

**Supporting Statement A for Justification for the OMB Clearance of the
*Office of the Assistant Secretary for Health***

COVID-19 by PCR Requisition Form

FY2020

Submitted to

Office of Management and Budget
Office of Information and Regulatory Affairs

Submitted by

Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of the Surgeon General

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A. Justification for the Collection of Information

Background

This is a request for the Office of Management and Budget (OMB) approval for a new one time collection of data from individuals who are participating in the federally supported, state managed, locally executed Community Based Testing Site (CBTS) program funded from March to May FY2020. CBTSs are focused on testing individuals who have symptoms of COVID-19 and healthcare facility workers and first responders who don't have symptoms. CBTSs are another tool for states, local public health systems and healthcare systems to use as they work together to stop the spread of COVID-19 in their communities.

As part of this CBTS program, a COVID-19 by PCR Lab Requisition Form is used to collect information from individuals who are participating in the federally supported, state managed, locally executed CBTS program to obtain COVID-19 laboratory testing. The COVID-19 by PCR Requisition Form will be used by approximately 200,000 individuals. The Lab Requisition form includes the ordering physician information, the laboratory account information, the date of collection, the time of collection; the individual's last name, first name, date of birth, gender, language, race, ethnicity, address, phone number, insurance carrier name, and whether the individual has provided informed consent and received a copy of the privacy notice. The information from the Lab Requisition form is shared with the ordering provider, the contracted laboratory companies, the cognizant state health department, and the contracted call center. Aggregate data is shared with HHS and FEMA.

1. Circumstances Making the Collection of Information Necessary

Collecting information on the PCR Lab Requisition form is necessary for the Office of the Assistant Secretary for Health (OASH) to perform its mission-critical work of ensuring that Community Based Testing Sites are properly managed and run. The data will inform the agency's ability to tailor the national response, effectively manage the CBTS program, ensure the contracted laboratories and call center have the requisite information to process individual laboratory tests, and ensure individuals are quickly and accurately informed of their COVID-19 lab results.

Exhibit 1 summarizes the data required for all individuals participating in the CBTS program.

Exhibit 1–COVID-19 by PCR Requisition Form

Type of Respondent: Participants (200,000)
Date of collection
Time of collection
Language
Race
Ethnicity
Last Name
First Name
Gender
Date of Birth
Address
City
State
Zip Code
Phone
Insurance Carrier Name
Group Number
Member/Individual Number
Patient has provided verbally informed consent

Patient has received a copy of the privacy notice

2. Purpose and Use of Information Collection

Collection of the information on the Lab Requisition form will benefit individuals by ensuring they can be tested for COVID-19. The collection of information on the Lab Requisition form will assist OASH in gathering demographic information, and providing timely information to contracted laboratories and the contracted call center.

The data collection activities will also provide information to OASH leadership to help them to more effectively manage the CBTS program. We anticipate that the aggregate data will be made available to HHS Departmental leadership, Congress, the Office of Management and Budget, the FEMA Task Forces, the National Response Coordination Center and the general public to determine if the CBTS program is reaching target vulnerable communities. Use of these data is vital for ensuring on-going improvement of the CBTS program and through dissemination efforts, broader understanding and support of programs designed to help individuals who are concerned about COVID-19 exposure and diagnosis.

The data required of all individuals participating in the CBTS program will enable OASH to describe the social and demographic characteristics (e.g., age, race, ethnicity) of CBTS participants. This demographic data will allow OASH to characterize the reach of the CBTS program, including the demographics and characteristics of the populations it is able to reach as well as the aggregate impact of COVID-19 on the populations interacting with the CBTS.

3. Use of Improved Information Technology and Burden Reduction

OASH will use electronic technology to reduce the burden of CBTS data reporting. All HHS employees collecting data at the CBTS locations will report aggregated performance data into a Web-based reporting system (Survey Monkey]) that will conform to all Department of Health and Human Services requirements and guidance for security, accessibility, and usability. Access to the data will be limited to staff of OASH, staff from FEMA, staff from the contracted laboratory companies and from the contracted call center. Participants will only have access to their individual lab results. The servers hosting the website and database will be actively maintained and patched with the latest relevant security updates as identified by information technology staff. Survey monkey will produce a fully validated data set (aggregate) that is ready for tabulation and analysis by OASH and FEMA staff. The aggregate data will be presented and housed in COVIDResponder.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed data collection is the only source of uniform data on from the CBTS program. No other source of data exists in the form needed by OASH to administer and monitor the CBTS program.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Not Collecting the Information/Collecting Less Frequently

OASH will use the CBTS data to administer the CBTS program. Collecting the data will enhance OASH's ability to monitor the CBTS program and allow individuals to obtain their individual labs.

If this data is not collected, individuals could not receive COVID-19 testing through the CBTS program. Additionally, OASH will not be able to describe fully the scope and impact of the CBTS program. OASH would not be able to use data to drive decision-making, such as where to set up the next CBTS location.

7. Special Circumstances

There are no special circumstances

8. Comments in Response to the Federal Register Notice/Outside Consultation

9. Explanation of Any Payment/Gifts to Respondents

OASH will not make payment or provide gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Web-based reporting system has been designed to ensure the security of the data obtained. No personal identifiers will be used in the reporting of any data. Verbal consent is requested from each individual who wants to participate in the CBTS program (see Attachment B).

11. Justification for Sensitive Questions

The primary goal of the CBTS program is to provide COVID-19 testing services to improve overall health of individuals. During the collection of the information on the Lab Requisition

form, individuals will be providing information of a potentially sensitive nature (such as participant race, ethnicity) in order to provide services and link participants to their lab results appropriately.

12. Estimated Annualized Burden Hours

The estimated annualized hour burden of responding to this information collection is **13,333 hours**, or an average of **4 minutes per individual; the respondent is the individual CBTS participant. OASH expects 200,000 individuals to participate in the CBTS program.** The hour-burden estimates include the time spent by HHS staff to transcribe the data from all CBTS locations, and enter aggregate data into Survey Monkey. The estimates exclude any hour burden associated with customary and usual practices that the individual would carry out in the absence of the CBTS reporting requirement.

13. Estimated Annualized Cost to R

None

14. Annualized Cost to Federal Government

The estimated annualized cost to the federal government for collecting data is \$100,000. The costs include the federal staff time associated with developing the requisition form, entering the data and reviewing the aggregate data.

15. Program Changes or Adjustments

This is a new data collection for the CBTS program.

16. Plans for Tabulation and Publication and Project Time Schedule

OASH requests the maximum 3-year clearance for the CBTS data collection to allow analysis of the data for three annual reporting periods (July 1 to June 30).

17. Display of Expiration Date for OMB Approval

The expiration date for OMB will be displayed on all data collection instruments.

18. Exceptions to Certification Statement.

There are no exceptions to the certification.

List of Attachments:

Attachment A: COVID-19 PCR Lab Requisition Form

Attachment B: Informed Consent Statement