

Compliance Review Questions Quick Guide

Last Updated April 6, 2022.

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

Q#	Compliance Review Question	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 the use of biological agents (including recombinant or synthetic nucleic acids)?	Biological agents include infectious and potentially infectious agents, human and non-human primate materials, biological toxins, and Genetically Engineered Models (GEMs). Recombinant or synthetic nucleic acids (r/s NA) molecules are as defined by the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.
Q4	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.)	The intent of this question is to determine if transferring the equipment, materials, or supplies requires a US government export license.
Q5	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.)	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.
Q6	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. If yes, provide a description of ITAR controlled items or data.	Please see https://orpa.princeton.edu/export-controls/policy/regulations for additional information regarding ITAR-controlled equipment, materials and 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 Proposal AR Quick Guide .
Q8	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.
Q9	During the course of this project, are you collaborating with, receiving funding from, or traveling to Belarus, Cuba, Iran, Iraq, North Korea, Russia, Syria, and/or Ukraine?	These countries are subject to OFAC sanctions (https://orpa.princeton.edu/export-controls/sanctioned-countries). Activities with these countries may require prior government authorization.
Q10	Specific to this project, are you collaborating with or receiving funding from persons or organizations located in China, Russia, and/or Saudi Arabia? If yes, please also ensure this relationship is described in the proposal documentation to be submitted to the sponsor.	The intent of this question is to capture collaborators actively engaged in this project, not all overseas collaborators with whom a PI is engaged.

Q11	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.
Q12	<p>Select if any of the following will be used for this project:</p> <ul style="list-style-type: none"> • 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 	<p>Please see additional information on these items:</p> <p>Chemicals of Interest: https://www.cisa.gov/publication/cfats-coi-list</p> <p>Particularly Hazardous Substances: https://ehs.princeton.edu/laboratory-research/chemical-safety/particularly-hazardous-substances</p> <p>Select Agents: https://www.selectagents.gov/SelectAgentsandToxinsList.html</p>
Q13	<p>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 https://orpa.princeton.edu/export-controls). If yes, please describe the export-controlled materials, equipment or information that may be received, including the Export Control Classification Number (ECCN), if known.</p>	<p>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.</p>
Q14	<p>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? If yes, please describe the secure or regulated data set(s), including the controls that apply.</p>	<p>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.</p>