

Increase Enrollment in the CDC-Recognized Lifestyle Change Program

Generic Information Collection (0920-1154)

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Supporting Statement Part B

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ATTACHMENTS

1. Pre-Session Survey
2. Post-Session Survey
3. Enrollment Materials & Referral Tracking Form
4. LCP Staff Interview Guide
5. Information Session Observation Tool
6. LCP Staff Interview Informed Consent
7. ABT IRB Approval Memo

1. Respondent Universe and Sampling Methods

The primary purpose of this formative research and tool development is to assess the sensitivity of the Pre-Session and Post-Session Surveys to detect mindset change¹ that may be associated with enrollment activities, primarily the behaviorally-focused Information Session implemented as part of the *Be Your Best* intervention. As such, our respondent universe includes all individuals from the general population who attend either a behaviorally-focused Information Session hosted by a pilot intervention (*Be Your Best*) site (n=6 sites) or a standard Information Session hosted by a pilot non-intervention site (n=6 sites). In order to attend either type of Information Session, attendees must be at risk for developing type 2 diabetes (or have prediabetes) and be age 18 years or older. Lifestyle change program (LCP) staff or Session Coaches will distribute the Pre-Session and Post-Session Survey to all Information Session attendees. Exhibit 1 displays the number of Information Session attendees expected to respond to the Pre-Session and Post-Session Surveys based on an assumption of up to 30 Information Session attendees per site (assuming two Information Sessions per LCP and up to 15 attendees per Information Session).

Exhibit 1. Number of Information Session Attendees Expected to Participate in Data Collection

Data Collection Activity	Intervention Sites (n=6; 30 attendees each)	Non-intervention Sites (n=6; 30 attendees each)	Total
Pre-Session Survey	180	180	360
Post-Session Survey	180	180	360

We will also collect data about the enrollment activities taking place prior to the start of the CDC National Diabetes Prevention Program’s lifestyle change program (LCP) at both intervention and non-intervention sites, as some sites may already utilize behaviorally-focused strategies as part of their recruitment efforts. This additional data collection will help us determine if the surveys are sensitive enough to detect mindset change by collecting information about the enrollment activities taking place or not taking place at each LCP. CDC’s contractor will conduct these data collection activities, which will include: 1) LCP Staff Interview Guide and 2) Enrollment Materials & Referral Tracking Form. The respondent universe for these tools includes any staff conducting LCPs onsite (e.g., LCP coaches) and those overseeing program activities (e.g., LCP coordinators, LCP administrators). We expect to conduct LCP Staff interviews with one to three staff members per site. One staff member per site will complete the Enrollment Materials and Referral Tracking Form. Exhibit 2 displays the number of LCP staff expected to take part in data collection by activity.

Exhibit 2. Number of LCP Site Staff Expected to Participate in Data Collection

¹ defined as a change in urgency and importance

Data Collection Activity	Intervention Sites (n=6 sites)	Non-intervention Site (n=6 sites)	Total Staff
LCP Staff Interviews	18 staff (up to 3 per site)	18 staff (up to 3 per site)	36
Enrollment Materials & Referral Tracking Form	6 staff (1 per site)	6 staff (1 per site)	12

CDC’s contractor will also conduct observations of Information Sessions using the Information Session Observation Tool during scheduled site visits. The observations will capture the core components of each Session whether occurring at sites implementing the *Be Your Best* Intervention or non-intervention sites.

2. Information Collection Procedures

At the beginning of the observation period, CDC’s contractor will mail all data collection materials to each LCP along with a data collection request and summary letter and a data collection reference guide. Members of the contractor’s team will schedule phone calls with each LCP to review the information included in the packet, review data collection activities for which LCPs will assist, and answer any questions from LCP staff prior to the beginning of any data collection.

Pre-Session and Post-Session Surveys

LCP staff who serve as the Information Session Leads will administer the Pre-Session Survey (Attachment 2) and Post-Session Survey (Attachment 3). At the beginning of the Information Session, the LCP Staff/ Information Session Coach will distribute paper versions of the Pre-Session Survey to all attendees. Stapled to these materials will be a set of 2 labels with a unique ID. Each attendee will be instructed to place one ID label at the top of the Pre-Session Survey. Once all Pre-Session Surveys are completed (before the session begins), the Session Coach will collect and place surveys in a folder. All attendees will be instructed to hold on to the second label until the end of the Session.

At the end of the Information Session, the session coach will distribute paper versions of the Post-Session Survey. Attendees will be instructed to place their remaining ID label at the top of the survey before completing. Once all surveys are completed, the Session Coach will collect all surveys and place them in a data collection folder.

Once the Information Session is over and attendees have left, the member of the CDC contractor’s team attending the session for observation will collect the surveys. The team member will enter the first page of the Pre-Session Survey into a secure electronic database while onsite and return the first page of the Pre-Session Survey to the Session coach before the end of the site visit. LCP staff will store the first page of the Pre-Session Survey in locked file

cabinets at each LCP as standard practice for LCPs. CDC's contractor will keep the second and third pages of the Pre-Session Survey and all of the Post-Session Survey, and will return these documents to the project lead upon returning to the office. The contractor will store all data in password-protected files on secured servers and personally identifiable information from the Pre-Session Survey will be stored separately and will not be associated with survey data.

Enrollment Material and Referral Tracking Form

CDC's contractor will send LCPs a hard copy of the Enrollment Materials & Referral Tracking Form (Attachment 4) by mail and an electronic copy by email. Members of the contractor's team will review this tool with LCP staff by phone (along with the other tools noted above) to ensure LCP staff understand the instructions, how to complete the tool, who would be best positioned to complete the tool, estimated time to complete and when the completed tool should be returned to the contractor. LCP staff at intervention (*Be Your Best*) and non-intervention sites will be instructed to begin tracking enrollment material distribution and referrals upon receiving the tool and update regularly until the first session of the next LCP is held.

Lifestyle Change Program Staff Interviews

Trained contractor staff will conduct LCP Staff Interviews using the LCP Staff Interview Guide (Attachment 5). CDC's contractor will work with sites to identify the individuals overseeing or conducting LCP enrollment activities and LCP sessions. Once individuals are identified, the contractor will work with LCPs to coordinate the date, time and location of the interviews. Interviews may be conducted individually or as a dyad or triad. To the extent possible, CDC's contractor will work to schedule interviews during site visits to allow for in-person discussion; however, if scheduling in-person interviews is not possible, CDC's contractors will coordinate phone interviews with LCP staff. A member of the contractor's team will send a calendar invitation for the interview. Those conducting the interviews will begin by reading the informed consent (Attachment 9) and asking LCP staff to indicate whether they do/do not consent to participate and if the interview can be audio-recorded.

Information Session Observation Tool

Trained members of the contractor's team will conduct the Information Session Observation. Team members will be trained on the core components of the *Be Your Best* Intervention and how to record information for Sessions that do not adhere to the *Be Your Best* guidelines. Trained members of the contractor's team will also assess LCP enrollment materials and the overall quality of Information Sessions using the Information Session Observation Tool (Attachment 6). The contractor will conduct practice sessions and assess inter-rater reliability across observers to ensure standardized data collection.

Once onsite, members of the contractor's team will attend LCP Information Sessions and complete the Information Session Observation Tool. Observers will sit in a place that will not

call attention to them and be discrete in completing the form. Observers will receive paper-based versions of the form and will enter data from the Observation Tool into the project database upon returning from the site visit. As noted earlier, contractor staff will complete this Observation Tool and therefore this tool has not been included in the burden estimate in Supporting Statement A (no burden to the general public). The total burden to the contractor for completing this activity is estimated at 18 hours (up to 1.5 hours for each of 12 Information Sessions).

3. Methods to Maximize Response Rates

Information Session Coaches will distribute Pre-Session and Post-Session Surveys to all attendees. The Session Coach will review the instructions and read off questions and response options so the tools are easy to complete. Attendees will be informed by the Session Coach that they do not have to participate or can skip any question they would like to skip.

The LCP Staff Interview Guide was designed with particular focus on open-ended questions to allow respondents to provide detailed responses; however LCP staff members will have the option to skip questions they are not comfortable answering. Members of the contractor’s team conducting the interview will inform respondents that they have the right to end their participation at any time. CDC’s contractor will work with sites to identify staff working with LCPs to ensure the most complete picture of how LCP enrollment activities are conducted. Furthermore, interviews will be scheduled at a time that is convenient for staff members.

Response rates do not apply to the Observation Tool; to the extent possible, all Information Sessions held at intervention and non-intervention sites during the study period will be observed.

4. Test of Procedures or Methods to be Undertaken

As noted in Supporting Statement A (Exhibit 1), the Pre-Session and Post-Session Surveys have been developed using step-by-step guidance outlined by Haynes, Richard, and Kabany (1995) to ensure content validity during instrument development. These steps include an iterative process to refine content and wording through both internal project team review as well as external review by population members. To this end, we plan to field test the Pre-Session and Post-Session Surveys as well as the Enrollment Material & Referral Tracking Form and LCP Staff Interview Guide with up to 2 LCP sites simultaneously with OMB review and to be completed by mid-March 2018.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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