

1. Identification of the Information Collection

1(a) Title of the Information Collection

Recordkeeping for Institutional Dual Use Research of Concern (iDURC) Policy Compliance

EPA ICR Number 2530.03, OMB Control No. 2080-0082

1(b) Short Characterization/Abstract

The White House Office of Science and Technology Policy issued the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (iDURC Policy) in September 2014. The purpose of the Policy is to identify Dual Use Research of Concern (DURC) and implement risk mitigation measures where applicable. DURC applies to life science research that provides knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

Institutions subject to the iDURC Policy are those within the United States that (1) receive funding from the U.S. Government to conduct or sponsor life sciences research and (2) conduct or sponsor research that involves one or more of the 15 agents or toxins identified in the iDURC Policy, even if the research is not supported by U.S. Government funding. Institutions outside of the United States that receive U.S. Government funding to conduct or sponsor research that involves one or more of the 15 agents or toxins identified in the iDURC Policy are also subject to the Policy. The iDURC Policy requires that institutions subject to the Policy provide education and training on DURC for individuals conducting life sciences research with one or more of the 15 agents or toxins identified in the iDURC Policy. It is also required that they maintain education and training records for the term of the research grant or contract.

EPA is submitting an information collection request for the requirement of institutions to maintain these training records. EPA's Office of Research and Development may choose to collect these records to ensure policy compliance.

2. Need for and use of the Collection

2(a) Need/Authority for Collection

The White House Office of Science and Technology Policy issued the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (iDURC Policy) on September 2014. It became effective on September 24, 2015 (79 FR 57589). All federal departments and agencies are required to implement this policy. The iDURC Policy requires institutions to maintain training records for individuals conducting life sciences research with one or more of the 15 agents or toxins identified in the Policy. The goal of this collection is to ensure that all personnel involved in conducting life sciences research with one or more of the 15 agents or toxins identified in the iDURC Policy understand what DURC is, how to mitigate

risk, and how to communicate research findings in a responsible manner through the use of training and education.

2(b) Practical Utility/Users of the Data

The iDURC Policy requirement for training records helps institute a culture of responsibility for individuals conducting life science research with one or more of the 15 agents or toxins identified in the Policy.

3. Non duplication, Consultations, and Other Collection Criteria

3(a) Non duplication

Training information requested from institutions under this ICR is required by the iDURC Policy, which is being implemented by all federal departments and agencies. There are no other sources available to collect this information.

3(b) Public Notice Required Prior to ICR submission to OMB

To comply with the 1995 Amendments to the Paperwork Reduction Act (PRA), EPA solicited public comment on this ICR for a 60-day period prior to its submission to OMB. EPA published notice (84 FR 20352) in the *Federal Register* (FR) on May 9, 2019 requesting comment on the estimated respondent burden and other aspects of this ICR. EPA did not receive any comments. An additional FR notice will be published when this ICR is submitted to OMB. The public comment period for this additional notice will be 30 days.

3(c) Consultations

EPA consulted with one private sector organization, Battelle (Brian O'Shea, 615-424-4831). This consultation confirmed the burden estimation of this ICR. EPA consulted with a potential private sector organization, RTI International, but they do not conduct research subject to the iDURC Policy. EPA is currently funding 10 projects that are subject to the Policy, 2 of which are conducted by non-Federal organizations and are subject to Paperwork Reduction Act requirements. EPA attempted to contact the non-Federal entities on multiple occasions but were unable to identify participants to provide feedback on the burden of this ICR.

3(d) Effects of Less Frequent Collection

The iDURC Policy requirement for training records helps institute a culture of responsibility for individuals conducting life science research with one or more of the 15 agents or toxins identified in the Policy. A less frequent collection of these training records may result in non-compliance with the Policy by EPA and/or U.S. Government-funded institutions. Non-compliance with the Policy could potentially result in the release of knowledge, information, products, or technologies that could be directly misapplied and pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

3(e) General Guidelines

This collection requires record retention beyond the 3-year limit noted in 5 CFR 1320.5(d)(2). This requirement is driven by the iDURC Policy itself which stipulates that records must be saved for three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation. No other provisions requiring special justification under 5 CFR 1320.5(d)(2) are triggered.

3(f) Confidentiality

This information is required to be withheld from the public pursuant to Section 107(a) of the Ethics in Government Act of 1978. Agency personnel shall not publicly release the information contained therein.

If EPA chooses to collect this information, the designated official will store it on the EPA DURC SharePoint Site, which is only accessible to those who have the appropriate privileges. EPA does not intend to publish or make public any of the information that may be collected through this information request.

3(g) Sensitive Questions

This information collection does not require sensitive information be disclosed by respondents.

4. The Respondents and the Information Requested

4(a) Respondents/NAICS Codes

The iDURC Policy states that institutions subject to the Policy are those within the United States that both receive funding from the U.S. Government to conduct or sponsor life sciences research and conduct or sponsor research that involves one or more of the 15 agents or toxins identified in the iDURC Policy, even if the research is not supported by U.S. Government funding. Institutions outside of the United States that receive U.S. Government funding to conduct or sponsor research that involves one or more of the 15 agents or toxins identified in the iDURC Policy are also subject to the Policy. Institutions that do not receive U.S. Government funding for life sciences research, but conduct life sciences research that has potential to generate knowledge, information, products, or technologies that could be used in a manner that results in harm, are not subject to oversight as articulated in the Policy; however, they are strongly encouraged to implement internal oversight procedures consistent with the culture of shared responsibility and notify the National Institutes of Health (NIH) of any research that is determined to be DURC. NIH will refer the notification to the appropriate agency based upon the nature of the research. The North American Industry Classification System (NAICS) code for Research and Development in the Physical, Engineering and Life Sciences is code 54171.

4(b) Information Requested

(i) Data items, including record keeping requirements

Per iDURC Policy, the research institution is required to store training records for the term of the research grant or contract, plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation. EPA may contact the institution via email requesting these records to ensure policy compliance. Additional information is found in section 5(b).

(ii) Respondent Activities

The U.S. Government developed a compendium of tools to assist investigators and research institutions in the implementation of DURC oversight, including training and education on DURC. Institutions may wish to address dual use topics in existing courses on research ethics or the responsible conduct of research. Per iDURC Policy, institutions may require additional record keeping and should designate an individual responsible for maintaining documentation. Institutions should ensure that all individuals involved in research subject to iDURC Policy have completed this training and provided records of such training to the institution.

5. The Information Collected—Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

To comply with the iDURC Policy, the EPA may have to analyze, evaluate, summarize, and/or report on the training records from institutions subject to the iDURC Policy.

5(b) Collection Methodology and Management

Information collected from institutions subject to the iDURC Policy must be useful, accurate, reliable, and retrievable. Institutions must comply with the practices and procedures outlined in the Policy, which includes ensuring data quality. Non-compliance with the iDURC Policy may result in suspension, limitation or termination of U.S. Government funding, or loss of future U.S. Government funding opportunities for the non-compliant U.S. Government-funded research project and of U.S. Government funds for other life sciences research at the institution.

If necessary, the designated official from EPA may collect the information via email and store it on the DURC SharePoint Site. The EPA DURC SharePoint Site is listed as For Official Use Only, and access to the site is managed by EPA's Office of Homeland Security. EPA does not intend to publish or make public any of the information that may be collected through this information request.

5(c) Small Entity Flexibility

This collection of information is not reasonably expected to impact small businesses or other small entities. For research institutions in low-resource environments outside of the U.S. that

receive U.S. Government funds, EPA may consider serving as the implementing Institutional Review Entity, as the funding Agency, thereby providing the necessary oversight and compliance with the iDURC Policy.

5(d) Collection Schedule

Institutions subject to the iDURC Policy should certify that they will comply with the Policy at the time of seeking or receiving EPA funding. These institutions must notify the U.S. Government funding agency within 30 calendar days of any research that involves one or more of the 15 agents and one or more of the 7 experiments, including whether it meets or does not meet the definition of DURC. Principal Investigators must ensure that laboratory personnel (i.e. those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research with one or more of the 15 agents or toxins identified in the iDURC Policy have received education and training on DURC. These training records must be maintained by the institution for the term of the research grant or contract, plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation. EPA may choose to collect these records to ensure compliance with the Policy at any time.

6. Estimating the Burden and Cost of the Collection

6(a) Estimating Respondent Burden

The mean hourly wage for life, physical and social science occupations is listed in the Bureau of Labor Statistics' website: https://www.bls.gov/oes/current/oes_nat.htm#19-0000. The mean hourly wage for this occupation group is \$35.76. In this ICR, that wage rate is multiplied by the standard overhead factor of 1.6 to produce a total hourly labor cost of approximately \$57.21 (rounded to \$58).

It is estimated that each respondent will take 30 minutes to complete the training and complete recordkeeping activities. Approximately 40 respondents could be requested to submit recordkeeping statements annually. These are one-time activities for the life of the research grant/contract. Multiplying the estimated number of respondents (40) by the estimated respondent labor cost (\$58), by the number of hours (.50), we estimate the total dollar burden for this ICR to be \$1,160 annually.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

Respondent Activities	Burden Hours per Respondent	Burden for Respondent (\$35.76 per labor hour multiplied by 1.6 for overhead equals \$58)	Number of Respondents per Year	Total Respondent Cost per Year
Education & Training	.33	\$19	40	\$760

	(20 min)			
Recordkeeping for Training	.17 (10 min)	\$10	40	\$400
Total	.5 hours	\$29	40	\$1,160

Annual Cost for Respondents

(ii) Estimating Capital and Operations and Maintenance Costs

There are no capital or operations and maintenance costs.

(iii) Capital/Start-up Operating and Maintenance (O&M) Costs

There are no capital/startup operating and maintenance costs.

(iv) Annualizing Capital Costs

There are no annualized capital costs.

(c) Estimating Agency Burden and Cost

Information Collection Activity	Annual Hours	Annual Costs
Analyzing, Evaluating, Summarizing, and/or Reporting on Training Records	0.5	\$26.50

The Agency estimates that it would require 30 minutes for one staff member to review and evaluate training records performed by a GS-11 employee. The annual salary for a GS-11, Step 1 in Washington, DC is \$69,581. The hourly rate including benefits is \$53.52 (\$33.45 hourly rate x 1.6 multiplier).

6(d) Estimating the Respondent Universe and Total Burden and Costs

See 6(a) and 6(b).

6(e) Bottom Line Burden Hours and Cost Tables

EPA estimates a total of 40 respondents would be required to take training and maintain records of that training for the duration of this ICR. On average, EPA has funded five research projects per year that involve one or more of the 15 agents or toxins identified in the iDURC Policy through a contract/grant mechanism. Previous consultations with Project Officers determined that there are about 6-8 respondents per research project. Average annual total costs are estimated to be \$1,160.

(i) Respondent Tally

Bottom-Line Annual Burden and Cost for Respondents

Respondent Activities to Complete the Survey	Burden Hours/Respondent	Number of Hours per Year	Burden for Respondent (\$23.60 per labor hour multiplied by 1.6 for overhead equals \$38)	Number of Respondents Per Year	Total Cost Per Year
Total Per Year	.5	20	\$29	40	\$1,160
3 Years	1.5	60	\$29	120	\$3,480

(ii) The Agency Tally

Bottom-Line Annual Agency Burden and Cost

	Agency Hours for Each Respondent	Number of Hours Per Year	Labor Cost Per Year	Total Agency Cost Per year
Agency Total	.5	20	\$530	\$530
3 Years	1.5	60	\$1,590	\$1,590

(iii) Variations in the Annual Bottom Line

We do not anticipate major variations in the annual bottom line burden hours and costs for the respondents or the Agency.

6(f) Reasons for Change in Burden

There is a decrease of 52 burden hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is a result of adjustments in estimates of time required for recordkeeping duties. The previous ICR was a first-time estimate of the number of hours it would take for individuals to complete training and maintain those records, based on similar training efforts that were in place at the time. The EPA-developed DURC training, as one example, requires about 20 minutes of an individual’s time, with an additional 10 minutes for maintaining those records. Since then, in EPA’s consultation with the private sector, the Agency learned that DURC training had been incorporated into ongoing and broader biosecurity and biosafety training and that the recordkeeping responsibilities covered in this ICR consume significantly less time than originally anticipated. Total burden hours have been adjusted accordingly.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average of 0.5 hours per response. Burden means the total time, effort, or financial

resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjusting the existing ways to comply with any previously applicable applications and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit, or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket Number EPA-HQ-2016-0010, which is available for online viewing at www.regulations.gov, or in person viewing at the Office of Mission Support Docket in the EPA Docket Center (EPA/DC), EPA William Jefferson Clinton West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. – 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Office of Mission Support Docket is (202) 566-9744. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-2016-0010, OMB Control No. 2080-0082 in any correspondence.