Category 1 and Category 2 Research: The DURC/PEPP Storm Coming to Your Institutional Biosafety Committee

February 25, 2025

Speakers:

#COGRFeb25

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Michael Betteken, Compliance Manager: IBC, ESCRO, DURC, Hemp, Office of Research Integrity & Assurance, Cornell University

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Moderator: Kris West, Director, Research Ethics & Compliance, COGR

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Presentation Overview

- Overview of USG Policy for Oversight of DURC and PEPP ("New DURC/PEPP Policy"), Main "Pain Points," and Possible Changes on the Horizon – Sherry Bohn
- Implementation of the New DURC/PEPP Policy:
  - Cornell University – Michael Betteken
  - Penn State University – Sepideh S. Hockley
  - Texas A&M University – Jessica Bourquin
- Panel Discussion – All panelists
- Q&A and Session Close-Out

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Overview of New DURC/PEPP Policy

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United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens of Enhanced Pandemic Potential – May 2024: A Discussion

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New DURC and PEPP Policy

Provides a unified oversight framework for Dual Use Research of Concern (DURC) and Pathogens with pandemic potential (PPP)

Goes into effect May 5, 2025

Supersedes

- 2012 USG Policy for Oversight of Life Sciences Dual Use Research of Concern
- 2014 USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- 2017 Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)

New Definitions

- **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 misapplied to do harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, 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
- **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. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential.

New Policy Aims to Identify:

Category 1 Research (DURC)

- Based on *current* understanding, the research can be *reasonably* anticipated to provide, or does provide, knowledge, information, products, or technologies that could be misapplied to *do harm* with *no — or only minor — modification* to pose a *significant* threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security
- Expands covered agents from BSAT list to all RG3/4 (and strongly encourages RG2)

Category 2 Research (PEPP)

- Based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security as specified in the policy
- Agents covered include: A PPP, or any pathogen that will be modified in such a way that is ***reasonably anticipated*** to result in a PPP

Compare Experimental Outcomes – They are Different

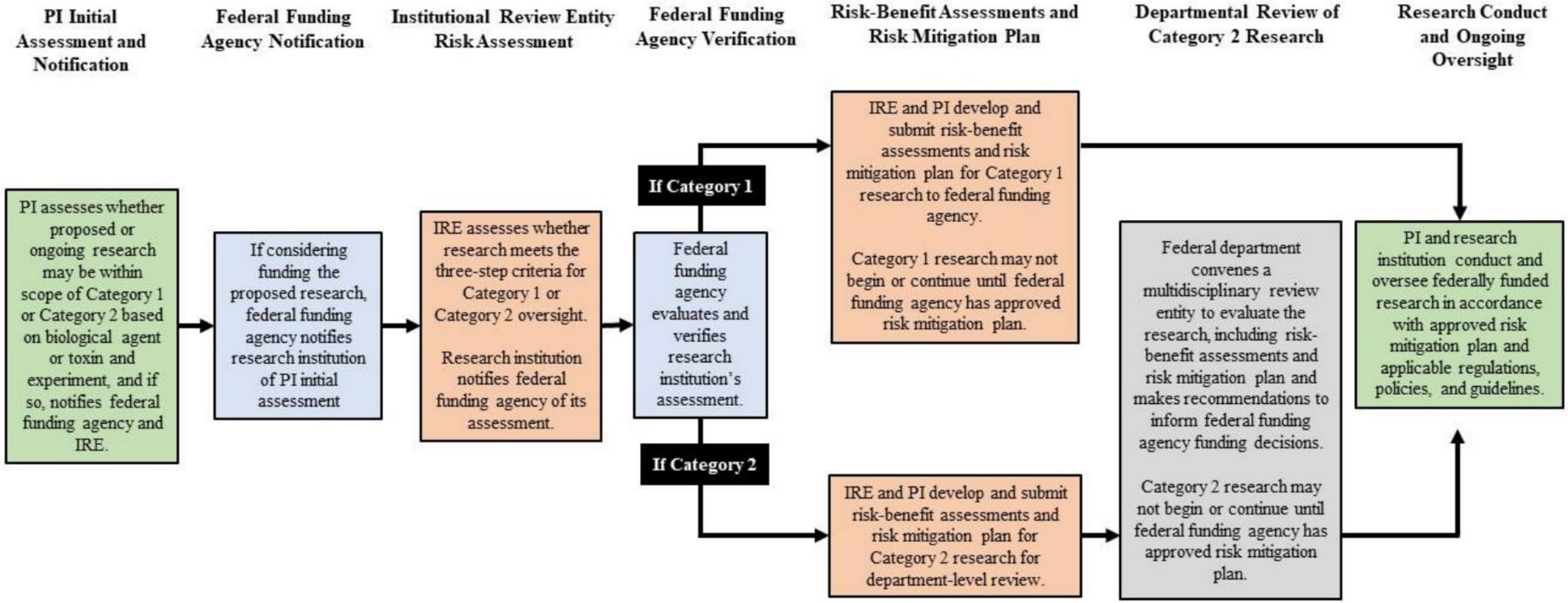
DURC

1. Enhance the harmful consequences of the agent or toxin?
2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin?
3. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies?
4. Increase the stability, transmissibility, or ability to disseminate the agent or toxin?
5. Alter the host range or tropism of the agent or toxin?
6. Enhance the susceptibility of a host population to the agent or toxin?
7. Generate or reconstitute an eradicated or extinct agent or toxin or will synthetic biology techniques be used to construct a pathogen, toxin, or potentially harmful product?

Category 1

1. Increase transmissibility of a pathogen within or between host species
2. Increase the virulence of a pathogen or convey virulence to a non-pathogen
3. Increase the toxicity of a known toxin or produce a novel toxin
4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin
5. Alter the host range or tropism of a pathogen or toxin
6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin
9. Enhance the susceptibility of a host population to a pathogen or toxin

Overview of Review Process for Category 1 or Category 2 Research

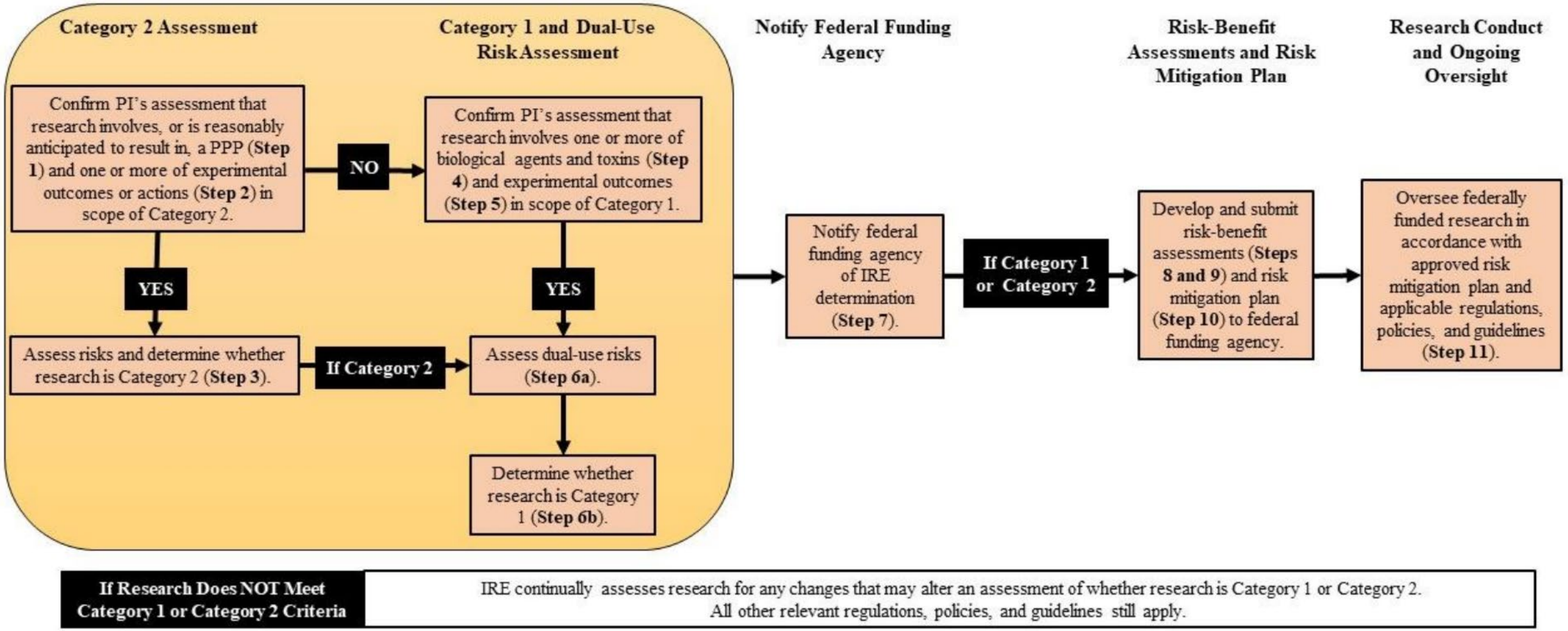


If Research Does NOT Meet Category 1 or Category 2 Criteria	PI continually assesses research for any changes that may alter an assessment of whether research is Category 1 or Category 2. All other relevant regulations, policies, and guidelines still apply.

Key

PIs | Federal funding agencies | Research institutions | Federal departments

IRE Review Process for Category 1 and Category 2 Research



If Research Does NOT Meet Category 1 or Category 2 Criteria	IRE continually assesses research for any changes that may alter an assessment of whether research is Category 1 or Category 2. All other relevant regulations, policies, and guidelines still apply.

Ongoing IRE Oversight/Review

- Continually assess research for any changes that may alter a Category 1 or Category 2 assessment
- Annually review Category 1 risk mitigation plans (this could extend to progress reviews)
- Semi-annually review Category 2 risk mitigations plans (this could extend to progress reviews)

Additional Entity Duties

Responsible for ensuring that PIs are aware of and executing the responsibility to do an initial assessment of their research and notifying the funder and IRE

Ensure research meeting the scope for Category 1 will not proceed until the funder approves the risk mitigation plan

Ensure research meeting the scope for Category 2 will not proceed until the funder determine the potential benefits and justifies the potential risk and approves the risk mitigation plan

Ensure research that is identified as potentially falling within the scope of Category 1 or 2 during the course of experimentation, is halted by the PI and the PI notifies the funder and IRE

Ensure responsible communication of research results

IRE policies must be publicly available

Report instances of failure to follow the policy within 30 calendar days

Annually provide formal assurance to relevant federal funding agencies

Here to help!

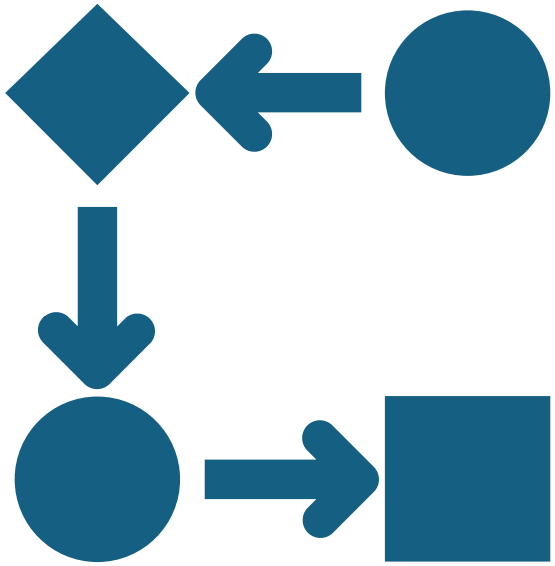
IMPLEMENTATION GUIDANCE
for the
United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

May 2024

Where Do We Start?

- Lots of feelings about this policy…
- Lots of “I heard”, “what if”, and “what does that mean” going on…
- How do we collect it all?
  - Logistics
  - Technology
  - Cost / Staffing
  - Training / Resources
  - Unintended Consequences
  - Timing

Logistics



- Scope
  - strongly encourages non-federally funded work to comply.
  - strongly encourages all work outside Category 1 and Category 2 be assessed. Concerned entity leadership may want to overprotect and require all recombinant and BSL-2 work be included.
- Will current research be paused? Unclear – may be up to the funding agency?
- How many protocols will be covered? Unclear.
- Entity IRE will now need to review pre-award. The IBC or safety office does not generally review proposals. The concern is that significant effort will go into reviewing pre-award proposals that will not receive funding. This reduces resources for oversight of funded research. Could lead to EHS/IBC being seen as a barrier to grant submittal process.
- Will entities have a “file manager” as in FSAP to streamline communication and assist with process? Concerned the PI is on their own until research is deemed “eligible for federal funding”.

Technology

How are assessments being submitted to the agencies?

Some entities use cloud-based research management systems and some are in word/pdf documents.

The implementation guidance has terms like “Select all applicable additional measures from this menu to summarize the risk mitigation measures”. Does this imply there is a tool that all entities will use to allow for consistency and efficiency? Will this track progress through the process? Can the entity monitor the process? When will the tool become available?

Will communication between entities and agencies be managed within such a tool to ensure continuity? (ex. FSAP portal)

Cost/Staffing

- Public institutions are stressed and contracting budgets.
- Entities cannot provide cost estimate for compliance, since parameters are unclear.
- However, it is understood that:
  - Pre-award review is not currently common practice;
  - Role of ICDUR may be enhanced;
  - NIH implementation guidance creates an Authorized Organizational Representative (AOR), but no information on what constitutes that;
  - If the IRE is separate from IBC, entity compliance administration (biosafety officer, compliance manager) will need to manage a new committee;
  - If IRE is IBC, IBC will see increased workload
    - IBCs are becoming difficult to staff and engage
  - Administrative support staff will be needed to track status and manage communication.
    - Many IBC do not have the coordinator or analyst positions the IRB and IACUC may have.

Training /Resources

- Concerned that entities are deemed responsible for developing training on the policy. For consistency, OSTP should provide the training materials for entities to incorporate into their site-specific offerings.
- Concerned the policy has not been finalized, and submission tools not available, for entities to train PI and admin staff on before May 2025.

Unintended Consequences

- Research on important topics becomes “too hard” to do
- Researchers leaving entities because they do not feel supported
- Critical work is paused (ex. GOF pause that interrupted St. Jude annual flu vaccine development)

Timing

- OSTP holds entities to timeframes, but no timeframes proposed related to ensuring agency review is timely.
- Policy states entities need to be compliant by May 2025, but we have heard NIH will go first and others should follow their process?
- NIH stated that OSTP expects it to take 2-3 cycles to perfect the process.
- Entities cannot be training PIs and admin staff now if the process has not been solidified.
- Entities cannot propose budget to hire new staff and train them by May 2025 as we cannot predict scope or burden.

What Can ABSA International Do?

- Engage our membership
  - Surveys
  - Community of practice to support members in implementing the process
  - Collect experiences
- Provide comments – Technical and Legislative Regulatory Review Committee
  - Develop and implement an effective method for reviewing and commenting on issues or regulatory concerns that impact the ABSA membership or the health or safety of the environment. Respond to requests for comments by regulatory agencies proposing new or amended regulations. Develop "white papers" and other guidance documents.
- Training Vehicle
  - Webinars – can be collaboration with OSTP and/or regulated entities
  - Pre-Conference course
  - Affiliate meetings – often co-hosted (ex. ABSA and ASM local chapters can partner to hold meeting)
- Provide Resources
  - Recorded training, useful links, lessons learned
  - *Applied Biosafety*
- Partner!

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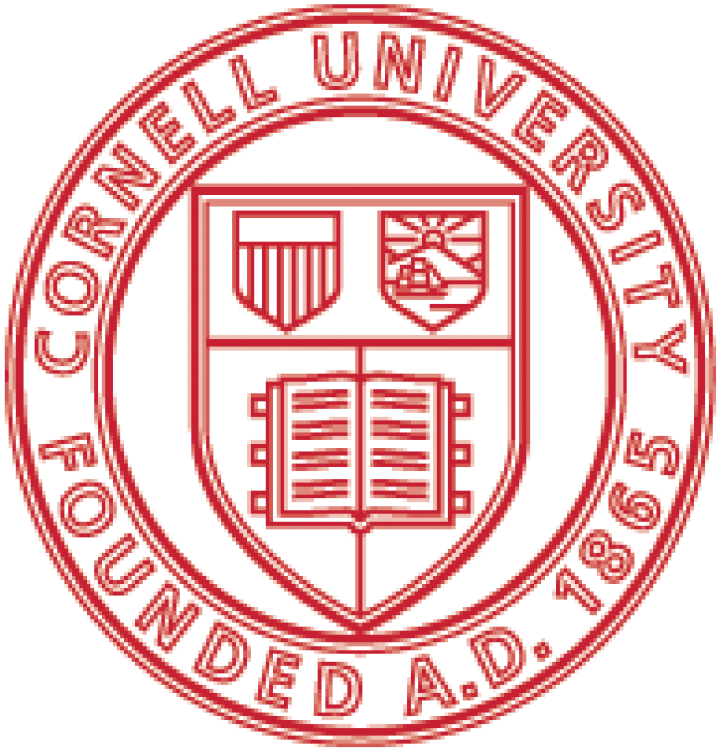
Policy Implementation



Cornell University

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Cornell University: Plans to implement a program compliant with the new DURC PPP/PEPP Policy

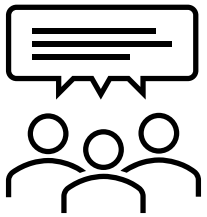
Research&Innovation

Michael Betteken PhD, CPBCA
Compliance Manager: IBC, ESCRO, DURC, Hemp
Cornell University

Cornell Program Development and Implementation Framework

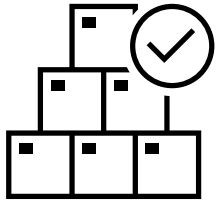
Initial Assessment & Impact (May 2024)

- Scope: 22 research groups with PPP agents
- Analysis of research portfolio and resource allocation
- Timeline implementation



Program Structure

- Cross-functional working group established
  (Research Admin, Faculty, Safety, IT, Legal)
- DURC-IRE membership and ICDUR oversight
- DURC Research Coordinator program management



Implementation & Deliverables

- Comprehensive process documentation and guidance
- Information system modifications
- Communication strategy and stakeholder engagement

Guidance Documents for DURC Program

PI Self-assessment

- Step-by-step project evaluation process
- Helps identify DURC Research

Risk Assessment draft template

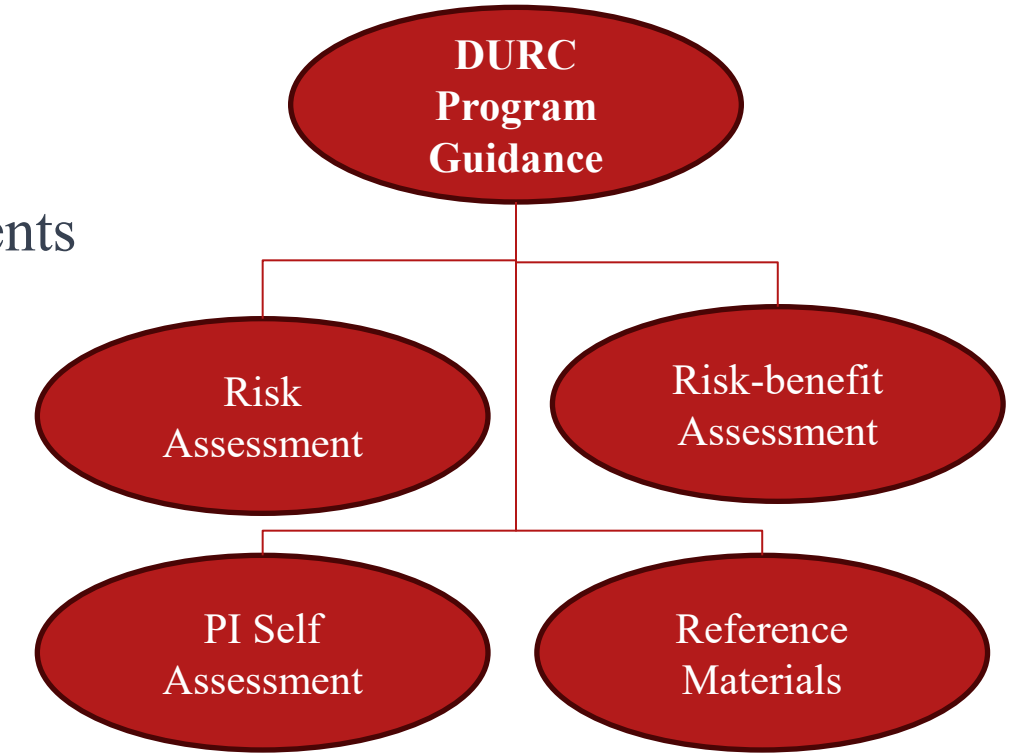
- Aligned with implementation guide requirements
- Standardized evaluation format

Risk-benefit assessment draft template

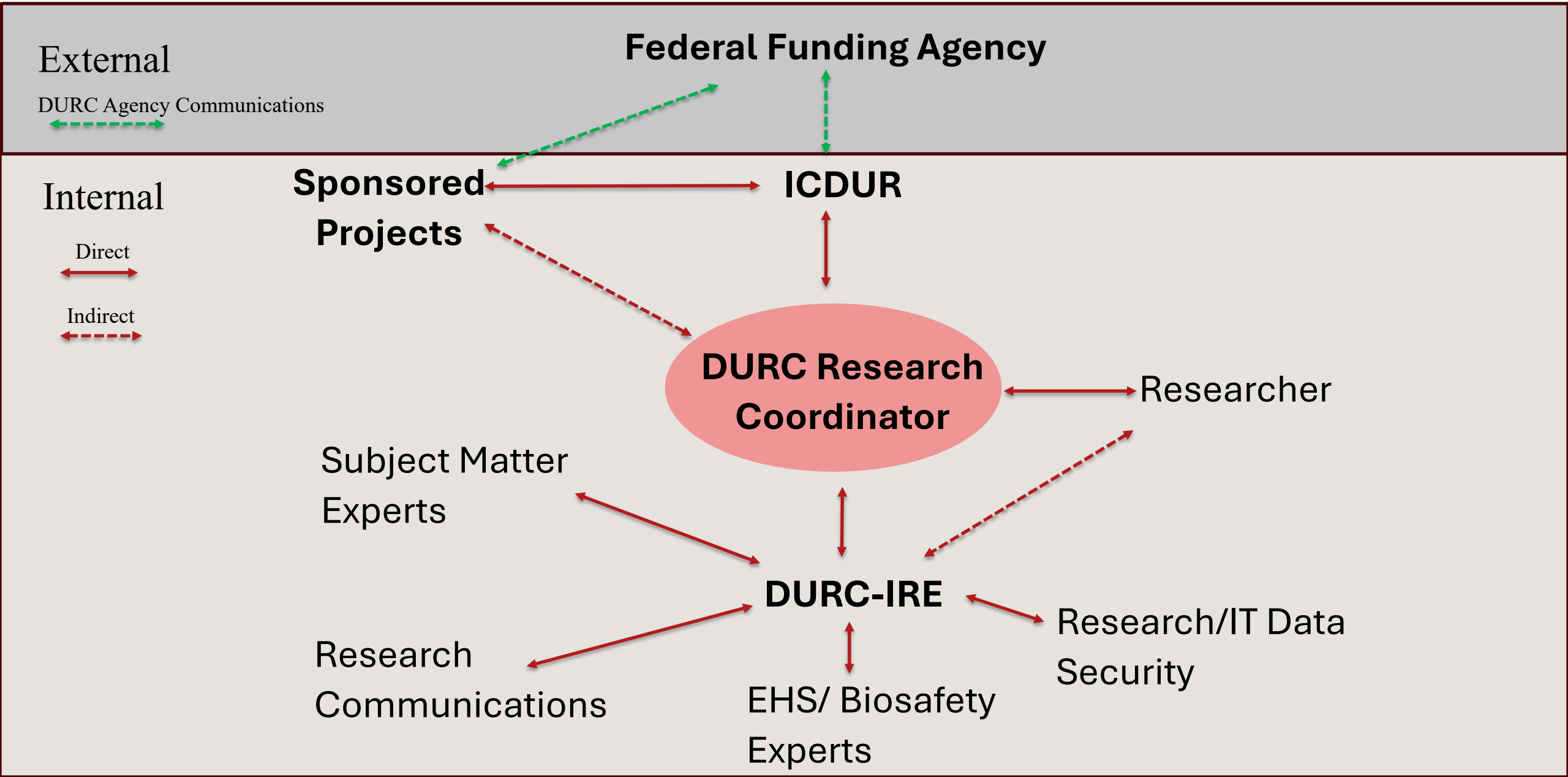
- Comprehensive analysis framework
- Addresses new policy considerations

Reference Materials

- PPP Agents & Toxins guide
  - User-friendly format for quick reference



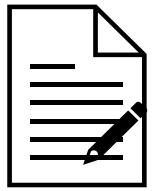
DURC Information & Communication Pathways



Initial Steps: Grant Submission Process

Step 1: PI preparation

- Prepares grant proposal with DURC determination
- Guidance: PI self-assessment or consultation with DURC Research Coordinator

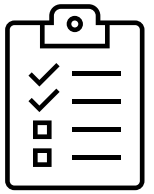


Step 2: Proposal submission

- PI and OSP submit grant proposal

Step 3: Funding Agency Review

- Agency requests DURC determination
- Sponsored projects system adds DURC-IRE confirmation



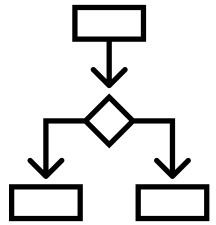
Step 4: Initial Assessment

- PI works with DURC Research Coordinator to complete DURC determination for review by DURC-IRE

DURC Determination Process

Step 5: DURC-IRE Review

- Reviews assessment and makes determination
- Two possible outcomes
  - DURC: Move to Step 6
  - Not DURC: Move to Step 8 (next slide)*

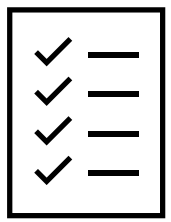


Step 6: Communication and Planning

- DURC Coordinator works with PI to complete
  - Risk Assessment
  - Risk-benefit Assessment

Step 7: Assessment Review

- DURC-IRE reviews risk and risk-benefit assessment
- DURC-IRE approves assessment
- Move to Step 9 (next slide)



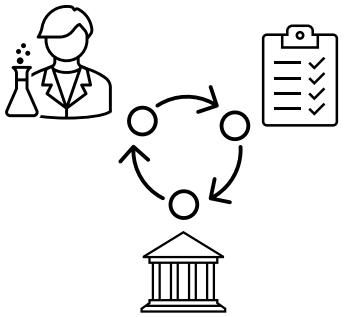
Final Steps: Agency Review and Implementation

Step 8: Communication and Planning (DURC) (NOT DURC)

- ICDUR/AOR conveys determination/assessments to funding agency
- Funding Agency approves determination/assessments

Step 9: Project Implementation

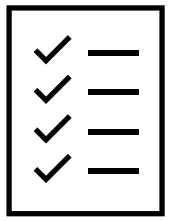
- Project begins
- DURC-IRE conducts annual reviews on DURC Research
- Annual reports to funding agency



Identifying Potential DURC Research Early

Early Identification IBC registrations system

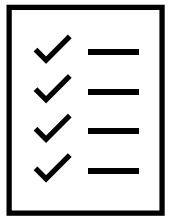
- DURC section for PPP/PEPP identification
  - PI-self assessment check list
  - DURC Research Coordinator proactively identifies
  - Prepares PIs for proposal process



Identification before Proposal stage

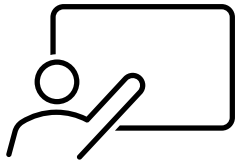
- PI Support tools
  - Education
  - PI self-assessment checklist
  - Consultation with DURC Research Coordinator

Implementation strategy



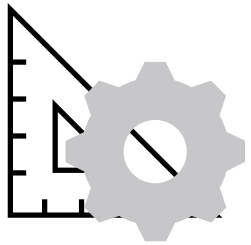
Communication Plan- Multi-faceted Broad Approach

- Attend meetings to inform GCOs, Research Administrators, Researchers
- Targeted outreach by DURC Research Coordinator to PIs with PPP agents/toxins
- Broad research communications to all federal grant researchers



Training- Formal and Informal

- Deploy a formalized training module (CITI or in-house developed)
- Develop and deploy training and education materials
- Launch training sessions for key stakeholders



System & Tools Implementation

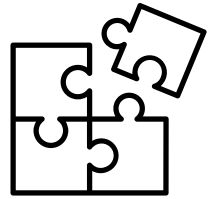
- Enhance IBC/SP system with DURC
- Deploy PI self-assessment tools
- Implement standardized templates
  - Risk assessment, Risk-benefit, and other materials

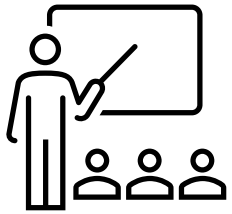
<u>Flexibility is key to success</u>

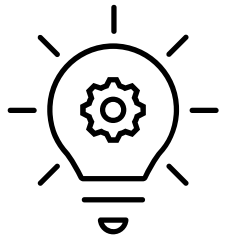
Cornell's DURC Implementation: Key Takeaways

Success Factors

- Early engagement
- Clear communication pathways
- Flexible implementation strategy
- Standardized tools and templates
- Engage with Professional and Peer Organizations







Thank you

Michael Betteken
DURC Research Coordinator
Cornell University

PI Self-Assessment Tool for Category 1 and Category 2 Research

Instructions: Answer the following questions about your research project. If you answer "Yes" to any question in Sections A and B, your research may fall under Category 1 or 2 and must be referred to your Institutional Review Entity (DURC-IRE) for further assessment.

Section A: Category 1 PPP

1. Does your research involve any of the following agents or toxins? [ ] Yes [ ] No
    - List of agents/toxins (e.g., highly pathogenic avian influenza H5N1, SARS-CoV, etc.)
2. Is your research reasonably anticipated to produce, or does it intentionally produce, any of the following experimental effects? [ ] Yes [ ] No
    1. Increase transmissibility of a pathogen within or between host species;
    2. Increase the virulence of a pathogen or convey virulence to a non-pathogen;
    3. Increase the toxicity of a known toxin or produce a novel toxin;
    4. Increase the stability of a pathogen or toxin in the environment or increase the ability to disseminate a pathogen or toxin;
    5. Alter the host range or tropism of a pathogen or toxin;
    6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
    7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions;
    8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; or
    9. Enhance the susceptibility of a host population to a pathogen or toxin.

Section B: Potential Enhanced Pandemic Pathogens (PEPPs)

3. Does your research involve a pathogen that is likely capable of wide and uncontrollable spread in human populations? [ ] Yes [ ] No

4. If yes to question 3, is this pathogen likely to cause significant morbidity and/or mortality in humans? [ ] Yes [ ] No

5. Is your research reasonably anticipated to create, transfer, or create any of the results below? [ ] Yes [ ] No

    i. Enhance transmissibility of the pathogen in humans;

    ii. Enhance the virulence of the pathogen in humans;

    iii. Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection; or

    iv. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

Section C: Risk Assessment

6. Based on current understanding, could your research be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied to pose a significant threat to public health, agriculture, the environment, or national security? [ ] Yes [ ] No
7. If you answered "Yes" to any question in Sections A or B, please briefly describe the nature of your research and the specific concerns and share these with the DURC research coordinator (contact information): [Text entry box]

Section D: Next Steps

If you answered "Yes" to any question in Sections A or B:

1. If you are currently completing the compliance section of a sponsored project, answer yes to the question “DURC question in RASS-SP”
2. Contact your Institutional Review Entity (DURC-IRE) via the DURC Research Coordinator for a comprehensive review of your planned work.
3. Be prepared to work with the DURC Research Coordinator to put together the needed documents for DURC-IRE review.
4. Do not proceed with the research until you receive guidance from your DURC-IRE and, if necessary, the relevant funding agency.

If you answered "No" to all questions: Your research likely does not fall under Category 1 or 2 at this time. However, continue to monitor your research for any changes that might alter this assessment.

Reminder: This self-assessment tool is a preliminary screening device. The final determination of whether research falls under Category 1 or 2 will be made by your DURC-IRE and the relevant funding agency.

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Policy Implementation

PennState

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Penn State Implementation and Compliance Plan: USG Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

Sepideh S. Hockley, M.B.A.
Director of Research Safety and Compliance
(IBC, IRE, ESCRO, Isotopes, Drones, Scientific Diving)
Office for Research Protections

February 25, 2025

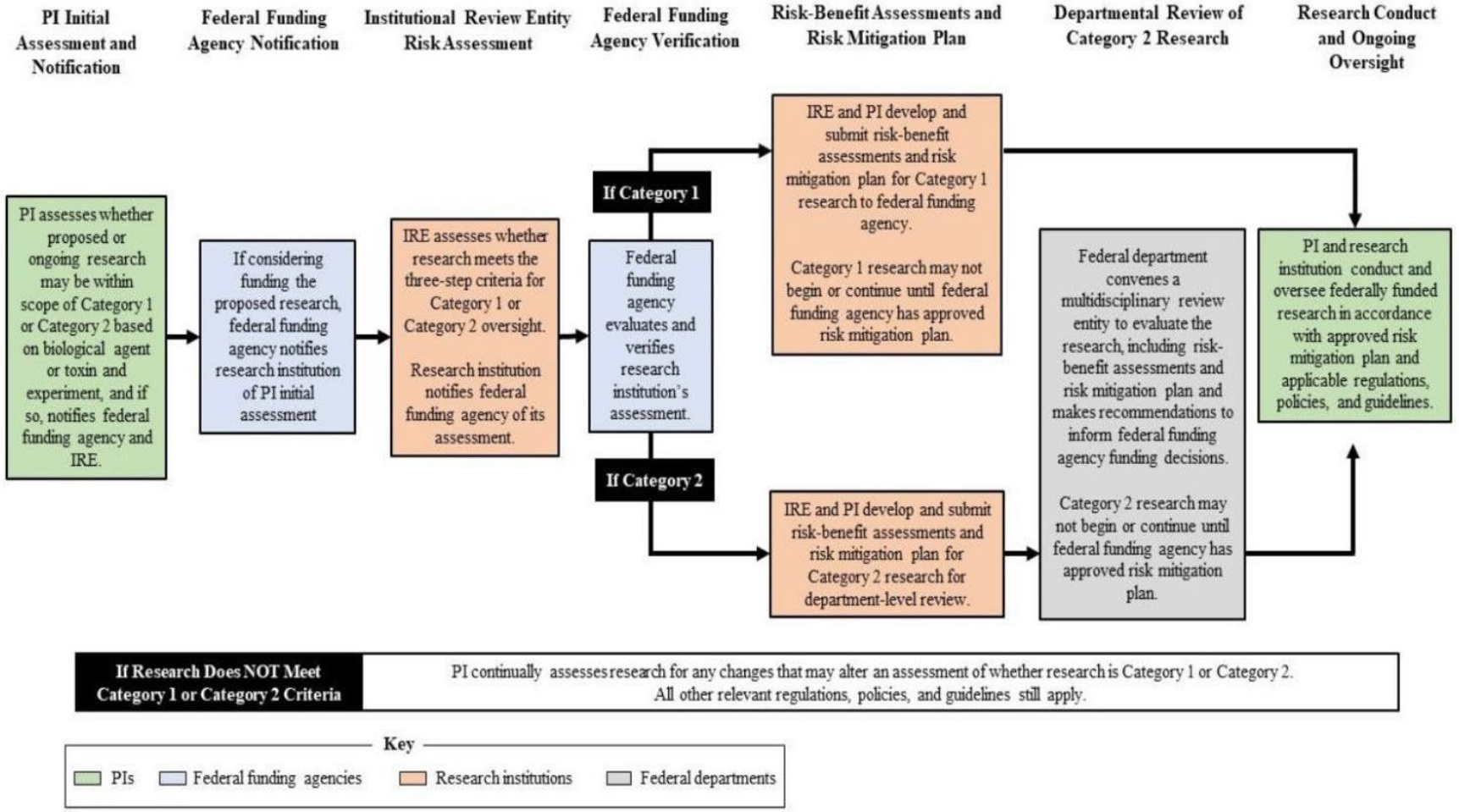
PennState

Multi Step Implementation Approach

- **Assess Impact of Policy Change**
  - Federally funded projects: 4
  - Non-federally funded projects: 4
  - Penn State will adopt the NIH recommendation to extend oversight to non-federally funded DURC/PEPP research through the IRE
- **Education and Outreach**
  - Compliance team participation in IBC/IRE peer group discussions
  - Communicate changes to University research and safety committees to raise awareness

Develop an Implementation and Compliance Plan

Figure 1. Overview of Review Process for Category 1 or Category 2 Research. Depicts the general workflow for review and assessment of research under to the Policy involving PIs (green boxes), research institutions (peach boxes), federal funding agencies (blue boxes), and federal departments (gray box).



Develop an Implementation and Compliance Plan

General Process of Oversight:

1. **PI Self-Assessment Form:** PI must assess their research to determine if Category 1 or Category 2 or neither. Must be completed before submitting a proposal to the federal funding agency
2. **Federal Funding Agency Notification:** Federal agency reviews proposal, and if it intends to fund, notifies the University. This triggers IRE notification and engagement
3. **IRE Assessment:** IRE reviews the PI's initial assessment, determines the appropriate research category, and notifies the funding agency. The funding agency evaluates and verifies the IRE's determination
4. **Risk Mitigation:** If research is Category 1 or 2
   - IRE and PI conduct a risk-benefit assessment
   - Draft a Risk Mitigation Plan (RMP) for approval by the federal funding agency

Develop an Implementation and Compliance Plan

General Process of Oversight Cont'd:

5. **Category 2: Federal Department Review:** Federal department convenes a multi-disciplinary review entity
6. **Ongoing Compliance:**
   - **Category 1:** RMP is reviewed annually
   - **Category 2:** RMP is reviewed semi-annually
   - If Category 1 or 2 research is identified during experimentation, work must be halted immediately, and the funding agency and IRE must be notified for reassessment.
7. **Ongoing Assessment of Category 1 or 2 Agents:** Continuous review of research involving these agents and protocol amendments involving experimental changes require reassessment to determine if they fall under Category 1 or 2.

Develop an Implementation and Compliance Plan

Responsibilities:

- **Researchers/PIs:**
  - Conduct initial and ongoing self-assessments of research associated with the agents that fall under the DURC policy.
  - Collaborate with the IRE on risk-benefit analyses.
  - Draft and implement Risk Mitigation Plan (RMPs) in coordination with the IRE when research is classified as Category 1 or 2.
  - Ensure ongoing compliance with approved RMPs for Categories 1 or 2 research

Develop an Implementation and Compliance Plan

Responsibilities (Cont'd):

- **Institutional Oversight:**
  - Establish and maintain internal policies/procedures for DURC and PEPP oversight
  - Maintain records of assessments, RMPs, and compliance activities
  - Assess research with agents that fall under the new DURC policy to determine if research falls under Category 1 or 2
  - Submit required reports to federal agencies
  - Provide formal assurance to NIH that the institution is operating in compliance with the policy.
  - Provide education and training to researchers and staff involved in high-risk research

Plan of Action

- **Integration of Oversight**
  - Merge the stand alone IREs at University Park (and commonwealth campuses) and College of Medicine and restructure into a subcommittee of the University Park IBC
- **Process Development**
  - PI Self-Assessment Form for PIs to complete at proposal submission
  - Modify the automated proposal notification system to include three compliance verification steps:
    1) At proposal submission stage – to notify the IRE
    2) At the intent to fund stage – to initiate IRE review
    3) At award stage – to confirm IRE approval status
  - Create templates for risk-benefit analysis, and Risk Mitigation Plan

Plan of Action

- **Training and IRE Review:**
  - Modify the electronic protocol submission system (Huron) to reflect policy changes.
  - Assign updated CITI DURC training as an annual requirement for users working with Category 1 and 2 agents and track compliance
  - Maintain a continuing review process across campuses to ensure ongoing compliance and oversight and satisfy the NIH formal “Assurance” requirement
  - Revise Penn State DURC Policy to align with USG Policy changes
- **Education and Outreach**
  - Communication plan: notification to researchers, Q&As, video tutorials, webpage, and newsletter announcements
  - Scheduled meetings with PIs, as needed

Further Clarification Needed from USG

- **Liaison to Federal Funding Agency:**
  - NIH identifies the AOR to submit the DURC/PEPP materials
  - USG Implementation Guidance identifies the ICDUR
  - Roles of AOR, ICDUR, and IO need to be further defined

References

- Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential
- NIH Implementation of the U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

Thank you!

Questions? Contact:

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PennState

Policy Implementation

#COGRFeb25

TEXAS A&M UNIVERSITY

COGR

Implementation of the 2024 United States Policy on DURC and PEPP at Texas A&M University

Jessica R. Bourquin, PhD, CBSP

Director of Biosafety, BSO, ARO

February 25, 2025

TEXAS A&M UNIVERSITY

Division of Research

DURC/PEPP oversight at a glance

Institutional Review Entity (IRE)

Texas A&M's IBC serves as the IRE

Members include a breadth of experience

- Ad hoc reviewers utilized as necessary

Institutional Contact for Dual Use Research of Concern (ICDUR)

The Associate Director of the Office of is the designated ICDUR

- They are also the Responsible Official for the entity's Select Agent Program
- Will liaise with AORs on behalf of the IRE

Training

IRE trained by ICDUR to properly perform required duties

Researchers complete updated DURC/PEPP training online

- Subsequently complete pre-assessment for currently approved work, and all proposed research

THE TEXAS A&M UNIVERSITY RULE FOR USE OF BIOHAZARDS

Biosafety Footprint- 11 IBCs across 23 cities

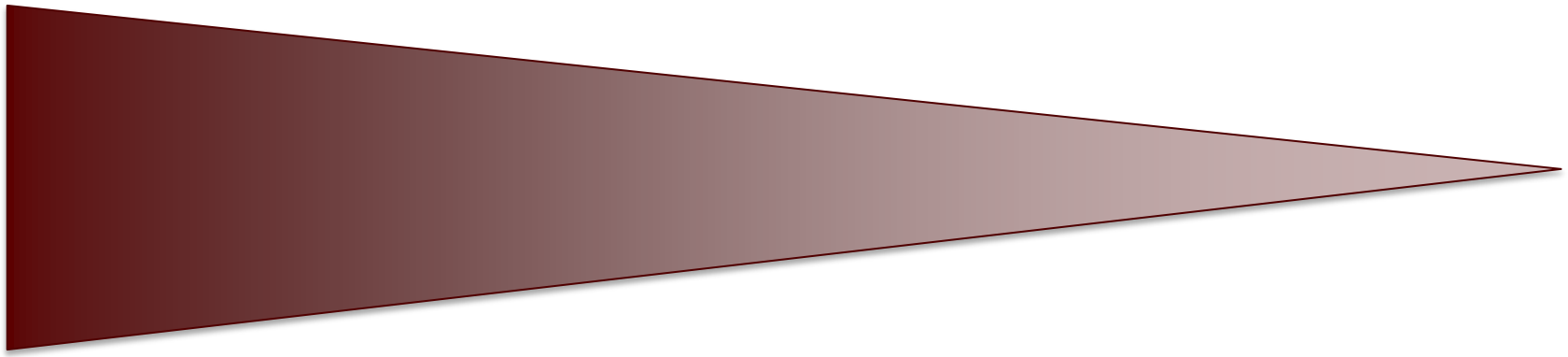
All activities with biohazards requires IBC approval

Extensive research compliance outreach

Ingrained in our culture

DURC/PEPP Oversight Process

Does the research aim to produce one of the 10 listed experimental effects?



PI Initial Assessment

PLEASE ANSWER THE FOLLOWING QUESTIONS REGARDING ALL OF YOUR RESEARCH INVOLVING BIOHAZARDOUS MATERIALS, AS DEFINED BY THE (CURRENTLY APPROVED AND PROPOSED) REGARDLESS OF FUNDING SOURCE.

1. Increase transmissibility of a pathogen within or between host species, including enhancing the transmissibility of the pathogen in humans;
2. Increase the virulence (e.g. the ability of a pathogen to cause disease) of a pathogen or convey virulence to a non-pathogen, including enhancing the virulence of the pathogen in humans;
3. Increase the toxicity of a known toxin or produce a novel toxin;
4. Increase the stability of a pathogen or toxin in the environment, or increase the ability to disseminate a pathogen or toxin (e.g., improving characteristics of the pathogen or toxin such as environmental stability and aerosolubility);
5. Alter the host range or tropism of a pathogen or toxin;
6. Decrease the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods;
7. Increase resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions (e.g., antimicrobials, antivirals, antitoxins, vaccines);
8. Alter a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin, including enhancing the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection;
9. Enhance the susceptibility of a host population to a pathogen or toxin; or
10. Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP.

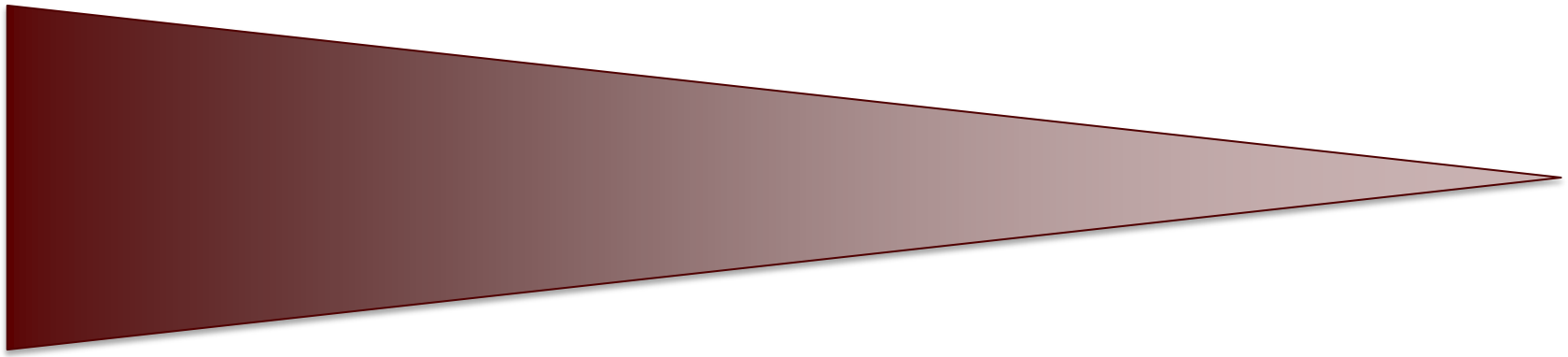
DURC/PEPP Oversight Process

Does the research involve one or more of Category 1 agent or toxin or a potential pandemic pathogen ?

→

Does the research aim to produce one of the 10 listed experimental effects?

→



PI Initial Assessment

Category 1 Agents

- All Select Agents and Toxins listed in the Select Agent Regulations.
- All Risk Group 4 pathogens and a subset of Risk Group 3 pathogens listed in the “NIH Guidelines”.
- Biological agents that the current edition BMBL recommends be handled at Biosafety Level 3 (BSL-3) or Biosafety Level 4 (BSL-4).
- Biological agents for which the Institutional Biosafety Committee (IBC) identifies as needing BSL-3 or BSL-4 containment based on a risk assessment.
- Biological agents added during future updates to the DURC/PEPP Implementation Guidance referenced in Section 4.

Category 2 Agents:

- A potential pandemic pathogen
  - 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.
- Any pathogen modified such that it is reasonably anticipated to result in a PPP

DURC/PEPP Oversight Process

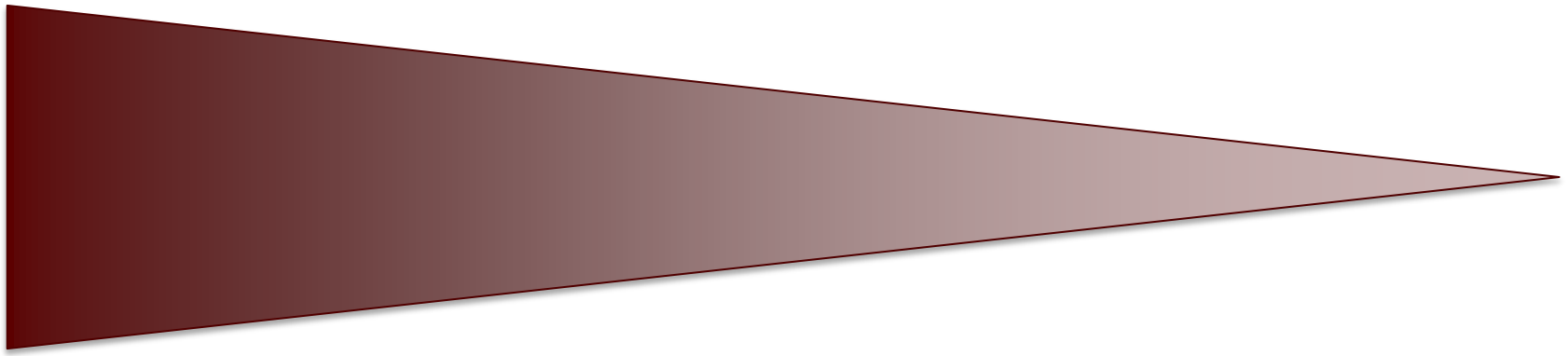
Does the research involve one or more of Category 1 agent or toxin or a potential pandemic pathogen ?

→

Does the research aim to produce one of the 10 listed experimental effects?

→

Does the research meet the definition of DURC?



Institutional Review Entity (IRE)

The IRE makes the determination of whether the research meets the definition of DURC.

If the research does not meet the definition DURC/PEPP, the research is not subject to additional review or oversight by the IRE unless the federal funding agency, while reviewing the IRE's determination, determines otherwise.

In such cases, the research will undergo continuous assessment throughout its lifecycle for potential Category 1 or Category 2 research.

DURC/PEPP Oversight Process

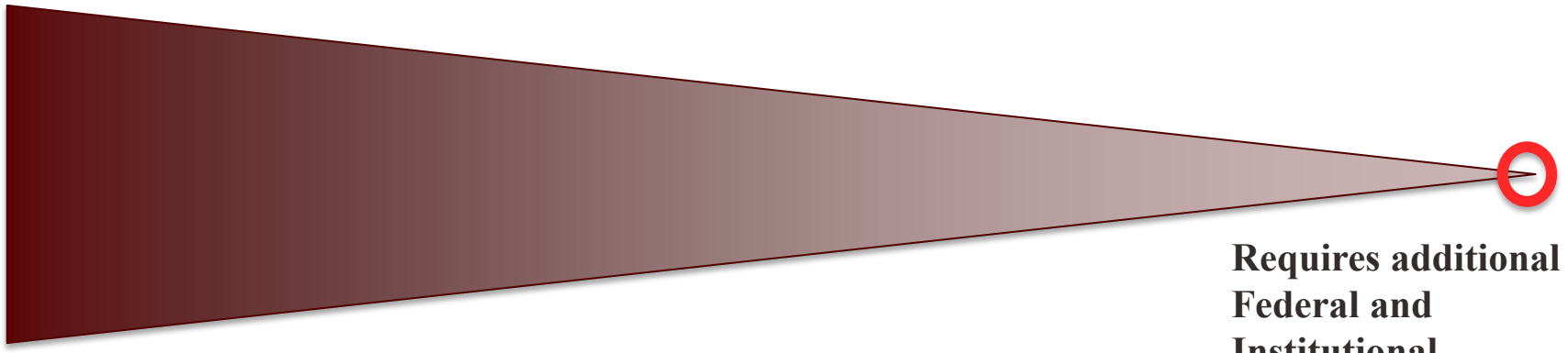
Does the research involve one or more of Category 1 agent or toxin or a potential pandemic pathogen ?

→

Does the research aim to produce one of the 10 listed experimental effects?

→

Does the research meet the definition of DURC/PEPP?



Requires additional Federal and Institutional oversight and risk mitigation strategies.

Determination and Communication

Institutional Review Entity (IRE)

- The IRE's determination is communicated to the PI and the funding agency.
- The ICDUR will serve as the point of contact and a resource for the AORs, who communicate directly with the funding agencies.
- The IRE works with the appropriate funding agency to develop a risk mitigation plan.
- The IRE reviews the risk mitigation plan at least annually and modifies the plan, as necessary.

DURC/PEPP Risk Mitigation

Managing the risks associated with the DURC/PEPP research is recognized as an important biosecurity issue & is a shared responsibility:

- Coordinated through the Office of Biosafety, in the Division of Research
- Ongoing process
- Risk mitigation plans in development for higher risk agents (non DURC/PEPP related)

- Researchers
  - PI, their staff and students
- Institutional officials
  - Office of Biosafety (ICDUR, BSO), Research Security and Export Controls, Sponsored Research Services
- Local Officials
  - Public health, first responders
- Federal Government
  - Federal Select Agent Program, FBI Counterterrorism Agents

THANK YOU

Texas A&M University
Office of Biosafety
Division of Research

Panel Discussion

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