

Agency Updates from EPA

FEDERAL DEMONSTRATION PARTNERSHIP
MAY 5, 2016



Updates



EPA Subaward Policy

Human Subjects Research General Term and Condition

Dual Use Research of Concern

Other

EAP Subaward Policy



- **Effective March 29, 2016**
- **Supersedes EPA's previous Subaward Policy contained in Part 2, Section 01 of EPA's Assistance Administration Manual**
- **Applies to all financial assistance agreements awarded to pass-through entities including new agreements and incremental or supplemental amendments to existing agreements**

EPA Subaward Policy



- Establishes the requirements and procedures for Grants Management Offices and Program Offices in making determinations regarding subrecipient eligibility, overseeing pass-through entity monitoring and management of subawards, and authorizing fixed amount subawards under 2 CFR 200.330, 200.331, and 200.332 (“the applicable regulations”)
- For the purposes of this Policy subawards do not include loans, loan guarantees, interest subsidies and principal forgiveness, purchases of insurance or similar transactions entered into with borrowers by recipients of revolving loan fund capitalization grants or other EPA financial assistance agreements

EAP Subaward Policy



- Implements new regulatory requirements and addresses recommendations from OIG audits of assistance agreements containing subawards
- UGG codifies standards for distinguishing between subawards and contracts at 2 CFR 200.330 and EPA's Subaward Policy provides additional guidance consistent with that regulation

EPA Subaward Policy



- 2 CFR 200.331, pass-through entities must include a number of provisions in subaward agreements and implement effective systems to monitor and guide subrecipient performance; EPA's Subaward Policy provides guidance on how EPA will oversee compliance with those requirements
- OIG has recommended that EPA enhance its oversight of pass-through entities to ensure that subawards are used in appropriate circumstances, costs are reasonable and that pass-through entities effectively monitor subrecipient performance; EPA's Subaward Policy includes provisions that respond to the OIG's recommendations

EPA Subaward Policy



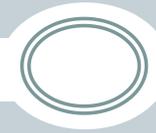
- National Term and Condition on all assistance agreements
- Fixed Amount Subawards Pilot at the request of EPA Grant Program Office
- Foreign work? – Must obtain EPA approval prior to award
- Subawarding to individual – Must obtain EPA approval
- Template for Subaward Agreements

EPA Subaward Policy: Training for Recipients



- [EPA Subaward Policy Training Webinar for Recipients and EPA Subaward Cross Cutter Requirements](#)
- Available at: <https://www.epa.gov/grants/epa-subaward-policy-additional-resources>

Human Subjects Research General Term and Condition

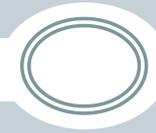


Human Subjects Research General Term and Condition



- Already applied to all research assistance agreements
- Included in the terms and conditions applied to all assistance agreements to ensure that all recipients understand their responsibilities, and prevent them from conducting Human Subjects Research (even inadvertently) without EPA HSRRO approval.

DURC/iDURC



**DUAL USE RESEARCH OF CONCERN
INSTITUTIONAL DUAL USE RESEARCH OF CONCERN**

DURC/iDURC



- **United States Policy for Oversight of Life Sciences Dual Use Research of Concern**
- **United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern**

EPA Implementation



EPA Order on Policy and Procedures on Life Sciences Research and Dual Use Research of Concern



- **Developing EPA Order to implement the USG Policies on DURC and iDURC for the Agency**
- **Includes:**
 - Purpose
 - Authority
 - Policy
 - Applicability
 - Definitions
 - Requirements
 - Responsibilities (office level, including Office of Grants and Debarment)

EPA Grants Implementation



EPA Grants Implementation



- Notification to potential applicants
- Request for Applications/Proposal Clause
- Grants Flow chart
- Funding Recommendation Questions
- Grants Term and Condition
- Programmatic Baseline Monitoring Questions
- DataMart Report

Notification to Potential Applicants



- Besides the Federal Register Notice [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#), 79 Federal Register (FR) 57589 (<https://federalregister.gov/a/2014-22770>), the Office of Grants and Debarment issued a general notification to potential applicants on the EPA Office of Grants and Debarment website
- <https://www.epa.gov/grants/dual-use-research-concern-assistance-agreements-durc>

Notification to Potential Applicants



- **The Notification identifies the**
 - Purpose
 - Background on the USG DURC and iDURC policies
 - Intended EPA Policy and Implementation
 - Additional Resources
 - Inquiries

Request for Applications/Proposal Clause



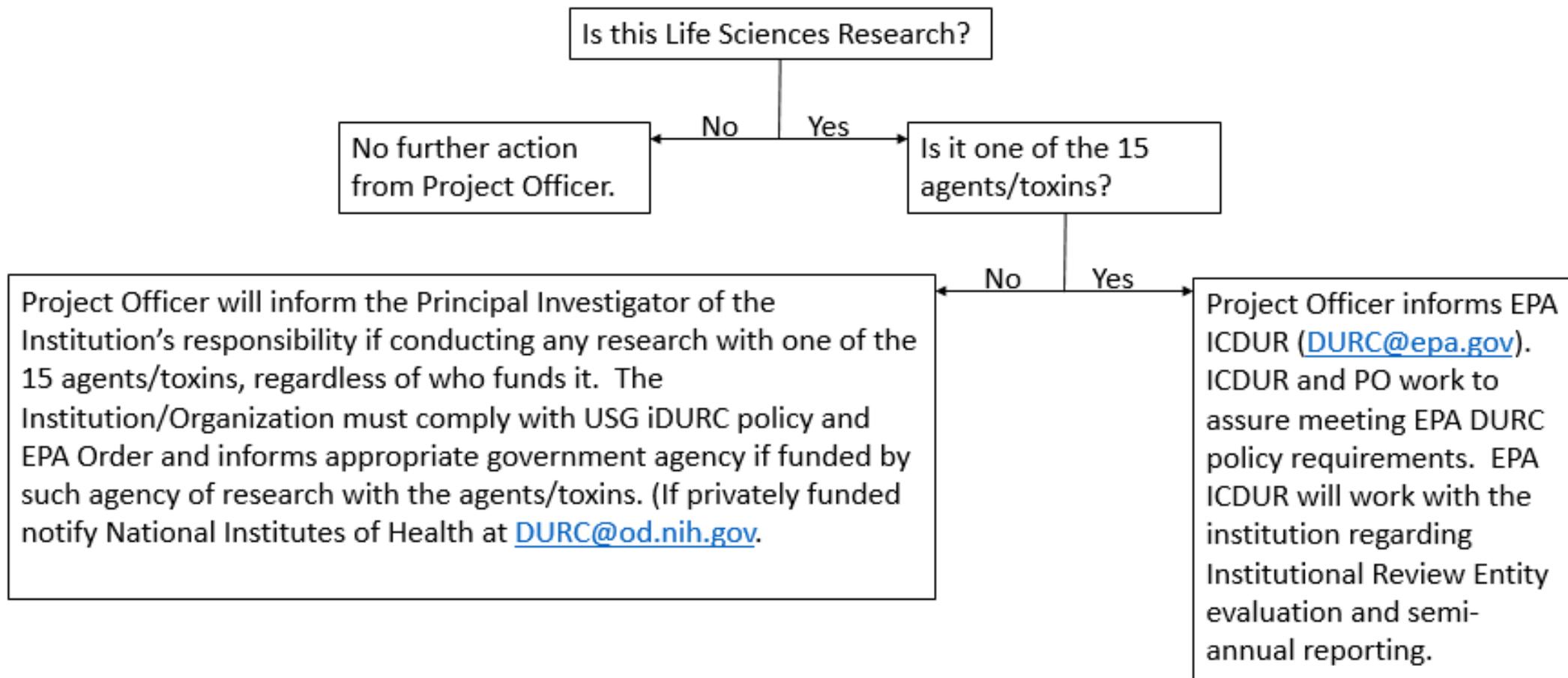
- The following clause is included in the boilerplate section of RFAs/RFPs:

Life Sciences Dual Use Research of Concern

Projects awarded under this solicitation that involve life sciences research as defined in [insert DURC EPA Policy or USG policy] that uses one or more of the agents or toxins identified in sections III.1 of the [United States Policy for Oversight of Life Sciences Dual Use Research of Concern \(DURC Policy\)](#) and 6.2.1 of the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, \(iDURC Policy\)](#) are subject to requirements of the EPA DURC Policy

DURC workflow for grants and cooperative agreements

Identified in any phase of the grants life cycle e.g. funding recommendation or notification from the recipient after award



Funding Recommendation Questions



- Currently in IGMS, Question B.9 asks “Is this a research agreement?” Yes or No answer.
- Add the following question as B.9.d. – If B.9. answers Yes then required to answer B.9.d:
 - Is this life sciences research (EPA Order on Policy and Procedures for Managing Dual Use Research of Concern, Section 5.H.)?
- If B.9. answers Yes, Project Officer will inform the Principal Investigator of the Institution’s responsibility if conducting any research with one of the 15 agents/toxins, regardless of who funds it. The Institution/Organization must comply with USG iDURC policy and EPA Order and informs appropriate government agency if funded by such agency of research with the agents/toxins. If privately funded notify National Institutes of Health at DURC@od.nih.gov.

Funding Recommendation Questions



- If Yes B.9.d.1 answer, Does this life science research use or anticipate use of one or more of the agents and toxins listed below. (list of the 15 agents/toxins will be provided as check boxes)
- If Yes to one of the 15 agents/toxins, Project Officer informs EPA ICDUR (DURC@epa.gov) ICDUR and PO work to assure meeting EPA DURC policy requirements. EPA ICDUR will work with the institution regarding Institutional Review Entity evaluation and semi-annual reporting.

Grants Term and Condition



- DURC/iDURC Grant Term and Condition to be placed in the General T&C
 - The recipient agrees to conduct all life science research* in compliance with EPA's Order on the Policy and Procedures for Oversight of Dual Use Research of Concern (EPA DURC Order) and [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) (*iDURC Policy*). If the recipient is an institution within the United States that receives funding through this agreement, or from any other source, the recipient agrees to comply with the iDURC Policy if they conduct or sponsor research involving any of the agents or toxins identified in Section 6.2.1 of the iDURC Policy. If the institution is outside the United States and receives funding through this agreement to conduct or sponsor research involving any of those same agents or toxins, the recipient agrees to comply with the iDURC Policy. The recipient agrees to provide any additional information that may be requested by EPA regarding DURC and iDURC. The recipient agrees to immediately notify the EPA Project Officer should the project use or introduce use of any of the agents or toxins identified in the iDURC Policy. The recipient's Institution/Organization must also comply with USG iDURC policy and EPA DURC Order and will inform the appropriate government agency if funded by such agency of research with the agents or toxins identified in Section 6.2.1 of the iDURC Policy. If privately funded the recipient agrees to notify the National Institutes of Health at DURC@od.nih.gov.

Grants Term and Condition



- Grant Specific Programmatic Term and Condition, if answer yes to Funding Recommendation Question “Is it one of the 15 agents/toxins?”
 - The recipient agrees to not initiate any life science research involving agents and toxins identified in sections III.1 of the [United States Policy for Oversight of Life Sciences Dual Use Research of Concern \(DURC Policy\)](#) and 6.2.1 of the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, \(iDURC Policy\)](#) until appropriate review and clearance by the recipient institution’s Institutional Review Entity. The recipient agrees to suspend life sciences research in the event that the IRE determines the life sciences research meets the definition of DURC in the USG Policy and the recipient agrees to notify the EPA ICDUR (DURC@epa.gov) of the institution’s determination.

Programmatic Baseline Monitoring Questions



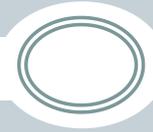
- Add the following to question 6g in Programmatic Baseline Monitoring
- Changes in the project's approved scope of work [Note: If a change in scope of work introduces one of the following agents or toxins the EPA Policy on DURC/iDURC must be followed: list the 15 agents and toxins]
 - Changes are:
 - Approved and recipient notified
 - Conditionally approved and recipient notified
 - Denied and recipient notified
 - Enter Explanation: []
 - Comments:
- The Project Office will be required to enter in the “Enter Explanation” section of question 6g of programmatic baseline monitoring any new information regarding DURC if previously not identified in the Funding Recommendation.

DataMart Report



- **With the click of a button EPA will be able to:**
 - Identify what is life sciences research from FR question B.9.d.
 - Identify what is potential DURC research from FR Question B.9.d.1
 - Grant Number
 - Institution
 - Project Officer
 - AOR
- **Additional fields can be added for EPA DURC Oversight office**
- **This will greatly assist in the bi annual inventory of DURC projects (in September 2015 no grants were on the inventory)**

Contact Information



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