utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.


**Type of Collection:** 3-year extension of a currently approved collection.

**OMB No. 0990–0260**


Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

**Likely Respondents:** institutions and institutional review boards.

### Annualized Burden Hour Tables

**Table 1—Estimated Annual IRB Recordkeeping Burden**

<table>
<thead>
<tr>
<th>Common rule provision</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities</td>
<td>6,000</td>
<td>16</td>
<td>96,000</td>
<td>12</td>
<td>1,152,000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>96,000</td>
<td></td>
<td>1,152,000</td>
</tr>
</tbody>
</table>

**Table 2—Estimated Annual Third-Party Disclosure Burden**

<table>
<thead>
<tr>
<th>IRB approval or disapproval of research</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>.109(d) [Pre-2018 and 2018 Requirements]—Written notification</td>
<td>6,000</td>
<td>25</td>
<td>150,000</td>
<td>0.5</td>
<td>75,000</td>
</tr>
<tr>
<td>.116(a) and (b) (Pre-2018 Requirements)/.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent</td>
<td>6,000</td>
<td>25</td>
<td>150,000</td>
<td>0.5</td>
<td>75,000</td>
</tr>
<tr>
<td>.116(h)—[2018 Requirements]—Posting clinical trial consent form</td>
<td>425</td>
<td>5</td>
<td>2,125</td>
<td>0.5</td>
<td>1,063</td>
</tr>
<tr>
<td>.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent</td>
<td>6,000</td>
<td>20</td>
<td>120,000</td>
<td>0.5</td>
<td>60,000</td>
</tr>
<tr>
<td>.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived</td>
<td>6,000</td>
<td>5</td>
<td>30,000</td>
<td>.5</td>
<td>15,000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>452,125</td>
<td></td>
<td>308,563</td>
</tr>
</tbody>
</table>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

**FOR FURTHER INFORMATION CONTACT:** Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–
SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) prepares a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the Federal Register during the first week of each month, in accordance with section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and section 9.17 of the Mandatory Guidelines using Oral Fluid. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines. If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

The Mandatory Guidelines using Oral Fluid were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809; January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70814). The Mandatory Guidelines using Oral Fluid were first published in the Federal Register on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the Federal Register on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine testing. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid effective October 10, 2023 (88 FR 70814), the following HHS-certified laboratories meet the minimum standards to conduct drug specimen validity tests on oral fluid specimens:

DynaCare*, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–726–235–4890

Laboratory Corporation of America, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Labs Line, 1125 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295 (Formerly: Legacy Laboratory Services) 

MetroLab, Laboratory Corporation of America, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387


Laboratory Corporation of America, 10404 24th Ave. NE, Seattle, WA 98125, 206–775–2802, 800–800–2387

Laboratory Corporation of America, 1212 SW 5th Ave., Portland, OR 97201, 503–368–3300/800–368–3300

Laboratory Corporation of America, 2060 Broadway, Suite 1000, New York, NY 10023, 212–791–0200/800–368–3300

Laboratory Corporation of America, 2000 Woodland Park Drive, Oxford, MS 38655, 662–636–7466/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)


Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 2 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only
DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary
[Docket No. DHS–2024–0015]

Department of Homeland Security Data Privacy and Integrity Advisory Committee: Request for Applicants for Appointment

AGENCY: Department of Homeland Security (DHS).

ACTION: Request for applicants for appointment to the Department of Homeland Security Data Privacy and Integrity Advisory Committee.


DATES: Applications for membership must reach the Department of Homeland Security Privacy Office via email or fax within 45 days of the date of this notice.

ADDITIONAL INFORMATION:

The DHS Office of the Secretary is seeking applicants for the Department of Homeland Security Data Privacy and Integrity Advisory Committee (DPC).

FACSIMILE:

Public Health Advisor, Division of Workplace

OMB Controller, Office of the Secretary

Office of the Secretary

Division of Workplace

Public Health Advisor, Division of Workplace Programs

[FR Doc. 2024–12104 Filed 5–31–24; 8:45 am]

BILLING CODE 4162–20–P

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation

Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Biopharmaceutical Laboratories)

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories continued under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS’ NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory as meeting the minimum standards of the current Mandatory Guidelines published in the Federal Register. After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program. DOT established this process in July 1996 (61 FR 37015) to allow foreign laboratories to participate in the DOT drug testing program.

Anastasia D. Flanagan,

Public Health Advisor, Division of Workplace Programs