

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB NO. 0930-0158)—Extension

SAMHSA's Mandatory Guidelines for Federal Workplace Drug Testing Programs will request OMB approval for the Federal Drug Testing Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644) dated April 13, 2004, and for the information provided by laboratories for the National Laboratory Certification Program (NLCP).

The Federal Drug Testing Custody and Control Form is used by all Federal agencies and employers regulated by the Department of Transportation to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report

results, and for Medical Review Officers to make a determination. The Federal Drug Testing Custody and Control Form approved by OMB three years ago is being resubmitted for OMB approval without any revision.

Prior to an inspection, a laboratory is required to submit specific information regarding its laboratory procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the laboratory's testing procedures before arriving at the laboratory.

The NLCP application form has not been revised compared to the previous form.

The annual total burden estimates for the Federal Drug Testing Custody and Control Form, the NLCP application, the NLCP inspection checklist, and NLCP recordkeeping requirements are shown in the following table.

| Form/respondent | Burden/response (hrs.) | Number of responses | Total annual burden (hrs.) |
|---------------------------------------|------------------------|---------------------|----------------------------|
| Custody and Control Form | | | |
| Donor | .08 | 7,096,000 | 567,680 |
| Collector | .07 | 7,096,000 | 496,720 |
| Laboratory | .05 | 7,096,000 | 354,800 |
| Medical Review Officer | .05 | 7,096,000 | 354,800 |
| Laboratory Application | 3.00 | 3 | 9 |
| Laboratory Inspection Checklist | 3.00 | 100 | 300 |
| Laboratory Recordkeeping | 250.00 | 50 | 12,500 |
| Total | | | 1,786,809 |

Written comments and recommendations concerning the proposed information collection should be sent by August 21, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: July 15, 2009.

Dennis O. Romero,

Deputy Executive Officer and Deputy Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive

Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

High Diversity/High Affinity Domain Antibody Library

Description of Invention: Available for licensing and commercial development is a highly diverse domain antibody (dAb) library providing antibodies that bind with high affinity to a variety of antigen targets. Antibody diversity is inherently limited by using only three CDRs of either light chain variable domain (LCDRs) or heavy chain variable domain (HCDRs). This novel dAb library is designed using light chain variable domain 3 (LCDR3) and heavy chain variable domain (HCDR3), which are of primary importance for creating binding site diversity in the human immune system. The library contains 2.5×10^{10} dAbs. Human naturally occurring LCDR3s were grafted onto HCDR1 of m0. These antibodies are of very small size (15-17 kDa), high