Executive Board

UCLA Policy 995: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

Table of Contents

UCLA Academic Senate
Executive Board

March 7, 2025

Roger Wakimoto
Vice Chancellor for Research and Creative Activities (VCRCA)

Re: UCLA Policy 995: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

Dear Vice Chancellor Wakimoto,

At the March 6, 2025, meeting of the Executive Board (EB), members discussed proposed revisions to UCLA Policy 995 on dual use research concern (DURC) and pathogens with enhanced pandemic potential (PEPP) and committee feedback.

Members voted unanimously in favor of a motion to forward the enclosed committee feedback on the proposed policy.

Thank you for the opportunity to review and provide advisement.

Sincerely,

Kathleen Bawn
Chair, UCLA Academic Senate

Encl.

Cc: April de Stefano, Executive Director, UCLA Academic Senate
Anna Joyce, Director of Administrative Policies and Strategic Initiatives, UCLA Administrative Policies and Compliance Office
Andrea Kasko, Immediate Past Chair, UCLA Academic Senate
Megan McEvoy, Vice Chair/Chair Elect, UCLA Academic Senate

UCLA Academic Senate
Graduate Council

3125 Murphy Hall
410 Charles E. Young Drive East
Los Angeles, California 90095

February 24, 2025

To: Kathleen Bawn, Chair, UCLA Academic Senate

From: Deepak Rajagopal, Chair, Graduate Council

Re: UCLA Policy 995: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

At its meeting on February 14, 2025, the Graduate Council reviewed and discussed the proposed *UCLA Policy 995: Dual Use Research of Concern and Pathogens (DURC) with Enhanced Pandemic Potential (PEPP)* and offered the following for the Executive Board's consideration.

As UCLA Policy 995 is related to the *Proposed Presidential Policy – Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, members shared similar concerns regarding the policy implication for life sciences departments and programs, implementation of the policy in practice, and impact on faculty and graduate student research. Some members noted that it would be challenging to comply if the list of agents and toxins constantly changed.

Some members also expressed concern about linking research to federal funding, given the uncertainty of NIH funding, and queried about the possibility of separating research from federal funding.

We appreciate the opportunity to express our views on this matter. If you have any questions, please contact us via Graduate Council Analyst, Emily Le, at ele@senate.ucla.edu.

UCLA Policy 995: Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) – Key Review Draft

Issuing Officer:	Vice Chancellor for Research and Creative Activities
Responsible Dept:	Office of Research and Creative Activities
Effective Date:	TBD
Supersedes:	UCLA Policy 995, dated 1/1/2016

I. PURPOSE & SCOPE

~~Dual use research refers to research conducted for legitimate purposes that can be utilized for both benevolent and harmful purposes. Effective oversight of dual use research involves identification of Dual Use Research of Concern (DURC) and its associated risks, and devising ways to mitigate these risks.~~ The United States Government Policy for Oversight of ~~Life Sciences~~ Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (USG Policy) sets forth requirements for ~~the ongoing review and oversight of DURC~~oversight of certain types of federally funded life sciences research with biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. The University of California Office of the President has issued a DURC and PEPP Policy for system-wide application of the USG Policy. This Policy incorporates and implements the UC and USG policies and outlines the responsibilities of those individuals and committees at UCLA who are accountable for executing the requirements of th~~i~~ose Policies~~y~~.

Although the USG Policy applies to federal departments and agencies that fund or sponsor specific research with biological agents or toxins, this Policy applies the same evaluation and oversight requirements to all research, regardless of funding mechanism, conducted at UCLA or under the campus auspices.

~~**This Policy applies to Life Sciences research that involves the 15 agents and toxins and 7 categories of experimental effects of concern listed in this Policy.**~~

II. DEFINITIONS

For the purposes of this Policy:

Dual Use Research of Concern (DURC) is 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 do harm with no, or only minor, modification to pose a significant threat with ~~broad~~ potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materi~~a~~l, or national security.

~~**Dual Use Review Entity (DURE)** (referred to as "Institutional Review Entity" or "IRE" in the USG and UC policies) is a UCLA committee that establishes and implements internal policies and practices that allow for the identification and oversight of DURC and reviews proposed research that will utilize a DURC agent.~~

Institutional Contact for Dual Use Research (ICDUR) is an individual designated by the UCLA Vice Chancellor for Research and Creative Activities ~~to serve~~ as the point of contact for questions regarding compliance with and implementation of the ~~requirements for the oversight of DURC~~USG Policy. ~~as well~~The ICDUR also serves as the liaison (as necessary) between UCLA and the relevant ~~USG~~ federal funding agency.

Institutional Review Entity (IRE) is a committee responsible for oversight of research with specific agents and toxins as defined by the USG Policy.

Life Sciences is the study or use of~~are~~ living organisms, viruses, or ~~(e.g., microbes, human beings, animals, and plants) and~~ their products, including all disciplines, ~~and~~ methodologies, and applications of biology (including biotechnology, genomics, proteomics, bioinformatics, and pharmaceutical and biomedical research and techniques). ~~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.~~

Pathogen with Enhanced Pandemic Potential (PEPP) is a type of pathogen with pandemic potential (PPP) resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security.

Pathogen with Pandemic Potential (PPP) is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans. Examples include H5N1 influenza viruses, SARS-CoV and SARS-CoV-2, and MERS.

Principal Investigator (PI) is an employee of UCLA (normally with an academic appointment), who is or becomes eligible under UCLA Policy 900, to submit a proposal for extramural support for a research, training, or public service project, who personally participates in the project to a significant degree, and who has primary responsibility for the scientific, technical, and administrative conduct, and reporting of the project, including financial matters. A Principal Investigator who is the head of a training or public service project may be known as a Project Director or Project Administrator.

~~A~~ **Risk Mitigation Plan (RMP)** is developed by the IRE, in partnership with the PI, and describes measures to be instituted for the conduct and communication of Category 1 and Category 2 research (as outlined below). The RMP will include details of the risks identified by

the IRE in its review of the research, and an explanation of the risk mitigation strategy or strategies that are being implemented to address those risks.

III. POLICY STATEMENT

The USG Policy identifies two Categories of research that must be proactively assessed by the PI when described as part of a federal grant application:

- Category 1 Research - Research within the scope of Category 1 corresponds to "dual use research of concern." Refer to Appendix A and the IRE website for a full description of biological agents and toxins, and experimental outcomes related to Category 1.[1]
- Category 2 Research [2]- Research within the scope of Category 2 corresponds to "pathogens with enhanced pandemic potential" research. Refer to the IRE website for detail about the biological agents and experimental outcomes related to Category 2.

~~Research~~ Proposed and ongoing research that may fall within the scope of ~~uses any quantity of one or more of the agents or toxins~~ Category 1 or Category 2 must be evaluated by the PI during preparation of a federal funding proposal and an initial determination provided in the grant application. At the time of proposal submission, UCLA will certify institutional compliance with the research oversight framework described in the USG Policy.

A federal funding agency that is considering funding a grant involving research that may fall within the scope of Category 1 or Category 2 will notify UCLA upon completion of a merit review, prompting the Institutional Review Entity (IRE) to evaluate the PI's initial assessment and confirm whether research is within the scope of Category 1 or Category 2.

If research is determined to fall within the scope of Category 1 or Category 2:

- The IRE will perform a risk-benefit assessment and develop a draft risk mitigation plan (RMP), describing conduct and communication of the research.
- Documentation of the IRE risk-benefit assessment and draft RMP will be provided to the federal funding agency for evaluation and further risk-benefit analysis. Agency approval of the RMP must be obtained prior to initiating Category 1 or Category 2 research.
- PIs must provide progress reports to the federal funding agency on a schedule consistent with the category of research and the agency's reporting requirements.
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If the IRE determines that the proposed research does not fall within the scope of Category 1 or Category 2:

- The IRE will report this determination to the federal funding agency.

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- The PI will continuously monitor the research during the course of the award and report any changes that warrant reassessment to the IRE.
- ~~listed below and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects of concern listed below, must be evaluated for DURC potential.~~
- ~~**A. Agents and Toxins**~~

1. ~~Avian influenza virus (highly pathogenic)~~
2. ~~Bacillus anthracis~~
3. ~~Botulinum neurotoxin (in any quantity)~~
4. ~~Burkholderia mallei~~
5. ~~Burkholderia pseudomallei~~
6. ~~Ebola virus~~
7. ~~Foot-and-mouth disease virus~~
8. ~~Francisella tularensis~~
9. ~~Marburg virus~~
10. ~~Reconstructed 1918 Influenza virus~~
11. ~~Rinderpest virus~~
12. ~~Toxin-producing strains of Clostridium botulinum~~
13. ~~Variola major virus~~
14. ~~Variola minor virus~~
15. ~~Yersinia pestis~~

~~**B. Categories of Experimental Effects of Concern**~~

1. ~~Enhances the harmful consequences of the agent or toxin~~
2. ~~Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification~~
3. ~~Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies~~
4. ~~Increases the stability, transmissibility, or the ability to disseminate the agent or toxin~~
5. ~~Alters the host range or tropism of the agent or toxin~~
6. ~~Enhances the susceptibility of a host population to the agent or toxin~~
7. ~~Generates or reconstitutes an eradicated or extinct agent or toxin listed under "Agents and Toxins," above~~

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UCLA has established the ~~Dual Use Review Entity (DURE)~~Institutional Review Entity (IRE) to assess and oversee proposed and ongoing research that may fall within the scope of Category 1 or Category 2, and has appointed an Institutional Contact for Dual Use Research (ICDUR) within the Office of Research Policy & Compliance. ~~Through the ICDUR, the DURE works with the PI to assess whether research that uses one or more of the agents or toxins also produces, aims to produce, or is reasonably anticipated to produce one or more of the seven categories of experimental effects of concern listed above.~~

~~For research anticipated to produce at least one of the seven effects, the DURE will conduct a risk assessment to determine whether the research meets the definition of DURC. Anticipated benefits of the research will be considered in conjunction with the previously identified risks in order to develop a draft risk mitigation plan to guide the conduct and communication of the DURC; this plan must be approved by the relevant USG funding agency, if applicable.~~

~~The ICDUR and DURE will adhere to the general procedures detailed in the UC DURC Policy and in compliance with the USG Policy.~~

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IV. RESPONSIBILITIES

A. Principal Investigator (PI)

In accordance with the USG Policy, prior to initiating research and continuously throughout the research lifecycle, ~~a~~the PI is required to:

- Identify whether the research is reasonably anticipated to be within the scope of Category 1 or Category 2~~Through the ICDUR, notify the DURE when the research involves one or more of the agents or toxins listed in Section III.A~~;
- ~~Work with the DURE to determine if research produces one or more of the seven listed effects in Section III.B~~Upon identification of Category 1 or Category 2 research, notify the federal funding agency and IRE;
- Work with the ~~DU~~IRE to assess the ~~dual use~~ risks and benefits of the proposed research and develop a draft ~~risk mitigation measures~~RMP;
- Conduct ~~DURC~~ Category 1 and Category 2 research in accordance with the provisions of~~in~~ the approved ~~risk mitigation plan~~RMP;
- Provide progress reports on a schedule corresponding to the category of research and agency requirements;
- Be knowledgeable ~~of~~about, and comply with, all institutional, UC, and USG policies~~,~~ and requirements for ~~DURC oversight~~Category 1 and Category 2 research;
- Ensure that laboratory personnel conducting ~~DURC~~ research within the scope of this P~~p~~olicy have received education and training ~~on DURC~~ as required by the ~~DU~~IRE and any ~~risk mitigation plan~~RMPs; and
- ~~Following the above preparatory process, PIs must c~~Communicate ~~DURC~~ Category 1 and Category 2 research responsibly and in compliance with the approved ~~risk mitigation plan and maintain communication with the DURE related to any concerns or compliance with the approved mitigation plan~~RMP.

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B. ~~Dual Use~~Institutional Review Entity (~~DUI~~IRE)

~~Potential DURC~~ Research subject to this P~~p~~olicy will be referred to the IRE via a PI self-report ~~generally be identified during the UCLA Institutional Biosafety Committee (IBC) review process or via PI self-report~~ and after notification from a federal funding agency. If research is determined to ~~have a DURC potential~~fall within the scope of Category 1 or Category 2, the ICDUR and ~~DUI~~IRE will ~~implement the following steps~~:

- Notify the PI that the proposed work meets the criteria for ~~DURC~~Category 1 or Category 2;
- Conduct a risk-benefit assessment on the proposed research;
- Develop a draft RMP in collaboration with the PI~~risk mitigation plan~~ for the ~~identified DURC using USG's risk mitigation template~~research;
- Provide education and training for individuals conducting ~~DURC~~Category 1 and Category 2 research, as needed;
- Review all active RMPs ~~risk mitigation plans~~ at least annually (shorter cycles may be imposed, especially for Category 2 research) and modify as needed; and
- Maintain records of ~~the institutional DURC~~IRE reviews and completed ~~risk mitigation plan~~RMPs for the term of the research grant or contract plus three years after its completion~~, but no less than eight years~~.

V. COMPLIANCE

~~As per the USG Policy, n~~Non-compliance with this Policy may result in remediation, mandatory training, and/or employment consequences up to and including informal counseling, adverse performance evaluations, and correction action/discipline in accordance with University and UCLA policies and any relevant collective bargaining agreements. ~~suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant PI and of USG funds for other Life Sciences research at UCLA. Non-compliance may also subject UCLA to other potential penalties under applicable laws and regulations.~~

VI. REFERENCES

1. United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Release date: May 6, 2024;
2. USG Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);
3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). Amended April 5, 2024;
4. University of California – Policy: Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential;
5. UCLA Policy 900, Principal Investigator Eligibility.

Issuing Officer

/s/ Roger Wakimoto

Vice Chancellor for Research and Creative Activities

Appendix A

Category 1 Agents and Toxins

HHS Select Agents and Toxins

1. Abrin
2. *Bacillus cereus* Biovar *anthracis*
3. Botulinum neurotoxins
4. Botulinum neurotoxin producing species of *Clostridium*
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol
9. Eastern Equine Encephalitis virus
10. Ebola virus
11. *Francisella tularensis*
12. Lassa fever virus
13. Lujo virus
14. Marburg virus
15. Mpox virus
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)
20. SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
21. Saxitoxin
22.

South American Haemorrhagic Fever viruses:

22. Chapare
23. Guanarito
24. Junín
25. Machupo
26. Sabia
27.
28. Staphylococcal enterotoxins (subtypes A,B,C,D,E)
29.
30. T-2 toxin
31.
32. Tetrodotoxin
33.

Tick-borne encephalitis complex (flavi) viruses:

30. Far Eastern subtype
31. Siberian subtype
32.
33. Kyasanur Forest disease virus
34.
35. Omsk hemorrhagic fever virus
36.
37. Variola major virus (Smallpox virus)
38.
39. Variola minor virus (Alastrim)
40.
41. *Yersinia pestis*

Overlap Select Agents and Toxins

37. *Bacillus anthracis*
38. *Bacillus anthracis* Pasteur strain
39. *Brucella abortus*

40. *Brucella melitensis*
41. *Brucella suis*
42. *Burkholderia mallei*
43. *Burkholderia pseudomallei*
44. Hendra virus
45. Nipah virus
46. Rift Valley fever virus
47. Venezuelan equine encephalitis virus
48.

USDA Veterinary Services (VS) Select Agents and Toxins

48. African horse sickness virus
49. African swine fever virus
50. Avian influenza virus
51. Classical swine fever virus
52. Foot-and-mouth disease virus
53. Goat pox virus
54. Lumpy skin disease virus
55. *Mycoplasma capricolum*
56. *Mycoplasma mycoides*
57. Newcastle disease virus
58. Peste des petits ruminants virus
59. Rinderpest virus
60. Sheep pox virus
61. Swine vesicular disease virus
62.

USDA Plant Protection And Quarantine (PPQ) Select Agents and Toxins

62. *Coniothyrium glycines*
(formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
63. *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
64. *Ralstonia solanacearum*

65. *Rathayibacter toxicus*
66. *Sclerophthora rayssiae*
67. *Synchytrium endobioticum*
68. *Xanthomonas oryzae*
69.
70.

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Appendix B, Risk Group 4 and subset of Risk Group 3

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Risk Group 4 (RG4) - Bacterial Agents

None

Risk Group 4 (RG4) - Fungal Agents

None

Risk Group 4 (RG4) - Parasitic Agents

None

Risk Group 4 (RG4) - Viral Agents

- Arenaviruses
  - Guanarito virus
  - Lassa virus
  - Junin virus (except the candid #1 vaccine strain listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
  - Machupo virus
  - Sabia
- Bunyaviruses (Nairovirus)
  - Crimean-Congo hemorrhagic fever virus
- Filoviruses
  - Ebola viruses

- Marburg viruses

- Flaviruses - Group B Arboviruses
  - Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

- Herpesviruses (alpha)
  - Herpesvirus simiae (Herpes B or Monkey B virus)

- Paramyxoviruses
  - Equine Morbillivirus (Hendra virus)

- Hemorrhagic fever viruses as yet undefined

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia*

- Bartonella
- Brucella including B. abortus, B. canis, B. suis
- Burkholderia (Pseudomonas) mallei, B. pseudomallei
- Coxiella burnetii (except the Phase II, Nine Mile strain listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)
- Francisella tularensis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) – Bacterial Agents Including Chlamydia)
- Orientia tsutsugamushi (was R. tsutsugamushi)
- Pasteurella multocida type B -"buffalo" and other virulent strains
- Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. typhi (R. mooseri)
- Yersinia pestis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)

Risk Group 3 (RG3) - Fungal Agents*

None

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions*

- Alphaviruses (Togaviruses) - Group A Arboviruses
    - Chikungunya virus (except the vaccine strain 181/25 listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
    - Semliki Forest virus
    - Venezuelan equine encephalomyelitis virus (except the vaccine strains TC-83 and V3526, see Appendix B-II-D (RG2) – Viruses)
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Arenaviruses
    - Flexal
    - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- Bunyaviruses
    - Hantaviruses including Hantaan virus
    - Rift Valley fever virus
- Coronaviruses
    - SARS-associated coronavirus (SARS-CoV)
    - Middle East respiratory syndrome coronavirus (MERS-CoV)
- Flaviviruses - Group B Arboviruses
    - Japanese encephalitis virus (except those strains listed in Appendix B-II-D Risk Group2 (RG2) - Viruses)
    - Yellow fever virus
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Orthomyxoviruses
    - Influenza viruses 1918-1919 H1N1 (1918 H1N1), human H2N2 (1957-1968), and highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1).
- Poxviruses
    - Monkeypox virus (Clade I & Clade II containing nucleic acids coding for clade I MPVX virus virulence factors)
- Prions
    - Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob

disease and kuru agents)(see Section V-C, Footnotes and References of Sections I through IV, for containment instruction)

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EXCLUDED RG3 Agents:

- Human immunodeficiency virus (HIV) types 1 and 2
- Human T cell lymphotropic virus (HTLV) types 1 and 2
- Simian immunodeficiency virus (SIV)
- Mycobacterium tuberculosis, Mycobacterium bovis
- Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors
- Vesicular stomatitis virus
- Coccidioides immitis (sporulating cultures; contaminated soil)
- Histoplasma capsulatum, H. capsulatum var. duboisii

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Risk Mitigation Plan (RMP) is developed by the IRE, in partnership with the PI, and describes measures to be instituted for the conduct and communication of Category 1 and Category 2 research (as outlined below). The RMP will include details of the risks identified by the IRE in its review of the research, and an explanation of the risk mitigation strategy or strategies that are being implemented to address those risks.

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- Category 2 Research - Research within the scope of Category 2 corresponds to "pathogens with enhanced pandemic potential" research. Refer to the IRE website for detail about the biological agents and experimental outcomes related to Category 2.

Proposed and ongoing research that may fall within the scope of Category 1 or Category 2 must be evaluated by the PI during preparation of a federal funding proposal and an initial determination provided in the grant application. At the time of proposal submission, UCLA will certify institutional compliance with the research oversight framework described in the USG Policy.

A federal funding agency that is considering funding a grant involving research that may fall within the scope of Category 1 or Category 2 will notify UCLA upon completion of a merit review, prompting the Institutional Review Entity (IRE) to evaluate the PI's initial assessment and confirm whether research is within the scope of Category 1 or Category 2.

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If the IRE determines that the proposed research does not fall within the scope of Category 1 or Category 2:

- The IRE will report this determination to the federal funding agency.
- The PI will continuously monitor the research during the course of the award and report any changes that warrant reassessment to the IRE.

UCLA has established the Institutional Review Entity (IRE) to assess and oversee proposed and ongoing research that may fall within the scope of Category 1 or Category 2, and has appointed an Institutional Contact for Dual Use Research (ICDUR) within the Office of Research Policy & Compliance.

IV. RESPONSIBILITIES

A. Principal Investigator (PI)

In accordance with the USG Policy, prior to initiating research and continuously throughout the research lifecycle, the PI is required to:

- Identify whether the research is reasonably anticipated to be within the scope of Category 1 or Category 2;
- Upon identification of Category 1 or Category 2 research, notify the federal funding agency and IRE;
- Work with the IRE to assess the risks and benefits of the proposed research and develop a draft RMP;
- Conduct Category 1 and Category 2 research in accordance with the provisions of the approved RMP;
- Provide progress reports on a schedule corresponding to the category of research and agency requirements;
- Be knowledgeable about, and comply with, all institutional, UC, and USG policies and requirements for Category 1 and Category 2 research;
- Ensure that laboratory personnel conducting research within the scope of this Policy have received education and training as required by the IRE and any RMPs; and

- Communicate Category 1 and Category 2 research responsibly and in compliance with the approved RMP.

B. Institutional Review Entity (IRE)

Research subject to this Policy will be referred to the IRE via a PI self-report and after notification from a federal funding agency. If research is determined to fall within the scope of Category 1 or Category 2, the ICDUR and IRE will:

- Notify the PI that the proposed work meets the criteria for Category 1 or Category 2;
- Conduct a risk-benefit assessment on the proposed research;
- Develop a draft RMP in collaboration with the PI for the research;
- Provide education and training for individuals conducting Category 1 and Category 2 research, as needed;
- Review all active RMPs at least annually (shorter cycles may be imposed, especially for Category 2 research) and modify as needed; and
- Maintain records of IRE reviews and completed RMPs for the term of the research grant or contract plus three years after its completion.

V. COMPLIANCE

Noncompliance with this Policy may result in remediation, mandatory training, and/or employment consequences up to and including informal counseling, adverse performance evaluations, and correction action/discipline in accordance with University and UCLA policies and any relevant collective bargaining agreements.

VI. REFERENCES

1. United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. Release date: May 6, 2024;
2. USG Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);
3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). Amended April 5, 2024;
4. University of California – Policy: Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential;
5. UCLA Policy 900, Principal Investigator Eligibility.

Issuing Officer

/s/ Roger Wakimoto

Vice Chancellor for Research and Creative Activities

Appendix A

Category 1 Agents and Toxins

HHS Select Agents and Toxins

1. Abrin
2. *Bacillus cereus* Biovar *anthracis*
3. Botulinum neurotoxins
4. Botulinum neurotoxin producing species of *Clostridium*
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol
9. Eastern Equine Encephalitis virus
10. Ebola virus
11. *Francisella tularensis*
12. Lassa fever virus
13. Lujo virus
14. Marburg virus
15. Mpox virus
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)
20. SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
21. Saxitoxin

South American Haemorrhagic Fever viruses:

22. Chapare
23. Guanarito

24. Junín
25. Machupo
26. Sabia
27. Staphylococcal enterotoxins (subtypes A,B,C,D,E)
28. T-2 toxin
29. Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

30. Far Eastern subtype
31. Siberian subtype
32. Kyasanur Forest disease virus
33. Omsk hemorrhagic fever virus
34. Variola major virus (Smallpox virus)
35. Variola minor virus (Alastrim)
36. *Yersinia pestis*

Overlap Select Agents and Toxins

37. *Bacillus anthracis*
38. *Bacillus anthracis* Pasteur strain
39. *Brucella abortus*
40. *Brucella melitensis*
41. *Brucella suis*
42. *Burkholderia mallei*
43. *Burkholderia pseudomallei*
44. Hendra virus
45. Nipah virus
46. Rift Valley fever virus
47. Venezuelan equine encephalitis virus

USDA Veterinary Services (VS) Select Agents and Toxins

48. African horse sickness virus
49. African swine fever virus
50. Avian influenza virus

51. Classical swine fever virus
52. Foot-and-mouth disease virus
53. Goat pox virus
54. Lumpy skin disease virus
55. *Mycoplasma capricolum*
56. *Mycoplasma mycoides*
57. Newcastle disease virus
58. Peste des petits ruminants virus
59. Rinderpest virus
60. Sheep pox virus
61. Swine vesicular disease virus

USDA Plant Protection And Quarantine (PPQ) Select Agents and Toxins

62. *Coniothyrium glycines*
    (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
63. *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
64. *Ralstonia solanacearum*
65. *Rathayibacter toxicus*
66. *Sclerophthora rayssiae*
67. *Synchytrium endobioticum*
68. *Xanthomonas oryzae*

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Appendix B, Risk Group 4 and subset of Risk Group 3

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Risk Group 4 (RG4) - Bacterial Agents

None

Risk Group 4 (RG4) - Fungal Agents

None

Risk Group 4 (RG4) - Parasitic Agents

None

Risk Group 4 (RG4) - Viral Agents

- Arenaviruses

  - Guanarito virus
  - Lassa virus
  - Junin virus (except the candid #1 vaccine strain listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
  - Machupo virus
  - Sabia
- Bunyaviruses (Nairovirus)
  - Crimean-Congo hemorrhagic fever virus
- Filoviruses
  - Ebola viruses
  - Marburg viruses
- Flaviruses - Group B Arboviruses
  - Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses
- Herpesviruses (alpha)
  - Herpesvirus simiae (Herpes B or Monkey B virus)
- Paramyxoviruses
  - Equine Morbillivirus (Hendra virus)
- Hemorrhagic fever viruses as yet undefined

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia*

- Bartonella
- Brucella including B. abortus, B. canis, B. suis
- Burkholderia (Pseudomonas) mallei, B. pseudomallei
- Coxiella burnetii (except the Phase II, Nine Mile strain listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)
- Francisella tularensis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) – Bacterial Agents Including Chlamydia)
- Orientia tsutsugamushi (was R. tsutsugamushi)
- Pasteurella multocida type B -"buffalo" and other virulent strains
- Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. typhi (R. mooseri)

- Yersinia pestis (except those strains listed in Appendix B-II-A, Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)

Risk Group 3 (RG3) - Fungal Agents*

None

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions*

- Alphaviruses (Togaviruses) - Group A Arboviruses
    - Chikungunya virus (except the vaccine strain 181/25 listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
    - Semliki Forest virus
    - Venezuelan equine encephalomyelitis virus (except the vaccine strains TC-83 and V3526, see Appendix B-II-D (RG2) – Viruses)
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Arenaviruses
    - Flexal
    - Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
- Bunyaviruses
    - Hantaviruses including Hantaan virus
    - Rift Valley fever virus
- Coronaviruses
    - SARS-associated coronavirus (SARS-CoV)
    - Middle East respiratory syndrome coronavirus (MERS-CoV)
- Flaviviruses - Group B Arboviruses
    - Japanese encephalitis virus (except those strains listed in Appendix B-II-D Risk Group2 (RG2) - Viruses)
    - Yellow fever virus
    - Other viruses as listed in the reference source (see Section V-C, Footnotes and References of Sections I through IV)
- Orthomyxoviruses
    - Influenza viruses 1918-1919 H1N1 (1918 H1N1), human H2N2 (1957-1968), and

highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1).

- Poxviruses
    - Monkeypox virus (Clade I & Clade II containing nucleic acids coding for clade I MPVX virus virulence factors)
- Prions
    - Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob disease and kuru agents)(see Section V-C, Footnotes and References of Sections I through IV, for containment instruction)

EXCLUDED RG3 Agents:

- Human immunodeficiency virus (HIV) types 1 and 2
- Human T cell lymphotropic virus (HTLV) types 1 and 2
- Simian immunodeficiency virus (SIV)
- Mycobacterium tuberculosis, Mycobacterium bovis
- Clade II of MPVX viruses unless containing nucleic acids coding for clade I MPVX virus virulence factors
- Vesicular stomatitis virus
- Coccidioides immitis (sporulating cultures; contaminated soil)
- Histoplasma capsulatum, H. capsulatum var. duboisii