

Information Collection Request

New

National Diabetes Prevention Program (DPP) Introductory Session Project

Supporting Statement Part B

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PART B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The proposed information collection will be conducted during two phases of this project: (1) Phase 1: Introductory Session Landscape Assessment and (2) Phase 2: Introductory Session Evaluation.

Phase 1. Introductory Session Landscape Assessment

The purposes of Phase 1 and the Landscape Assessment (***Attachment 1*** for CDC-recognized organizations, ***Attachment 1aa*** for class locations) are to increase knowledge of recruitment strategies, specifically introductory sessions, used by CDC-recognized organizations to increase enrollment in the National Diabetes Prevention Program Lifestyle Change Program (National DPP LCP); understand how 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 (Phase 2). As such, our respondent universe for Phase I consists of National DPP LCP staff. We will administer the survey (***Attachment 1***) to all National DPP CDC-recognized organizations (approximately 1,700). We will send a modified version of the survey (***Attachment 1aa***) to additional class locations (approximately 540) for those organizations that offer the National DPP LCP in multiple settings. We will initially distribute the web-based survey via email; however, non-respondents will receive a hard-copy survey in the mail. The survey will take approximately 15 minutes to complete. Based on the contractor's experience administering web-based surveys followed with hard-copy surveys, we expect a 30% response rate within 6 weeks of the initial e-mail invitation. ***Exhibit 1*** summarizes the calculations behind the expected final sample size.

Exhibit 1. Number of CDC-Recognized Organizations Expected to Participate in Phase 1 Data Collection

Type of Respondents	No. in Respondent Universe	Sampling Frame	Expected Response Rate	Expected No. in Final Sample
LCP Staff (Individuals) from National DPP CDC-Recognized Organizations	2,240	2,240	30%	672

Phase 2. Introductory Session Evaluation

The primary aim of the Introductory Session Evaluation is to evaluate the effectiveness of introductory sessions, specifically a CDC-developed behaviorally-informed¹ introductory session known as the Be Your Best (BYB) Discovery Session, on enrollment compared with other types of introductory sessions that organizations currently use. As such our respondent universe consists of two types of respondents: (1) National DPP LCP staff who responded to the Introductory Landscape Assessment during Phase 1 data collection and (2) all individuals who either attended a BYB Discovery Session or a standard Introductory Session. In order to attend either type of Introductory Session, attendees must be at risk for developing type 2 diabetes (or have prediabetes) and be age 18 years or older.

We will select a sample of Phase 1 Landscape Assessment survey respondents to recruit a total of 132 CDC-recognized class locations offering the National DPP LCP to participate in the various data collection efforts. We will select among interested and eligible Phase 1 class locations that, taken together, are geographically dispersed, a mix of rural and urban settings, and hosted by various types of organizations (e.g., YMCAs, employer worksites, community-based organizations) to ensure heterogeneity of classes. To detect an absolute difference of 10 percentage points across the two arms (i.e., BYB Discovery Session, standard introductory sessions) with $\alpha = 0.05$ and 80% power with an intraclass correlation of 0.05, 1,140 total participants are required in the study. Assuming a minimum of 10 participants per introductory session, the power calculations require a minimum of 114 classes. Power is maximized if both arms have equal number of participants; therefore, we propose randomizing at least 60 class locations to the BYB Discovery Session arm and at least 60 class locations to the standard care arm for a total of 120 class locations. We will recruit 132 class locations to account for possible attrition during the evaluation due to nonsubmission of data/dropout, ultimately expecting to collect data from at least 120 classes. We will randomize selected and interested National DPP LCP class locations to implement either CDC's BYB Discovery Session ($n = 66$) or implement their introductory session as usual ($n = 66$). **Exhibit 2** summarizes the calculations behind the expected final sample size.

From the 132 selected class locations, LCP staff will collect data on registration and first-session attendance in the lifestyle change program among introductory session participants (**Attachment 4** Registration and Attendance Tracking Form). This data collection tool (a Microsoft Excel sheet) is expected to take approximately 15 minutes for LCP staff to complete and then upload to the study's FTP site. Concurrently, the contractor will assess whether BYB Discovery Session activities were implemented as intended before, during, and after each session among the 66 class locations implementing the BYB Discovery Session (**Attachment 5** BYB Discovery Session Implementation Fidelity Checklist). This checklist (a Microsoft Excel sheet) is expected to take approximately 90 minutes for LCP staff to complete during the Discovery Session and then upload to the study's FTP site.

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

Exhibit 2. Number of LCP Class Location Staff Expected to Participate in Phase 2 Data Collection

Data Collection Activity	Be Your Best Discovery Session Locations (n=66)	Existing Introductory Session Locations (n=66)	Total	Expected Response Rate	Expected No. in Final Sample
Registration and Attendance Tracking Form	66 staff (1 per class location)	66 staff (1 per class location)	132 staff	90%	120 staff
BYB Discovery Session Implementation Fidelity Checklist	66 staff (1 per class location)	N/A	66 staff	90%	60 staff

Participants attending either the BYB Discovery Session or an existing introductory session will complete a Pre-Session Survey (*Attachment 2*) and a Post-Session Survey (*Attachment 3*) to identify participant biases that serve as barriers to enrolling in the National DPP lifestyle change program. Biases assessed in these surveys include 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 outweighs the program’s future benefits (program burden). LCP staff will administer the paper-based surveys to session attendees. Each survey will take approximately 10 minutes to complete. LCP staff will mail completed surveys back to the contractor. The contractor will use Entry Point Plus, a validated system used for central data entry, for data Pre- and Post-Survey collection and management. *Exhibit 3* summarizes the calculations behind the expected final sample size.

Exhibit 3. Number of Introductory Session Participants Expected to Participate in Phase 2 Data Collection

Data Collection Activity	Be Your Best Discovery Session Locations (n=66)	Existing Introductory Session Locations (n=66)	Total	Expected Response Rate	Expected No. in Final Sample
Pre-Session Survey	1,320 participants (up to 20 per class location)	1,320 participants (up to 20 per class location)	2,640	80%	2,112 participants
Post-Session Survey	1,320 participants (up to 20 per class location)	1,320 participants (up to 20 per class location)	2,640	80%	2,112 participants

B.2 Procedures for the Collection of Information

The proposed information collection will be conducted during two phases of the study: (1) Phase 1: Introductory Session Landscape Assessment and (2) Phase 2: Introductory Session Evaluation.

Phase 1. Introductory Session Landscape Assessment

A registry of all current CDC-recognized organizations offering the National DPP LCP can be found here: https://nccd.cdc.gov/DDT_DPRP/Registry.aspx. We will use the contact information in this registry to administer the Landscape Assessment (***Attachment 1***) to all CDC-recognized organizations listed in this registry (approximately 1,700 organizations). Because contact information for individual class locations are not widely available through the registry, a CDC-recognized organization staff member that completes the Landscape Assessment will provide business contact information for their additional class locations. We will then send a modified version of the Landscape Assessment (***Attachment 1aa***) to the additional class locations (approximately 540) following the administration of the survey to CDC-recognized organizations. This modified version of the survey will contain questions only pertinent to individual class locations and will not duplicate efforts already collected from their parent organization.

Five days before the Landscape Assessment is administered, CDC will email all CDC-recognized organizations to describe the study and notify them of the forthcoming communication by the contractor (***Attachment 1a***). CDC contractors will send up to five rounds of communication to potential respondents during this data collection effort:

- Initial e-mail with an embedded link to the relevant survey instrument (***Attachment 1b***);
- Reminder e-mail (to non-respondents) with an embedded survey link (***Attachment 1c***), sent 2 weeks after the initial e-mail;
- Follow-up reminder e-mail (to non-respondents) with an embedded survey link (***Attachment 1d***), sent 4 weeks after the initial e-mail;
- Final reminder (to non-respondents), sent 6 weeks after the initial e-mail (see ***Attachment 1e***);
- Hard copy reminder letter with a hard copy survey enclosed along with a pre-paid return envelope addressed to the contractor's office (***Attachment 1f***);
- Thank you e-mail, sent 1 week after survey responses are received (see ***Attachment 1g***).

Based on the contractor's experience administering web-based surveys followed with hard-copy surveys, we expect a 30% response rate within 6 weeks of the initial e-mail invitation. The survey contains 38 questions (35 in the class location version), including a mix of open- and close-ended questions. The survey will employ skip patterns and display only the appropriate questions depending on the respondent's answers to previous questions.

We will store collected information in Voxco, the contractor's web-based survey platform, and download and store on secure servers. We will perform quantitative analyses that will involve using descriptive statistics to determine frequency distributions and corresponding variances for responses to each assessment question. Analysis will focus on the organization and program characteristics, the class characteristics, and the introductory session content and delivery.

Staff trained in the appropriate research methods will conduct all analyses. We will store all information on a secure shared drive with access limited to project team members.

Phase 2. Introductory Session Evaluation

CDC will email each class location selected to participate in the Introductory Session Evaluation (n=132) to describe the study and notify them of the forthcoming communication by the contractor (***Attachment 2a***). CDC contractors will send the following additional communications to all selected class locations:

- Initial e-mail introducing the purpose of the evaluation, the study design, key project team members and inviting them to confirm their willingness to participate (***Attachment 2b***);
- Accompanying data collection overview sheet (***Attachment 2c***)
- Recruitment reminder emails (to non-respondents) (***Attachments 2d, 2e, 2f***) (at approximately weeks 1, 3, and 5)
- Reminder e-mail sent out monthly during data collection regarding any completed data collection instruments that have not been received by the contractor (to non-respondents) (***Attachment 2g***)
- Final reminder email for class locations with outstanding data collection instruments (***Attachment 2h***).

BYB Discovery Session Implementation Fidelity Checklist

Class locations assigned to implement the BYB Discovery Session (up to 66 class locations) will complete and submit the BYB Discovery Session Implementation Fidelity Checklist which contains elements that need to be completed before, during, and after each session. We will train

all class locations to accurately document all BYB Discovery Session activities and LCP staff will complete this form during BYB Discovery Session delivery. After class locations upload their checklists to the sFTP sites, the contractor will download the files from the sFTP accounts within 1 business day following the data submission due date. After download, we will store data on Health Insurance Portability and Accountability Act (HIPAA) of 1996–compliant project servers. This tool contains 50 data entry fields. We will perform quantitative analysis using Stata 15.

Registration and Attendance Tracking Form

All class locations (BYB Discovery Session and existing Introductory Sessions) participating in the Introductory Session Evaluation will submit a Registration and Attendance Tracking Form (up to 132 sites). As detailed in the data collection overview document (***Attachment 2c***), all class locations should begin to complete the Registration and Attendance Tracking Form one week prior to an Introductory Session and track participant registration and attendance for three weeks. After class locations upload their Registration and Attendance Tracking Form, the contractor will download the files from the sFTP accounts within 1 business day following the data submission due date. After download, data will be stored on HIPAA-compliant project servers. The tool has 65 fields for data entry. Quantitative analysis will be carried out in Stata 15.

Pre- and Post-Session Surveys

Lifestyle change program (LCP) staff at each class location will administer Pre- and Post-Session Surveys at the beginning and end of the introductory sessions. These surveys are the only data collection tool that will not be submitted through the sFTP site. Rather, the contractor will ship blank questionnaires and pre-paid/pre-labeled envelopes to return the completed surveys to all participating class locations. LCP staff will label all surveys with a unique participant ID and the pre- and post-introductory session responses will be linked using the participant ID. Additionally, we will link data from the Registration and Attendance Tracking Form to the participant ID so that all data per participating class location can be aggregated/analyzed together. Upon receipt of the participant surveys from each of the class locations, the contractor will use Entry Point Plus, a validated system used for central data entry, for collecting and managing data. The Pre-Session Survey has 17 questions and the Post-Session Survey has 18 questions. We will perform quantitative analysis in Stata 15.

B.3 Methods to Maximize Response Rate and Minimize Nonresponse

We will use multiple strategies to maximize response rates. Both phases of the study will begin with CDC sending potential participants a pre-notification letter, emphasizing the importance of their contributions to this work and encouraging their voluntary participation in these studies. Also, drafts of the data collection instruments for both phases were shared with internal CDC stakeholders, a survey design and optimization expert, program evaluation experts,

and diabetes prevention subject matter experts for review and feedback throughout the development process. Including pre-addressed, pre-paid return envelopes will also minimize the burden on returning completed hard-copy Landscape Assessment surveys as well as the Introductory Session Evaluation's Pre-Session Survey and Post-Session Survey.

Additionally, for Phase 1, we will provide multiple rounds of communication, including the introductory e-mail notification with survey link, three reminder e-mails with survey link, and a mailed reminder letter with hard-copy survey (**Attachments 1b–1f**), to assist in maximizing response with the goal of achieving a 30% response rate. As mentioned above, Division of Diabetes Translation (DDT) staff will send an initial prenotification letter (**Attachment 1a**) to the CDC-recognized lifestyle change program points of contact letting them know they will receive an e-mail invitation to participate in a survey [Landscape Assessment]; based on previous experience with web-based surveys, we expect programs to be more likely to open a letter from DDT staff and also more likely to respond to the survey. We will use a tailored, recognizable e-mail address (e.g., [DPP Lifestyle Change Program Survey@rti.org](mailto:DPP_Lifestyle_Change_Program_Survey@rti.org)) to send the survey-related e-mails so that respondents are more likely to open the e-mail. The web-based mode of the Landscape Assessment was selected to minimize burden. The survey will take the respondent approximately 15 minutes to complete, and the survey will be accessible across multiple browsers (e.g., Internet Explorer, Google Chrome, Mozilla Firefox) and devices (e.g., smartphones, tablets, laptops). We plan to keep the survey open for 6 weeks, sending the first reminder e-mail 2 weeks after launching the survey, the second reminder e-mail 4 weeks after launching the survey, and the final reminder e-mail 6 weeks after launching the survey. At the end of data collection, we will calculate response rates of CDC-recognized organizations by organization characteristics (e.g., recognition status, average class size, type of program, and setting of programs). The characteristics of the final sample will be compared to the organizational characteristics of all CDC-recognized organizations in the DPRP Registry to evaluate representativeness.

For Phase 2 data collection efforts, we will have a team of study coordinators assigned to a number of class locations who will facilitate data collection and provide technical assistance (e.g., with the sFTP site). DDT staff will send an initial prenotification letter (**Attachment 2a**) to the points of contact at the CDC-recognized lifestyle change programs whose affiliate class locations indicated they would like to be contacted about the Introductory Session Evaluation inviting them to participate in the evaluation; based on previous experience, we expect programs to be more likely to open a letter from DDT staff and also more likely to participate with CDC's invitation. We will send an introductory recruitment email (**Attachment 2b**) accompanied by a 2-page data collection overview (**Attachment 2c**) to potential participants, followed by up to three reminder recruitment emails (**Attachments 2d, 2e, and 2f**) and up to two data collection reminder emails (to LCP staff) (**Attachments 2g and 2h**). Class locations assigned to implement the BYB Discovery Session (up to 66 classes) will be compensated up to \$1,450 to compensate 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 and preparing materials for 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 for time, primarily to cover costs for LCP staff to implement their usual introductory sessions. 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.

Additionally, for both Phase 1 and Phase 2, we will make sure CDC project officers who oversee grantees who may be affiliated with or fund the CDC-recognized organizations who offer the National DPP lifestyle change program are aware of which class locations are participating in this evaluation and can contact the CDC evaluation leads with any questions.

B.4 Test of Procedures or Methods to be Undertaken

To ensure that items and responses are understood by respondents on the surveys (Landscape Assessment, Pre-Session Survey, and Post-Session Survey), the Registration and Attendance Tracking Form, and the BYB Discovery Session Implementation Fidelity Checklist, CDC and contractor staff who have considerable experience with the National DPP lifestyle change program as well as the BYB introductory session content reviewed all of the data collection instruments. Edits were based on feedback provided by subject matter experts. In addition, all data collection instruments underwent rigorous editorial review to ensure clarity of content and plain-language. We will further test the web-based Landscape Assessment to ensure accessibility across multiple browsers and devices and to confirm that content and skip patterns were programmed correctly.

Contractor staff also tested the amount of time it took to complete each instrument to ensure accurate estimates are provided to participants. According to the results from these tests, the average time to complete the Landscape Assessment (Phase 1) was approximately 10 minutes, and the estimated time range for actual respondents to complete the instrument is 15 minutes. The average time to complete the Pre-Session Survey (Phase 2) was 5 minutes, and the estimated time range for actual respondents to complete the instrument is 10 minutes. Similarly, the average time to complete the Post-Session Survey (Phase 2) was 5 minutes, and the estimated time range for actual respondents to complete the instrument is 10 minutes. Both the Pre-Session and Post-Session surveys were further tested to assess the sensitivity of these tools designed to measure participant biases that serve as barriers to enrolling in the National DPP lifestyle change program during a demonstration of the BYB Discovery Sessions (Office of Management and Budget [OMB] Control Number: 0920-1154). The average time to complete the Registration and Attendance Tracking Form (Phase 2) was 10 minutes, and the estimated time range for actual respondents to complete the instrument is 15 minutes. Finally, the estimated time range for actual respondents to complete the BYB Discovery Session Implementation Fidelity Checklist (Phase

2) is 90 minutes, as it contains elements that need to be completed before, during, and after each Discovery Session.

B.5 Individuals Consulted on Statistical Aspects or Analyzing Data

DDT assumes oversight and responsibility for the development of the overall assessment design, data collection, and analysis. Deborah Porterfield, Project Director, and Pamela Williams, Associate Project Director, are the people primarily responsible for collecting the information and interpreting the findings. The individuals responsible for overseeing instrument design, data collection, and analysis are the following:

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