INTERNATIONAL RESEARCH SUPPORT TEAM

Broderick Grady
Associate Director
Office of Research Support

Adam King
Assistant Director
Office of Research Support

irst@duke.edu
Duke University values our international collaborations in research and education and the scholars and students from around the world who contribute to our academic mission.

The University is committed to building and supporting an inclusive and diverse research community.

Such collaborations are vital to our work in advancing education, research, and health locally, nationally, and globally.
MAJOR INTERNATIONAL RISK AREAS

Two “touch points” where IRST could add significant value:

• Recruitment/Onboarding of Faculty
  • Countries where Duke has no presence/experience
  • Lack of understanding of Duke processes/concerns
  • Identification of major administrative support

• Pre-award process
  • Identifying foreign components and other international collaborations
  • Budgeting appropriately
  • Coordinating with other Duke offices to setup the project for success
WHAT IS A FOREIGN COMPONENT?

“The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.”

- NIH Grants Policy Statement, Section 1.2
WHAT IS A FOREIGN COMPONENT?

But what if I don’t handle an NIH-focused portfolio?

The International Activities tab is currently geared towards identifying NIH Foreign Components.

But the information we’re gathering has real value regardless of Sponsor.

The Tab will evolve and capture more crucial information.

Helps GMs, and the Pre-Award offices, spot potential concerns.
This question connects to the “foreign component” for NIH, but is applicable to all submissions (not just NIH).
COUNTRY CODES

• Previously a free text box; lacked consistent entries
• “Find Country” function: works based on 3-letter code or country name
  • Typing “KHM” or “Camb” are both going to lead you to Cambodia
• There is a TBD option for projects who do not know at time of proposal which countries are involved
  • TBD includes “Worldwide” (NSF)

Pro tips: selecting the same country twice will de-select that country.
These are the same country codes you see in the Enrollment Report (except TBD)
FOREIGN COMPONENT IN SPS

Foreign Justification

Foreign Activities Detail

Does Project Involve:

- Use of human subjects at a foreign site?
- Use of vertebrate animals at a foreign site?
- Foreign travel for the purpose of data collection, surveying, sampling or similar activities?
- Use of facilities or instrumentation at a foreign site?
- Receipt of any financial support or resources from a foreign entity specific to this project?
- Any activities that may have an impact on U.S. foreign policy, either through involvement in the affairs of or the environment of a foreign country?
- Collaborations with investigators at a foreign site that are anticipated to result in co-authorship?
  - Does any of the work leading up to co-authorship take place outside of the U.S.?

This co-authorship collaboration is not considered to be a foreign component since the work leading up to co-authorship is not being performed outside of the U.S.

If applicable, provide clarifying information for the questions above (for Duke use only):
DOES PROJECT INVOLVE...?

Use of human subjects at a foreign site?

YES

if obtaining the following at a foreign site (either directly or through any collaborator)

- Data about the research subjects through intervention or interaction with the subject(s)
- Identifiable private information about the research subject(s)
- The informed consent of human subject(s)
DOES PROJECT INVOLVE...?

Use of vertebrate animals at a foreign site?

YES
if at a foreign site using...

✓ Live, vertebrate animal(s) in:
  ✓ research training,
  ✓ experimentation,
  ✓ biological testing
  ✓ Or related purposes
### DOES PROJECT INVOLVE...?

Foreign travel for the purpose of data collection, surveying, sampling or similar activities?

<table>
<thead>
<tr>
<th>YES</th>
<th>Any U.S.-based project personnel (including external collaborators and any subrecipients) will travel outside the U.S. for the purpose of:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ data collection,</td>
</tr>
<tr>
<td></td>
<td>✓ surveying,</td>
</tr>
<tr>
<td></td>
<td>✓ sampling</td>
</tr>
<tr>
<td></td>
<td>✓ Or similar activities directly related to the project</td>
</tr>
</tbody>
</table>

This does not include general travel for professional meetings or conferences.
## DOES PROJECT INVOLVE...?

**Use of facilities or instrumentation at a foreign site?**

<table>
<thead>
<tr>
<th>YES if...</th>
<th>Any U.S.-based project personnel (including external collaborators and any subrecipients) or foreign collaborator will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✅ Use facilities at a foreign site</td>
</tr>
<tr>
<td></td>
<td>✅ Use instrumentation at a foreign site</td>
</tr>
<tr>
<td></td>
<td>For efforts directly related to the project</td>
</tr>
</tbody>
</table>
**DOES PROJECT INVOLVE...?**

Receipt of any financial support or resources from a foreign entity specific to this project?

<table>
<thead>
<tr>
<th>YES</th>
<th>Any U.S.-based project personnel (including external collaborators and any subrecipients) or foreign collaborator will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ Receive financial support</td>
</tr>
<tr>
<td></td>
<td>✓ Receive other substantive resources</td>
</tr>
<tr>
<td></td>
<td>From a foreign entity to support work proposed for this project</td>
</tr>
</tbody>
</table>

*If resources are received from a foreign entity by the project personnel but are not specifically related to this project, ensure the support is listed on Other Support/Current & Pending and/or in Biosketch, but do not mark “Yes”*
DOES PROJECT INVOLVE...?

Any activities that may have an impact on U.S. foreign policy, either through involvement in the affairs of or the environment of a foreign country?

**EXAMPLES**

- Direct collaboration with foreign government ministries, departments, and/or employees
- Use of foreign government-owned data, facilities and/or equipment
- International research involving politically-sensitive issues
**DOES PROJECT INVOLVE...?**

Collaborations with investigators at a foreign site that are anticipated to result in co-authorship?

<table>
<thead>
<tr>
<th><strong>YES</strong></th>
<th>Substantive work, such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>✓ data collection,</td>
</tr>
<tr>
<td></td>
<td>✓ surveying,</td>
</tr>
<tr>
<td></td>
<td>✓ sampling or the like;</td>
</tr>
<tr>
<td></td>
<td>will be performed at a foreign site, and there are plans to publish those results with foreign co-authors</td>
</tr>
</tbody>
</table>

Manuscript preparation related solely to substantive work performed in the U.S. is not considered a foreign component
Frequently, there are situations where a foreign postdoc may work on a project at Duke, then return to their home country prior to a manuscript being published on which the postdoc will be a co-author.

In this situation the answer to the questions above would be “Yes” to the first question and “No” to the second question.

For the purposes of determining whether a foreign component is present, the above combination of answers (Yes then No) will result in an overall “No” answer in regards to whether the authorship activity constitutes a foreign component.
• The text entered in this box can be used to provide additional information that you think may help clarify answers to questions, the co-authorship conditional question, etc.
• Clarifying information is required if the ‘Project Involves Activities Outside US’ question is “Yes” and the responses to the guide questions are not in agreement
• The text in this box will NOT be submitted to sponsors—it is for internal Duke use only
• This text box does not replace the required foreign component attachment for NIH and AHRQ submissions
If you have checked “Yes” to the question regarding activities outside of the U.S. or partnership with international collaborators AND the sponsor is NIH or AHRQ, then a “Foreign Justification” attachment is required.

- Per NIH, “Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.”

- In the body of the text, begin the section with a heading indicating “Foreign Justification” and name the file “Foreign Justification.”

- If DOD is the sponsor, this attachment will only show up in Grants.Duke if a document has been attached in SPS.

For all federal sponsors, the document attached here will be displayed in Grants.Duke as Item 12 – Other Attachment 1 – Foreign Justification.
How will the International Activities Tab interact with Grants.Duke?

“Activities outside the U.S. or partnership with international collaborators” feeds into Grants.Duke and onto the SF-424

This hasn’t changed

The country codes will also flow into the SF-424
• The Foreign Justification document can be found in the “Other Attachments” section of the “Attachments” tab in Grants.Duke.
• For NIH proposals, it will be called Item 12 – Other Attachment 1 - Foreign Justification.
• For DoD proposals, the up/down arrows can be used to change the order in which the Foreign Justification document will be sent.
Mark “Yes” if any physical item will enter or exit the U.S. for purposes directly related to this project. This includes any means of transfer (i.e., via shipment, luggage, hand carry, etc.). If “Yes” is marked, provide details such as:

- Material names or description
- Destinations
- Purpose

**Answering “Yes” to this question will trigger an e-mail to Duke’s Office of Export Controls to alert them to the transfer.**
What will need to be completed on the proposal before routing?

- Initialized records, or records that are RFC, will need to answer the following questions before being routed:
  - If 'Project Involves Activities Outside U.S.' is Yes, at least one country must be entered
  - For NIH/AHRQ, the foreign justification attachment is required if the 'Project Involves Activities Outside U.S.' is Yes and the proposal is New or a Competing Renewal
  - All guide questions must be answered
  - Clarifying information is required if the ‘Project Involves Activities Outside US’ question, and the responses to the guide questions, are not in agreement (e.g., you marked “No” for the Activities Outside US question but Yes to a guide question)
  - Transfer of Materials question must be answered
  - An explanation of the Transfer of Materials must be provided if the question has been marked “Yes”
### NON-DISCLOSURE OF INTERNATIONAL ACTIVITIES

**What are the risks to the PI and the Institution if an international activity is not disclosed?**

<table>
<thead>
<tr>
<th>To the Principal Investigator:</th>
<th>To the University:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All awards held until issue resolved (can take months)</td>
<td>• Reputational harm</td>
</tr>
<tr>
<td>• Potential removal from all federal projects</td>
<td>• Unrecovered costs or funds returned to sponsor</td>
</tr>
<tr>
<td>• Reputational harm</td>
<td>• Regulatory concerns</td>
</tr>
<tr>
<td></td>
<td>• Legal/Taxation Issues</td>
</tr>
</tbody>
</table>
INTERNATIONAL SUBAWARDS

We can help you think through...

EXAMPLES include...

✓ Subrecipient versus contractor/consultant
✓ DUNS and SAM.gov registrations for international organizations
✓ Connect research teams with Duke colleagues to address conflicts of interests, disclosures, and data & material transfers
## FLY AMERICA ACT

### Regulation to Resources

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2 CFR 200.474 (e) – Cost Principle</td>
<td>• Duke Financial Services Topical Summary</td>
</tr>
<tr>
<td>• <strong>Required</strong> for travel on federally-funded projects</td>
<td>• Duke Financial Services – Procurement - Travel Page</td>
</tr>
<tr>
<td>• 41 CFR 301-10: Exceptions to FAA</td>
<td>• Information about travel agencies and Duke World Travel Services</td>
</tr>
<tr>
<td>• Cost savings do NOT matter</td>
<td>• Concur – Travel &amp; Expense reporting tool...Coming Soon</td>
</tr>
<tr>
<td>• For some federal sponsors, prior approval is required for any international travel.</td>
<td>• Fly America Compliant Bookings</td>
</tr>
</tbody>
</table>