

undetermined agents, undetermined sources, undetermined transmission, or undetermined risk factors annually. The projected average number of respondents is 200 per EEI, for a total of 12,000 respondents. CDC estimates

the average burden per response is 0.5 hours and each respondent will be asked to respond once. Therefore, the total estimated annual burden hours are 6,000. These estimates are based on the reported burden for EEIs that have been

performed during the previous two years. OMB approval is requested for three years. There are no costs to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours (in hours)
Emergency Epidemic Investigation Participants.	Emergency Epidemic Investigation Data Collection Instruments.	12,000	1	30/60	6,000
Total	6,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-19BOI; Docket No. CDC-2019-0074]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National Diabetes Prevention Program (DPP) Introductory Session Project. This information collection aims to help CDC 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 a behaviorally-focused intervention known as Be Your Best (BYB) Discovery

Session compared with other already occurring introductory sessions.

DATES: CDC must receive written comments on or before November 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0074 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of

previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

National Diabetes Prevention Program (DPP) Introductory Session Project—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program Lifestyle Change Program (National DPP LCP) is 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. This proposed project's primary purposes are to (1) increase knowledge of recruitment strategies, specifically introductory sessions, used by CDC-recognized organizations to increase enrollment in the National DPP LCP (Phase 1), and (2) evaluate introductory sessions, specifically a CDC-developed behaviorally-informed introductory session known as the Be Your Best (BYB) Discovery Session, on enrollment compared with other types of introductory sessions that organizations currently use (Phase 2).

CDC is requesting OMB approval to collect information needed for this evaluation. For Phase 1 of this project, the Introductory Session Landscape Assessment, CDC is seeking approval to disseminate a brief Landscape Assessment (survey) to all National DPP CDC-recognized organizations (approximately 1,700) and their affiliate class locations (up to 540). The survey will initially be disseminated electronically (web-based survey), and then a hard copy will be mailed to non-respondents. 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 the subsequent Phase 2 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 (to be completed by up to 2,640 introductory session attendees), (2) Post-Session Survey (to be completed by up to 2,640 introductory session attendees), (3) Registration and Attendance Tracking Form (to be completed by up to 132 LCP staff), and (4) Discovery Session Implementation Fidelity Checklist (to be completed by up to 66 LCP staff). The Pre-Session and Post-Session Surveys will be distributed as

hard copies to introductory session attendees. The BYB Discovery Session Implementation Fidelity Checklist and the Registration and Attendance Tracking Form will be designed in Microsoft Excel and distributed to participating LCP staff using secure FTP upload for LCP personnel to complete electronically.

Information collected will be analyzed 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 data collection is important because if the BYB Discovery Session is determined to be an effective recruitment strategy compared with other existing introductory sessions, it should be promoted to maximize the National DPP's potential to reduce type 2 diabetes incidence. CDC requests approval for 1,572 Burden Hours annually. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
LCP Staff	Landscape Assessment	2,240	1	15/60	560
Introductory Session Attendees (Individuals)	Pre-Session Survey	2,640	1	10/60	440
Introductory Session Attendees (Individuals)	Post-Session Survey	2,640	1	10/60	440
LCP Staff	Registration Attendance and Tracking Form.	132	1	15/60	33
LCP Staff	BYB Discovery Session Implementation Fidelity Checklist.	66	1	90/60	99
Total					1,572

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Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0242]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. DATES: Fax written comments on the collection of information by October 4, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0667. Also include the FDA docket number found in brackets in the heading of this document.