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)
Household Participants	Individual Questionnaire	4,000	1	20/60	1,333
	Household Questionnaire	1,680	1	15/60	420
	Blood collection (no form)	4,000	1	10/60	667
Total					2,420

Jeffrey M. Zirger,

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

[FR Doc. 2020–10411 Filed 5–14–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0051]

Request for Information Concerning Personnel and the Retention of Next Generation Sequencing Data in Clinical and Public Health Laboratories

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

ACTION: Notice with request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on personnel performing bioinformatics activities in clinical and public health laboratories; storage and retention of next generation sequencing (NGS) data files; and maintenance of sequence analysis software. The comments will be used by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for deliberation and possible recommendations about future changes to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

DATES: Written comments must be received on or before July 14, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0051 by any of the following methods. CDC does not accept public comment by email.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Heather Stang, MS, MT, Division of Laboratory Systems, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, GA 30329, Attn: Docket No. CDC–2020–0051.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, MT, Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4018, telephone (800) 232–4636; email: *dlsinquiries@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data about topics related to personnel performing informatics activities, as well as data storage and retention practices related to the use of next generation sequencing (NGS) technology. In addition, CDC invites comments specifically on the following questions:

(1) What are the roles and responsibilities for all personnel performing bioinformatics or pathology/laboratory informatics activities? What training is considered essential for each of the roles? What competencies are considered essential for each of the roles? What minimum educational requirements (degrees or courses) are required for each of the roles?

(2) What are the challenges for recruitment and retention of bioinformatics or pathology/laboratory informatics personnel?

(3) What are examples of how NGS data files are used in addition to generating a clinical test result?

(4) What NGS data files should be retained for quality assurance, repeat analyses, or subsequent analyses? How long should these NGS data files be retained?

(5) What are the challenges and approaches for laboratories to maintain and utilize previous versions of sequence analysis software?

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. Do not submit public comments by email. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Background and Brief Description

Clinical laboratory testing technology has advanced significantly since the CLIA regulations were first implemented approximately 30 years ago. Next generation sequencing (NGS) technologies provide the high-throughput capability to rapidly and cost-effectively sequence large regions and mixed populations of DNA and RNA, when compared to traditional sequencing methods. This technology results in a significant increase in data that requires specialized analysis to derive a clinically meaningful result. NGS has led to improvements in diagnoses and patient care in many areas of medicine that include medical genetics, pediatrics, oncology, and microbiology. In some instances, NGS has led to life-saving diagnoses and treatment pathways, not achievable using other testing modalities. One element that differentiates NGS from most laboratory methodologies is its

significant reliance on informatics to achieve a meaningful and reportable result. As a consequence, clinical laboratories require personnel knowledgeable in bioinformatics or pathology/laboratory informatics to design and manage the bioinformatics analysis.

While CLIA regulations apply to clinical NGS testing, there is a lack of clarity regarding how the general CLIA quality system and personnel requirements should be specifically implemented for the NGS bioinformatics components. In April 2019, CLIAC made eight recommendations regarding CLIA's application to NGS-based technologies. This request for information is soliciting comments from the public for more information on topic areas mentioned in two of the recommendations, specifically, the qualifications of personnel performing bioinformatics activities; storage and retention of NGS data files; and maintenance of sequence analysis software. The April 2019 CLIAC summary is available in the docket under the Supporting Materials tab and at *https://www.cdc.gov/cliac/past-meetings.html.*

The qualifications and responsibilities of personnel performing the informatics component of the testing process are not addressed in the CLIA regulations. For the purpose of this request for information, the informatics component of NGS includes the analysis of NGS machine-generated data and subsequent computational processes. Therefore, CDC is asking the public to describe different responsibilities of personnel providing bioinformatics or pathology/laboratory informatics expertise such as validating and assuring that the informatics pipeline meets documented performance specifications.

CDC is also interested in learning the skills, training, and education of personnel who will fill bioinformatics or pathology/laboratory informatics positions, and how clinical and public health laboratories can recruit and retain personnel with these identified skills.

Lastly, the NGS testing process generates large amounts of data and requires multiple file types. CLIA regulations specify at 42 CFR 493.1105(a)(3) that all analytic systems records must be kept for at least two years, but the regulations do not specify the types of data to be captured or the retention time for a given data type. The regulations do not address the capability to access and reanalyze the data after the test is performed. This capability may require retention of the version of software used in the original analysis. CDC requests comment from the public on this topic.

Dated: May 12, 2020.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2020–10461 Filed 5–14–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19BHC]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Evaluation of the DP18–1815 Cooperative Agreement Program: Category A, Diabetes Management and Type 2 Diabetes Prevention to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 5, 2019, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Evaluation of the DP18–1815 Cooperative Agreement Program: Category A, Diabetes Management and Type 2 Diabetes Prevention—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 (CDC) Division of Diabetes Translation (DDT) and Division for Heart Disease and Stroke Prevention (DHDSP) are submitting this new information collection request (ICR) for an evaluation of the recently launched five-year Cooperative Agreement program CDC–RFA–DP18–1815PPHF18: Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke, hereafter referred to as ''1815''. This cooperative agreement funds all 50 State Health Departments and the Washington, DC health department (hereafter referred to as ''HD recipients'') to support investments in implementing evidence-based strategies to prevent and manage cardiovascular disease (CVD) and diabetes in high-burden populations/communities within each state and the District of Columbia. High burden populations/communities are those affected disproportionately by high blood pressure, high blood cholesterol, diabetes, or prediabetes due to socioeconomic or other characteristics, including access to care, poor quality of care, or low income. The 1815 program is a collaboration between DDT and DHDSP and is structured into two program categories aligning with each