IRES Proposal Development (PD)

Preparer Training

Presented by:
Office of Sponsored Projects

Revised 09/18/2020
Welcome and Introductions

- Your Name
- Your Department
- Your Role
- Duration of employment at Yale

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<tr>
<th>IRES PD Contacts</th>
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<tr>
<td><strong>Amy Ellis</strong></td>
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<tr>
<td>Director</td>
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<td>Proposal &amp; Award Management</td>
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<td><strong>Danielle O’Brien</strong></td>
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<td>Team Lead</td>
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<td>Proposal Management</td>
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<td><strong>IRES Technical Support</strong></td>
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<td>Ed Mahon</td>
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</table>
Agenda

Day 1
- IRES Overview
- Introduction to Proposal Development (PD)
- Proposal Initiation & Creation (S2S)
- Basic Budgeting

Day 2
- Review Day 1
- Certification & Approval Process Overview (Routing)
- Proposal Initiation & Creation (Non-S2S)
- Advanced Budgeting

Day 3
- Review Day 2
- Child Records
- Contract Record/Clinical Trial Record
- Support
Integrated Research Enterprise Solution (IRES)

These integrated modules facilitate the preparation, review and submission of sponsored project proposals.

- **Proposal Tracking (PT)**
  a database used to capture and store pre-award and award information.

- **Conflict of Interest (COI)**
  used by faculty and others to disclose financial relationships on holdings that may conflict with the conduct of sponsored research.

- **Proposal Development (PD)**
  used to create and submit proposals; and captures data for the Proposal Tracking (PT) module.
## PD Access

Users are granted access to the PD module after completion of the OSP PD training course. Access is granted as follows.

<table>
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<tr>
<th>Role</th>
<th>Access</th>
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<tbody>
<tr>
<td>Preparers</td>
<td>Ability to create records for proposals assigned to your department’s Cost Center.</td>
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<tr>
<td>Departmental Approvers</td>
<td>Ability to create and review records for proposals assigned to your department’s Cost Center.</td>
</tr>
<tr>
<td>Office of Sponsored Projects (OSP) Approvers</td>
<td>Ability to create, review and submit records University-wide.</td>
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</table>
• **Non-S2S (Non-System-2-System):** All proposals not submitted to Grants.gov

• **S2S (System-2-System):** All proposals submitted to Grants.gov

• **PD Record:** The main proposal record.

• **Parent Record:** A main proposal record

• **Child Record:** A record linked to a parent record
Export Controls

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.

What are Export Control laws?

- Laws and regulations which prohibit the unlicensed “export” of certain technologies (information, software, and items) to foreign entities. The purpose of such laws is to prevent enemies from getting access to certain technologies which may be harmful to the US, e.g., keeping nuclear technology out of N. Korea.
- Export control laws apply to all activities at Yale, not just research.

Export Administration Regulations (EAR) cover what technologies?

- Goods, software and technology on the CCL are primarily commercial in nature not military. (Items that have military application are covered under ITAR.
- Items such as high-speed computers, biological pathogens, encryption software, lasers.
Export Controls

The Fundamental Research Exclusion (FRE):

• The results of research performed as fundamental are not subject to export control laws and regulations.
• Fundamental research, as used in the export control regulations, includes basic or applied research in science and/or engineering at an accredited institution of higher learning in the U.S. where the resulting information is ordinarily published and shared broadly in the scientific community.

Office of Foreign Assets Control (OFAC) Embargoes and Sanctions

• OFAC is within the Department of Treasury and enforces economic embargoes and trade sanctions based on US foreign policy and national security goals.
• Nearly all activities with these countries will be prohibited unless a license is requested from and issued from the U.S. government. T-5 countries: Cuba, Iran, N. Korea, Syria, Ukraine-Crimea (Russian related).
• More targeted sanctions against: the Balkans (Albania, Bosnia, Croatia, Macedonia, and Serbia), Belarus, Burundi, Central African Republic, Congo, Iraq, Lebanon, Libya, Somalia, Venezuela, Yemen and Zimbabwe.

Note: FRE is the only acceptable type of research performed at Yale.
The **Yale University Standards of Business Conduct** articulates the ethical and legal principles that govern business dealings by Yale faculty and staff.

**Appropriate Treatment of Confidential Information**

In their various capacities, Yale faculty and staff become privy to confidential information of many different types. Such information may concern students, patients, employees, or research sponsors, for example, or it may be proprietary information of an enterprise licensing Yale intellectual property or otherwise subject to contractual or legislated obligations of confidentiality. Yale faculty and staff are expected to inform themselves about applicable obligations and to maintain the confidentiality of such information, safeguarding it and using it only as any applicable restrictions permit.

**Consequences of Violation**

Violations of these Standards, of laws and regulations, or of related University policies and procedures may carry disciplinary consequences, up to and including dismissal.

*In accordance with Policy 1601, individuals must not share their NetIDs and passwords.*
Create a New Proposal

See Handout Exercises #1, #2, #3
Certifying and Approving a Proposal
Received via Yale e-mail

Received via the IRES “My Messages Inbox”

When a proposal is routed for certification and approval the recipient will receive a notification via both their Yale E-mail and IRES Inbox.
Routing Emails – Approval Required

From: "IRES, SysAdmin" <ires@yale.edu>
Date: September 9, 2019 at 9:59:22 AM CDT
To: "O’Brien, Danielle" <danielle.obrien@yale.edu>
Subject: Approval Required: O’Brien - ACARES Office of Sponsored Projects CC0051 - 20-002008

Ms. Danielle Lara O’Brien has submitted a proposal for internal routing and approval. The details for the proposal referred to in this email and to which you have been identified as a required approval are as follows:

PI: J. Jonathan Amarakon
Title: "Environmental Determinants of Toximia in Dopamine Receptors"
Sponsor: Simons Foundation
Owning Org: ACARES Office of Sponsored Projects CC0051
Deadline Date: 05-Nov-2019

Please review the proposal and complete the approval status (Approve or Return to Submitter) within the reviewer dashboard. Do NOT add comments. Instead, contact your department administrator if you have questions. (Comments are auditable and cannot be deleted)

To access the dashboard, click the link to the right: Reviewer Dashboard

Note: If logging in from a non-Yale location, you must log in through the Yale Virtual Private Network (VPN) prior to accessing the Reviewer Dashboard. For VPN information, click here

Detailed Reviewer Dashboard Instructions:

1. Review the Proposal documents and select Reviewed from the Review Status drop down.
2. Do NOT add comments. Instead, contact your department administrator if you have questions. (Comments are auditable and cannot be deleted)
3. Click Ready to Submit (bottom right) or contact your department administrator if you have questions. Do NOT select Not Ready to Submit.
4. Click Close (upper right) to close the Review Dashboard

If you have questions or comments, please contact IRES@yale.edu
Routing Emails – Outstanding Approval

From: IRES, SysAdmin [mailto:IRES@yale.edu]
Sent: Monday, September 16, 2019 9:01 AM
To: O’Brien, Danielle <danielle.obrien@yale.edu>
Subject: Outstanding Approval: Meyer - MEDBIO Biomedical - SATU CC1943 - 20-009998

A proposal has been submitted into internal routing and is awaiting your action. The details for the proposal referred to in this email and to which you have been identified as a required approval are as follows:

PI: Dr. Tracy Meyer
Title: "Image Analysis for Metabolic Asymptomatic Disease"
Sponsor: National Institutes of Health
Owning Org: MEDBIO Biomedical - SATU CC1943
Deadline Date: 05-Aug-2019

Please review the proposal and complete the approval status (Approve or Return to Submitter) within the reviewer dashboard. Do NOT add comments. Instead, contact your department administrator if you have questions. (Comments are auditable and cannot be deleted)

To access the dashboard, click the link to the right: Reviewer Dashboard
Note: If logging in from a non-Yale location, you must log in through the Yale Virtual Private Network (VPN) prior to accessing the Reviewer Dashboard. For VPN information, click here

Detailed Reviewer Dashboard Instructions:
1. Review the Proposal documents and select Reviewed from the Review Status drop down.
2. Do NOT add comments. Instead, contact your department administrator if you have questions. (Comments are auditable and cannot be deleted)
3. Click Ready to Submit (bottom right) or contact your department administrator if you have questions. Do NOT select Not Ready to Submit.
4. Click Close (upper right) to close the Review Dashboard

If you have questions or comments, please contact IRES@yale.edu
From: IRES, SysAdmin <IRES@yale.edu>
Sent: Monday, September 9, 2019 10:59 AM
To: Ellis, Amy <amy.ellis@yale.edu>
Subject: Requested Proposal Review: O'Brien - ACARES Office of Sponsored Projects CC0051 - 20-002008

You asked to be included in the routing of certain proposals submitted for external funding. The details for the electronic proposal referred to in this email and to which you have access is as follows:

PI: Sawyer Mallinson  
Title: "Dynamics of Single Cell Regeneration in Vascular Neurons"  
Sponsor: Simons Foundation  
Deadline Date: 05-Nov-2019  
Owning Org: ACARES Office of Sponsored Projects CC0051

To access the electronic proposal, click the proposal link to the right: Open Submission Package

If you are unable to access all tabs within the Proposal Development (PD) record, please access the proposal record through IRES Proposal Tracking (PT) by logging into the IRES main page: IRES Login

Any comments that you would like to provide regarding this electronic proposal can be sent to Ms. Danielle Lara O'Brien or the Office of Sponsored Projects directly.
### Screenshot of Reviewer Dashboard

**Accessing item as Delegate for Adrienne Marable**

**Proposal - Initial Application**

- **Number:** 20-002031
- **Title:** Yale training grant of internal medicine and pediatric fellows in Allergy & Immunology
- **Sponsor:** National Institute of Allergy and Infectious Diseases/NIH/DHHS
- **Submitted:** 24-Sep-2019 3:41:11 PM

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<td>24-Sep-2019 3:41:19 PM</td>
<td>Un-Reviewed</td>
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#### Instructions:

1. Mark as ‘Reviewed’ for all
2. Select ‘Ready to Submit’
3. Click ‘Accept’ to the certification statement
4. Close
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Day 3
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Create a Non-S2S Proposal

See Handout Exercises #4, #5, #6, #7
Advanced Budgeting

See Handout Exercise #6
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Creating Other Types of Records

Child, Contract and Clinical Trial Records
Creating a Child Record

- Using PT (Edit), Open the Parent Record
- Click ‘Add New PD’
- Copy PI and Sponsor only
- Select Proposal Type
  - Non Competing Continuation / Supplement / Just in Time
- Enter the project dates and confirm budget period
- Create proposal
- Select appropriate template
  - Non System-to-System (Generic Template) / Revised Budget Template / Non-Competing Continuation Template
- Follow previous instructions for completing tabs

**PD Quick Guides and How to Create a Child Record:** [https://your.yale.edu/policies-procedures/guides/pd-quick-guides](https://your.yale.edu/policies-procedures/guides/pd-quick-guides)
Creating a Contract Record

- Follow previous steps 1-7 for creating a New ‘Non System to System’ Proposal

- On the ‘Setup Questions’ tab ensure you change the Template to ‘CONTRACT ROUTING’
Creating a Contract Record

- If a budget is included with the agreement, complete the ‘Budget’ tab
- Update the ‘Personnel’ tab if additional personnel are necessary
- On the ‘Internal Documents’ tab, upload all relevant documents including, but not limited to, the Scope of Work and Draft Agreement
- When completing the Regulatory Form ensure you change the Instrument Type to ‘CONTRACT ROUTING’

Additional information on Contracts: [https://your.yale.edu/research-support/office-sponsored-projects/contracts-yale](https://your.yale.edu/research-support/office-sponsored-projects/contracts-yale)
Creating a Clinical Trial Record

- Follow previous steps 1-7 for creating a New ‘Non System to System’ Proposal
- On the ‘Setup Questions’ tab ensure you change the Template to ‘CORPORATE CLINICAL TRIAL’
Creating a Clinical Trial Record

- Update the ‘Personnel’ tab if additional personnel are necessary
- No budget is required, mark the ‘Budget’ tab as Completed
- On the ‘Internal Documents’ tab, upload documents per User Guide (link below)
- When completing the Regulatory Form ensure you change the Instrument Type to ‘CONTRACT ROUTING’

PD User Guide for Clinical Trials: https://your.yale.edu/policies-procedures/other/ires-proposal-development-pd-clinical-trials
If you said NO to Human Subjects on an NIH S2S submission

- You are still required to answer the additional question:
  - Does the proposed research involve human specimens and/or data?

- If the answer is again NO, there is nothing further required to complete the tab
- If the answer is YES, you will be required to upload an explanation as to why the application does not contain human subjects. Once uploaded, you will be able to complete the tab
• If you said YES to Human Subjects on an NIH S2S submission

• Click to add a new Study Title for either ‘New Study’ or ‘Delayed Onset Study’

• Follow all directions in the ‘Forms F Series – Annotated Form Set for NIH Grant Applications’
  • https://your.yale.edu/research-support/office-sponsored-projects/resources/osp-forms
Human Subjects Tab – NIH S2S Submission

- **YES to using a Single IRB (sIRB)?**
  - At time of proposal submission: must upload an sIRB Plan, budget should include IRB Review Fees and must upload an HRPP Approval Letter

- **Human Research Protection Program**
  - [https://your.yale.edu/research-support/human-research](https://your.yale.edu/research-support/human-research)
  - [https://your.yale.edu/research-support/human-research/reliance-agreements/sirb-multi-site-research](https://your.yale.edu/research-support/human-research/reliance-agreements/sirb-multi-site-research)

- **Templates available**
Take the Online Survey!

We value your feedback!

We just sent an email with a link to the class online survey

We’ll come back in 10 minutes and resume the final portion of the class.
## IRES PD Resources

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<tr>
<td>OSP Online Resources</td>
<td><strong>OSP Website</strong>&lt;br&gt;<a href="https://your.yale.edu/research-support/office-sponsored-projects">https://your.yale.edu/research-support/office-sponsored-projects</a></td>
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<td>OSP Support</td>
<td><strong>OSP Website: Contact Information</strong>&lt;br&gt;<a href="https://your.yale.edu/research-support/office-sponsored-projects/sponsored-projects-contacts">https://your.yale.edu/research-support/office-sponsored-projects/sponsored-projects-contacts</a></td>
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<td>OSP Brown Bag for Research Administrator Meetings</td>
<td><strong>OSP Brown Bag Website</strong>&lt;br&gt;<a href="https://your.yale.edu/research-support/office-sponsored-projects/osp-educational-opportunities/osp-research-1">https://your.yale.edu/research-support/office-sponsored-projects/osp-educational-opportunities/osp-research-1</a></td>
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<tr>
<td>OSP News &amp; Updates</td>
<td><strong>OSP Website</strong>&lt;br&gt;<a href="https://your.yale.edu/research-support/office-sponsored-projects/osp-news-updates">https://your.yale.edu/research-support/office-sponsored-projects/osp-news-updates</a></td>
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Questions?

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<tr>
<th>Amy Ellis</th>
<th>Phone: (203) 737-4264</th>
<th>Email: <a href="mailto:amy.ellis@yale.edu">amy.ellis@yale.edu</a></th>
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