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Policies and Procedures

Title: Dual Use Research of Concern

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This P&P sets forth the duties and responsibilities regarding Dual Use Research of Concern.

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1. Purpose

The purpose of this Policies and Procedure (P&P) document is to implement a regular review process for research conducted or funded by the Agricultural Research Service (ARS) that involves certain high-consequence pathogens and toxins with potential for Dual Use Research of Concern (DURC). This P&P establishes a process to identify and provide oversight of DURC and describes a process to develop risk mitigation plans when appropriate. The fundamental aim of this oversight is to preserve the benefits of ARS life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

This P&P delineates the roles and responsibilities of ARS and those with whom ARS cooperates on DURC research, and provides requirements and performance standards for review of life sciences research, identification of potential DURC, and development and implementation of risk mitigation measures for DURC, where applicable.

This P&P is ARS' implementation of the [United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern](#) and the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#).

2. Background

Life sciences research is essential to the scientific advances that underpin improvements in public health and safety, agriculture (including crops and other plants and animals), the environment, materiel¹, and national security. Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called “dual use research.” For the purposes of this P&P, 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, or national security.

In general, there are risks associated with life sciences research, such as accidental exposure of personnel or the environment to a pathogen or toxin. Many existing and complementary statutes, regulations, and guidelines are in place to address risks associated with biosafety, physical security, and personnel reliability. Some risks relate directly to the characteristics of DURC, specifically the risk that knowledge, information, products, or technologies resulting from the research could be used in a manner that results in harm or threatens society. DURC should be evaluated for possible risks, as well as benefits, in all of these domains, to ensure that risks are appropriately managed and benefits realized. This P&P addresses dual use research risks holistically, that is, the risk that knowledge, information, products, or technologies generated from life sciences research could be used in a manner that results in harm.

¹ Materiel includes food, water, equipment, supplies, or material of any kind.

It is important to note that life sciences research that meets the definition of DURC often increases our understanding of the biology of pathogens; makes critical contributions to the development of new diagnostic, prevention, and treatment measures; improves public, animal, and plant health surveillance; and enhances emergency preparedness and response efforts. Thus, designating research as DURC should not be seen as a negative categorization, but simply an indication that the research may warrant additional oversight in order to reduce the risks that the knowledge, information, products, or technologies generated could be used in a manner that results in harm. As a general matter, designation of research as DURC does not mean that the research should not be conducted or communicated.

Nothing in this P&P should be read as superseding U.S. Department of Health and Human Services or the Department of Agriculture statutory authority to regulate the possession, use, or transfer of biological agents and toxins that have the potential to pose a severe risk to public health and safety, animal and plant health, or animal and plant products; or provisions of the select agent regulations found in the Code of Federal Regulations (CFR) at 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331; nor the Export Administration Regulations (EAR) at 15 CFR Parts 730-774, and the International Traffic in Arms Regulations (ITAR) at 22 CFR Parts 120-130. Note that the term “dual use” should not be interpreted to indicate which regulations govern the export of these items, and that some of the DURC agents/experiments are controlled by the ITAR and not the EAR.

This P&P updates the previous version by the addition of training requirements, recordkeeping requirements, and the requirement that this P&P be reviewed at least annually and updated as needed.

3. Definitions

For the purpose of this P&P, DURC is life sciences research that:

- Involves one or more of the following agents or toxins listed in Section 4.1, “Agents and Toxins;” and
- Produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 4.2, “Categories of Experiments” based on current understanding; and
- 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, or national security.

“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, synthetic 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 for understanding life at the level of ecosystems, organisms, organs, tissues, cells, and molecules.

Extramural research is that which is funded by ARS under a grant, contract, cooperative agreement, or other agreement and not conducted directly by ARS and is referenced also by the term “agreements.”

Intramural research is that which is directly conducted by ARS and is referenced also by the term “projects.”

“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.

“Cooperating institution” is an institution with whom ARS has entered into an agreement to conduct DURC research that where ARS is providing direct support (funding, or in-kind (including ARS employee time)).

“Institutional Contact for Dual Use Research” (ICDUR) is an individual designated by an institution to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant United States Government (USG) funding Agency (ARS). ARS’ ICDUR is called the ARS Contact for Dual Use Research (ACDUR).

“Institutional Review Entity” (IRE) is a committee established by the institution as described in the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#).

ARS DURC Review Committee (DRC) is ARS’ Institutional Review Entity (IRE) as required by the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#).

4. Scope

Under this P&P, ARS DURC review will focus on ARS research that involves one or more of the following agents or toxins listed in Section 4.1, “Agents and Toxins,” that produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 4.2, “Categories of Experiments” and that 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, or national security.

4.1 Agents and Toxins

The 15 Agents and toxins covered by this P&P are those defined in the [United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern](#), which are:

- Avian influenza virus (highly pathogenic),
- Bacillus anthracis,
- Botulinum neurotoxin,
- Burkholderia mallei,
- Burkholderia pseudomallei,
- Ebola virus,
- Foot-and-mouth disease virus,
- Francisella tularensis,
- Marburg virus,
- Reconstructed 1918 Influenza virus,
- Rinderpest virus,
- Toxin-producing strains of Clostridium botulinum,
- Variola major virus,
- Variola minor virus, and
- Yersinia pestis.

4.2 Categories of Experiments

Categories of experiments covered by this P&P are those that use the agents and toxins listed in Section 4.1 and:

- Enhance the harmful consequences of the agent or toxin;
- Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification;

- Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- Increase the stability, transmissibility, or the ability to disseminate the agent or toxin;
- Alter the host range or tropism of the agent or toxin;
- Enhance the susceptibility of a host population to the agent or toxin; or
- Generate or reconstitute an eradicated or extinct agent or toxin listed above.

5. Policy

Effective oversight of ARS research depends on the commitment and diligence of location leadership, scientists, and their staff. Therefore, it is essential that all ARS research personnel receive basic training that is needed to maintain a general awareness and understanding of DURC. Personnel involved in projects involving one or more of the agents listed in Section 4.1 of this P&P will be required to complete advanced training in order to ensure consistent and conscientious monitoring and oversight of all research activities.

Only those scientists in ARS units designated by ACDUR may conduct research on the agents and toxins listed in Section 4.1 and must do so under the oversight of the Office of National Programs (ONP) and only at a location with a certificate of registration from the [Federal Select Agent Program](#). The remainder of this P&P applies only to ARS research projects in these designated units, including associated extramural agreements.

ARS will review all research projects that involve research on any of the agents and toxins listed in Section 4.1 to evaluate them and all associated agreements as to whether any have experiments that fall into those defined in Section 4.2. This review will include, at a minimum, initial project plans or statements of work for agreements, deviations in plans, and required biannual progress reports. New plans and deviations will be reviewed within 30 days of notification. This review will be done at least biannually.

If a DURC experiment is identified, the ARS DRC shall assess the risks and benefits of each project, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk.

The ACDUR will work with the DRC to develop necessary and appropriate risk mitigation measures in collaboration with the ARS scientist, the Area Office, and ONP based on the risk assessment. The resulting risk mitigation plan must be uploaded as a supporting document in the project's record in Agricultural Research Information System (ARIS).

A risk mitigation plan may include, but not be limited to, the following risk mitigation measures:

- Modifying the design or conduct of the research;
- Applying specific or enhanced biosecurity or biosafety measures;
- Evaluating the efficacy of existing medical countermeasures (MCM), or conducting experiments to determine MCM efficacy against agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications;
- Use of references to available DURC educational tools such as those found at <http://oba.od.nih.gov/biosecurity/biosecurity.html>;
- Regularly reviewing of emerging research findings for additional DURC; and
- Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly.

If the risks posed by the research cannot be adequately mitigated with the measures described above, ARS will determine whether it is appropriate to:

- Not provide funding or other support for the research,
- Appropriately classify or terminate the research,
- Not allow the results of the research to be published or limit access to research results², or
- Change the objectives of the research.

Additional guidance on how to conduct a risk assessment is found in “[Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information](#)”.

Annual progress reports from those ARS scientists and Principal Investigators (PIs) from Cooperating Institutions for extramural research who are working with the 15 agents and toxins listed in Section 4.1 will be reviewed by the Research Leader (RL) and, as relevant, the Location Coordinator (LC), the Laboratory Director (LD), or the Center Director (CD), followed by review by the Area Office, and ONP to determine if there is a threat of DURC being generated, and if so, applying potential mitigation measures as described above as necessary.

² Actions taken to restrict the publication of technology may have implications under export control laws and regulations (e.g., 15 CFR parts 730-774 and 22 CFR parts 120-130).

All research results from experiments using the 15 agents and toxins listed in Section 4.1 will be reviewed annually with the annual progress report by the RL and, as relevant, the LC/LD/CD, followed by review by the Area Office, and final approval from ONP. All publications and changes in publications as communications will also require similar approval. All approvals will be recorded and maintained in ARIS.

Research that is under review or has been determined to be DURC shall not be conducted until an approved risk mitigation plan is in place;

6. Responsibilities

6.1 ARS Scientists

ARS scientists shall notify the ACDUR as soon as the scientist initiates plans for research (intramural or extramural) that involves one or more of the agents or toxins listed in Section 4.1; that may produce, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in Section 4.2. The scientist will submit their initial DURC assessment of this research to the ACDUR who shall conduct the initial review of the research for DURC. Research that is under review or has been determined to be DURC shall not be conducted until an approved risk mitigation plan is in place.

In addition, ARS scientists will:

- Report any deviations in the research or outcomes throughout the course of the research project;
- Within 60 days of DRC initial determination that their research is DURC, develop risk mitigation plans for DRC approval in collaboration with the Area Office, the appropriate National Program Leader (NPL), and the ACDUR that:
 - Address the identified risks in conjunction with the identified anticipated benefits,
 - Are done in accordance with the USG funding agency requirements for research funded by external Federal agreements, and
 - Conform to additional guidance on risk mitigation measures found in Appendix D of the Companion Guide to the USG Policy for Local Institutional Oversight of DURC (<http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf>);
- Follow all provisions of a DRC-approved risk mitigation plan;
- Be compliant with all rules and regulations from the Federal Select Agent Program and any other Federal, State, or local agencies which provides oversight of the potential DURC agents;

- Work with the appropriate ARS Institutional Biosafety Committee (IBC) to ensure that biosafety and security are in compliance with all rules and regulations of ARS and other relevant Federal, State, and local regulations;
- Be knowledgeable about and comply with all ARS and USG polices and requirements for oversight of DURC;
- Maintain a current and complete list of laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, visiting scientists, and external collaborators who are not employed by ARS or the Federal Government) conducting life sciences research with one or more of the agents listed in Section 4.1 of this P&P, ensure these individuals have received education and training on DURC, and have been granted an appropriate background and security clearance, through the System for Award Management (SAM)³ or through an alternate process that is deemed as acceptable;
- Submit a current and complete list of laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, visiting scientists, and external collaborators who are not employed by ARS or the federal government) to the ARS Contact for Dual Use Research (ACDUR) at least once each year and/or whenever there is a staffing change;
- Follow USDA procedures regarding collaborators who are foreign nationals, including submission of a detailed description of information or data the individual intends to retain following return to the country of origin, an explanation for the release of this information, and if an export license is required prior to release; and
- Communicate DURC in a responsible manner throughout the research process (i.e., in all forms of communications, not just in publications) and in compliance with the approved risk mitigation plan.

6.2 Research Leaders, Location Coordinators/Laboratory Directors/Center Directors, and Area Directors

RLs, LCs/LDs/CDs (as appropriate), and Area Directors (ADs) will:

- Work together in collaboration with their scientists, the appropriate NPL, and the ACDUR to develop risk mitigation plans for DRC approval;

³ Any government, business, grantee or organization (known as an “Entity” in SAM) wishing to do business with the federal government under a Federal Acquisition Regulation (FAR)-based contract, or anyone applying for federal grants, cooperative agreements or other forms of federal financial assistance through Grants.gov, must be registered in the System for Award Management (SAM). ARS uses SAM to verify that a non-governmental scientist and/or organization entering into an agreement with the Agency has not been debarred from doing business with the Federal government. USDA has implemented a specific process for background and/or security clearance investigations of personnel who require access to sensitive or classified information, which is separate and distinct from SAM.

- Review annual progress reports from those ARS scientists and PIs from Cooperating Institutions for extramural research who are working with the 15 agents and toxins listed in Section 4.1 to determine if there is a threat of DURC being generated;
- Annually review all research results, publications, and changes in publications as well as communications from experiments using the 15 agents and toxins listed in Section 4.1 with the annual progress report; and
- Ensure compliance with this P&P and approved risk mitigation plans; promptly reports instances of non-compliance to the ACDUR.

6.3 Deputy Administrator, Animal Production and Protection, Office of National Programs

The Deputy Administrator, Animal Production and Protection (APP), ONP will:

- Appoint an NPL to provide oversight of the DURC review process,
- Appoint an ONP staff person to be the ACDUR,
- Chair the DRC and appoint its members, and
- Ensure oversight of all of the 15 potential DURC agents in accordance with the Government Policy.

6.4 National Program Leaders

NPLs responsible for DURC projects will:

- Ensure that Program Direction and Resource Allocation Memorandums (PDRAMs) involving any of the listed DURC agents is coded correctly for DURC potential;
- Review annual progress reports from ARS scientists and PIs from Cooperating Institutions for extramural research who are working with the 15 agents and toxins listed in Section 4.1 to determine if there is a threat of DURC being generated;
- Work in collaboration with the scientists, RL, LC/LD/CD (if relevant), AD, and the ACDUR to develop risk mitigation plans for DRC approval;
- Review and approve 115's submitted from projects with DURC potential and ensure that the DRC approved risk mitigation measures are described in the 115 and have been implemented.

6.5 ARS Contact for Dual Use Research

The ACDUR will:

- Be the ARS' point of contact for questions regarding compliance with and implementation of the oversight of research that falls within the scope defined in Section 4;
- Represent the Agency on all matters concerning DURC;
- Report on ARS DURC oversight as required by USG policy;
- Designate which ARS units have permission to work on the agents and toxins listed in Section 4.1 based upon the need to do such research and the capability of the unit to safely do so and follow all relevant laws, regulations, and policies;
- Ensure that ARS complies with all USG and USDA policy on DURC;
- Report to the Chair of the DRC upon notification by a scientist of plans that may involve DURC as required by Section 6.1;
- Maintain listings of laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, visiting scientists, and external collaborators who are not employed by ARS or the Federal Government) for each project involving one or more of the agents listed in Section 4.1 of this P&P, and ensure these individuals have completed all mandatory training and security requirements;
- Provide and oversee education and training on DURC for scientists working in units with DURC potential and having permission to work on the agents and toxins listed in Section 4.1 and maintain records of education and training for 8 years (or for DURC approved projects of greater than 5 years in length, for the duration of the project plus 3 years);
- Develop, provide, and document training on [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#), Department and ARS policy on DURC to DRC members regarding their roles and responsibilities;
- Work in collaboration with scientists, the RL, the LC/LD/CD (if relevant), the AD, and the relevant NPL to develop risk mitigation plans for DRC approval; and

- Serve as the executive secretary for the ARS DRC with the following responsibilities:
 - Recording minutes at the DRC meetings;
 - Developing and maintaining relevant files, correspondence, and reports generated by the DRC;
 - Providing timely notification of DRC determination of DURC status (positive or negative) of reviewed projects to the scientist, Area Office, NPL and relevant USG funding agencies as appropriate;
 - Maintaining records of DRC reviews and completed risk mitigation plans for the term of the research project plus 3 years after its completion, but no less than 8 years, including ensuring that approved risk mitigation plans are uploaded as a supporting document in the project's record in ARIS;
 - As necessary, assisting the scientists conducting life sciences research when questions arise about whether their research may require further review or oversight; and
 - Ensuring this P&P is reviewed at least once each year, and updated as needed.

The ACDUR shall provide notification within 10 business days to the scientist, Area Office, and relevant NPL that the research has been determined to be DURC by the DRC according to USG and ARS policy. This initial notification shall include:

- The name(s) of the ARS scientist(s);
- The project title and the ARIS log number;
- Agreement number(s) if applicable;
- The name(s) of the agents listed in Section 4.1;
- A description of why the research is deemed to produce one or more of the experimental effects listed in Section 4.2;
- A description of the basis for the DRC determining that the research meets the definition of DURC; and
- DRC suggested mitigation options.

For DURC research funded by another USG agency, the ACDUR shall:

- Provide initial notification as described above for a DURC research project as determined by the DRC to the USG funding agency;

- Notify the USG funding agency within 30 calendar days of any change in the status of a DURC project (including of a determination that the research no longer meets the status of DURC) and of any changes to risk mitigation plans (such changes have to be approved by the Agency);
- Notify the funding Agency within 30 calendar days of instances of noncompliance with this Policy, as well as mitigation measures undertaken to prevent recurrences of similar noncompliance;
- Provide documentation to USG funding agencies when requested that ARS is in compliance with all aspects of the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#).

6.6 ARS DURC Review Committee

The DRC is ARS' IRE as required by the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#).

The DRC is composed of at least five members including:

- The Deputy Administrator, APP,
- The ACDUR,
- The ARS Biosafety Officer,
- NPLs representing each of the major disciplines for which ARS currently has DURC research, and
- An AD.

The DRC shall:

- Assess the risk and benefits of each project for which a potential DURC experiment has been identified, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk;
- Work with the ACDUR to develop necessary and appropriate risk mitigation measures in collaboration with the appropriate scientist, the RL, the LC/LD/CD (if relevant), the AD, and the relevant NPL;
- Approve a draft mitigation plan within 30 days; and

- Review all active risk management plans biannually and provide reports of projects with the potential for DURC to USDA Office of Homeland Security and Emergency Coordination that will be included in the USDA DURC report that goes to the White House Office of Science and Technology Policy.

6.7 Extramural Research

ARS will follow all of the policies and procedures of the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) for all extramural research involving DURC.

7. Compliance

7.1 For ARS Employees

Non-compliance with this P&P may result in termination of funding and potential disciplinary action as appropriate, up to and including termination of employment.

7.2 For Cooperating Institutions

Non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project. In addition, USG funds for other life sciences research at the institution may be lost, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

8. Appeals

Scientists may appeal decisions regarding research that the DRC has determined to be DURC by writing a letter of appeal to the Associate Administrator, ONP through their line management (RL, LC/LD/CD, and AD).

The letter should include the following:

- The reason and scientific basis for the appeal and
- Appropriate scientific/regulatory/policy literature references and other information as to why the decision of the DRC was incorrect.

The Associate Administrator, ONP shall assemble and chair a panel of relevant subject matter experts from within or outside of the Agency to review the initial DRC classification and the basis for the appeal.

Based on the review the Associate Administrator, ONP will provide a response to the petitioner to either grant or deny the appeal.

9. Authorities

- [United States Government 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](#)

10. Abbreviations

ACDUR	ARS Contact for Dual Use Research
AD	Area Director
APP	Animal Production and Protection
ARIS	Agricultural Research Information System
ARS	Agricultural Research Service
CD	Center Director
DURC	Dual Use Research of Concern
DRC	DURC Review Committee (ARS)
EAR	Export Administration Regulations
IBC	Institutional Biosafety Committee
ICDUR	Institutional Contact for Dual Use Research
IRE	Institutional Review Entity
ITAR	International Traffic in Arms Regulations
LC	Location Coordinator
LD	Laboratory Director
MCM	Medical Countermeasures
NPL	National Program Leader
ONP	Office of National Programs
P&P	Policies and Procedures
PDRAM	Program Direction and Resource Allocation Memorandum
PI	Principal Investigator
RL	Research Leader
USG	United States Government

Approved by:

Date of Approval:

Steven M. Kappes
Associate Administrator