

**Harvard Pilgrim Health Care, Inc.**  
**Harvard Pilgrim Health Care Institute, LLC**  
*Office of Sponsored Programs and Office of Research Integrity & Compliance*

**Policy and Procedure**

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**TITLE:** Export Controls and Restricted Party Screening in Procurement and Payment

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**PURPOSE:**

This policy is intended to prevent Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (together HPHC/I) from making prohibited payments to individuals or entities found on any government-issued restricted, blocked, or denied party lists, and to ensure compliance with all laws and regulations that pertain to the conduct and dissemination of research, including export control regulations.

Activities subject to this policy may include but are not limited to: contracts requiring pre-screening of payees, international subcontracts, procurement transactions, honoraria, payroll, compensation to research study participants, and the transfer of items and information regulated for reasons of national security, trade sanctions policy, anti-terrorism, or non-proliferation.

Compliance depends on timely screening of prospective vendors and payees and appropriate responses by HPHC/I personnel when HPHC/I identifies listed parties.

**PERSONS AFFECTED:**

This policy & procedure (P/P) applies to all HPHC/I personnel engaged in research, teaching, or research administration activities in support of the charitable and educational mission of HPHC/I.

**POLICY:**

HPHC/I shall not enter into contracts, conduct business, or otherwise participate directly or indirectly, in any activities with any entity or person found on any government-issued restricted, blocked, or denied party lists. HPHC/I shall comply with all applicable legal, regulatory and contractual requirements intended to prevent it from making prohibited payments to individuals or entities, including those from sanctioned or embargoed countries, found on any government-issued restricted, blocked, or denied party lists.

HPHC/I is fully committed to complying with all laws and regulations that pertain to the conduct and dissemination of research, including export control regulations. HPHC/I activities include expanding human knowledge through analysis, innovation, and insight. HPHCI Researchers

(e.g., faculty members, visiting scholars, and post-doctoral fellows) collaborate with colleagues across the Institute, at affiliated institutions, and at other research institutions in the United States and around the world. During the course of such open research, it is likely that at one time or another, it may intersect with US Export Control regulations that impose access, dissemination, or participation restrictions on the transfer of items and information regulated for reasons of national security, trade sanctions policy, anti-terrorism, or non-proliferation.

### **Exclusions to the export control regulations**

- a) **Fundamental Research;** research at HPHCI will normally be considered fundamental research unless the HPHC/I or its researchers accept sponsor restrictions on publication of scientific and technical information resulting from the project or activity. Conducting fundamental research is key to maintaining an environment of openness in an academic setting. The *results* of research performed as fundamental research are not subject to export control laws and regulations. No license is needed to share these results, even if they relate to items or technologies that are otherwise controlled. This exclusion permits HPHC/I to allow foreign members of their communities (e.g., students, faculty, and visitors) to participate in research projects involving export-controlled information at HPHC/I in the U.S. without the need for a license. However, it does not permit the transfer of export-controlled information, materials, or items abroad, even to research collaborators, except under very limited circumstances. The Fundamental Research Exclusion *applies only to the dissemination of research data and information, not to the transmissions of material goods.*

Fundamental Research exclusions are destroyed if HPHC/I accepts any contract clause that:

- Forbids the participation of foreign persons;
- Gives the sponsor a right to approve publications resulting from the research; or
- Otherwise operates to restrict participation in research and/or access to and disclosure of research results.

“Side deals” between a PI and Sponsor to comply with such requirements, even though not stated in the research contract, may destroy the fundamental research exclusion and expose both the PI and HPHC/I to penalties for export control violations and may violate the Department of Population Medicine’s policies on openness in research.

- b) **Publicly Available/Public Domain:** Fundamental research is distinguished from research that results in information that is restricted for proprietary reasons or national security reasons (subject to Export Control Regulations, or EAR) or pursuant to specific U.S. government access and dissemination controls (subject to International Traffic in Arms Regulations, or ITAR). However, the following public domain exclusions might apply:

- Publicly available technology and non-encryption software, such as information that is the subject of an open patent application, published in a book or periodical, released at an open conference anywhere, available on a website accessible by the public with no access controls or information that will be published is not subject to the EAR.
  - Information which is already published and generally accessible to the public is not subject to ITAR. Information that is available through books, periodicals, patents, open conferences in the United States, websites accessible to the public with no access controls, or other public release authorized by the U.S. government, is considered in the public domain.
- c) **Educational Information:** information that is considered general educational material is also excluded from export control regulations:
- EAR: Release of information by instruction in catalog courses and associated teaching laboratories of academic institutions is not subject to EAR.
  - Information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges and universities is not subject to ITAR.

#### **DEFINITIONS:**

Consolidated Screening List (CSL): a list of parties for which the United States Government maintains restrictions on certain exports, reexports or transfers of items.

Deemed Export: Generally, any item (commodities, software or technology, technical information, blueprints, design plans, circuit boards, etc.) subject to the Export Administration Regulations (EAR) that is shipped or transmitted from the United States to a foreign destination is an export. In addition, technology, know-how, and non-encryption source code that is released to foreign nationals within the U.S. is “deemed” to be an export to the country where the person is a resident or citizen and could be subject to licensing requirements. This is what is commonly known as the “deemed export” rule.

Export: includes any oral, written, electronic or visual disclosure, shipment transfer or transmission of commodities, technology, information, technical data, assistance or software codes to anyone outside of the U.S. (including US citizen), a non-US individual (wherever they are), or a foreign embassy or affiliate.

Foreign Nationals: are any persons or entities who do not fall into one of the following categories:

- United States citizens;
  - Lawful permanent residents of the United States;
  - Refugees, asylees, and similarly protected individuals;
- Entities of the United States government, including both state and federal agencies; or Corporations, business associations, and other organizations incorporated or otherwise authorized to do business in the United States.

*Fundamental Research:* Basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

*System for Award Management (SAM.gov):* SAM.gov is the official U.S. Government website for entities who wish to conduct business with the U.S. Government. Entities with SAM registrations are able to utilize the site to find registration status and exclusion information for other entities.

## **PROCEDURE:**

### **Duties of Associate Grant Coordinator**

HPHC/I may contract for software services (such as Visual Compliance) or use other appropriate methods to implement appropriate screening of prospective payees against the SAM and CSL databases (“Restricted Party Screening”). Individuals and entities to be screened include but are not limited to employees, students, independent contractors, and vendors. Finance, Human Resources, the Office of Sponsored Programs (OSP) and Research Administration will cooperate with requests for data to support such screenings.

Appropriate actions to prevent prohibited transactions based on screening results will be taken, which may include but are not limited to: notifying other HPHC/I stakeholders, notifying the prohibited party, terminating contractual negotiations, and cancelling payment or procurement transactions.

It is the responsibility of the Associate Grant Coordinator (AGC) to perform Restricted Party Screening:

1. On individuals, subcontractors, and sub-awardees supported by research grants and contracts.
2. On all identified subcontract institutions and key personnel prior to submission to the funding agency.
3. Prior to the addition of a new subcontract or vendor to an existing award, the AGC will perform Restricted Party Screening of each subcontract institution or vendor.
4. The AGC will also check the Visual Compliance System when HPHC is receiving a grant from a foreign institution.

If at any time an individual or entity name appears during the Restricted Party Screening, the Director, Research Integrity & Compliance Officer (DRICO) shall be notified immediately for appropriate action.

## **Duties of Principal Investigators**

Export control regulations apply most frequently to international collaborations, foreign travel, and shipping or carrying items to other countries. When export controls apply—for example, when we use disclosure-restricted technical information to generate our fundamental research or hand carry items outside the US in our baggage—the export of regulated items, information, or software may require approval from the US Government in the form of an export license. An export license permits "controlled" tangible items or software to be sent outside of the US, or controlled information or software code to be shared with foreign persons, either in the US or abroad.

Most of the information or software that HPHC/I shares with its colleagues and research partners is not export controlled or subject to trade sanctions, and the majority of tangible items that HPHC/I exports (like materials, components, or equipment), do not require export licenses since they are generally not destined to countries of concern or to individuals or organizations subject to US embargoes or sanctions. However, all HPHC/I personnel are required to demonstrate their due diligence and to document their adherence to US export controls and trade sanctions laws when such laws apply.

The PI (or designee) at HPHC/I shall complete the Sponsored Projects application in Cayuse SP Proposals regarding Export Control. The PI will identify whether:

- there are other HPHC/I study personnel with citizenship of a country other than the United States;
- if HPHC/I will receive funds from a foreign institution;
- if HPHC/I will issue subcontracts to foreign institution;
- if any vendors, consultants, strategic technical partners or other external collaborators from foreign countries or incorporated outside the U.S. be utilized for the project;
- if any work take place in a country other than the country in which a collaborator is incorporated;
- if HPHC/I faculty or staff will travel to a foreign country to conduct work related to the project or attend a project related conference;
- if any research materials, equipment (including HPHC laptops or network connected cell phones), or data accompany HPHC/I faculty or staff when they travel outside of the United States; or
- if any research materials, equipment (including HPHC laptops), data, or biospecimens will be shipped outside of the United States.

If the PI identifies intention to travel outside of the U.S. with research materials, HPHC/I equipment, or data, the PI must secure approval from Point32Health, Inc. See *Policy and Procedure on International Travel and Foreign Collaborations*.

The PI is also responsible for disclosing all export issues cited above to their Grants Manager (GM) at any time throughout the life cycle of a project. The DRICO will then review all instances related to Export controls either as submitted with the initial proposal, or via a Task created by the GM should the PI identify an Export issue after the initial proposal is submitted.

### **Duties of the Director, Research Integrity & Compliance Officer (DRICO)**

The DRICO will review the Export Control tab in Cayuse and will consult with the AGC who will run a Visual Compliance screening for personnel identifying non-US citizenship, foreign funds, collaborators or institutions, and/or a screening on international conference location as indicated by the PI. The DRICO will “approve” the Export Control review in Cayuse to confirm no restrictions or concerns were identified during the screening. Comments may be entered in Cayuse during the Export review noting any exceptions. If the PI has identified that research materials, equipment, or data will accompany faculty or staff outside of the US, the DRICO will notify the GM that the PI is required to obtain approval from Point32Health IT team. The DRICO will note this exception in Cayuse when approving the Export Review.

If the review returns information that discloses a country of concern or identifies the potential need for an Export license, the DRICO will consult with the GM to confirm the project falls under the category of *Fundamental Research* and to confirm the Institute and/or researchers have not accepted any sponsor restrictions on publication of scientific and technical information resulting from the activity or project as the work would no longer be considered Fundamental Research. The DRICO may consult with the DOSP, and/or the HPHCI Vice President, Administration & Finance regarding other instances where a potential Export Control issue has been identified prior to approving or returning the request to ‘in-development’.

If an Export review is required mid-study, the GM will create a Task in Cayuse to alert the DRICO that an Export review is required. The GM will provide details consistent with the ‘Duties of Principal Investigators’ described above. The DRICO will review the request and “close” the Task. The DRICO will then create a new Task and assign to the GM to “approve” the Export Control review in Cayuse to confirm no restrictions were identified during the screening. Comments may be entered in Cayuse during the Export review noting any exceptions.

### **Training**

All HPHCI personnel shall participate in training on U.S. export control laws and regulations at least once every four years and more frequently if there are significant changes to this policy or related regulations that affect the responsibilities of researchers or research staff, or as determined by HPHCI.

HPHCI uses an online Export Controls training program provided by the Collaborative Institutional Training Initiative (CITI). The CITI training program can be found at: [www.citiprogram.org](http://www.citiprogram.org) (See, *Policy and Procedure on Training*).

### **Penalties for Non-Compliance**

Failure of any HPHCI/I personnel to comply with this Policy and/or the requirements of any applicable federal export control regulations may lead to disciplinary action up to and including unpaid suspension or termination of employment.

<b>Department:</b> OSP Grants & Contracts/Office of Research Integrity & Compliance	<b>Title:</b> Export Controls and Restricted Party Screening in Procurement and Payment
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<b>Replaces P/P Dated:</b> 11/28/2017	
<b>Related Documents:</b>	
<p><b>References:</b></p> <p><u>Bureau of Industry and Security, U.S. Department of Commerce:</u> (<a href="http://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl">http://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl</a>)  <a href="https://www.pmddtc.state.gov/ddtc_public/ddtc_public">https://www.pmddtc.state.gov/ddtc_public/ddtc_public</a></p> <p><a href="http://developer.trade.gov/">http://developer.trade.gov/</a></p> <p><a href="http://business.usa.gov/consolidated-screening">http://business.usa.gov/consolidated-screening</a></p> <p><a href="https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/consolidated.aspx">https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/consolidated.aspx</a></p> <p>Policy and Procedure: Requisitioning for Goods and Services  Policy and Procedure: Subrecipient Monitoring  Policy and Procedure: International Travel and Foreign Collaborations</p>	