Research Compliance Principles

For Research Administrators

Presented by:
Office of Sponsored Projects
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30-8:45</td>
<td>Welcome and Introduction</td>
<td>Kathi Goodfriend</td>
</tr>
<tr>
<td>8:45-9:15</td>
<td>Conflict of Interest</td>
<td>Erika McCarthy</td>
</tr>
<tr>
<td>9:15-9:45</td>
<td>Administration of Human Research Studies</td>
<td>Monika Lau</td>
</tr>
<tr>
<td>9:45-10:15</td>
<td>Administration of Research Involving Animals</td>
<td>Troy Hallman</td>
</tr>
<tr>
<td>10:15-10:30</td>
<td>10-Minute Break</td>
<td></td>
</tr>
<tr>
<td>10:30-11:00</td>
<td>Environmental Health &amp; Safety</td>
<td>Stephanie Perry</td>
</tr>
<tr>
<td>11:00-11:30</td>
<td>Export Controls</td>
<td>Don Deyo</td>
</tr>
<tr>
<td>11:30-12:00</td>
<td>Test Your Knowledge Quiz</td>
<td>Kathi Goodfriend</td>
</tr>
</tbody>
</table>
Topics Covered

- Conflict of Interest
- Human Participants
- Animals in Research & Teaching
- Environmental Health & Safety
- Export Controls
**Program Speakers**

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Office</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donald Deyo, PhD</td>
<td>Director, Contracts and Export Control Licensing</td>
<td>Office of Sponsored Projects (OSP)</td>
<td>203.785.3817</td>
<td><a href="mailto:donald.deyo@yale.edu">donald.deyo@yale.edu</a></td>
</tr>
<tr>
<td>Monika Lau, Ed., CIP</td>
<td>Education, Training and IRB-of-Record Specialist</td>
<td>Human Research Protection Program (HRPP)</td>
<td>203.737.4434</td>
<td><a href="mailto:monika.lau@yale.edu">monika.lau@yale.edu</a></td>
</tr>
<tr>
<td>Troy Hallman</td>
<td>Director</td>
<td>Office of Animal Research Support (OARS)</td>
<td>203-737-5236</td>
<td><a href="mailto:troy.hallman@yale.edu">troy.hallman@yale.edu</a></td>
</tr>
<tr>
<td>Erika McCarthy</td>
<td>COI Specialist</td>
<td>Conflict of Interest Office (COI)</td>
<td>203-737-7139</td>
<td><a href="mailto:erika.mccarthy@yale.edu">erika.mccarthy@yale.edu</a></td>
</tr>
<tr>
<td>Kathi Goodfriend</td>
<td>Training Manager</td>
<td>Office of Sponsored Projects (OSP)</td>
<td>203-785-3036</td>
<td><a href="mailto:kathi.goodfriend@yale.edu">kathi.goodfriend@yale.edu</a></td>
</tr>
<tr>
<td>Stephanie Perry</td>
<td>Lead Administrator</td>
<td>Environmental Health and Safety (EHS)</td>
<td>203.737.2122</td>
<td><a href="mailto:stephanie.perry@yale.edu">stephanie.perry@yale.edu</a></td>
</tr>
</tbody>
</table>
Conflict of Interest
Topics Covered: Conflict of Interest (COI)

- COI Disclosure Requirements at Yale
- Key Term: Significant Financial Interests (SFI)
- NSF Requirements
- PHS Regulations & Disclosure of Third Party Paid Travel
- Grant Application and Award Considerations
  - Subrecipient Requirements
- Roles & Responsibilities
- Review Process at Yale
- Resources
Yale's Disclosure Requirements

Who at Yale must disclose?

- All faculty and non-faculty personnel responsible for the design, conduct or reporting of research

“Responsible” personnel include:
- PIs
- Co-PIs
- Any other individuals the PI identifies as responsible for the design, conduct or reporting of the research
  - may include individuals at subrecipient organizations, collaborators, contractors, consultants & consortium participants

- All faculty with >50% appointment
- All faculty with administrative responsibilities (e.g., deans, department chairs, program directors, section chief)
- All members of research compliance committees
Yale’s Disclosure Requirements

**WHAT?**

- Significant Financial Interests (SFIs)* that are reasonably related to one’s teaching, research, clinical, administrative or other Yale responsibilities.

---

**WHEN?**

- Annually (based on date of last disclosure)
  
  OR
  
  - Within 30 days of any material changes in one’s outside interests or one’s University activities, whichever comes first.

---

**HOW?**

- Via the web-based disclosure form
- A link to the disclosure form is posted on the COI website.

---

* Significant Financial Interest (SFI) definitions and thresholds for disclosing SFIs differ according to funding source or circumstances.

---

* An active Yale NetId and password are required to log on to the disclosure form.
Yale’s Disclosure Requirements

Highlights

▪ Branched COI Policy and branched Disclosure form, based on funding circumstances:
  • PHS Pathway (NIH and other agencies/sponsors that adopted the PHS regulations)
  • NSF Pathway
  • Yale Pathway (Non-PHS, Non-NSF funding sources, such as industry, or no sponsored research)
  • NSF/PHS Pathway (Hybrid for those investigators with both NSF & PHS funding)

▪ Only those financial interests that constitute a SFI (and that are reasonably related to one’s Yale activities) need to be disclosed to Yale

Exception: Intellectual Property (IP) related to one’s Yale activities must be disclosed (regardless of its value). Yale’s HRPP may consider IP rights and/or interests in its review of HIC protocols for purposes related to the protection of research participants.
<table>
<thead>
<tr>
<th>Significant Financial Interests (SFI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHS</strong></td>
</tr>
<tr>
<td>• Generally includes anything of monetary value <em>(including third party paid travel)</em> that when aggregated for the investigator and the investigator’s spouse or dependent children exceeds $5,000 during past 12 months*</td>
</tr>
<tr>
<td>• Any equity in a privately-held company</td>
</tr>
<tr>
<td>• Board of Directors or Officer of a non-Yale entity <em>(paid or unpaid for discloser only)</em></td>
</tr>
<tr>
<td><strong>NSF</strong></td>
</tr>
<tr>
<td>• Generally includes anything of monetary value that when aggregated for the investigator and the investigator’s spouse or dependent children exceeds $10,000 for the past 12 months OR next 12 months*</td>
</tr>
<tr>
<td>• Any equity in a privately-held company</td>
</tr>
<tr>
<td>• Board of Directors or Officer of a non-Yale entity <em>(paid or unpaid for discloser only)</em></td>
</tr>
<tr>
<td><strong>Non-PHS/NSF</strong></td>
</tr>
<tr>
<td>• Generally includes anything of monetary value that when aggregated for the investigator and the investigator’s spouse or dependent children exceeds $10,000 for the past 12 months*</td>
</tr>
<tr>
<td>• Any equity in a privately-held company</td>
</tr>
<tr>
<td>• Board of Directors or Officer of a non-Yale entity <em>(paid or unpaid for discloser only)</em></td>
</tr>
</tbody>
</table>

*SFI definitions and thresholds for disclosing SFIs differ according to funding circumstances. Detailed definitions and a list of inclusions and exclusions are described on the disclosure form and are posted as FAQs on the COI Office website.*
Overview NSF Requirements

National Science Foundation (NSF)
COI Policy

• Disclosure must be made to Yale \textit{by the time a proposal is submitted (hard stop if no current disclosure on file)}

• \textit{Before} expenditure of any funds, Yale makes a COI determination and manages, reduces or eliminates conflicts

• Yale must only notify NSF when Yale is unable to satisfactorily manage a conflict of interest

• Disclosures must be updated during the period of the award, either annually or as new SFIs are obtained

\textit{Also applies to all subawardee investigators and consultants who are identified by the PI as “responsible” for the research!}
Overview PHS Requirements

Applies to research funded by the NIH and other sponsors that mandate compliance with the PHS regulations.

Public Health Services (PHS) 42 CFR Part 50, Subpart F Responsibility of Applicants for Promoting Objectivity in Research

Purpose: To ensure that the design, conduct or reporting of the research will not be biased by any conflicting financial interest of the investigator

Also applies to all subawardee investigators and consultants who are identified by the PI as “responsible” for the research!

• Can submit proposals only if a PHS-compliant disclosure form is on file at Yale (hard stop if no current disclosure)

• **Before** expenditure of any funds, Yale must notify PHS agency of any Financial Conflict of Interest (FCOI) and how it has been managed

• Disclosures must be updated during the period of the award, either annually or as new SFIs are obtained (within 30 days of acquisition)

• Yale must submit annual FCOI reports (coordinated with progress reports)
Examples: Sponsors Applying PHS Regulations

- Administration on Aging (AoA)
- Administration for Children and Families (ACF)
- Agency for Healthcare Research & Quality (AHRQ)
- Agency for Toxic Substances & Disease Registry (ATSDR)
- Alliance for Lupus (ALR)
- American Cancer Society (ACS)
- American Heart Association (AHA)
- Arthritis Foundation (AF)
- California Breast Cancer Research Program (CBCRP)
- California HIV/AIDS Research Program (CHRP)

- Centers for Disease Control & Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources & Services Administration (HRSA)
- Indian Health Service (IHS)
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America (LFA)
- Patient-Centered Outcomes Research Institute (PCORI)
- National Institutes of Health (NIH)
- Substance Abuse & Mental Health Services Administration (SAMHSA)
- Susan G. Komen for the Cure

For a complete list visit the COI Frequently Asked Questions (FAQs) website
▪ Mandated training requirement for investigators (built into PHS branch of Yale’s disclosure form)

▪ Requirements for submitting FCOI Reports to NIH
  • Detailed information about the SFI, nature of the FCOI & the management plan
  • Annual FCOI updates (submitted in coordination with progress reports)

▪ If an Investigator has an FCOI on a PHS award through another institution and transfers that PHS award to Yale, the details of the FCOI need to be disclosed to Yale
▪ **Public accessibility of FCOIs on PHS-funded research**
  
  • For FCOIs reported to NIH, Yale must make information about the nature of the SFI publicly available
  
  • Web form for public to submit written requests directly to Yale’s COI Office (Yale must respond within 5 business days)

▪ **Negative consequences mandated by PHS if an investigator fails to comply with the regulations or with Yale’s COI policy**
  
  • e.g., failure to update disclosures (including travel reimbursed by a 3rd party) in a timely manner or to comply with management plans can result in the need for immediate re-training on Yale’s COI policy and PHS requirements, and could require retrospective reviews of research findings for potential bias (could result in the need to submit a mitigation report to the NIH)
Travel includes meals, transportation, lodging, and registration fees.

- **A third party directly pays, in whole or in part:**
  - for travel that is related to the investigator’s institutional responsibilities
  - for the investigator and/or the investigator’s spouse and/or dependent children

- **An investigator (and/or spouse and/or dependent children) pays for:**
  - travel that is related to the investigator’s institutional responsibilities, and a third party reimburses him/her for part or all of that travel.

- **Yale pays in whole or in part for:**
  - Travel, and the third party reimburses Yale (directly; not through a sponsored award or a broader contract to Yale).
More About Third Party Paid Travel

Includes Travel Paid By:

- For profit entities
- Most non profit entities, including external professional organizations and societies
- Academic journals and publishing companies
- Foreign Institutions of higher education
- Any government of another country

*Only if the aggregate amount exceeds $5,000 per year from any single entity (either for a single trip or for multiple trips)*
More About Third Party Paid Travel

Excludes Travel Paid By:

- Yale or funded by a sponsored award to Yale
- U.S. federal, state or local government agencies
- U.S. institutions of higher education
- U.S. research institutes that are affiliated with U.S. institutions of higher education
- U.S. academic teaching hospitals that are affiliated with U.S. institutions of higher education
- U.S. medical centers that are affiliated with U.S. Institutions of higher education

Examples of Yale affiliated organizations include: The John B. Pierce Laboratory, YNHH, CMHC, Haskins Laboratories, HHMI, and VACHS
More About Third Party Paid Travel

▪ Travel disclosures must occur within 30 days of returning from the trip that made the total exceed the $5,000 threshold (this may occur as a result of one or multiple trips).

▪ Yale’s Third Party Paid Travel Report for PHS Investigators is available through the Disclosure Form portal. Investigators can use this form to both keep track of and disclose reportable third party paid travel.

▪ Annually, the COI Office sends an email reminder to PHS Investigators, lead administrators and operations managers describing the actions Investigators need to take to comply with the PHS disclosure requirements re: third party paid travel.
How to Disclose Third Party Travel

- Investigators who have not yet submitted Yale’s PHS disclosure form should do so before submitting a Third Party Paid Travel Report.
- Investigators who have already submitted Yale’s PHS disclosure form can go directly to the Third Party Paid Travel Report.

Click here if you already submitted Yale’s PHS Disclosure Form and need to complete a Travel Report only.
Grant Application Considerations

Key Points for Proposals: Administrative Check List

- Before submitting a PHS (NIH) proposal to OSP:
  - Discuss roles and confirm with PI that individuals have been identified appropriately as key personnel or responsible personnel
    - PIs should carefully consider who they designate as “responsible” personnel, taking into account the person’s role on the project and the degree of independence with which s/he will work, rather than his/her title.
  - Confirm disclosures are current for all individuals identified as being responsible for the design, conduct or reporting of the research.
  - If the proposal includes a subrecipient, alert OSP immediately if a subrecipient responds that it does not have a PHS compliant policy.
- Proposals cannot be submitted if any of these items are not in place.
Grant Application Considerations

Subrecipient Requirements

• If a subrecipient does not have a compliant policy, Yale will provide a generic model policy (and disclosure template) for the subrecipient institution to adopt and implement
  – Subrecipient investigators must submit disclosures to their institution by the time of application
  – For NIH-funded research, subrecipient investigators must update disclosures within 30 days of acquiring a new SFI, and update their disclosure at least annually during the period of the award
Subrecipients

- Subrecipients must certify that they have a PHS compliant policy before the subaward is issued or continued.

- Prior to the expenditure of funds under the subaward:
  - The subrecipient institution must report any FCOIs to Yale.
  - Yale must submit FCOI reports to the NIH.

- Subrecipient institutions must report to Yale new FCOIs (within 30 days) and submit to Yale annual FCOI reports (in conjunction with progress reports) to enable Yale to comply with its reporting obligations under the PHS regulations.
  - This requirement will be part of the terms and conditions of the subaward.
Key Points and Reminders for Awards

- All responsible personnel must have a current and appropriate disclosure on file
  - An award CANNOT be set-up if a COI disclosure for ANY of the responsible individuals is not filed
  - When a SFI exists, a transactional review of the disclosure against the awarded sponsored research project is required, and any conflicts must be managed, reduced or eliminated before the award can be set up

- If applicable, Yale must submit a FCOI report to the NIH awarding component prior to the expenditure of funds

- Before new responsible personnel can be added to a project
  - The individual must have a current and appropriate disclosure statement on file
  - If the individual has a significant financial interest, the Conflict of Interest Office must complete a transactional review and any conflicts must be managed, reduced or eliminated before the individual starts working on the project

*These requirements also apply to subawards.*
### Roles and Responsibilities

#### COI Office
- Serves as key contact for the University community re: COI regulations and disclosure requirements
- Accepts and triages disclosures
- Facilitates activities and transactional reviews of annual disclosures and sponsored projects
- Communicates & monitors management plans when a COI has been identified that has the potential to affect research or other University activities
- Handles FCOI notifications and annual FCOI reports to sponsors
- Responds to requests for information re: FCOIs reported on PHS-funded research

#### OSP
- Prior to proposal submission, OSP verifies that all individuals listed as “responsible” on the Transum form have current and appropriate disclosures of file
- Prior to award set up, verifies that all “responsible personnel” have a current and appropriate disclosure on file, and that no COI holds are indicated (i.e., any necessary transactional reviews were completed)
- Partners with department business offices to ensure subrecipient requirements are in order, prior to proposal submission and award set up;
- Notifies COI Office when new “responsible personnel” with a transactional review case status are being added to PHS-funded research
Roles and Responsibilities (continued)

Investigators

• Submit timely disclosures
• Re-disclose, as required, any material changes to SFIs within 30 days (for “responsible personnel” on PHS-funded projects, this includes reportable third party paid travel)
• PIs: Appropriately identify those individuals who are responsible for the design, conduct or reporting of the research
• PIs: Ensure all “responsible personnel” have a current and applicable disclosure on file before they begin work on PHS funded projects

Department Business Office

Prior to proposal submission:

• Track and monitor compliance with disclosure requirements* to ensure that current and appropriate disclosures are on file prior to proposal submission and before award set up
• Ensure that new “responsible personnel” have a current and applicable disclosure on file (with an appropriate review status) before they begin work on PHS-funded projects
• Ensure subrecipient requirements are in order, prior to proposal submission

*Reporting tools are available on the COI website
Activities Review

- Review of an individual’s external significant financial interests (SFI) in relation to his/her overall non-research Yale responsibilities.
- Does the SFI have the potential to affect academic, teaching, clinical or administrative responsibilities?
Transactional Review

- Relates to sponsored research projects.

- Does the presence of an SFI *directly and significantly* affect the design, conduct, or reporting of the research or could the research have a direct & significant affect on the SFI (i.e., affect the objectivity of the investigator in carrying out the specific funded research)?
Review Process: No Outside Interests

No outside activities or financial interests ("AAN")

No Review

Case status is automatically assigned to reflect No COI holds for award setups.
Review Process: Outside Interests

No SFI

- COI Office expedites disclosure as “No SFI”
- No further review is required
- No COI Holds on award setups

SFI*

- COI Offices updates status to SFI: Pending
- All disclosures with SFIs are labeled as Transactional Review Required
- Further review required by COIC Committee (or designee)

SFI Reviews

- Activities Review: SFIs in relation to overall Yale responsibilities
- Transactional Review (TR): SFIs in relation to each sponsored research project
  (10 sponsored projects = 10 TRs + the annual Activities Review)

*SFI Determination guided by PHS and NSF definitions & Yale policy
Department administrators can use the Case Status Report to view and monitor the COI disclosure date, type and status for any Yale person who is required to submit an External Interests Disclosure online form.

![Case Status Report](image-url)
<table>
<thead>
<tr>
<th>Case Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactive</td>
<td>Disclosure requirement no longer applicable</td>
</tr>
<tr>
<td>Required</td>
<td>No disclosure on file and submission of annual disclosure is required</td>
</tr>
<tr>
<td>Expired</td>
<td>Disclosure was submitted is &gt; 365 days, and has expired</td>
</tr>
<tr>
<td>AAN</td>
<td>“All Answers No”: No external activities or interests were disclosed (i.e., responded “no” to all screening questions)</td>
</tr>
<tr>
<td>Pending</td>
<td>Disclosure is under COI review</td>
</tr>
<tr>
<td>No SFI</td>
<td>No SFIs were disclosed</td>
</tr>
<tr>
<td>Transactional Review</td>
<td>SFIs were disclosed and require further review for potential conflicts with research proposals and University activities</td>
</tr>
</tbody>
</table>
Resources: Review Status Report

- The Review Status Report displays the status of any reviews associated with a disclosure. Reviews that correspond to sponsored research projects are listed with the Yale proposal number.

**Activity review:** This is a review of the disclosure to determine if there are any potential conflicts with University activities.

**Transactional review:** This is a review of a research award against the most recent disclosure for the individual(s) identified as responsible for the design, conduct, or reporting of a specific sponsored research project.
<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
<th>Action for Award Setup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pending</td>
<td>Review is pending or in progress</td>
<td>On Hold</td>
</tr>
<tr>
<td>No SFI</td>
<td>Review is complete and no SFIs were identified</td>
<td>No Hold</td>
</tr>
<tr>
<td>SFI: Pending</td>
<td>Review indicates a SFI: transactional or activity review is in progress</td>
<td>On Hold</td>
</tr>
<tr>
<td>SFI: No COI</td>
<td>Review is complete: SFIs were identified, but do not present potential conflicts of interest</td>
<td>No Hold</td>
</tr>
<tr>
<td>SFI: COI</td>
<td>Review is complete: SFI presents a potential conflict of interests (a management plan was developed to mitigate the conflict[s])</td>
<td>No Hold</td>
</tr>
</tbody>
</table>
COI Resources

- **Conflict of Interest Office** (COI) website
  - Online [Disclosure Form](#)
  - FAQs for External Interest Disclosure form Instructions
  - [Yale’s COI Policy and Procedures](#)
  - [COI FAQs](#) including disclosure and review process
  - [Research Model COI Policy](#) and [Disclosure form](#)

- **IRES Reporting Portal**
  - Link to Case Status and Review Status reports

- **Office of Sponsored Projects Resources** website
| COI Office | Pat George  
203-785-4774  
patricia.george@yale.edu | Althea Morgan  
203-785-4773  
althea.morgan@yale.edu |
|------------|--------------------------------------------------|--------------------------------------------------|
| Call Center:  
203-737-5954 | Kenneth Greenquist  
203-737-2306  
kenneth.greenquist@yale.edu | Jill D. Pagliuca  
203-785-6307  
jill.pagliuca@yale.edu |
| Email:  
conflicts@yale.edu | Erika McCarthy  
203-785-5191  
erika.mccarthy@yale.edu |
Questions?

Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.
Human Participants

Yale Human Research Protection Program (HRPP)
Topics Covered: Human Subjects

- Human Research Protection Program overview
- Research requiring review by an IRB
- Levels of the IRB Review
- Collaboration with external investigators
- External IRBs
- Where to get information when needed
IRB Reviews

Yale Human Research Protection Program (HRPP)

Compliance    IRB    Billing    Education

Social, Behavioral, Educational (Human Subjects Committee (HSC))
Biomedical (Human Investigation Committee (HIC))

HSC    HIC I/la    HIC II    HIC III    HIC IV
3xRA    3xRA    2xRA    2xRA    2xRA

RA – Regulatory Analyst
If the project falls into the category of *Research Involving Human Subjects*, IRB review is required.
IRB Decision Tree

Is it research?

- NO: IRB Review is not required
- YES:
  - Does it involve human subjects?
    - NO: IRB Review is not required
    - YES: Submission to the IRB IS required
Key Terms: Research

- **Research:**
  - Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - Examples of projects that do not fall into this category: Quality Improvement (QI/QA), case study
Key Terms: Human Subject

- **Human Research Participant (Participant):** Also referred to as human subject/study subject/volunteer/research subject. Living individual(s) about whom a researcher obtains:
  - Data through intervention or interaction with the individual
  - Identifiable private information

Examples of studies not involving human subjects:
- Research using tissues obtained post-mortem
- Surveys about policies and not people
- Studies using deidentified data.
Levels of IRB Review

- **Exemptions**
  - Less than minimal risk
  - Fits into one of 6 categories

- **Expedited**
  - Minimal Risk
  - Fitting into one of 9 expedited review categories

- **Full Board**
  - Greater than minimal risk studies
  - Not fitting into any of the expedited categories
  - Controversial issues
  - Studies involving IND
Exemptions

- Exemptions: Federally designated category of research
- Does not require annual review
  - However, any changes to the protocol must be submitted to the IRB for review. Depending on the change, the exemption may no longer be appropriate.
Expedited vs. full Board

**Expedited:**
- Research is reviewed by one person in the office (Chair or a designee)

**Full Board:**
- Research must be reviewed at the fully convened IRB meeting
  - 5 meetings a month for HIC and 1 meeting for HSC
Life Cycle of the Protocol

- Initial Approval
- Amendments
- UPIRSOs, Noncompliance
- Study closure
- Renewals

UPIRSO: Unanticipated Problems Involving Risk to Subjects or Others
Protocol Submission/Review Principles

Annual Renewals

▪ Most of the time the IRB reviews and approves human research at least annually

▪ The PI must:
  • Keep the IRB approval “current” by obtaining re-approval from the IRB before the expiration date of the approval
  • Submit the re-approval to the IRB 60 days prior to expiration

▪ The protocol approval cannot expire!
  • If there is an expiration in IRB approval, human research cannot continue.
  • There is NO grace period.
Amendments to the Protocol

- All changes to the protocol must be approved by the IRB prior to implementation
  - Change in study personnel
  - Addition or change in a funding source associated with the project
  - Change in study procedures, sites, subject payments
Why is understanding of engagement important?

- Research involving human subjects requires IRB review:
  - If Yale’s agent is engaged in research, then Yale is engaged
  - Yale engagement = Yale IRB approval
Engagement

General Rule:

- An institution is considered *engaged* in a *non-exempt* human subjects research when its employees or agents, for the purposes of the research project, obtain:
  1. Data about the research subjects through intervention or interaction with them
  2. Identifiable private information about the research subjects, or
  3. The informed consent of human subjects for the research.
Engagement:

- Institutions that receive federal money for the non-exempt human subjects research
  - Even where all activities involving human subjects are carried out by employees or agents of another institution (subrecipient).

- No exception to that rule:
  - If you get federal money for research, you are considered engaged and IRB approval is required.
Engagement in Research

- **Individuals from institutions without an IRB:**
  - Unaffiliated Investigator Agreement

- **Individuals from institutions with an IRB:**
  - Approvals from the IRB of the engaged institutions
  - IRB Authorization Agreements (IAA) between the engaged institutions
External IRBs

- Some of the research studies at Yale are under oversight of external IRBs (IAA, commercial IRBs)

- The Grantee is still responsible for the conduct of the study

- Even when Yale IRB does not serve as the IRB of Record:
  - There will still be a protocol record in IRES IRB.
  - The approval letter from the IRB of Record serves as the official documentation of approval.
Consultation

When in question...

▪ Call the Regulatory Analyst from your team: 203-785-4688

▪ Email HRPP@yale.edu or human.subjects@yale.edu

▪ View resources on the HRPP website
Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.
Animals in Research & Teaching
Topics Covered: Animal Research

- Animal Care and Use Program
- Regulatory Organizations
- Roles and Responsibilities
- Protocol Submissions
- Training
- Faculty
- Summary
The Animal Care and Use Program (ACUP)

- **Institutional Official (IO)**
  - Ultimate responsible for the Program
  - Allocates resources needed to ensure the Program’s overall effectiveness

- **Attending Veterinarian**
  - Regulatory authority to oversee all animal care
  - Oversees Yale Animal Resource Center (YARC), the operational/service organization providing for the purchasing, husbandry, breeding, veterinary care, and final disposition of animals

- **Institutional Animal Care and Use Committee (IACUC)**
  - Regulatory committee that:
    - (a) reviews and approves animal activities
    - (b) evaluates the program
    - (c) recommends program refinements to the IO
    - (d) investigates animal welfare concerns
  - Comprised of scientists (11), veterinarians (3), non-scientists (2), community representatives (2), and other members (1 EHS)

- **Research Community:** scientific faculty, post-docs, students, and staff
Key Terms - IACUC & OARS

- **Protocol**
  - The description of proposed animal work (research, teaching, or testing) submitted to the IACUC for review and approval

- **Proposal (for a sponsored award)**
  - A request for financial support of a project or activity submitted to a sponsor

- **Congruency**
  - A requirement of the NIH, DoD, and a few foundations
  - A comparative review of the protocol and proposal to ensure that all animal procedures described in the proposal are approved by the IACUC

- **IACUC Approval**
  - The Full Committee or Designated Members review and approval protocols
  - OARS, through Managing Animals Protocol & Studies (MAPS), document approval in IRES (PT)
  - PIs are informed of IACUC approval
  - Animals may not be used for research, teaching or testing without IACUC approval
ACUP Administrative Support Offices

- **Office of Animal Research Support (OARS)**
  - Administrative support of IACUC review and inspection processes, investigator training, and conducting congruency
  - Research support for:
    - Animal research faculty in protocol design, and
    - Assisting the laboratories maintain compliance with federal/state requirements and Yale-specific policies (staying within the “guardrails”)

- **Office of Sponsored Projects (OSP)**
  - Communicates with OARS regarding proposal/animal protocol congruency issues usually during the award set-up process

- **Office of Environmental Health and Safety (EHS) and Employee Health (EH)**
  - Works with IACUC/OARS regarding personnel safety and use of hazards in animal research
Lines of Authority and Collaboration

Solid lines represent clear lines of authority. Dotted lines represent the need for collaboration and communication.
“Regulatory” Organizations

- **Office of Laboratory Animal Welfare (OLAW)**
  - Administers the Public Health Service Policy
  - Approves Yale’s Animal Welfare Assurance
    - Describes how Yale complies with the PHS Policy
    - Required for any institution using PHS or NSF funds
  - Periodic or for-cause inspections

- **United States Department of Agriculture (USDA)**
  - Research Registration is required if “using” animals, e.g., under the USDA definition of “animal”
  - Registration indicates that Yale will follow the Animal Welfare Act and Regulations
  - Annual inspections

- **AAALAC International**
  - Accreditation is a voluntary (not regulatory) a peer assessment of the animal research program
  - Required for direct collaborations with the NIH
  - Triennial site visits
Key Roles and Responsibilities

- **Principal Investigator**
  - Complies with federal/state requirements, Yale policies, and other official guidance
    - Obtains necessary approvals for use of animals in research
    - Conducts research in accordance with the IACUC-approved protocol
    - Ensures staff noted on the protocol are adequately trained and monitor staff to ensure the work conducted is in accordance with the approved protocol
    - Reports animal welfare concerns or non-compliance to OARS or compliance hotline (1-877-360-YALE)
    - Completes periodic required training
  - Assumes overall responsibility of animal research in the laboratory, even if s/he has no direct animal contact
Key Roles and Responsibilities

- **Departmental Business Office**
  - Be aware of all sponsor’s animal requirements at time of proposal submission
    - Indicate “yes” to Animal Subjects on the Regulatory form in IRES PD
  - Understand Yale’s protocol review and submission requirements
    - Ensure that OSP/OARS is aware of all animal work under a subaward to another entity
  - Develop a thorough understanding of NIH Just-In-Time requirements
    - Notify OSP/OARS at first Just-In-Time notification (approximately 60 days) for congruency review
  - Notify OARS/YARC regarding new and/or exiting faculty
    - Utilize Yale’s [Exiting Faculty Checklist](#)
Protocol Submissions

▪ New protocols
  • No animal research teaching or testing may be performed unless approved by the IACUC
  • Average time from submission to approval is approximately 6 weeks

▪ Three-year de novo review
  • IACUC is required to conduct a complete review of a protocol at least once every three years
  • PIs are reminded of the 3-year cycle coming to a close at approximately 90 days prior to the expiration date
  • Protocols should be submitted at least 60 days prior to expiration date to avoid a lapse in approval
    – If approval lapses, animal work (research) cannot continue
      – Animals are moved to the University's holding protocol
      – Basic husbandry and veterinary services will continue, but will likely be charged to a non-sponsored account
Protocol Submissions

- **Annual renewals**
  - The IACUC must review protocols no less than annually (USDA-species only)
  - Principal Investigators (PIs) receive a reminder e-mail in advance of the anniversary date

- **Modification to approved protocols**
  - Significant changes to the protocol must be approved by the IACUC prior to implementation
  - A significant change includes but is not limited to:
    - Adding a new procedure or changing approved procedures
      - From non-survival to survival surgery;
      - Resulting in potentially greater pain, distress, or degree of invasiveness
    - Housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
    - Changes in or adding new species
    - Change in study objectives
    - Change in Principal Investigator
  - Veterinary Verification Consultation (VVC) and administrative review
Required Training and Facility Access

- The PI and personnel listed on the research protocol (including individuals employed outside of Yale) must complete required training
  - IACUC will not authorize personnel to be associated with a protocol unless the required training is completed
    - Working with the IACUC (AALAS)
    - Medical Surveillance (Employee Health)
- Additional required training depends on the level of animal handling, previous experience, and specific procedures
  - PQF and training plan
  - Rodent Basic Principles
  - Lab-based training
- Yale offers on-line courses through AALAS Learning Library (https://www.aalaslearninglibrary.org)
- OARS offers hands-on and in-person training sessions
- Access to animal facilities is granted only after medical surveillance completion
Onboarding New Faculty

▪ Include YARC and OARS offices on recruitment itinerary/agenda

• YARC
  – Assures adequate vivarium space exists
  – If animals must be transferred/imported to Yale, an IACUC protocol should be in place prior to animals being imported

• OARS
  – Begins the protocol submission process
  – Assists PIs in converting/rewriting their previous institution’s protocol to the Yale protocol model
  – Transfers AALAS training transcript (if applicable)

• Protocol approval prior to shipping animals is strongly encouraged
  – Departmental accounts will be charged if animals are brought into Yale on the University's holding protocol prior to IACUC approval
  – Retroactive charging to the award once IACUC approval has been granted is generally not permitted
Exiting Faculty

- **Ensure appropriate measures are taken to closeout the PI’s research program at Yale**
  - Notify YARC
    - animals can be prepared for shipment to the PI’s next institution
  - Notify OARS
    - arrange for transferring protocol(s) to another PI if research personnel are staying at Yale
  - Notify OSP
    - arrange subaward back to Yale if animals are permanently staying at Yale, if applicable
Reminders for Administrators

✓ Ensure PIs complete proposals correctly
✓ Ensure sponsor requirements are completed in a timely fashion so as not to jeopardize an award
✓ Ensure protocols do not expire if the animal research is continuing and animals are on census
✓ Ensure animal costs are not charged to a sponsored award if the protocol is expired
✓ Ensure animal costs are not charged to a sponsored award that has not been deemed congruent with the protocol to which the animals are assigned
✓ Contact OARS regarding animal concerns or any other animal research related issues
✓ Notify the OARS and YARC prior to the arrival of new faculty or faculty leaving Yale
OARS Contact Information

- **Troy Hallman**, Director, (203) 737-5236
- **Protocol Liaisons**
  - Matthew Mercier, (203) 785-2852 (T)
  - Bryan Brown, (203) 737-6217
  - Shrilatha Balakrishna, (203) 785-6244
  - Tracy Kloczynski, (203) 737-7646 (T)
- **Policy Manager**
  - Alli Czarnecki, MLAS, Policy Manager, (203) 737-5144
- **Researcher Training Program**
  - Layne Ochman, MHS, Training Manager, (203) 737-5576
- **Kelly Fusco**, CPIA, Associate Director, IACUC Administration, (203) 785-2623
- **Protocol Approval Unit**
  - Carol Murgo, CPIA, Assistant Director, (203) 785-6494
  - Shannon Denison, Coordinator, (203) 785-4779
- **Administrative Support**
  - Isabella Murphy, Programming Assistant, (203) 737-2881
- **Claudia Swanson**, BS, LATG, Associate Director, Post-Approval Monitoring, (203) 737-1406
- **Research Support Services**
  - Brandon Dorry, LATg, Specialist, (203) 785-5983
  - Matthew Seager, Ph.D., Specialist, (203) 785-5991
  - Jinah Han, Ph.D., Specialist, (203) 785-3641
Questions?

Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.
Environmental Health & Safety
Topics Covered

- Overview of Environmental Health & Safety (EHS)
- Safety Advisors
- Restricted Items Policy
- Controlled Substances
- Faculty and Keeping Labs Safe
- EHS Resources and Contact Information
What does EHS do?

1. Provide emergency response 24/7
2. Conduct laboratory surveys and inspections
3. Manage regulated waste
4. Provide training
5. Provide authorizations and registrations
6. Investigate accidents, injuries, and near-misses
7. Review construction and renovation project designs
What does EHS do? continued

8. Oversee research material shipping
9. Provide environmental permitting and sampling
10. Test and certify safety-critical equipment
11. Conduct indoor air quality assessments
12. Assess workplace ergonomics
13. Conduct Sponsored Project (grant) reviews
14. Authorize minors and visiting undergraduates in research labs and clinics
Safety Advisors

- Safety Advisors are:
  - trained in all hazards for lab and non-lab areas
  - assigned by building
  - the primary point of contact

- Perform safety audits and surveys

- Perform ergonomics and indoor air quality investigations

- Provide on-site training
Find Your Safety Advisor

Yale University

Yale Environmental Health & Safety

Home > Find Your Safety Advisor

Find Your Safety Advisor

To search for your safety advisor, enter your building’s name, street address or Yale building acronym and click the “Apply” button.

Search

bash

Bass Center
266 Whitney Avenue
New Haven, CT 06511
Building Code: BASS

Bass Library
110 Wall Street
New Haven, CT 06511
Building Code: BASSLB

Josh Armstrong
Safety Advisor
203-785-3727
josh.armstrong@yale.edu

James D’Addio
Safety Advisor
203-785-3677
james.daddio@yale.edu

http://ehs.yale.edu/safety-advisor
Restricted Items Policy

- Procedure to identify and restrict the purchase of certain regulated, high hazard, or safety critical equipment

  - Restricted Items include:
    - High hazard chemicals
    - Radioactive materials
    - Regulated biological materials
    - Controlled substances
    - Biosafety cabinets
    - Safety critical equipment
    - Large shop tools and equipment
    - Animals
Restricted Items Policy

- **Workflow for Workday orders:**
  - PI or lab personnel places order
  - PI or business office gives financial approval
  - EHS reviews order to insure:
    - Vendor is approved
    - Adequate safety infrastructure and experience is in place
    - PI is registered & authorized for these materials
  - After EHS approval, PO is created and routed to vendor

- **Restricted items can hold up larger order**
  - Recommend separate order to avoid delays
Sponsored Projects

- **Safety Advisor reviews:**
  - Lab safety training history
  - Records from last 3 inspections
  - Any outstanding problems or violations

- **Safety Advisor follows up with labs on findings**
Controlled Substances

- Separate federal and state requirements:
  - US Drug Enforcement Admin “registration”
  - CT Drug Control Division “license”

- Cannot hold single institutional blanket authorization – must be PI-specific

- Process:
  - CT Application --> inspection --> license, then:
  - DEA application w/CT number --> registration

- EHS facilitates applications, inspections, renewals and witnessed disposals
## EHS Integrator

**Name:** Yale Administration  
**Department:** EHS Integrator

**Safety Advisor:** Perry, Stephanie  
**Safety Advisor Phone:** 203-785-2199

### Principal Activity

<table>
<thead>
<tr>
<th>Activity Category</th>
<th>Activity</th>
<th>Profile Status</th>
<th>Status Date</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological</td>
<td>Animal Use</td>
<td>Added</td>
<td>4/12/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Biological</td>
<td>Biological - State Registered</td>
<td>Added</td>
<td>4/12/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Biological</td>
<td>Biological Material Use</td>
<td>Added</td>
<td>1/29/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Biological</td>
<td>Biological Safety Level 2</td>
<td>Added</td>
<td>4/12/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Biological</td>
<td>Bloodborne Pathogen Use</td>
<td>Added</td>
<td>2/19/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Biological</td>
<td>CAD - Annual Chargeback</td>
<td>Added</td>
<td>11/9/2012</td>
<td>Remove</td>
</tr>
<tr>
<td>Chemical</td>
<td>Chemical Use</td>
<td>Added</td>
<td>1/29/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Controlled Substance</td>
<td>Controlled Substance Use</td>
<td>Added</td>
<td>1/29/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Radiation</td>
<td>Radioactive Material Use</td>
<td>Added</td>
<td>1/29/2010</td>
<td>Remove</td>
</tr>
<tr>
<td>Chemical</td>
<td>Satellite Accumulation Area</td>
<td>Added</td>
<td>6/24/2010</td>
<td>Remove</td>
</tr>
</tbody>
</table>
Faculty - Coming to or Leaving Yale?

- **Involve your Safety Advisor as early as possible to:**
  - Review equipment and supplies for shipment to/from Yale:
    - Some equipment may need decommissioning prior to shipping or retesting upon arrival
    - Supplies such as chemicals may need specialized packaging and registration prior to shipment supplies transfers
- **Evaluate lab infrastructure for intended work**
- **Provide information on Yale safety procedures and requirements to expedite start-up upon arrival**
- **Organize pre-move clean-outs to eliminate leaving behind “unknowns”**
Planning a Renovation or Move?

✓ Don't forget EHS!
✓ Especially important for labs and clinical areas
✓ Early design and safety advice to project team
✓ Safety equipment types and placement
✓ Pre-construction planning to minimize disruptions, noise, and dust
✓ Moving regulated materials
✓ Pre-demolition clearances
✓ Re-occupancy equipment testing and certification
✓ Be sure to review the Laboratory Closure and Decommissioning Policy
EHS Door ID Cards

- Replaces hand-written cards
- Describes hazards and entry requirements, which is critical to fire department and other first responders
- Uses real-time data
Visits by Regulatory Agencies

- Verify credentials
- Ask them the purpose of their visit
- Request they await responsible departments
  - EHS for OSHA, NRC, EPA, DEP, drugs
  - IACUC for drugs in research animals
- Seat them comfortably
- Contact EHS
Minors and Visiting Undergraduates

- Provost policy:
  - Minors Participating in Research or Clinical Activities
  - Visiting Undergraduates Participating in Research or Clinical Activities

- Minor students aged 16-17 may work in a University research laboratory

- Must be part of an education program approved by the Dean, Department Chair, and EHS

- Visitors and minors must complete required safety trainings

- EHS Integrator web application

- Minors and visiting undergraduates new to Yale are added to Sponsored Identity (not to Workday)
Published 6 times per year

Automatically emailed to all Faculty, Staff and Students

Ideas for articles always welcome
## EHS: Contact Information

<table>
<thead>
<tr>
<th>Environmental Health and Safety</th>
<th>EHS Emergencies (spills, odors): 203-785-3555</th>
</tr>
</thead>
<tbody>
<tr>
<td>135 College Street, Suite 100</td>
<td>Environmental Health &amp; Safety website: <a href="http://ehs.yale.edu">http://ehs.yale.edu</a></td>
</tr>
<tr>
<td>Monday to Friday</td>
<td>Email: <a href="mailto:ehs@yale.edu">ehs@yale.edu</a></td>
</tr>
<tr>
<td>8:30 AM to 5:00 PM</td>
<td>facebook.com/yaleEHS</td>
</tr>
<tr>
<td>203-785-3550</td>
<td>yammer.com/yaleEHS</td>
</tr>
</tbody>
</table>
Questions?

Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.
Export Controls
Agenda – Export Controls

- Key Terms
- Regulatory Scheme
- Policy Implications
- Role of PI
- Role of Administrator
- Resources
Key Terms

▪ What are Export Control Laws?
  • Laws and regulations which prohibit the unlicensed “export” of certain technologies (information, software, and items) to foreign entities.
  • Export controls apply to all activities at Yale, not just research.
Key Terms

- An export is defined as:
  - A shipment of controlled articles or items outside of the U.S.
  - The release, transmission or disclosure of information (controlled software, technology, or data) to any foreign entity in the U.S. (a “deemed export”) or outside the U.S.
    - By email, telephone, website, visual inspection or other form of communication
  - Use or application of controlled technology for the benefit of a foreign entity
Key Terms

- Export examples:
  - Sending advance telecommunications hardware to a company located in Turkey.
  - Taking a laptop on an international trip
  - Faxing blueprints detailing how to construct a biological fermenter to a faculty researcher in Japan.
  - Emailing technical information related to a piece of equipment, such as a technical manual, to a graduate student from South Korea working in a lab at Yale (the “deemed export”).
Key Terms

**What is a deemed export?**

- The transfer or disclosure by any means...
  - of information or technical data concerning export controlled items, software or information
  - to a foreign entity (this includes foreign nationals)
  - in the U.S. (including on the Yale Campus)
Key Terms

- **The Fundamental Research Exclusion (FRE)**
  
  - Excludes from the export control laws 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.
    
    - NIH, NSF, vast majority of research at Yale is fundamental.
    
    - Applies only to information resulting from the research and not to tangible articles.
Key Terms

- **The Fundamental Research Exclusion (FRE)**
  - Applies to most research conducted at Yale
  - However, if Yale accepts awards with the following terms and conditions, the FRE may not apply:
    - Prohibition of participation of foreign nationals in the research, (e.g., some NASA awards).
    - Requirement for the approval of publications or that research results and data generated in the conduct of the research are treated as confidential.
Export Administration Regulations (EAR)

- Covers technologies, commodities and software with both a commercial and military application found on the CCL, hence the phrase “dual use”. Most applicable to Yale.
  - Commerce Control List categories (CCL)
  - 0 = Nuclear materials, facilities and equipment, and miscellaneous items
  - 1 = Materials, Chemicals, Microorganisms and Toxins
  - 2 = Materials Processing
  - 3 = Electronics
  - 4 = Computers
  - 5 = Telecommunications and Information Security
  - 6 = Sensors and Lasers
  - 7 = Navigation and Avionics
  - 8 = Marine
  - 9 = Propulsion Systems, Space Vehicles, and Related Equipment
Regulatory Scheme

- **Office of Foreign Assets Control (OFAC)**
  - Enforces sanctions applied to specified transactions with specified users/countries such as terrorists, international narcotics traffickers and those engaged in the proliferation of weapons of mass destruction.
  - Restricts transactions with Cuba, Iran, Syria, North Korea, and Crimea (Russia-Ukraine), most heavily. Also includes the Balkans, Belarus, Burundi, Central African Republic, Congo, Iraq, Lebanon, Libya, Somalia, Venezuela, Yemen and Zimbabwe, even those in the nature of an academic collaboration.
  - Without a license from the U.S. may prohibit payments or providing anything of “value” to nationals of sanctioned countries and some specified entities/individuals.
  - Yale uses screening software to check against Gov’t lists to prevent Yale from entering into a prohibited transactions.
Policy Implications for Yale

Why is knowing about export controls important?

- A large number of foreign students and researchers conduct research at Yale.
- Information whether by visual inspection, verbal disclosure by cell phone, web sites, or email is easy to transfer and hard to monitor.
- External parties may be providing information to Yale researchers which are subject to export controls.
- Yale policy prohibits any restrictions on the participation of foreign students, faculty, and researchers in the research enterprise.
Why is knowing about export controls important? (continued)

- There is potential for personal and criminal liability for violating the EAR and OFAC
- PIs can help ensure that the University avoids being debarred and/or suspended from government contracting
- PIs play a part in the protection of Yale’s reputation
Role of PI

- Be aware that interactions with foreign collaborators or the shipment of items, software or information outside the U.S. might require:
  - A license
  - Prevent foreign students, staff, faculty from participating in research
  - Prevent researchers from sending controlled materials, items equipment to foreign countries proposal

- If submitting a sponsored project proposal, complete all the compliance questions on the TranSum or Regulatory Form

- Review with OSP award documents where a sponsor has imposed
  - Publication restrictions
  - Access and participation restrictions
# Regulatory Form in PD (Snapshot)

## Guidance on Export Controls and Electronic Devices in International Travel

**NOTE:** When selecting associated countries, all OFAC sanctioned countries [The Balkans (Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Macedonia, Montenegro, Romania, Serbia), Belarus, Burundi, Cuba, Congo, Iran, Iraq, Liberia, Libya, Lebanon, North Korea, Somalia, Sudan, Syria, Venezuela, Yemen and Zimbabwe] are identified with an asterisk (*). **NOTE:** If the project involves any interaction with people or institutions in Cuba, Iran, North Korea, Sudan, Russia-Ukraine-Crimea or Syria, you must contact the Director, Export Controls Licensing at 203-785-3817 or donald.deyo@yale.edu.

1. Will this project involve the transfer of or provision for equipment, materials, data, software, confidential information or services outside the US?  
   - Yes  
   - No

1a. To a collaborator named in the proposal:
   - Yes  
   - No

Select Country

1b. To a collaborator NOT named in the proposal:
   - Yes  
   - No

Select Country

1c. To a subrecipient:
   - Yes  
   - No

Select Country Subrecipient Name

2. Will this project involve any foreign travel, especially foreign travel with a laptop, computer or other electronic devices?  
   - Yes  
   - No

Select Country Travel with a laptop, computer or other electronic device?

3. Did the solicitation RFP, RFQ, RFA and/or discussions with the sponsor indicate potential use or involvement of publication restrictions or export-controlled items or information?  
   - Yes  
   - No

4. Does solicitation (FOA, RFA, RFP, RFQ, etc.) include data security requirements, e.g., FERPA, FISMA, HIPAA or Privact Act?  
   - Yes  
   - No

If yes, see [Yale Research Policies](mailto:) for additional information.
Role of Administrator

What specifically can administrators do?

• Alert OSP of an identified export control issue on the TranSum or PD Regulatory Form

• Review award documents with PIs for:
  – Publication restrictions
  – Access and participation restrictions

• Be aware of the export control laws when:
  – Scheduling travel
  – Ordering/shipping
  – Appointing foreign nationals
  – International payments
OSP Export Controls Contact

Donald T. Deyo, Ph.D.
Director, Contracts and Export Control Licensing
Office of Sponsored Projects
donald.deyo@yale.edu
203-785-3817
Export Controls Resources

- The Office of Sponsored Projects: Export Controls website
- The Office of Sponsored Projects: Guidelines on Export Controls
- The Office of Research Administration: Guidelines on Export Controls.
- Visit the Yale University International Toolkit FAQs website for additional information
Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.
Conflict of Interest

- Conflict of Interest website: https://your.yale.edu/research-support/conflict-interest
- Conflict Interest Disclosure Form: https://ires.yale.edu/WebPortal/Main.asp?Mode=COIUserSearch
- FAQ's for External Interest Disclosure Form Instructions: https://your.yale.edu/research-support/conflict-interest/frequently-asked-questions-coi/faqs-external-interest-disclosure
- PHS agencies and sponsors that have adopted the PHS regulations: https://your.yale.edu/research-support/conflict-interest/frequently-asked-questions-coi
- COI Policies and Procedures: https://your.yale.edu/research-support/conflict-interest/coi-policies-procedures
- COI FAQs (Frequently Asked Questions) including disclosure and review process: https://your.yale.edu/research-support/conflict-interest/frequently-asked-questions-coi
- IRES Reporting Portal: COI Reports http://decisionsupport.yale.edu/iresreporting.html
- Office of Sponsored Projects Resources website: https://your.yale.edu/research-support/office-sponsored-projects/resources
Resources and Websites Referenced in this Presentation

**Conflict of Interest (continued)**

- Model COI form:  
  https://your.yale.edu/policies-procedures/forms/model-coi-form

- Research Model COI policy:  
  https://your.yale.edu/policies-procedures/other/research-model-coi-conflict-interest-policy

- Model COI Disclosure form:  
  https://your.yale.edu/policies-procedures/forms/model-coi-conflict-interest-disclosure-form

**HRPP**

- HRPP website:  
  https://your.yale.edu/research-support/human-research/hrpp-about-us
Resources and Websites Referenced in this Presentation

**IACUC**

- IACUC Policies, Procedures, Guidelines and Instructions: [https://your.yale.edu/research-support/animal-research/policies-procedures-guidelines-and-instructions](https://your.yale.edu/research-support/animal-research/policies-procedures-guidelines-and-instructions)

- Exiting Faculty Checklist: [https://your.yale.edu/policies-procedures/other/exiting-faculty-checklist](https://your.yale.edu/policies-procedures/other/exiting-faculty-checklist)

- Animal Care and Use training and registration website: [https://bmsweb.med.yale.edu/tms/tms_enrollments.categories?p_own_cd=ACUC](https://bmsweb.med.yale.edu/tms/tms_enrollments.categories?p_own_cd=ACUC)

**Environmental Health and Safety**

- Minors Participating in Research or Clinical Activities [http://provost.yale.edu/policies/minors-participating-research-or-clinical-activities](http://provost.yale.edu/policies/minors-participating-research-or-clinical-activities)

- Visiting Undergraduates Participating in Research or Clinical Activities [http://provost.yale.edu/policies/visiting-undergraduates-participating-research-or-clinical-activities](http://provost.yale.edu/policies/visiting-undergraduates-participating-research-or-clinical-activities)

- Environmental Health & Safety website [http://ehs.yale.edu](http://ehs.yale.edu)

- EHS Integrator web application [https://ehsis.yale.edu/EHSIntegrator/Registration](https://ehsis.yale.edu/EHSIntegrator/Registration)
Resources and Websites Referenced in this Presentation

Export Controls

- Office of Sponsored Projects Export Controls website: 
  https://your.yale.edu/research-support/office-sponsored-projects/export-controls

- Office of Sponsored Projects Guidelines on Export Controls: 
  https://your.yale.edu/research-support/office-sponsored-projects/export-controls/guidelines-export-controls

- Office of Research Administration guidance regarding export controls: 
  https://your.yale.edu/export-controls-ora

- Yale and the World: International Toolkit FAQs: 
  http://world-toolkit.yale.edu/frequently-asked-questions

Additional Resources

- Office of Sponsored Projects Resources website: 
  https://your.yale.edu/research-support/office-sponsored-projects/resources

- Yale University Policies and Procedures: 
  https://your.yale.edu/policies-procedures
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAN</td>
<td>All Answers No</td>
</tr>
<tr>
<td>AV</td>
<td>Attending Veterinarian</td>
</tr>
<tr>
<td>CCL</td>
<td>Commerce Control List</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>EAR</td>
<td>Export Administration Regulations</td>
</tr>
<tr>
<td>EHS</td>
<td>Environmental Health &amp; Safety</td>
</tr>
<tr>
<td>FCOI</td>
<td>Financial Conflict of Interest</td>
</tr>
<tr>
<td>FRE</td>
<td>Fundamental Research Exclusion</td>
</tr>
<tr>
<td>HIC</td>
<td>Human Investigation Committee</td>
</tr>
<tr>
<td>HRPP</td>
<td>Human Research Protection Program</td>
</tr>
<tr>
<td>HSC</td>
<td>Human Subjects Committee</td>
</tr>
<tr>
<td>IAA</td>
<td>IRB Authorization Agreements</td>
</tr>
<tr>
<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
</tr>
<tr>
<td>IO</td>
<td>Institutional Office</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>IRB</td>
<td>Internal Review Board</td>
</tr>
<tr>
<td>ITAR</td>
<td>International Traffic In Arms Regulations</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>NSF</td>
<td>National Science Foundation</td>
</tr>
<tr>
<td>OARS</td>
<td>Office of Animal Research Support</td>
</tr>
<tr>
<td>OFAC</td>
<td>Office of Foreign Assets Control</td>
</tr>
<tr>
<td>OSP</td>
<td>Office of Sponsored Projects</td>
</tr>
<tr>
<td>PHS</td>
<td>Public Health Service</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>SFI</td>
<td>Significant Financial Interests</td>
</tr>
<tr>
<td>TR</td>
<td>Transactional Review</td>
</tr>
<tr>
<td>UPIRSO</td>
<td>Unanticipated Problems Involving Risk to Subjects or Others</td>
</tr>
<tr>
<td>YARC</td>
<td>Yale Animal Resource Center</td>
</tr>
</tbody>
</table>
Questions?

Email questions to: osp.trainings@yale.edu

You will receive a response within 2 business days.