RESEARCH ADMINISTRATION MANAGEMENT PORTAL

RAMP

RAMP | EXPORT CONTROL HOW TO GUIDE

BIOLOGICS ACCESS CONTROLS

This guide is designed to aid in the process of creating requests in the RAMP Export Control module. For further assistance, please contact RAMP Export Control Support at RAMP-ExportControl@fsu.edu.

BACKGROUND ON BIOLOGICS AND EXPORT CONTROLLED RESTRICTIONS:

Under the Export Administration Regulations ("EAR"), many bacteria, viruses, toxins, and fungi are highly regulated and are considered "controlled biologics." Access to these biologics may be restricted for unauthorized personnel (including certain foreign nationals) depending on the level of control required, laboratory controls present, and anticipated use of the biologic. In many cases, genetic material (e.g. genetically modified materials) containing any part or form of the controlled biologic is likewise regulated.

Unless otherwise noted, information about such biologics that is *already in the public domain* is not controlled; nor is information *resulting from fundamental research* that involves using the controlled biologics. However, information concerning the further development or pathogenicity of these materials that is explicitly restricted pursuant to a U.S. Government contract or restricted subaward thereof may be export controlled. This includes but is not limited to Dual Use Research of Concern (DURC).

It is unlawful under the EAR to transfer controlled biologics internationally to a foreign national or entity (including FSU personnel) located *outside* the United States *without an appropriate governmental authorization*. This export restriction is applicable even if there is an interinstitutional agreement that contemplates international collaboration: the export restriction operates independently of such an agreement and must be complied with according to the EAR regulations.

For purposes of potential access restrictions to which FSU (by contract) may be obligated to comply with, a foreign national is any person who is not a U.S. citizen, or permanent resident alien, or has special status in the U.S. (e.g., persons granted refugee or asylum status). Hence, a foreign national is any individual present in the U.S. on temporary immigrant visa status (e.g. H-1B, O-1, J-1, F-1, B-1 visa categories).

Violations of EAR regulations may result in substantial monetary penalties and criminal charges against both the institution and individual researchers. FSU personnel should exercise due care when using or sharing controlled biologic(s) to ensure that this use is consistent with any export restrictions incorporated into the research funding agreement, and to ensure that only those persons explicitly authorized under a *Biologics Access Control Plan* (BACP) are allowed access to the controlled biologic(s) covered herein. The BACP outlines the access and security controls that apply to access, use and storage of the controlled biologic(s) as authorized by FSU's Biosafety Office and Office of Research Compliance Programs.

Therefore, the RAMP Export Control Request Type of **Biologics Access Control** should be submitted only when controlled biologics are used in a BSL-2 or BSL-3. Approval of this type of request results in a *Biologics Access Control Plan* that will define the following areas:

- Level of Containment Required
- Physical Security
- Personnel Authorized to Access the Biologic
- Compliance Monitoring

Basic Information

Question 1, Select the employee responsible for this request:

This field will automatically populate the name of the person who creates the export control request. If the person creating the request is the responsible party, no changes are needed. If the person creating the request is a proxy for the responsible party (e.g., dept. rep.), be sure to perform the following steps:

Option 1 – Complete the request then update the responsible party	**Option 2 – Change the responsible party then complete the request**
1) Continue to complete the export control request. On the last page, Supporting Documents, click "Finish". 2) On the left navigation pane, click "Manage Editors List" activity. Add your (proxy's) name, and click OK. 3) On the left navigation pane, click "Edit Export Control" button. Change the responsible party's name on the "Basic Information" page to the appropriate person.	1) From the "Basic Information" page, click "Continue". On the next page, click "Exit". 2) On the left navigation pane, click "Manage Editors List" activity. Add your (proxy's) name, and click OK. 3) On the left navigation pane, click "Edit Export Control" button. Change the responsible party's name on the "Basic Information" page to the appropriate person and continue to complete the export control request.

Note: Only the named responsible party can submit the export control request. If you change the responsible party's name before you assign yourself as an Editor, you will no longer have access to this Request.

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1. * Select the employee responsible for this request: 	This field will automatically populate the name of the person who is logged into in the system.

Questions	How To Guide
2. * Type of request: **Visitor:** Select "Visitor" for Visiting Scholar (Paid or Unpaid) or Short-Term Visitor to (1) Register a foreign visitor for a stay of 14 days or less, or (2) To request approval to invite a foreign or domestic visitor for a stay of more than 14 days as a Visiting Scholar. See document in RAMP Export Control Help Center for assistance in determining when this Request Type should be selected versus selecting Visa (I 129 Part6) Request Type below. **Shipment:** Select "Shipment" to request an international shipment only. Approval is not required for domestic shipments. **Visa (I 129 Part 6):** Select "Visa (I 129 Part 6)" to request to hire a foreign national (international employee). This category includes postdoctoral scholars, FSU students, and Faculty, A&P, USPS, or OPS positions not falling under the Visiting Scholar policy. See document in RAMP Export Control Help Center for assistance in determining when this Request Type should be selected versus selecting Visitor Request Type above. **Sponsored Research, Collaborations, and other Agreements:** Select "Sponsored Research, Collaborations, and other Agreements" if the sponsored research involves components of Export Control (ITAR or EAR) - i.e., RAMP Grants submission indicates that an Export Control is involved in the project. **DD Form 2345:** Select "DD-2345" if FSU's DD Form 2345 is needed: (1) for DoD solicitations that involve access to export-controlled data, (2) for conference/meeting attendance with export-controlled material/data, (3) for export-controlled technical data exchange between vendors, (4) to obtain Request for Proposal (RFP) details with export-controlled data, (5) for DoD Research/Development projects involving export-controlled data, or (6) to participate in a Directly Arranged Visit (DAV) (Canada to U.S. or U.S. to Canada). ❍ Visitor ❍ Shipment ❍ Visa (I-129 Part 6) ❍ Sponsored Research, Collaborations, and other Agreements ❍ DD-2345 ❍ Biologics Access Controls Clear	Review the Background information on Page 1 to determine if this type of request is necessary. If so, select Biologics Access Controls.
3. * Title (max 50 characters):	Enter a title for this request. For example, "Biologics Access for Dr. Sam Smith"
4. * Principal Investigator:	Select the PI associated with this request. .
5. * Department or research unit:	Select the responsible department.

Questions	How To Guide
6. * Locations of biologics laboratory: [...] **Name** | **Building** | |	Select the location where the biologics will be used.
7. * What is the Biosafety Level of the lab? ☐ **BSL-2** ☐ **BSL-3**	Check the appropriate biosafety containment level for the associated biologic. If only a general research laboratory is used, submission of this Request is not necessary.
8. If externally sponsored, enter OMNI Project ID:	If applicable, enter OMNI Project ID.
9. * Project start date:	Entered the date the biologics will arrive on campus.
10. * Project end date:	Enter the date the biologics are no longer on campus.
11. Annual Review Due Dates: Annual Review #1: Annual Review #2: Annual Review #3: Annual Review #4:	Leave these fields blank. The Office of Research Compliance Programs will assign appropriate plan review dates.
12. Export restricted biologics and export classification: **Biologic name** | **Associated ECCN** | | **[+ADD]**	Enter the name of the controlled biologics. The Office of Research Compliance Programs will assign appropriate ECCNs.

Supporting Documents

Questions	How To Guide
1. Attach additional supporting documents: For both Visitor (Visiting Scholar (Paid and Unpaid)) and Visa (International Employee) Request Types, a completed and signed "Certification Regarding Participation in a Foreign Government Talent Recruitment Program (FGTRP)" must be uploaded here as a supporting document. For Visitor (Visiting Scholar (Paid and Unpaid)) Request Type, a completed and signed "Visiting Scholar Agreement Form" will be requested by the Office of Research Compliance Programs and uploaded here prior to finalizing the Request. + Add **Document Name** | **Date Modified** Please take this opportunity to review the information you have provided. It is very important that the responses in this submission be thorough and specific. Failure to respond to all requested items, to submit all required documents, or complete all personnel requirements will result in a delay in the review of this submission and may result in the submission being returned to the responsible party for correction or completion. Please note that this submission has not yet been submitted for review. Upon completing the information in this submission and clicking the "Finish" button below, the responsible party must also click the "Submit" activity from the submission workspace in order to forward this submission for review.	Provide any additional supporting documents (such as a Material Transfer Agreement) associated with or describing this Request.
Review and Submit: • Please review the entered information for accuracy before submitting. • Click "Finish" on this form to return to the workspace. • Update the Manage Editors activity as needed as described on Page 2. • On the left side of the workspace, click on the "Submit" activity and click "OK".	Be sure to complete the final steps outlined here to submit your Request for review.