Project Determination

CDC Diabetes Prevention Recognition Program (DPRP) Revision National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Project ID:	0900f3eb81c4553f
Accession #:	NCCDPHP-NDPP-11/30/20-4553f
Project Contact:	Philip Jacobs
Organization:	OS/OS/OSI
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	03/01/21
Estimated Completion Date:	02/28/24
CDC/ATSDR HRPO/IRB Protocol#:	N/A
OMB Control#:	OMB No. 0920-0909 (third revision)

Description

Priority

Urgent

Date Needed

12/03/20

Priority Justification

This research determination accompanies the final 30-day FRN for OMB ICR No. 0920-0909 (DPRP Standards); needing to be published no later than 12/20/2020.

Determination Start Date

12/01/20

Description

CDC’s Division of Diabetes Translation collects information needed to administer the National Diabetes Prevention Program’s (National DPP) quality assurance

program, the DPRP (OMB No. 0920-0909, exp. 02/28/2021). Through the DPRP, CDC recognizes organizations that successfully deliver the evidence-based National DPP Lifestyle Change Program (LCP) to participants who have prediabetes or are at high risk for type 2 diabetes. The National DPP LCP is based on a structured yearlong lifestyle intervention shown to be effective in a clinical research trial and in subsequent translation studies which demonstrated the program's effectiveness in communities and other real world settings. The DPRP Standards, initially approved in 2011 and revised in 2015 and again in 2018, specify criteria for the program and describe how organizations can achieve CDC recognition. Information currently submitted to CDC for recognition includes a one-time application form followed by biannual (every 6 months) transmission of evaluation data that allow CDC to assess each organization's fidelity to the DPRP's national quality standards and the progress achieved by participant cohorts. Full CDC recognition is awarded to qualifying organizations when program participants, in aggregate, achieve outcomes aligned to the comprehensive body of research studies.

IMS/CIO/Epi-Aid/Chemical Exposure Submission

No

IMS Activation Name

Not selected

Select the primary priority of the project:

Not selected

Select the secondary priority(s) of the project:

Not selected

Select the task force associated with the response:

Not selected

CIO Emergency Response Name

Not selected

Epi-Aid Name

Not selected

Assessment of Chemical Exposure Name

Not selected

Goals/Purpose

The goal of this information collection is to allow the Centers for Disease Control and Prevention (CDC) an additional three years of Office of Management and Budget (OMB) approval to continue collecting the information needed to administer the DPRP and information needed by the Centers for Medicare & Medicaid Services (CMS) to support the Medicare Expanded Model (Medicare Diabetes Prevention Program [MDPP]).

Objective

Based on experience with the DPRP from 2012–2020, and feedback from applicant organizations and internal and external partners, CDC proposes to revise the DPRP Standards and the associated information collection. In response to comments: We are seeking an updated research determination with this STARS entry, as well as creating a DMP (also within STARS).

Activities or Tasks

Secondary Data or Specimen Analysis

Target Population to be Included/Represented

General US Population

Tags/Keywords

Diabetes Mellitus, Type 2, participants who have prediabetes or are at high risk for type 2 diabetes

CDC's Role

CDC is recipient of private data/specimens FROM an institution

Method Categories

Method/Device Evaluation

Methods

CDC will collect participant-level, de-identified data directly from organizations via a comma separated value (CSV) Excel spreadsheet or a matching data system such as Data Reporting for Evaluation and Monitoring (DREM) (ICR PIA-201807-0095 1705 DREM; approved 03/21/2019) twice per year. CDC calculates averages across participant cohorts to determine organizational-level performance. Participant-level performance is not assessed by CDC. The subpopulation to be studied: The subpopulations for this data collection include CDC Division of Diabetes Translation (DDT) recipients and MDPP suppliers. Final responsibility for MDPP suppliers is that of CMS and not CDC. How data will be analyzed: Data analysis will include thematic and aggregate analysis of de-identified quantitative, and organizational qualitative, data using descriptive statistics (e.g., counts, means, range, standard deviation) for organizational-level recognition assessment.

Collection of Info, Data, or Bio specimens

CDC analyzes de-identified, participant-level evaluation data submitted by organizations to objectively assess adherence to the DPRP Standards and recognition criteria via a Coma Separated Value (CSV) file and a one-time, online Application file. A method of determining prediabetes status is collected to assess compliance with program eligibility standards. Participant-level identification codes and session attendance elements (session date, session type, weight, physical activity minutes, and optional pre- and post-intervention HbA1Cs) are used to evaluate recognition criteria. The elements are aggregated across participants to indicate whether an organization met the required percentage of overall recognition outcome goals. Collection of demographic information about program participants is necessary to ensure program effectiveness across sex/gender, ages (18+), socioeconomic status (SES) groups (measured by education level), and racial/ethnic groups. Participant process and outcome data include site-specific information (organization code). The organizations generate, assign, and maintain a coded identification number for each participant. Only de-identified, coded, participant-level information is transmitted to CDC. CDC recognizes that some of the participant-specific information (state of residence, ethnicity, race, age, sex/gender, insurance status, method of determining prediabetes status) when coupled with other data (organization code) might be considered PII. However, CDC does not receive or store specific names of persons and will not attempt to identify individuals by data linkages involving demographic, geographic, or outcome information. CDC will also not contact individual participants or disclose any participant-level data. In response to comments: Please note that the proposed information collection does not involve research with human subjects and IRB approval is not required as per 2014 Human Subjects Research Determination, RTI Evaluation of the National Diabetes Prevention Program Project 0211965.046.000.001 Juesta Caddell RTI IRB Director, and 06/07/2011 determination that this is "Public Health Practice." This is the ongoing continuation of the same project. In response to comments: Please note that this is Secondary Data Collection as the participant data is collected by the participating organizations, not by CDC (and no participant PII is shared with CDC). In response to comments: Please note that as the participant data is collected by the organizations and not shared in PII identifiable format, the CDC does not have a non-disclosure form. Neither does the CDC provide the Organizations who collect and keep the original

participant information with a suggested non-disclosure form.

Expected Use of Findings/Results and their impact

The required data elements are essential for monitoring the fidelity and effectiveness of the National DPP; providing targeted technical assistance to the CDC-recognized organizations; assisting CMS with implementation of the MDPP Expanded Model; and helping consumers, health care providers, and public and private payers identify quality organizations. Aggregate findings will be provided to organizations via evaluation reports and could be used for annual reports or journal articles, at CDC's discretion, in which case descriptive and/or regression analyses would be used.

Could Individuals potentially be identified based on Information Collected?

No

Will PII be captured (including coded data)?

No

Does CDC have access to the Identifiers (including coded data)?

No

Is an assurance of confidentiality in place or planned?

No

Is a certificate of confidentiality in place or planned?

No

Is there a formal written agreement prohibiting the release of identifiers?

No

Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office:

No

Institutions

Institution	FWA #	FWA Exp. Date	IRB Title	IRB Exp. Date	Funding #

Staff

Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/ Institution
Elizabeth Ely	03/25/2022				Data Use Contact	eke0@cdc.gov	770-488-8086	NATIONAL DIABETES PREVENTION PROGRAM TEAM
Philip Jacobs	11/13/2022				Contract Officer Representative	pdj6@cdc.gov	770-488-1661	NATIONAL DIABETES PREVENTION PROGRAM TEAM

DMP

Proposed Data Collection Start Date	03/01/21
Proposed Data Collection End Date	02/28/24
Proposed Public Access Level	Public, Restricted
Data Use Type	Other- Data from organizations is rarely shared, method is case by case.
Data Use Type Data Use Type URL	nationaldppcsc.cdc.gov (or direct request of DDT managers)
Data Use Contact	Miriam Bell or Beth Ely (Bell SIQT completed, pending upload)
Public Access justification	This submission has been reviewed by CDC's Information Collection Review Office, as well as DDT's program office, and both determined that the Privacy Act does not apply. Respondents are organizational entities, not individuals. Organizational consent is established by submission of the DPRP application form and evaluation data. Participation by organizations is strictly voluntary. Organizations may withdraw from the DPRP at any time by not transmitting evaluation data or for reasons specific to the organization. Although the DPRP Application Form includes PII (the name and contact information for each organizational entity's contact person and data preparer), this only provides information relating to their designated roles in the organization; personal information is

	not provided to CDC. The data submitted to CDC for evaluation purposes is identifiable by organizational entity. The participant-level evaluation data submitted to CDC does not (!!) include participant names, only participant codes. The organizational entity requesting CDC recognition through the DPRP assigns and maintains these participant codes. In response to comments: Names of organizations participating in the DPRP are"public" as participation is voluntary. Cross organization participant data (no PII) is generally restricted to internal use. However, it may be released (no PII) in response to highly-specialized individual requests (which are very rare, and addressed on a case by case basis).
How Access Will Be Provided for Data	CDC publishes organizational name, recognition status, organization website, and MDPP status on its Registry of Program; but, only aggregated (!!) data for participants is published. At the discretion of DDT or National DPP leadership, aggregated data at the organizational, state, regional, or national level may be shared with external partners for the purpose of preparing reports, manuscripts, or providing targeted technical assistance. In response to comments: Aggregate, cross organization participant data (no participant PII data as such is not kept by CDC) may be released in response to highly-specialized individual requests (which are very rare, and treated on a case by case basis). Requests may be made through the National DPP Customer Service Center (CSC) through "Contact National DPP" landing page selection or directly to DDT management as requests by high level partner organizations. Responses to these rare requests are highly individualized.
Plans for archival and long-term preservation of the data	Application form information and evaluation data are submitted to CDC via online forms. These transmission methods were reviewed and determined to be secure by CDC's Information Systems Security Officer; they align to Privacy Impact Assessment information approved by OMB in ICR No. 0920-1090: Formative and Summative Evaluation of Scaling the National Diabetes Prevention Program (National DPP) in Underserved Areas. Data are maintained on a password protected computer in secure CDC facilities and accessible only to DPRP staff (CDC personnel and onsite contractors) for approved analyses. CDC protects the data to the extent required by law. CDC does not collect, release, publish, or disclose PII relating to individual program participants. In response to comments: Currently data is expected to be kept within program more than 10 years as it is expected to remain programmatically useful for an extended period of time. Beyond that the data will be turned over to the Center (or Division level) Senior Records Liaison who will then determine long term record retention requirements according to the Scientific and Research Project Records Control Schedule which replaced the Research and Project Records (or future updates to this guidance). It is our expectation that this final determination will not be "permanent." As stated, until such a time we are maintaining our complete data set within program for the foreseeable future, expected to be at least the next 10 years.

Spatiality (Geographic Location)

Country	State/Province	County/Region

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	12/08/20	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: **PRA Applies**		12/09/20	Still-LeMelle_Terri (cse6) OMB / PRA
ICRO: **Returned with No Decision**		12/09/20	Zirger_Jeffrey (wtj5) ICRO Reviewer