EPA
ORDER

Classification No.: **1000.19**
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POLICY AND PROCEDURES FOR MANAGING DUAL USE RESEARCH OF CONCERN

1. **PURPOSE.** Life sciences research is essential to scientific advances in public health and safety, agriculture (including crops and other plants and animals), the environment, materiel (including food, water, supplies, and equipment), and national security. Certain types of research conducted for legitimate purposes can be used for both benevolent and harmful purposes. This Order establishes a systematic approach for Environmental Protection Agency (EPA) researchers to identify and mitigate when and how the risks that knowledge, information, products, or technologies produced by certain life sciences research may be misapplied in ways that pose significant threats with broad, potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

2. **AUTHORITY.** The Authorities for this Order are the: *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern* (DURC Policy) and the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (iDURC Policy), available at http://www.phe.gov/s3/dual-use/Pages/default.aspx and 79 Federal Register (FR) 57589 (https://federalregister.gov/a/2014-22770). This Order is also consistent with Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States* (http://www.gpo.gov/fdsys/pkg/FR-2010-07-08/pdf/2010-16864.pdf).

3. **POLICY.** EPA's Policy is that all research covered by this Order shall be subject to institutional review and oversight and conducted and communicated responsibly.

4. **APPLICABILITY.** This Order applies to:

   a. All unclassified research involving the agents or toxins defined in the DURC and iDURC Policies funded or conducted directly by EPA.

   b. All unclassified research involving the agents or toxins defined in the DURC and iDURC Policies sponsored or conducted by institutions within the United States that receive funding from EPA to conduct or sponsor life sciences research.

c. All unclassified research involving the agents or toxins defined in the DURC and iDURC Policies conducted or sponsored by institutions outside the United States that receive funding from EPA to conduct or sponsor such research.

5. **DEFINITIONS.**

a. "*Dual use research"* is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes. [iDURC Policy 4.B.]

b. *"Dual use research of concern"* (DURC) is a subset of dual use research defined as: life sciences research that, based on current understanding, can be reasonably anticipated to provide 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, materiel (including food, water, supplies, or material of any kind), or national security. [iDURC Policy 4.C.]

c. *"Institution"* is any government agency (Federal, State, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity conducting research. [iDURC Policy 4.D.]

d. *"Institutional Contact for Dual Use Research"* (ICDUR) is an individual designated by an institution to serve as a point of contact for questions regarding compliance with, and implementation of, the policies and procedures for the oversight of DURC. [iDURC Policy 4.E.]

e. "*Institutional Review Entity*" (IRE) is a committee established by an institution and empowered to execute the responsibilities outlined in the iDURC Policy. The IRE must be appropriately constituted and authorized by the institution to conduct dual use research reviews. [iDURC Policy 4.F.; 7.2.E.]

f. *"Principal Investigator"* (PI) is an individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project within one or more institutions. [iDURC Policy 4.I.]

g. *"Life Sciences"* pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules. [iDURC Policy 4.G.]

h. *"Life Sciences Research,"* for purposes of this Order, and based on the definition of research at 40 CFR §26.102(d), is a systematic investigation designed to develop or contribute to generalizable knowledge involving living organisms (e.g., microbes, human beings, animals, and plants) and their products. EPA does not consider the following activities to be research: routine product testing, quality control, mapping, collection of general-purpose statistics, routine monitoring and evaluation of an operational program, observational studies, and the training of scientific and technical personnel. [Note: This is consistent with Office of Management and Budget Circular A-11.]

i. "*Agents or Toxins*" refers to the agents and toxins listed in and subject to oversight in both the DURC and iDURC Policies. [DURC Policy III.1; iDURC Policy 6.2.1]

j. "*Categories of Experiments*" refers to the set of experiments and experimental effects listed in and subject to oversight in both the DURC and iDURC Policies. [DURC Policy III.2; iDURC Policy 6.2.2]

6. **REQUIREMENTS.** EPA's DURC oversight is intended to preserve the benefits of life sciences research, while minimizing the risk that the knowledge, information, products, or technologies generated by such research could be used in a manner that results in harm. Institutions subject to the iDURC Policy should certify that they will comply with that Policy at the time of seeking or receiving EPA funding.

To ensure compliance with these Policies, EPA will:

a. Implement internal policies and procedures to identify life sciences research that involves any of the agents or toxins defined in the DURC and iDURC Policies.

b. Provide education, training, guidance materials, and support to EPA PIs and other EPA individuals conducting life sciences research, that involves any agents or toxins defined in the DURC and iDURC Policies and maintain records of training.

c. Develop guidance materials to assist EPA personnel with Policy implementation and evaluation.

d. Establish an institutional review process, including designating an ICDUR and an IRE within the Agency, to assess whether life sciences research funded or conducted by EPA, that involves any agents or toxins defined in the DURC and iDURC Policies may meet the definition of DURC. EPA will evaluate the possible risk and benefits of research conducted by EPA to determine whether it meets the definition of DURC, and if so, develop a risk mitigation plan to guide the responsible conduct and communication of such research.

e. Review and provide a timely response to an institution's determination of whether research funded by EPA that involves any agents or toxins and categories of experiments as defined in the DURC and iDURC Policies also meets the definition of DURC. For research funded by EPA that meets the definition of DURC, EPA will evaluate the risk and benefits of the research while finalizing the funding agreement or award, and work with the institution to develop a risk mitigation plan that guides the responsible conduct and communication of such research, as appropriate.

f. Provide guidance and oversight, as necessary, to institutions within the United States that both (i) receive funding from EPA to conduct or sponsor life sciences research, and (ii) conduct or sponsor research involving any agents or toxins defined in the iDURC Policy, regardless of the funding source.

g. Provide guidance and oversight, as necessary, to institutions outside of the United States that receive EPA funding to conduct or sponsor research involving any agents or toxins defined in the iDURC Policy.

h. Conduct periodic reviews of all EPA funded or conducted life sciences research that involves any agents or toxins defined in the DURC and iDURC Policies for its potential to meet the definition of DURC and submit reports of these reviews in accordance with the DURC Policy.

i. Participate in interagency activities with other U.S. Government departments and agencies implementing the DURC and iDURC policies.

j. Review EPA's policies and procedures for complying with this Order and modify and improve implementation practices, as needed.

7. **RESPONSIBILITIES.** The following EPA responsibilities apply to reviewing and managing life sciences research subject to the DURC and/or iDURC Policies.

a. Office of Research and Development

i. The Office of Research and Development (ORD) provides overall EPA leadership and coordination regarding the implementation of the DURC and iDURC policies and this Order, including appointing an ICDUR, standing up and maintaining an IRE, conducting oversight, periodic reviews and

evaluations, and serving as the Agency's liaison to the White House Office of Science and Technology Policy on matters related to the implementation of the DURC and iDURC Policies.

b. Office of Homeland Security / Office of the Administrator

i. The Office of Homeland Security supports EPA's implementation of the DURC and iDURC Policies and this Order by transmitting periodic reports to the National Security Council (NSC), serving as a member of EPA's IRE, and serving as the Agency's liaison to the NSC on matters related to USG implementation and evaluation of the DURC and iDURC Policies.

c. EPA's Institutional Contact for Dual Use Research

i. EPA's ICDUR is responsible for serving as the Agency's point of contact for questions regarding compliance with, and implementation of, the procedures for overseeing research that involves any agents or toxins defined in the DURC and iDURC Policies. The ICDUR may serve as the liaison (as necessary) between external institutions and EPA project officers and/or principal investigators (PIs).

ii. EPA's ICDUR, in consultation with the IRE, will oversee EPA researchers' DURC training and may conduct oversight audits, as necessary, to determine compliance with the DURC and iDURC Policies.

iii. EPA's ICDUR is also responsible for responding to reports of non-compliance with the iDURC Policy.

iv. EPA's ICDUR may be consulted and provide advice and concurrence regarding final determinations of DURC, approving risk mitigation plans, and other issues related to research funded or conducted by EPA.

d. EPA's Institutional Review Entity

i. EPA's Institutional Review Entity (IRE) is a cross-agency, interdisciplinary group composed of at least five members that have sufficient breadth of expertise in dual use concepts and knowledge of relevant research, USG policies, risk management, biosafety and biosecurity best practices and policies and research communication and publication.

ii. EPA's IRE is responsible for institutional review and oversight of life sciences research conducted by EPA that involves any of the agents or toxins defined in the DURC and iDURC Policies, following an EPA PI's referral to the IRE. The IRE will review the PI's assessment of whether the research involves one of the categories of experiments defined in the DURC and iDURC Policies. If the IRE determines that the research involves one of the categories of

experiments, it then determines whether that research also meets the definition of DURC by evaluating the risks and benefits of the research.

iii. EPA's IRE is responsible for notifying EPA's ICDUR within 30 days of its review, of research being conducted by Agency researchers that may meet the definition of DURC. For research that meets the definition of DURC, the IRE will draft a risk mitigation plan in consultation with the PI and the ICDUR to guide PIs in conducting and communicating their research responsibly. The risk and benefit evaluation and mitigation plan will be transmitted to EPA's ICDUR for review within 90 days of the IRE making its determination. EPA's IRE, in consultation with the PI, should notify the ICDUR within 30 days of any change in the status of a DURC project and/or changes to the risk mitigation plan for review and approval. The IRE will review the plan at least annually and modify the plan as needed.

iv. EPA's IRE, in consultation with EPA's ICDUR, is also responsible for reviewing research funded by EPA that involves any agents or toxins defined in the iDURC Policy.

v. The IRE will also respond to determinations made by institutions that receive EPA funding for life science research regarding any research they are funding or conducting that may meet the definition of DURC, as appropriate. EPA's IRE and ICDUR will work with institutions to draft, review, and approve risk mitigation plans for research that meets the definition of DURC. EPA's IRE and ICDUR will provide a response to institutions that have submitted a risk mitigation plan within 30 calendar days of its receipt and assist them in finalizing their risk mitigation plan within 60 calendar days of its receipt.

e. Funding/Requesting Office

i. For life sciences research covered by this Order that is funded through EPA contracts, the funding/requesting office is responsible for notifying the Office of Acquisition Management (OAM) through their Advance Acquisition Plan or other funding mechanism that language regarding iDURC Policy compliance should be included in applicable new solicitations and contracts or in bilateral contract modifications, which can be requested on a case-by-case basis.

f. Office of Acquisition Management

i. Upon receiving an Advance Acquisition Plan (APP), bilateral contract modification request, or other appropriate request from the funding/requesting office that includes notification language regarding iDURC Policy compliance, OAM should insert appropriate language into the initial notice or solicitation (e.g. Request for Proposal) and resultant contract.

g. Office of Grants and Debarment

i. The Office of Grants and Debarment (OGD) is responsible for including appropriate notification language in the initial notice or solicitation (e.g. Request for Application) for any new assistance agreement that may involve life sciences research covered by this Order. This language serves to notify institutions applying for assistance agreements, both domestic and international, that they should comply with the iDURC Policy, if applicable.

ii. Prior to approving and awarding any new grant, assistance agreement, or other formal funding agreement, OGD is responsible for inserting terms and conditions for the receiving institution to comply with the iDURC Policy, if applicable.

iii. For interagency agreements, OGD will insert appropriate language into the agreement for compliance with the iDURC Policy.

h. Office of Administration and Resources Management

In the event that EPA's IRE determines that the research is DURC and the risks posed by the research cannot be mitigated by a risk mitigation plan, then the Office of Administration and Resources Management (OARM) will participate with other relevant EPA offices in a National Security Information classification review consistent with EPA Order 4850, National Security Decision Directive/NSDD-189 and EO 13526. If the results of the security review indicate that an original classification decision is recommended, the Administrator, as the EPA Original Classification Authority, will make a final classification determination.

i. EPA Federal Technology Transfer Act Coordinator

i. EPA's Federal Technology Transfer Act (FTTA) Coordinator is responsible for inserting language into *Letters of Intent* for *Cooperative Research and Development Agreements* as well as *Material Transfer Agreements*, that are signed by Laboratory and Center Directors, Program Office Directors, or Regional Administrators, that will notify the parties to these agreements of DURC and iDURC Policy requirements. If a Laboratory or Center PI is conducting research involving any of the agents or toxins defined in the DURC and iDURC Policies under an FTTA Agreement, he/she will comply with the DURC and iDURC Policies, as applicable.

j. EPA Principal Investigators

i. For research conducted by EPA, EPA PIs are responsible for notifying the IRE when the PI's research involves any of the agents or toxins that are defined in the DURC and iDURC Policies. For research involving those agents or toxins,

EPA PIs must also assess whether that research involves any of the categories of experiments defined in the DURC and iDURC Policies and provide that determination to the IRE. For research determined to be DURC, EPA PIs are responsible for working with the IRE to assess the risks and benefits of the DURC and to develop a risk mitigation plan.

ii. EPA PIs conducting research involving any agents or toxins defined in the DURC and iDURC Policies must be knowledgeable about DURC oversight policies and communicate their research responsibly. EPA PIs must ensure that they and all laboratory personnel collaborating on a project have been trained in carrying out the DURC and iDURC Policies, issues, and requirements. EPA PIs shall not commence new research that meets the definition of DURC until a risk mitigation plan has been approved. They must then conduct DURC in accordance with their risk mitigation plan. EPA PIs should notify the IRE immediately if there is a change in the status or nature of a DURC project or potential DURC project.

iii. EPA PIs, in consultation with the ICDUR and IRE, shall review their research involving any agents or toxins defined in the DURC and iDURC Policies and associated products prior to publication to preserve the benefits of their research and to mitigate the possibility that the results of such research are misused in a manner that could result in harm.

k. All EPA Employees

i. Any EPA employee who has knowledge that research subject to the DURC or iDURC Policies has not been reviewed by EPA's IRE or ICDUR should immediately notify EPA's ICDUR.

8. **SAVING PROVISION** Any and all modifications to the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) and United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (iDURC) Policies will automatically become part of this Order on the effective date of such modifications.