



## COMPLIANCE REVIEW QUESTIONS QUICK GUIDE

---

This table lists the questions on the Princeton ERA Compliance Review page in Grants and Agreements and provides additional information.

### **Q1. Does this project involve human subjects?**

The definition of human subjects can be found on the Human Research page of the [RIA website](#).

### **Q2. Are live, vertebrate animals used in this project?**

This includes work off campus, field work, subawards, etc.

### **Q3. Does this project involve research activities that fall under the oversight of Princeton University's Institutional Biosafety Committee (IBC)?**

An IBC registration is required for activities that involve:

- Recombinant and synthetic nucleic acid molecules (r/sNA), as defined in the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines).
- Biological Dual Use Research of Concern (DURC)
- Biological toxins
- Microorganisms, including viruses, bacteria, fungi, parasitic agents, and prions that could be harmful to humans, plants, or animals
- Infected research animals
- Genetically engineered models (GEMs)
- Human and non-human primate blood and tissues, and other animal tissues that may present zoonotic and/or other infectious disease concern(s)
- Field research with animals and/or animal specimens known to be reservoirs of zoonotic disease.

Please contact the IBC office for assistance: [IBC@princeton.edu](mailto:IBC@princeton.edu)

### **Q4. Human embryonic stem cells involved in this project**

In some cases, stem cell lines can be determined from your Funding Opportunity. Or, go to the NIH Human Embryonic Stem Cell Registry web site.

### **Q5. 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. xray)**
- **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**

Please see additional information on these items: [Chemicals of Interest](#), [Particularly Hazardous Substances](#), [Select Agents](#)

### **Q6. Does the project involve access to, use of, or generation of secure or regulated data sets (e.g., HIPAA, CUI, GDPR, etc.) among the project parties?**

Some proposal solicitations may indicate that the University is expected to receive, generate or transfer data subject to security or export control requirements. PIs also often have knowledge about such requirements that may not be spelled out in the solicitation, and certain corporate sponsored research projects do not have solicitations. Furthermore, this proposal-stage question would permit ORPA to involve the Information Security Office at an earlier stage of planning for the project to validate the need for and costs to support the secure research project data of the project.

**Controlled Unclassified Information ("CUI")** – CUI is information the federal government creates or possesses, or that an entity creates or possesses for or on behalf of the federal government, that a law, regulation, or government-

wide policy requires or permits an agency to handle using safeguarding or dissemination controls. CUI designations and safeguarding requirements are only applicable when mandated by a federal agency in a contract, grant, or other agreement. Examples of CUI data could include but are not limited to financial documents, invoices, engineering drawings, technical specification, diagrams, and blueprints.

**Personal Data as defined by the EU's General Data Protection Regulation ("GDPR")** – Regardless of where the data are processed, personal data relating to residents of the European Economic Area ("EEA") are protected by extraterritorial privacy law. Additionally, data which cross international borders may be subject to additional requirements or protections. Data in this category may include any type of PII data that directly or indirectly identify citizens or residents of the EU, or data which are shared with collaborators or entities in another country.

**Personal Information as defined by China's Personal Information Protection Law ("PIPL")** – Regardless of where the data are processed, personal information relating to residents of the People's Republic of China ("PRC") are protected by extraterritorial privacy law. Additionally, data which cross international borders may be subject to additional requirements or protections. Data in this category may include any type of PII data that directly or indirectly identify citizens or residents of China, or data which are shared with collaborators or entities in another country.

**Protected Health Information ("PHI") covered by the Health Insurance Portability and Accountability Act ("HIPAA")** – Personally identifiable information (PII) that is used in conjunction with medical records, including payment for medical care becomes Protected Health Information (PHI). Data in this category may include medical or health information from a healthcare provider, health plan, employer, or healthcare clearinghouse and relates to a person's physical/mental health or condition, the provision of health care to a person, or payment for the provision of health care to a person; or was created, received, maintained, or transmitted from a covered entity or business associate subject to HIPAA rules.

**Educational Records covered by the Family Educational Rights and Privacy Act ("FERPA")** – FERPA defines an education record as any record directly related to a student which contains personally identifiable information and is maintained by the university or a party acting on behalf of the university. Examples of FERPA protected data could include but are not limited to grades, transcripts, enrollment records, advising records, testing and assessment data, correspondence, class lists, student course schedules, and disciplinary records.

**Student financial records and other financial records covered by the Gramm-Leach Bliley Act ("GLBA")** – GLBA applies to higher education institutions specifically to the collection, storage and use of student financial records containing personally identifiable information, and to financial institutions and entities which receive customer information from other financial institutions. Examples of GLBA protected data could include but are not limited to tuition payment history, bank and credit card information, financial aid information (including FAFSA), parent financial records, credit reports and scores, account balances, payment history, investment information and loan application information.

**Q7. Is there a lab or facility space change that would result from this proposal?**

The intent of this question is to capture space needs that are beyond those currently available to the researcher and needed to complete the proposed research. An Ancillary Review is required; see the [AR Quick Guide for Proposals](#) or the [AR Quick Guide for Agreements](#).

**Q8. Does this project require Biosafety Level 3 or 4 (BSL-3 or BSL-4) handling?**

BSL-3 and BSL-4 means work with agents that may cause serious or potentially lethal disease.

**Q9. 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.**

Please see <https://orpa.princeton.edu/export-controls/policy/regulations> for additional information regarding ITAR-controlled equipment, materials and information.

**Q10. During the course of this project, are you collaborating with, receiving funding from, or traveling to any of the countries listed below? Check all that apply.**

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

These countries are subject to OFAC sanctions (<https://orpa.princeton.edu/exportcontrols/sanctioned-countries>). Activities with these countries may require prior government authorization.

**Q11. 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 (or agreement) documentation to be submitted to the sponsor. Check all that apply.**

- People's Republic of China (including Hong Kong and Macau)
- Russia
- Saudi Arabia

The intent of this question is to capture collaborators actively engaged in this project, not all overseas collaborators with whom a PI is engaged.

**Q12. Will any equipment, materials, or supplies be exported (including by hand-carrying) to another country by Princeton University in the course of this project? This includes Fabricated Equipment.**

The intent of this question is to determine if transferring the equipment, materials, or supplies requires a US government export license.

**Q13. 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?**

This question is intended to identify projects requiring the receipt (whether from the sponsor or via procurement) of items or technology that may require an export license in order to be shipped overseas or for a foreign person to have access to the item or technology. Please see <https://orpa.princeton.edu/export-controls/>.

**Q14. Do you anticipate working directly with any non-US persons not currently employed by a US institution in the course of this proposed research (or project) (e.g., by exchanging information, equipment, or materials)?**

Only collaborators on this project should be listed here. Princeton will use responses to determine if any US government restrictions apply to parties listed in this question. Please see <https://orpa.princeton.edu/export-controls/non-us-persons/restricted-party-screenings>.

**Q15. (Agreements only) Is this Non-Financial Agreement directly related to either an externally funded proposal, an existing external award/agreement, or an external award/agreement currently under negotiation? If yes, use the Manage Relationships activity to link to the funding proposal and/or agreement record.**

**Q15. (Grants only) Does this proposal require that additional administrative staff be hired?**

The addition of HR staff, budgeted or not budgeted in the proposal, is subject to approval by the Office of the Provost and the Office of Human Resources.

**Q16. (Grants only) Does this proposal require the creation of a new center, institute, or other administrative unit to support or administer it?**

Typically new centers or institutes are reviewed by the Academic Planning Group (APG).

**Q17. (Grants only) Does this proposal require the creation of a new course/set of courses or new credential (minor, certificate, degree)?**

As per the Academic Planning Group (APG), the addition of courses should be discussed with the head of the department or unit that will host the instructional component. The proposed addition of any credential program must also be discussed with the Office of the Dean of the College and/or the Office of the Dean of the Graduate School, depending on credential type.

Last update: 10/22/2024