Proposal Compliance Essentials

Part 1: What You Need to Know About the Princeton ERA Compliance Questions

Presented by:
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Proposal Compliance Essentials

First of a three-part series:

» Part 1: What You need to Know About the Princeton ERA Compliance Questions
  » December 12, 2023 | 9 a.m. – 10 a.m.

» Part 2: Disclosure Document Resources
  » January 24, 2024 | 9 a.m. – 10 a.m.

» Part 3: Budgeting Best Practices
  » February 26, 2024 | 9 a.m. – 10 a.m.
Why do we care about compliance?

- Regulatory/Compliance with the law
- In many cases, it is taxpayer money
- Sponsored funding comes with strings attached, the purpose of which are to help the researchers and the University be accountable (to the sponsor, to regulation, etc.)
- Compliance processes may seem burdensome, but they serve an important purpose: helping the researchers and Princeton steward other people’s money in a legal, ethical way that the University can stand behind
- While compliance questions can take time, ORPA is committed to streamlining compliance processes as much as possible
What are the Princeton ERA Grants Compliance Questions?

- The Compliance Questions relate directly to the scope of work (SOW) that is being signed off on by the Principal Investigator (PI), the department/center, and/or school and then routed to ORPA.

- The PI certifies via the PI assurance/Certify button that the information in the ERA record is true and accurate.

- The Compliance Questions each have a purpose.

- When a question is answered positively [yes] - another review is kicked off and additional information may be requested/needed.
Who answers the Princeton ERA Grants Compliance Questions?

The PI must answer the Compliance Questions

The PI can answer the Compliance Questions directly in the Princeton ERA system using the PI assurance and compliance quick guide

princeton_era-lead-pi-assurance-and-compliance-quick-guide.pdf

The PI can also answer the Compliance Questions via the Grants Proposal Assurance, or via the Funding Proposal Compliance Checklist, and the department administrator can complete the smart form
Where are the Princeton ERA Grants Compliance Questions in Princeton ERA?

- **All Funding Proposals [FP] in ERA include a Compliance SmartForm page where the answers to the questions are collected [under Edit Funding Proposal/Compliance Review]**

- **Compliance Questions** for Agreements that are non-financial [no FP] are collected on the Princeton ERA Agreements Assurance and the secondary ancillary review processes are manually initiated by the Grant and Contract Administrator (GCA)

- **Instructions for the FP Compliance Review SmartForm are on page 27 of the Funding Proposal Guide**

- The Ancillary Review functionality is used to track on many secondary reviews, including Ad Hoc reviews
Compliance Review SmartForm – Human Subjects, Vertebrate Animals and Biological Agents

Compliance Review

1. * Does this project involve human subjects? ☐
   - Yes ☐ No ☐ Clear

2. * Are live, vertebrate animals used in this project? ☐
   - Yes ☐ No ☐ Clear

3. * Does this project involve the use of biological agents (including recombinant or synthetic nucleic acids)? ☐
   - Yes ☐ No ☐ Clear
# Compliance Checklist - Human Subjects, Vertebrate Animals and Biological Agents

## Compliance Questions

*Please complete these compliance questions as they apply to this proposal submission. The Funding Proposal Administrative Contact must enter these responses onto the Funding Proposal Compliance page in Princeton ERA prior to proposal submission.*

1. Does this work associated with this agreement involve the following:

<table>
<thead>
<tr>
<th></th>
<th>Human Subjects</th>
<th>Live Vertebrate Animals</th>
<th>Biological Agents (including recombinant or synthetic nucleic acids)</th>
<th>Human Embryonic Stem Cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Yes</td>
<td>No</td>
<td>Select from List</td>
<td>Protocol No.</td>
</tr>
<tr>
<td>b</td>
<td>Yes</td>
<td>No</td>
<td>Select from List</td>
<td>Protocol No.</td>
</tr>
<tr>
<td>c</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Registration No.</td>
</tr>
<tr>
<td>d</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>List Cell Lines</td>
</tr>
</tbody>
</table>

2. Select if any of the following chemical or select agents will be used for this project.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select from List</td>
<td></td>
</tr>
</tbody>
</table>
If **NO** to Human Subjects is selected, no other information is needed.  
A non-human subject determination may be requested in certain circumstances (i.e. when it is unclear if the work is human subjects research).
Princeton ERA Compliance Process

Human Subjects

› If **YES** is selected for **Human Subjects** research, most often we would expect the secondary answer to be **pending** at the **proposal stage** (since this work is for a **new** proposal/scope of work).

  › The protocol number can simply be added/updated to approved in ERA during the award/JIT state.
  › This protocol information feeds to PRIME at award set up and end dates are reviewed at each funding increment (if any).
  › Some sponsors (Department of Defense) complete their own review prior to award.
  › If funded, the PI is responsible for making sure that the protocol is **aligned with the project SOW**. This includes that the research team and funding source(s) are all accurate in eRIA and covers the methods detailed in the scope of work.
  › PIs on a project and protocol should be aligned.

    › Be considerate of Mentors/PIs when working on Fellowship applications that include Human Subjects. The PI on a protocol is expected to be the PI/Mentor on the related sponsored project. Unusual circumstances should be discussed.
Princeton ERA Compliance SmartForm
Human Subjects – Update at JIT

1. * Does this project involve human subjects? 🎓
   - Yes ○ No Clear

   a. * Is this a clinical trial?
      - Yes ○ No Clear

   b. * Has the IRB Protocol been submitted?
      - Yes ○ No Clear

   c. * IRB Protocol Numbers:
      
      | IRB Number | Status | Exemption Numbers | Approval Date | Expiration Date |
      |------------|--------|-------------------|---------------|----------------|
      |            |        |                   |               |                |

      There are no items to display
If **NO** to Vertebrate Animals is selected, no other information is needed.
If **YES** is selected for **Vertebrate Animals** research, most often we would expect the secondary answer to be **Pending** (since this work is for a new proposal/scope of work)

- The protocol number can simply be added/updated to approved in ERA during the award/JIT state
- This protocol information feeds to PRIME at award set up and end dates are reviewed at each funding increment (if any)
- PIs on a project and protocol should be aligned
  - Be considerate of Mentors/PIs when working on Fellowship applications that include Vertebrate Animals. The PI on a protocol is expected to be the PI/Mentor on the related sponsored project. Unusual circumstances should be discussed.
Princeton ERA Compliance SmartForm

Vertebrate Animals

- If **YES** is selected for *Vertebrate Animals*, a Congruency Review may be a regulatory requirement.

- Congruency reviews ensure that the animal research activities in the project funded by the grant are covered by an IACUC approved protocol(s).

- Congruency review must be conducted by the RIA team for any proposals with animal research where congruency review is required by the sponsor.
  - Current sponsors requiring congruency reviews:
    - National Institutes of Health (NIH)
    - All NIH subdivisions (e.g. NCI, NHLBI, NIAID, NIDDKD, NIAAA, etc.)
    - National Science Foundation (NSF)
    - US Department of Health & Human Services (DHHS)
    - USDA National Institute of Food and Agriculture
    - American Heart Association (AHA)
    - Department of Veterans Affairs (VA)
    - March of Dimes (MOD)
    - Cystic Fibrosis Foundation (CFF)
    - Susan G. Komen for the Cure

- Department of Defense conducts their own review for congruency prior to award
Princeton ERA Compliance SmartForm
Vertebrate Animals

2. * Are live, vertebrate animals used in this project? ☐
   - Yes ☐ No ☐ Clear

a. * Has the IACUC Protocol been submitted?
   - Yes ☐ No ☐ Clear

b. * IACUC Protocol numbers:
   
<table>
<thead>
<tr>
<th>IACUC Number</th>
<th>Status</th>
<th>Approval Date</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There are no items to display
Princeton ERA Compliance Process
Vertebrate Animals

★ Congruency Review Process
  ★ Award moves into the Princeton ERA JIT state when award document arrives
  ★ Department Administrator adds a new Ancillary Review
    ★ Follow the instructions in the Funding Proposal Guide
      ★ Organization Review: Add “RIA-IACUC” as the reviewer
      ★ Review Type: Compliance Review
  ★ RIA reviews the grant application that includes the aims/objectives of the project and vertebrate animal section for the required congruency review
  ★ RIA initiates the additional biosafety congruency review (if needed)
  ★ ORPA Award Specialist cannot set up a chart string until this is completed and ancillary reviews are approved
Princeton ERA Compliance Process
Vertebrate Animals

▷ If **YES** is selected for **Vertebrate Animals** and a Congruency Review is **not** required
  ◇ A congruency review is not required for animal work when the sponsors does not require such a review.

▷ The PI is responsible for making sure that the protocol is aligned with the sponsored project aims/objectives.
  ◇ This includes that the research team and funding source are all accurate in eRIA and aligned with the full scope of the work.
3. * Does this project involve the use of biological agents (including recombinant or synthetic nucleic acids)?
   - Yes  ○ No  Clear

   a. * Has the IBC Registration been submitted?
      - Yes  ○ No  Clear

   b. * IBC Registration numbers:

      | IBC Registration | Status | Approval Date | Expiration Date |
      |------------------|--------|--------------|----------------|
      |                   |        |              |                |

      There are no items to display
If **YES** is selected for **Biological Agents**, most often we would expect the secondary answer to be **Pending** (since this work is for a new proposal/scope of work)

- The protocol number can simply be added/updated to approved in ERA during the award/JIT state
- This protocol information feeds to PRIME and end dates are reviewed at each funding increment (if any)
- PIs on a project and protocol should be aligned
  - Be considerate of Mentors/PIs when working on Fellowship applications that include Human Subjects. The PI on a protocol is expected to be the PI/Mentor on the related sponsored project.
If **YES** is selected for *Biological Agents*, a Congruency Review may be a regulatory requirement.

Congruency reviews ensure that the Biological Agent activities in the project funded by the grant are covered by an IBC approved protocol(s).

RIA initiates the IBC Congruency Review. No further action from Department.
Princeton ERA Compliance SmartForm
Chemical or Select Agent

12. * Select if any of the following will be used for this project: ☐
☐ Chemicals of interest as listed by the Dept of Homeland Security (6 CFR 72)
☐ Explosive, unstable, reactive materials or processes that could create these materials
☐ Generation of hazardous gases: highly toxic, pyrophoric, unstable reactive or corrosive
☐ Particularly hazardous substances: carcinogens, reproductive and developmental toxicants, or acutely toxic materials
☐ Unbound engineered nanomaterials
☐ Radiation producing equipment: Ionizing (e.g. x-ray)
☐ Radiation producing equipment: Non-Ionizing (e.g. microwave/radiofrequency)
☐ High power magnets or equipment that produces significant ambient magnetic fields (> 30 Gauss)
☐ Biological materials requiring biosafety level 2 or higher containment conditions
☐ Invertebrate animals that require containment facilities
☐ Toxins or biological materials regulated as Select Agents
☐ None of the above

Data is collected for Environmental Health and Safety (EHS) and available via a report.
Princeton ERA Compliance SmartForm

Data Security

<table>
<thead>
<tr>
<th>Data Security</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Does the project involve access to, use of, or generation of secure or regulated data sets (e.g., HIPPA, CUI, GDPR, etc.) among the project parties? Yes [ ] No [ ]</td>
</tr>
<tr>
<td>If yes, please describe the secure or regulated data set(s), including the controls that apply.</td>
</tr>
</tbody>
</table>

14. Does the project involve access to, use of, or generation of secure or regulated data sets (e.g., HIPPA, CUI, GDPR, etc.) among the project parties?  
- [ ] Yes  
- [ ] No  
- [ ] Clear  

- Please describe the secure or regulated data set(s), including the controls that apply.
Princeton ERA Compliance SmartForm

Data Security

- If **NO**, no other information is needed.
- If **YES** is selected for Data Security
  - ORPA may have follow up questions prior to proposal submission
  - Report is generated once per week
  - Answers are reviewed by Aaron Collie, Research Data Security Manager
  - This answer is also relevant in non-financial agreements and reviewed regularly by GCA and/or Liz Powell, Contracts Manager
  - Ancillary Review may be requested, if needed
  - Research Data Security Manager/Contracts Manager/GCA work with PI on any additional security plans, including requesting appropriate consistency with any IRB protocol(s)
## University Research Board (URB) Review Questions

4. Is there a lab or facility space change required for this project? If yes, attach details.
   - Yes [ ]
   - No [ ]

5. Does this project require Biosafety Level 3 (BSL-3) handling?
   - BSL-3 means work with agents that may cause serious or potentially lethal disease through inhalation route exposure.
   - Yes [ ]
   - No [ ]

6. Do you anticipate acquiring any materials, equipment or information that is controlled under the International Traffic in Arms (ITAR)?
   - Yes [ ]
   - No [ ]

   If yes, please enter the following:
   - Manufacturer Name [ ]
   - Model Number [ ]
   - Description of article or information being accessed [ ]

7. During the course of the project, are you collaborating with, receiving funding from or traveling to any of these countries?
   - Cuba [ ]
   - Iran [ ]
   - Iraq [ ]
   - North Korea [ ]
   - Syria [ ]
   - Ukraine [ ]
   - Russia [ ]
   - Belarus [ ]
   - None of these [ ]

8. Specific to this project, are you collaborating with or receiving funding from persons or organizations located in any of the countries listed below? If yes, please also ensure this relationship is described in the proposal documentation to be submitted to the sponsor.
   - China [ ]
   - Russia [ ]
   - Saudi Arabia [ ]
   - None of these [ ]
University Research Board (URB) Process Flow Chart*

1. Proposal Agreement Routed through Office of Research and Project Administration (ORPA) via Princeton ERA

2. Proposal flagged for URB Review @ proposal stage for:
   - Positive URB compliance question(s) checked
   - 30M threshold
   - Unusual risk/implications

3. Ancillary Review added in Princeton ERA to ORPA-URB

4. ORPA Assistant Director sends the Proposal Agreement scope of work (SOW) and associated documents to one division I/II URB reader and one division II/IV URB reader with reason proposal was flagged for review

5. URB readers review and anonymously ask questions of project PI (relayed via ORPA as needed)

6. If project involves sensitive countries (currently China, Russia, Saudi Arabia) DFR, DOF, and Provost have final approval

7. If fully approved, project may proceed; Ancillary Review removed

8. Both URB readers approve

9. Proposal/Agreement is reviewed by full URB

10. If project involves sensitive countries (currently China, Russia, Saudi Arabia) DFR, DOF, and Provost have final approval

11. If fully approved, project may proceed; Ancillary Review removed

12. One or both URB readers disapprove

*This process only applies to sponsored projects routed through ORPA

Office of Research and Project Administration
Princeton ERA Compliance Process

URB Review

- If all **NO**, no other information is needed
- If **YES**, the URB Review Process must be completed prior to acceptance of award
- Positive Answers are collected via a report and Ancillary Reviews are added manually
- Projects with unusual risk can also be flagged ad hoc
- The URB reviews the project for the overall risk (**including reputational risk**) to the university, not the proposed science
  - A report is also generated for all proposals over **30M** for a secondary URB Review
  - ORPA signing authority is capped at 30M
Princeton ERA Compliance SmartForm
Lab or Facility Space Change

7. * Is there a lab or facility space change that would result from this proposal?
   - Yes  ○ No  Clear

   * Please describe the lab or facility space change, including space requirements that are atypical in either nature or size
Princeton ERA Compliance Process
Space Change URB Review

- If **YES**, URB Review Process must be complete prior to acceptance of award
- A separate Ancillary Review is added for the Vice Provost for Space Programming
- If submitting through an engineering department, a separate Ancillary Review is added for SEAS
- Proposal documents and response from Vice Provost review is shared with the URB Readers
- If Vice Provost Ancillary Review is approved and both URB Readers approve, the URB Ancillary Review is cleared
- If not approved by both readers, review goes to the full URB
8. * Does this project require Biosafety Level 3 (BSL-3) handling? (BSL-3 means work with agents that may cause serious or potentially lethal disease through inhalation route exposure.)

- [ ] Yes
- [ ] No

Clear
Princeton ERA Compliance Process
BSL-3 URB Review

▷ If **YES**, the URB Review Process must be completed prior to acceptance of award

▷ A separate Ancillary Review is added for the Vice Provost for Space Programming

▷ Proposal documents and response from Vice Provost review is shared with the URB Readers

▷ If Vice Provost Ancillary Review is approved and both URB Readers approve, the URB Ancillary Review is cleared

▷ If not approved by both readers, review goes to the full URB
6. * Do you anticipate acquiring any materials, equipment, or information that is controlled under the International Traffic in Arms Regulations (ITAR)? No ITAR controlled items or information may be brought onto Princeton’s campus (this includes accessing ITAR controlled information from University networks or computers) without official University approval. ☐ Yes ☐ No    Clear

* Description of ITAR controlled items or data
Princeton ERA Compliance SmartForm ITAR - URB Review

▷ If **YES**, the URB Review Process must be completed prior to acceptance of award
▷ A separate Export Ancillary Review is also conducted
▷ Proposal documents and response from Export Review is shared with the URB Readers
▷ If Export Ancillary Review is approved and both URB Readers approve, the URB Ancillary Review is cleared
▷ If not approved by both readers, review goes to the full URB
* During the course of this project, are you collaborating with, receiving funding from, or traveling to any of the countries listed below?

- Belarus
- Cuba
- Iran
- Iraq
- North Korea
- Russia
- Syria
- Ukraine
- None of the above
Princeton ERA Compliance SmartForm Collaboration, Funding From or Travel to a country Embargoed under United States regulatory requirements **URB Review**

- **If** **YES**, the URB Review Process must be completed prior to acceptance of award
- A separate Export Ancillary Review is also conducted
- Proposal documents and response from Export Review is shared with the URB Readers
- **If** Export Ancillary Review is approved and both URB Readers approve, the URB Ancillary Review is cleared
- **If** not approved by both readers, review goes to the full URB
10. *Specific to this project*, are you collaborating with or receiving funding from persons or organizations located in any of the countries listed below? If yes, please also ensure this relationship is described in the proposal documentation to be submitted to the sponsor.

- China
- Russia
- Saudi Arabia
- None of the above
Princeton ERA Compliance Process
Sensitive Countries - URB Review

- If **YES**, the URB Review Process must be completed prior to acceptance of award
- A separate Export Ancillary Review is also conducted
- Proposal documents and response from Export Review is shared with the URB Readers
- If Export AR is approved, and both URB Readers approve, the Dean for Research reviews for Higher Level Approval with Provost and Dean of Faculty
- If not approved by both readers, review goes to the full URB
Princeton ERA Compliance Questions Export Control Questions

4. * Will any equipment, materials, or supplies be exported (including by hand-carrying) to another country by Princeton University in the course of this project? If yes, please include the manufacturer name & model number. (This includes Fabricated Equipment.)
   - Yes  ○ No

   * Item Description:
     Lenovo ThinkPad X-1 Carbon (2020)

6. * Do you anticipate acquiring any materials, equipment, or information that is controlled under the International Traffic in Arms Regulations (ITAR)? No ITAR controlled items or information may be brought onto Princeton’s campus (this includes accessing ITAR controlled information from University networks or computers) without official University approval.
   - Yes  ○ No  Clear

   * Description of ITAR controlled items or data
Princeton ERA Compliance Questions

Export Control Questions

9. * During the course of this project, are you collaborating with, receiving funding from, or traveling to any of the countries listed below?

- Belarus
- Cuba
- Iran
- Iraq
- North Korea
- Russia
- Syria
- Ukraine

13. * During the course of the project, do you anticipate receiving materials, equipment or information subject to the Export Administration Regulations (EAR), excluding those with a classification of EAR99, from the project sponsor or a third party? (See Export Control website for additional information.)

  - Yes  
  - No

* Please describe the export-controlled materials, equipment or information that may be received, including the Export Control Classification Number (ECCN), if known.
Princeton ERA Compliance Questions

ERA Reports

» Weekly reports are run to identify projects with potential export control concerns.
  » In **NO**, no other action is required.
  » If **YES**, Export Controls will review the responses and will likely follow up with the PI.

» Reports are run on other ERA Compliance Question responses to ensure compliance.
Princeton ERA – Compliance and Personnel SmartForm
Non-US persons not employed by a US institution

5. * Do you anticipate working directly with any non-US persons not currently employed by a US institution in the course of this proposed research (e.g., by exchanging information, equipment, or materials)? If yes, please list the name, country and employer for each non-US individual in the Personnel Page Question 3B. (Search the Princeton website for "Restricted Party Screening" for additional information.)

- Yes  - No

For subrecipients, add all personnel who are Senior/Key Persons for the project.

For all others, add all personnel provided in response to Compliance Review Question 5 as per the Funding Proposal Guide
Princeton ERA – Restricted Party Screening

Visual Compliance

- All project personnel are screened through Visual Compliance to check for restricted/debarred parties
  - Visual Compliance screening process is automated
    - Matches are reviewed by Export Controls
  - IMPORTANT for proper Visual Compliance Screening
    - Enter fields 3a–3h. Ensure Country (3g) is entered
    - Organization (4b) is required.
    - Enter full names of all individuals and organizations
      - Avoid using acronyms
Princeton ERA Quick Guides

Compliance Review Questions Quick Guide

This chart lists the questions on the Princeton ERA Compliance Review page and provides additional information.

<table>
<thead>
<tr>
<th>Q#</th>
<th>Compliance Review Question</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Does this project involve human subjects?</td>
<td>The definition of human subjects can be found on the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Human Research page of the RIA website.</td>
</tr>
<tr>
<td>Q2</td>
<td>Are live, vertebrate animals used in this project?</td>
<td>This includes work off campus, field work,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>subawards, etc.</td>
</tr>
</tbody>
</table>

Adding Proposal Ancillary Reviews Quick Guide

Please see the chart on the second page of this quick guide for specific reviewers, comments, and attachments that should be included in the ancillary review request depending on the scenario.

After clicking OK in #10, an email is sent to the person specified in #1 or the people associated with the "organization" in #1. The email will come from erasupport@princeton.edu (not from your email address).

- Only the comments in #6 are included in the email.

All ERA Guides by Role