NIH SEED Small Business 101: Managing Foreign Risk

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Speaker: Stephanie Fertig – Director, NIH Small Business Program

Good afternoon, everyone. Welcome to the NIH small Business 101 focused on managing foreign risk. My name is Stephanie Fertig. I'm the director of the NIH Small business program here within the Office of Extramural Research.

While we're going to provide information today, I do encourage you to go to our website cnih.gov. We do have a specific web page for foreign risk, where you can find information and resources and we do also have frequently asked questions. Our website is a wealth of information, particularly as you're preparing your application for the upcoming SBIR and STTR receipt dates.

Now, today, we're going to be really focused on what information you need to know for preparing those applications for that upcoming receipt date. It's important to note what foreign risk assessment is not because we do get a lot of questions around foreign risk assessment.

So what isn't foreign risk? Well, we really don't want to confuse foreign risk assessment with SB IR eligibility or work requirements. The eligibility requirements of the SBIR and STTR programs remain the same and you can find those eligibility requirements at the Small Business Administration's website and they have a great SBA eligibility guide to help you if you have specific questions on whether or not your small business is eligible for the small business programs.

You shouldn't confuse it with work requirements either. Work still must be done in the United States, and that hasn't changed. It's important to note one of the things that has changed is in our notice of funding opportunities. Those new parent solicitations that just recently ran out. We now only allow for unfunded international collaborations or foreign components to be considered. You should read more in section three of the notice of funding opportunity.
But again, these are not what we're talking about when we're talking about foreign risk assessment.

What we are talking about is foreign disclosure and risk management, which is a required program to assess foreign risks as required by the SBIR and STTR legislation. Now there were some changes to this requirement in the recent reauthorization and you can see detailed information about those in our notice of information NOTOD-26-074 the NIH released shortly after the reauthorization.

Today again, we're really going to be focused on what applicants need to know. We're going to talk about disclosure requirements and what you have to disclose with regards to your ties to foreign countries. HHS assessment of foreign security risks and the required denials of awards. Now again, as I stated, information can be found on our foreign disclosure and risk management web page. We have the process, the denial categories and case studies, and I'm going to get into the those case studies a little bit later. Those are great. We've heard nothing but positive feedback about those.

So disclosure is now required for all owners and covered individuals using the required disclosures of foreign affiliations or relationships to foreign countries form. I'm going to call it the foreign disclosure form to make sure that I don't have to say that entire title every time throughout this presentation. Now this disclosure is required and generally occurs after peer review and as part of the Just-In-Time process.

When we say covered individuals, we define covered individuals as individuals who contribute in a meaningful or substantive way to the scientific development or execution of an SBRS TTR project, or are identified by the small business in the application as senior key personnel. You're going to submit one form per application to reduce delays. You want to make sure that you've completed and answered all questions, you've signed the form, and you've reviewed the form.

Make sure that all of the text in the text boxes are visible. If the text is cut off from one of those text boxes, your form will be considered incomplete and that could again result in delays in considering and potentially getting your award. Those text boxes are really important and one of the most important takeaways I'd like you to get from the disclosure form section here is to utilize those text boxes. Add detail - even if you're not declaring or disclosing a specific foreign tie, even if you're selecting no to one of the questions, you can still add relevant details using those text boxes. It can be a place for you to explain or discuss relevant information to that question. When in doubt, disclose.

Now, I did say we're going to be focusing on the application process, but I do want to make sure that you understand there is a post award monitoring and reporting as well. SBR and STTR recipients are required to submit updated disclosure forms during an award, if there are specific changes. SBIR and STTR recipients are also supposed to indicate if a change has occurred during the annual interim and final progress reports. If no changes occurred, you indicate no. And you don't have to resubmit the foreign disclosure form, but if yes, you would then revise and submit your foreign disclosure form.

Between progress reports, if there's a prior approval request, you may need to update your foreign disclosure form or you are required within 30 days of any change to update the foreign disclosure form. So there are post award monitoring and reporting requirements. It's important to make sure that that if you do have an award and need to submit a foreign disclosure form, you submit on the correct grant phase and year. If you have an award and you need to submit a foreign disclosure form, please reach out and talk to your grants management specialist. If you have any questions on how or where to submit.

Assessment of foreign security risks is required prior to award, and again this is a requirement of the legislation. Assessment is done not just using the disclosure form and application, but uses multiple sources of information. This assessment is separate from the merit review process and generally occurs after peer review and again during that, Just-In-Time process. The assessment includes 8 required assessment categories and I'm going to show you that where those are located on our web page. So you can take a look at not just the required assessment categories, but what is what is the risk assessment being performed.

When we talk about risk assessment, you're going to see foreign countries of concern. Foreign countries of concern are currently currently determined as the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation and the Islam Islamic Republic of Iran. There are no additional foreign countries of concern that have been identified by the Secretary of State. You can find the most updated link to the foreign countries of concern on our website. It connects to the Small Business Administration's website, where that list is housed.

On our foreign disclosure and risk management website, if you Scroll down, you can see the risk assessment categories and specific areas and specific assessments that are done for each of those legislative requirements. I'm not going to read through every one of the categories today, but I do strongly encourage you to review each of them carefully as this is what the assessment will be based on.

One important thing to note is that many of these categories either are looking for active ongoing partnerships, involvement, financial obligations, or recent affiliations within the last year, we often get questions about how far back affiliations are assessed or how far back do we go when we're assessing affiliations and again we're looking for active ongoing or recent affiliations? As you can see here, for most of these categories.

If a risk is identified during the assessment process, and it falls under one of the required denial categories, NIH cannot make an award. And that is again per the most recent reauthorization. These six categories, these six required denial categories are:

- an owner or covered individual that is party to a malign foreign talent recruitment program.
- A business entity, parent company or subsidiary located in a foreign country of concern.
- An owner or covered individual that has a foreign affiliation with a research institution located in a foreign country of concern
- a security risk connecting the small business concern to an entity, including affiliates or individual on one of the restricted party lists that are the restricted party screening lists that are identified in the legislation (there are 8 lists there and we're going to go into there in just a go into those in a little more detail in a minute)
- A security risk with a primary source that is classified or a security risk that the federal agency determines warrants a denial identified during foreign risk assessment.

Unfortunately, sometimes we do find foreign risks in applications if we can't make an award due to a security risk, we do notify the small business and indicate which denial category or categories is relevant. No specific details of identified risks will be provided due to security sensitivities. NIH grants management and program staff including SEED staff, do not have additional information. SEED will not be able to provide additional information or specifics about the identified risks.

Applicants cannot appeal or address identified security risks prior to award. But small businesses can address those foreign risks and resubmit during the next receipt date. Assessments are done for each individual application submitted by the small business. When you resubmit your application, it's looked at completely and again it is looked at one at a time, individually and as a unique application.

Finding a foreign risk does not make a company ineligible for SBR and STTR in the future. In fact, we would like you to resolve and address the foreign risk, revise and resubmit.

Small business concerns are responsible for monitoring relationships with foreign countries of concern. Now, what does that mean?

I would encourage you to conduct your own due diligence and we have some questions to consider as you're looking at your company, partners and collaborators and putting together your application. This is not an exhaustive list, but hopefully will help you as you're thinking about what are some of the things that might be foreign risks.

- Does your small business have investment or partnerships from countries of concern? Do any of the owners or co founders?

- Did your small business or owners have prior investments or partnerships from countries of concern? If they're no longer active, make sure you provide those details on the disclosure form. That can be really important to show that while you did have a relationship, it's no longer active or ongoing.

- For covered individuals, named consultants, Sub Awards or CRO's on your application: are they on one of the restricted party lists identified in the legislation? If you Scroll down on our website, you'll see that we do include individual links to each one of the 8 restricted lists. We're working on developing a more cohesive list, a little easier way for you, when you're doing that due diligence. But right now, I encourage you to take a look at those links and those lists when you're looking at consultants, sub awards and CROs or individuals.

- Another thing to think about is, are the companies are any of the companies that you plan to work with, owned by entities or individuals in a country of concern? Are they a subsidiary of a company 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 and countries of concern?

- Have those collaborations recently ended if they're no longer active? Again, it's important to provide those details on the disclosure form. The disclosure form is a place not just to indicate current collaborations, but also those that have prior have ended previously.

- Are there additional details that you'd like the foreign risk assessment team to know?

This is not an exhaustive list as I've stated, but hopefully this helps as you're thinking about your own due diligence. And while answers to any one of these, may not automatically mean that there there's a foreign risk, it helps you be able to think about conducting your own due diligence and make sure you fill out the foreign disclosure form completely and correctly.

The most important piece of advice: review case studies and our case study list is growing. We've gotten a lot of positive feedback on the case studies. We're up to 14 right now. You can find those on our website and I'm going to go through some of the most common issues that we find and which case studies, those relate to.

So let's start with case study number six, which is a common issue that we see foreign risks due to a contractor. So in this case we have a small business. Now the small business itself doesn't have any foreign risk. They don't have ownership or investment from foreign countries of concern. There's no concern with the small business.

However, in the application, the small business proposes a contract with a company and we're going to call it ABC to provide Research Services for its project. ABC is a subsidiary of a business owned by an entity in a foreign country of concern. So while ABC may be operating in the United States, it's wholly owned by an entity in one of those foreign countries of concern. Collaborating with that subsidiary, unfortunately inadvertently exposes the small businesses intellectual property to potential exploitation by the parent company.

In this case, the award would be denied and that's because the small business has proposed this contract to a subsidiary of a country of a company in a foreign country of concern. That would formalize the foreign affiliation between the research institution and covered individuals. The small business concern would receive a notification that there was a denial due to a security risk that the federal agency determines warrants a denial, and it shows that that denial was identified during foreign ownership and financial ties that the foreign ownership and financial ties risk assessment category.

Well, what can companies do? Remove the risk and disclose.

So case 13 talks about termination of CRO services. This is a situation where a small business concern has contracted Research Services from CRO X. They've worked with and used CROX for prior projects. The small business is planning to use CROX for their next project. And they're applying for funding from HHS. While applying, one of the individuals in their company takes on the responsibility of doing that due diligence prior to award. They search through every one of their partners. They look to make sure that there are no issues that they can see that would potentially create a foreign risk. Through this search, they discover that CRO X is actually on one of those lists.

As a result, the small business ends work agreements with CROX and identifies and uses an alternative company. Now that alternative company doesn't show up on any of the of the restricted lists. It doesn't have ownership by a company for many of the restricted lists, so they've done their due diligence on selecting this alternative company and have moved forward with the alternative company in the application.

The small business then notes in the foreign disclosure form that they did have a prior relationship with CROX, but they've terminated it as of the specific date. No other security risks are found in this case study, and as a result, the small the award can be made because the small business has no security risk and they proactively prior to award removed the risk and disclosed the information in the foreign disclosure form.

Another example of removing the risk and disclosure is case 14, which is confirmation of determination of affiliation. In this case a small business supplying for an STTR grant, because it's important to note this requirement is not just for SBIRS, but for STTRs as well.
In preparing the application material again, the company PIs do that internal due diligence and discover that one of its partners is owned by an entity in a foreign country of concern.

Before applying for an STTR, the company terminates the affiliation and indicates in the foreign disclosure form that that affiliation is no longer active and has been terminated as of that specific date. In this case, there are no other security risks and therefore the award can move forward.

So these are three examples of case studies, but more case studies can be found on the foreign disclosure and risk management website. And what you'll see on that with those case studies, again, it's not just those things that create risk, but also what is not considered risk, which is I think just as important, we do get a number of questions about that as well.

I'm going to encourage you to go to our website seed.nih.gov. I know it is the time of preparing the applications for the upcoming receipt date. If you do have questions on application preparation as you're going for that September receipt date, email seedinfo@nih.gov. I would encourage everyone to apply early. It is important to apply early because there's no late submission, so it’s extremely important to make sure that you put that application in in advance of the receipt date.

With that I'm happy to answer at least a few questions on the foreign risk assessment process. So there is a question about those text boxes and we're going to be taking questions specifically in the Q&A. We're not going to be taking live questions today, so if you do have a question, I do encourage you to put those questions in the Q&A box and we will be making the slides, the transcripts and the recording available on our website approximately a week or so after our webinar today so those will be made available.

Now, one of the questions was around that text box in the foreign disclosure form. As I noted, one of the most important things you can do in a disclosure form is provide additional information if it's applicable to you or your company or any of the covered individuals.

So yes, you can absolutely put information in that text box, regardless of which answer yes or no you select, and in fact, again, we really do encourage you to add more information if it's applicable in the foreign disclosure form. So you can certainly add additional information. And we do get questions about additional information even if you select no.

There's a hypothetical question, but I think it's an important one and again really utilizes the foreign disclosure form. If for any application, you've selected a company, but as the application is going through the review process, you discover or determine that that company was bought out, by an individual or an entity in a country of concern, when you submit the foreign disclosure form, you can indicate that you were affiliated with a company and then terminated that affiliation.

While we will not appeal or mitigate. We understand that different affiliations or things may change up until the Just-In-Time process. That's why it exists - to provide information about other support, and that foreign disclosure form with the most current and recent most current and up-to-date information. So you should put whatever the current updated affiliations you have in that foreign disclosure form at that time, and if anything has been terminated, or if you've ended an affiliation with an entity, you should put that in the foreign disclosure form.

Again, it is important to note that we will be providing this slide deck, the recording, and the transcript on our website. But also our information on our website is really valuable and we do try to keep that updated as I said. Our case studies do change. We do add to those case studies and we do try to add resources as applicable. The recording and this webinar should be linked on that foreign risk assessment web page, so I do encourage you to take a look at the website and really utilize that as one significant resource.

So I am getting a number of questions in the chat associated with getting additional information or getting more elaborate information on the specifics associated with a denial.
As noted, we will we are not able to provide additional information about a denial beyond the specific categories associated with the denial. So we will tell you that it there was a foreign risk identified and this is the denial category or categories associated with that. We will indicate which of the foreign risk assessment categories that is associated with, so which one of those assessment categories. Again, you can find details about those assessment categories on our website in that in that big table in the middle of our website is associated with that denial.

If you use that information to do again your own due diligence and determine where the foreign risk may be, it's also important to note there may be more than one foreign risk, and so resolving one risk you need to resolve all foreign risks in order for an app there. There needs to be no foreign risks in order for an application to move forward.

So I'm looking and I do see a number of the questions are really the same. So, given that, I think I'm gonna pause briefly to see if there are any additional questions.

So there is an additional question and I think it's important to address it's associated with publications of research papers. We do get a number of questions if simply being on a research paper is enough to be considered a foreign risk. The answer is no. Simply having a peer reviewed publication is not enough to be considered an issue by itself with no other factors. That publication could be indicative of a foreign collaboration, or of a foreign risk.

Also important to note, simply having a patent in a foreign country in a foreign country is not automatically a foreign risk. And I would encourage you, if you do have foreign patents, again read through the foreign risk assessment categories specifically associated with patents.

There is a comment about if someone gets a denial and the company resolves what they believe resolves the risk - can NIH move forward with an award? Well, as I noted at this time, we are not providing the specific details and we're not allowing for appeals or companies to address identified security risks prior to award.

You are encouraged though, and I really want to emphasize this, to address your foreign risks and resubmit the next receipt date. The great thing about NIH is that we do have 2-3 standard receipt dates a year. We have multiple opportunities for you to come in and we do open topic solicitations. That means we are unlike some of the other agencies who only have a specific topic open for a specific time. We're interested in those great ideas across the board that could be applicable to NIH's mission space. That's true for all three of our receipt dates for our parent solicitations. So you can come in, revise your application, come in for that next receipt date.

Finding a foreign risk does not, I repeat, does not make your company ineligible for SBIR and STTR funding. And so I want to make sure that everyone knows we do want you to identify those risks. Do that due diligence, revise and resubmit.

Now there was a question about case Case 14 and I think that's great. There was the question in case 14. What specifically should be in this form?

In the foreign disclosure form, you can note in the foreign disclosure form that you no longer have a specific affiliation. You can indicate that there's no foreign affiliations, but at the same time you can indicate that you had a prior affiliation. You can put that information in the text box. You could provide information associated with that prior affiliation, and that it was terminated and provide the date of termination.

So you can provide that while, yes, while you don't currently have a foreign affiliation, you did previously and you can provide that information into the foreign disclosure form, not the application. The foreign disclosure form is not part of the initial application submission but is part of the just in time process.

For those who are new to NIH, just in time occurs after peer review, when grants that are being considered for funding are asked for additional information, such as the other support information about animal or human subjects and information about the SBIR/STTR certification forms as well as the foreign disclosure form. So you're gonna be providing that foreign disclosure form at the just in time, and you can provide the information about any prior affiliations in that form.

I do get a number of questions associated with citizens of a foreign country of concern.
I get it enough that I'm going to take a minute and there was a question specifically about citizens of a foreign country of concern and how that's handled in the risk assessment process. So if you look at the case studies, we actually have a specific case study associated with citizenship, family or travel. And so I would encourage you to look at case 11 and I'm going to there's there's a little bit of a spoiler here. There's no denial, as noted, for foreign countries of concern citizenship, families, or travel.

So you can see in this situation in this specific case study, this fictitious Dr. Ross received a PhD from an institution located in the country of concern where he is a citizen and a former resident of the country of concern and visits family back in that country of concern.

But they don't have any current affiliations with that with institutions or companies located in that country of concern. So while yes, they still have family in that country of concern, they don't have any current affiliations. Foreign risk assessment confirmed that they don't have any current foreign affiliations. And there's no other security risks. And as a result, the award can be made in this case.

So having citizenship from a foreign country of concern or family or travel visiting family in a country of concern does not indicate a foreign risk.

In the chat we have included a couple of links and one is about the just in time process. Thank you to my team for putting that in there. If you have questions specifically about the just in time process or you were going through the just in time process, do make sure to reach out and talk to your grants management specialist. They're the ones that are going to be reaching out to you during to gather that information during the just in time process and can help make sure that you've submitted everything that you need in order to continue your application to in order to allow your application to be considered.

So there are a number of very specific situations and instances in the Q&A, and I'm not going to go into specific instances or specific grants in the Q&A, but I am trying to highlight a couple of some broader themes. Again, I encourage you to review the case studies and see what kinds of specific instances and things may create a concern. Or as in case number 11, not mean a concern at all. So with that, I'm going to bring this webinar to a close. However, I do encourage you if you have questions to reach out, to read the foreign disclosure and risk management website. The frequently asked questions are located up in the corner here. And that's true not just for foreign risk, but those frequently asked questions cover broader application questions as well that you may have as you're preparing your application for the upcoming September receipt date or other receipt dates in the future.

You can see we have a direct link to the webinar today. That's where information associated with this webinar, including slides, the recording and the transcript, will be located.
And if you do have questions about your application, as you're preparing your application, email seedinfo@nih.gov and we can assist you with that.

I want to thank everyone for joining us today and we look forward to seeing you on the next webinar.