NIH Small Business 101: Managing Foreign Risk

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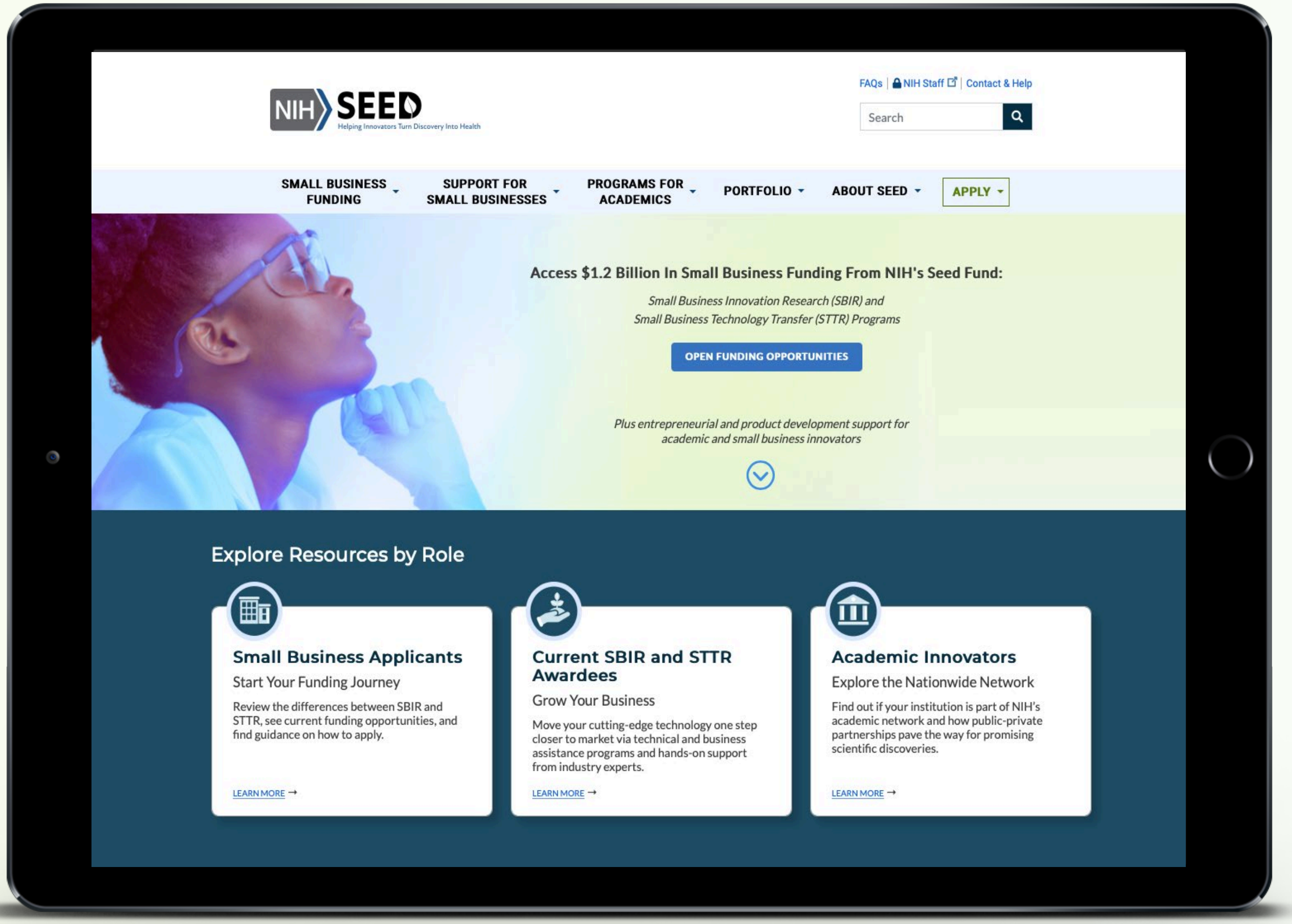
This presentation may include presenter's notes.

NIH SEED

Small Business Program Website



seed.nih.gov/foreignrisk

What Foreign Risk Assessment is NOT

Don’t confuse foreign risk assessment with SBIR eligibility or work requirements:

- Eligibility requirements remain the same (SBA eligibility guide: sbir.gov/apply)
- Work still must be done in the US
  - Foreign subawards/subcontracts: Only unfunded international collaborations or foreign components will be considered (Section III. in the Notice of Funding Opportunity)

Foreign Disclosure and Risk Management

Program to assess foreign security risks is required by 15 U.S.C. § 638, as amended.

See NOT-OD-26-074

- Disclosure Requirements - Ties to Foreign Countries
- HHS Assessment of Foreign Security Risks
- Required Denial of Awards

Process, denial categories, and case studies can all be found on the public SEED Foreign Disclosure and Risk Management webpage!

Disclosure Requirements - Ties to Foreign Countries

Disclosure is required for all owners and covered individuals using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form

- A “covered individual” is defined as all individuals who
  - contributes in a substantive, meaningful way to the scientific development or execution of the SBIR/STTR project; or
  - are identified by the small business in the application as senior key personnel.

- Submit one form per application
- To reduce delays: complete, sign, and review- all text must be visible
- Use text boxes to add detail- even when selecting “no” to a question
- **When in doubt- disclose!**

Post-Award Monitoring and Reporting

- SBIR or STTR Recipients are required to submit an updated disclosure form to report any of the following changes during award:
  - any change to a disclosure on the disclosure form;
  - any material misstatement that poses a risk to national security; and
  - any change of ownership, change to entity structure, or other substantial change in circumstances of the small business concern that poses a risk to national security.
- SBIR or STTR annual, interim, and final Research Performance Progress Reports (RPPRs): Indicate if a change has occurred
  - If "no"- no need to resubmit the disclosure form
  - If "yes"- you are required to submit a revised disclosure form
- Between RPPR submissions:
  - Prior approval requests may require updated disclosure forms
  - Updated disclosure forms are required within 30 days of any change

Make sure to submit on the correct Grant, Phase, and Year!

HHS Assessment of Foreign Security Risks

- Assessment of Foreign Security Risks is required prior to award
- Uses multiple information sources: Not just the disclosure form and application
- Separate from the merit review process
- Assessment Includes:
  - Cybersecurity practices
  - Patent analysis
  - Employee analysis
  - Foreign ownership (including the financial ties and obligations)
  - Foreign affiliations
  - Investment relationships
  - Technology licensing agreements or joint ventures
  - Business relationships
- Assessment requirements are on the webpage!
- Foreign Countries of Concern: People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran

Required Denial of Awards

- NIH <u>cannot</u> make an award if it is determined the small business concern submitting the application or proposal has:
  - an owner or covered individual that is party to a malign foreign talent recruitment program
  - a business entity, parent company, or subsidiary located in the People's Republic of China or another foreign country of concern
  - an owner or covered individual that has a foreign affiliation with a research institution located in the People's Republic of China or another foreign country of concern
  - a security risk connecting the small business concern to an entity, including any affiliates of the entity, or individual on one of the restricted party screening lists identified in 15 U.S.C. § 638 (listed on the webpage)
  - a security risk with a primary source that is classified
  - a security risk that the federal agency determines warrants a denial identified during foreign risk assessment

Foreign Risk Identified in your Application?

- If NIH cannot make the award due to a security risk, small business will receive the denial category(ies)
  - No specific details of identified risks due to security sensitivities
  - NIH grants management and program staff (including SEED) do not have additional information
- Applicants cannot appeal or address identified security risks prior to award
- Small businesses can address a foreign risk and resubmit next receipt date
  - Assessments are done for each application submitted by a small business
  - A finding of foreign risk DOES NOT make a company ineligible for SBIR/STTR in the future
- Small businesses are responsible for monitoring relationships with foreign countries of concern

Conduct Your Own Due Diligence

Some Questions to Consider

- Does your small business have investment or partnerships from countries of concern? Do any of the owners?
- Did your small business or owners have prior investments/partnerships from countries of concern?
    - If they are no longer active, provide the details on the disclosure form

For covered individuals, named consultants and subawards/CROs:

- Are they on one of the restricted party screening lists identified in 15 U.S.C. § 638 (listed on the webpage)?
- Are companies owned by entities/individuals in a country of concern?
- Who are their current collaborators?
    - Are they currently collaborating with entities or individuals in countries of concern?
    - Have they received funding from entities in countries of concern?
- Have they recently ended a collaboration with entities or individuals in countries of concern?
    - If they are no longer active, provide the details on the disclosure form

Most Important Advice? Review Case Studies

Case studies can all be found at SEED Foreign Disclosure and Risk Management!

Foreign Risk Case Studies

NIH has observed several concerns regarding foreign research security risks in previous grant applications and contract proposals. The scenarios below have been developed using observations from real cases.

- Case 1 - Malign foreign talent recruitment program involvement
- Case 2 - Subsidiary located in a foreign country of concern
- Case 3 - Foreign affiliation with a research institution located in a foreign country of concern
- Case 4 - Security risk connected to an entity on a USG Entity List
- Case 5 - Small business located in a foreign country of concern *and* patent concern
- Case 6 - Contract with a business whose parent company is in a foreign country of concern
- Case 7 - In-kind financial ties to a research institution located in a foreign country of concern

Common Issue: Foreign risk due to a contractor

Case 6 - Contract with a business whose parent company is in a foreign country of concern

- A small business applicant has no ownership or investments from foreign countries of concern.
- However, in the application, the small business proposed a contract with a company, ABC Company, to provide research services for its project.
- ABC Company is a subsidiary of a business owned by an entity in a foreign country of concern. Collaborating with the subsidiary inadvertently exposes the small business's intellectual property to potential exploitation by the parent company.

Result: The award was denied because the small business proposed a contract to a subsidiary of a company in a foreign country of concern that would formalize a foreign affiliation between a research institution and covered individuals. The small business concern (SBC) receives the following notification:

> The application cannot be funded as required by criteria defined in 15 U.S.C. § 638, as amended. It has been determined that the small business concern has:
>
> - a security risk that the Federal agency determines warrants a denial identified during:
>   - Foreign Ownership and/or Financial Ties foreign risk due diligence assessment

What to Do: Remove the risk and disclose

Case 13 - Termination of CRO Services

- A small business concern has contracted research services from "CRO X" for previous research projects. The small business has been planning to use "CRO X" in their new project applying for small business funding from HHS.
- While preparing to apply, a co-PI takes on part of the small business' internal review for security risks by checking each company the small business engages or proposes to engage with against restricted entity lists. The co-PI searches each list for the companies as well as their parent companies.
- Through this search, the co-PI discovers that "CRO X" is on the DoD 1260H List of Chinese Military Companies Operating in the United States. The Small Business Innovation and Economic Security Act of 2026 specifically prohibits funding small businesses with affiliations with listed entities or their subsidiaries.
- As a result, the small business ends its current work agreements with "CRO X" and uses an alternate company that is not named nor has a parent company named on restricted entity lists. The small business checks that the alternate company is not owned, operated, or controlled by a foreign country of concern-based individual or entity.
- The application submitted proposes working with the alternate company, and the small business applicant attests in the Foreign Disclosure Form that the previous relationship with "CRO X" has been terminated as of a specific date.
- During HHS foreign risk due diligence review, no other security risks are found.

Result: The award can be made because the small business concern does not have a current affiliation with an entity or subsidiary of an entity on a restricted entity list and foreign risk assessment did not find any other security risks consistent with the Small Business Innovation and Economic Security Act of 2026.

What to Do: Remove the risk and disclose

Case 14 - Confirmation of termination of affiliation

- A small business is interested in applying for an STTR grant. In preparing application materials and performing internal due diligence for security risks, the PI discovers that a company the small business currently partners with is owned by an entity in a foreign country of concern.
- Before applying for an STTR, the small business completely terminates its affiliation with the company.
- In the STTR application, the small business submits a Foreign Disclosure Form and avows that the affiliation and all connections to the original company have been terminated as of a particular date.
- The small business and all covered personnel have no other security risks.

Result: The award can be made because the small business concern does not have a current affiliation with an entity in a foreign country of concern and foreign risk assessment did not find any other security risks consistent with the Small Business Innovation and Economic Security Act of 2026.

Case studies can all be found at SEED Foreign Disclosure and Risk Management!

Connect with SEED

seed.nih.gov/

SEEDinfo@nih.gov

NIH Central Resource for Research Grants and Funding Information:
grants.nih.gov

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