge of occupations in this role from other National DPP evaluations. We included community health workers, nurse practitioners, dieticians/nutritionists, pharmacists, health educators, and healthcare social workers. We captured average salaries from the Bureau of Labor Statistics and

averaged the hourly wages from the different categories of LCP staff and divided by the average number of hours worked by someone in the US per year.

The average hourly wage of an Introductory Session/BYB Discovery Session participant was calculated taking the median personal income per person in the US and dividing by the average number of hours worked by someone in the US per year. We captured these metrics from the Federal Reserve Bank of St. Louis, with additional information from the U.S. Bureau of the Census (U.S. Bureau of the Census, 2017).

Exhibit 10. Phase 2 Annualized Cost to Respondents

Type of Respondent	Form Name	No. of Respondents	Total Burden (in hours)	Average Hourly Wage	Total Cost (Total burden in hours multiplied by respondent hourly wage)
Information Session Attendees (Individuals)	Pre-Session Survey	2,640	440	$17.47	**$7,687**
	Post-Session Survey	2,640	440	$17.47	**$7,687**
Staff at community-based organizations (Individuals)	Registration and Attendance Tracking Form	132	33	$40.77	**$1,345**
	BYB Discovery Session Implementation Fidelity Checklist	66	99	$40.77	**$4,036**
Total					**$20,755**

U.S. Bureau of the Census. (2017), Real median personal income in the United States [MEPAINUSA672N]. Retrieved from FRED, Federal Reserve Bank of St. Louis website: https://fred.stlouisfed.org/series/MEPAINUSA672N

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

A.14 Annualized Cost to Federal Government

Costs to the federal government include the costs of CDC personnel associated with the project and the cost of a contractor for information collection and management. The total

annualized cost to the government is $528,134. The breakdown of how that estimate was reached is below (see ***Exhibit 11***).

A CDC DDT federal employee will supervise the proposed evaluation instruments, who will act as a task lead and technical monitor. This level of effort includes approximately 15% of a GS-13 Health Scientist's time, a $102,609 annual salary (total $15,392). Two other CDC DDT staff will support the task lead in her role. The level of effort for two staff include approximately 5% of a GS-12 Program and Management Analyst's time, a $94,137 annual salary (total $4,707) and approximately 5% of a GS-11 Health Scientist's time, a $65,448 annual salary (total $ 3,273). CDC staff, in close consultation with the contractor, will oversee all activities and ensure that data collection is being conducted in accordance with OMB requirements. They will also assist in instrument development, interpretation of findings, and report preparation.

The development of data collection instruments, data analysis, and reporting is being conducted under a contract with CDC's evaluation contractor. The base and option period contract for evaluation of the program totals $2,017,352.00 over a 4-year period and includes costs for data management, programming, reporting, and dissemination.

Exhibit 11. Estimated Annualized Cost to the Federal Government

Staff	Annualized Cost
FEDERAL STAFF (project planning, management, OMB review, analysis of findings, and report writing)	**$23,372**
GS-13 Health Scientist at 15% FTE	$15,392
GS-12 Management and Program Analyst at 5% FTE	$4,707
GS-11 Health Scientist at 5% FTE	$3,273
EXTERNAL CONTRACTOR (instrument development, OMB package preparation, project implementation, data collection, data analysis, final report development, dissemination of findings)	**$504,338**
TOTAL	**$527,710**

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16.1 Plans for Tabulation/Data Analysis

We will maintain all Phase 1 and Phase 2 data securely on the contractor's server, which is only accessible to the authorized staff. We will analyze quantitative survey data using descriptive, bivariate, and multivariate analysis. Briefly, we will provide summary statistics on all items on each instrument at the class location level. We will use bivariate analyses (e.g., two sample *t* tests or chi-square measures of association) to examine any differential effects in outcomes based on staffing levels; organizational characteristics; area-level characteristics; implementation fidelity; or participant attitudes, perceptions, beliefs, and intentions. As sample size allows, we will use multivariable modeling to perform two separate models on our outcomes of interest. One model will calculate the intervention effect on participant registration status, and the other will calculate the intervention effect on participant first-session attendance. Each model will compare the average participant registration status/average participant first-session attendance for the classes that implemented the BYB Discovery Session with the average participant registration status/average participant first-session attendance for the regular Introductory Sessions (i.e., standard care).

CDC's timeline is outlined in ***Exhibit 12***. CDC's contract with the evaluation contractor ends September 30, 2022 (option year included).

Exhibit 12. Data Collection Time Schedule (Base & Option Periods)

Activity	Time Schedule
Phase 1. Introductory Session Landscape Assessment	
Initiate Landscape Assessment (begin first, 6-week period of data collection)	June 2020
Send DDT pre-notification letters to CDC-recognized organizations	May 2020
Send email introduction and survey explanation to CDC-recognized organizations with survey link	June 2020
Complete first period of data collection	July 2020
Initiate second, 6-week data collection period for CDC-recognized organization class locations; send email introduction and survey explanation to CDC-recognized organization class locations with survey link	July 2020
Complete second period of data collection	August 2020
Report findings in an Introductory Session Landscape Assessment report to CDC	September 2020

(continued)

Exhibit 12. Data Collection Time Schedule (Base & Option Periods) (continued)

Activity	Time Schedule
Phase 2. Introductory Session Evaluation	
Identify and recruit class locations for Introductory Session Evaluation (begin 3-month period)	March 2021
Implementation and data collection training and technical assistance (begin 4-month period)	June 2021
Begin introductory session Introductory Session Evaluation implementation and data collection (begin 6-month period)	September 2021
Report findings in Introductory Session Evaluation report to CDC	August 2022
Webinar to disseminate methods and key findings	September 2022

A.16.2 Plans for Publication

We anticipate that findings from both Phase 1 (base period) will be reported in a final Introductory Session Landscape Assessment report and peer-reviewed journal. We will summarize findings from Phase 2 data collection in a comprehensive final report, and a peer-reviewed journal. We will incorporate findings from both Phase 1 and Phase 2 data collection efforts into a webinar presentation to CDC grantees and National DPP LCP providers.

A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

Display of OMB expiration date is acceptable.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.

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