



Fogarty International Center

NIH Policy Updates, Grants Pre- & Post-Award Management, FAQs, and Case Studies

Grants to Foreign Institutions/International Organizations and Domestic Grants with Foreign Components

2023 SRAI Annual Meeting

NIH FIC Grants Office



Fogarty International Center

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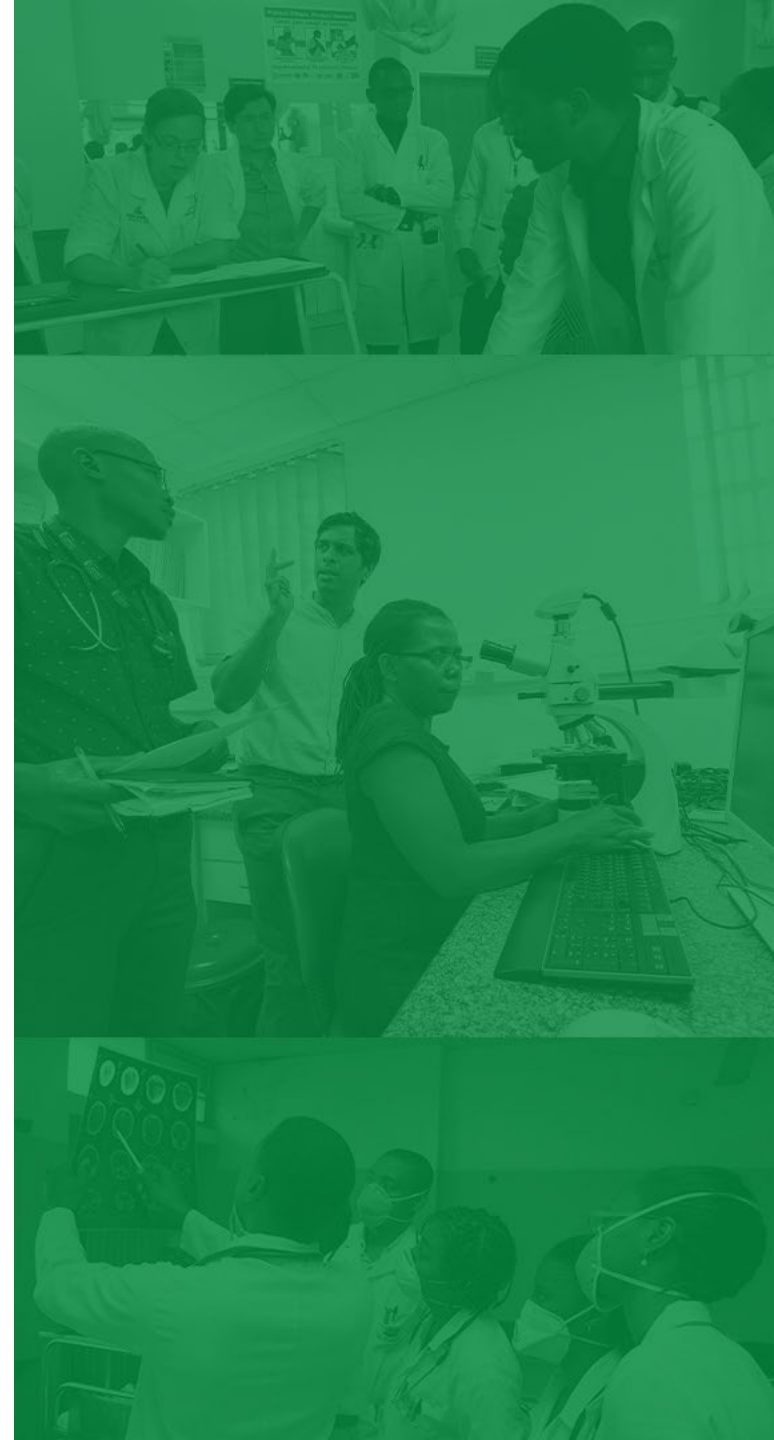


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Policy Updates

Presented by: Satabdi
Raychowdhury



Policy Updates: Foreign Subawards

- NOT-OD-23-182 and 133: NIH Final Updated Policy Guidance for Subaward/Consortium Written effective January 1, 2024
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html>
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-133.html>

Policy Updates: Foreign Subawards

All About NIH Subaward Agreements: Webinar

- Oct. 17, 2023, 1:00 – 2:00 PM EST
- The NIH Office of Policy for Extramural Research Administration (OPERA) as they guide you through the various sections of a subaward agreement, offering detailed guidance and highlighting key policies.
- Gain insights and seek clarification during the live Q&A.
- Free, virtual event

<https://nexus.od.nih.gov/all/2023/09/26/all-about-nih-subaward-agreements-webinar-on-oct-17/>

Policy Updates: Foreign Subawards

Effective January 1, 2024, written agreements for foreign subawards must *contain a provision* requiring foreign subrecipients to *provide access* to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a *frequency of no less than once per year*, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

Grant recipients will need to be compliant with this updated policy guidance by March 2, 2024.

<https://grants.nih.gov/policy/subawards>

FAQs: <https://grants.nih.gov/faqs#/subawards.htm?anchor=4304>

Policy Updates: Data Management and Sharing (DMS) Plan

- NOT-OD-23-185: Prior Approval Requests for Revisions to an Approved Data Management and Sharing (DMS) Plan Must be Submitted Using the Prior Approval Module
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-185.html>
- NOT-OD-23-132: Updates to NIH Genomic Data Sharing Policy Institutional Certification Forms
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-132.html>
- NOT-OD-22-198: Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-198.html>

Policy Updates: SAM Registration

- NOT-OD-23-153: Update - NIH Response to Registration Issues in SAM.gov

SAM has made marked improvements and put new measures in place to help resolve the backlog. Consequently, effective July 14, 2023, the previous exception to the Late Application Policy will be revoked.

- No excuse for late applications due to late SAM registrations

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-153.html>



Grants Pre- and Post-Award Management

Presented by: Mollie Shea
& Vicky Tran



Systems Award Management (SAMs)

- A **yearly renewal** with SAM is needed to keep your Grants.gov registration active
 - NIH policy: The expiration date cannot be within 30 days of the budget start date.
 - (e.g., A grant with a 12/1 start date cannot have a SAM.gov entity expiration date before 12/31)
- **ALWAYS** MAINTAIN AN ACTIVE SAM REGISTRATION

SAM.gov Entity Registration

If you're experiencing difficulties...

- Contact the Federal Service Desk through SAM.gov early and often if you are having trouble with your entity account.
 - **FIRST** submit an electronic Help Desk Ticket,
 - **THEN** call the Help Desk.
 - **ONLY** create **one** help desk ticket.
- **IF YOUR SAM.GOV REGISTRATION IS NOT COMPLIANT WE CANNOT ISSUE ANY FUNDS**

Mailing Addresses and Contact Information

- All mailing/physical addresses and contact information for the PD/PI, Grantee Institution, and Business Office must be **correct, current, and identical** across all systems (eRA Commons, SAM, NCAGE, PMS, and EIN*)
 - EIN (NIH generated number): Ensure you are using the correct number that is the same across **all** systems
- Corrections must be made through the respective system's helpdesk
- Misaligned information **will** cause delays with the award and possibly not allow access to funds

Successor-in-Interest versus Name Change

Successor-in-Interest (SII)

- Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the **transfer of all of the assets** of the recipient or the **transfer of that part of the assets** involved in the performance of the grant(s).
- A SII may result from legislative or other legal action, such as a merger or other corporate change.

Name Change

- Action whereby the name of an organization is changed **without** otherwise affecting the rights and obligations of that organization as a recipient.

Successor-in-Interest versus Name Change

Successor-in-Interest (SII)

- Albert Einstein College of Medicine, Inc. (AECOM, Inc.) became Albert Einstein College of Medicine.
- AECOM, Inc. ceased to exist.
- Albert Einstein College of Medicine took over administration of all awards that had been with AECOM, Inc.
- The new entity had a new name, new EIN #, and a new UEI #.
- EIN # **changes**

Name Change

- Mount Sinai School of Medicine changed their organization name to Icahn School of Medicine at Mount Sinai.
- EIN # does **not** change

Reporting Requirements

	Non-SNAP Award	SNAP Award
Annual Research Performance Progress Report (RPPR)	Due <u>60 days</u> before budget start date	Due <u>45 days</u> before budget start date
Federal Financial Report (FFR)	<p>Due at 90 days after the end of the quarter</p> <p>i.e., budget period ends, 2/28; calendar quarter ends, 3/31, Annual FFR due, 6/30</p>	<p><u>Final</u> Federal Financial Report (Final-FFR) will be due at 120 days after the end of the quarter in which the budget period ends</p> <p>i.e., budget period ends, 2/28; calendar quarter ends, 3/31, Final FFR due, 6/30</p>

Closeout Reporting Requirements

- Final or Interim Research Performance Progress Report (RPPR)
- Final Federal Financial Report (FFR)
- Final Invention Statement and Certification
- Due no later than 120 days after the project end date
- After 180 days, the award enters unilateral closeout!

RPPR Guidance

- The RPPR is completed using the eRA Commons
 - Only the PD/PI or the PD/PI delegate may initiate a RPPR
 - **Focus on the reporting period**
- **Specific Supplemental Guidance for FIC Grantees:**
 - <http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx>
 - Refer to guidance for your grant's appropriate type (SNAP or non-SNAP) and activity code (Education, Standard or Career)
 - [SNAP awards \(R01, R03, R21, K01, K43\)](#)
 - [Education-type RPPR \(D43, R25, U2R\)](#)
 - [Non-SNAP Standard awards \(D71, G11, R03, R21, U01\)](#)
- Refer to the [NIH RPPR Instruction Guide](#)

Annual RPPR Reporting

RPPR Sections especially relevant for Foreign Components:

- C.1 Publications
- D.1 Participants
- E.4 Dollars spent in foreign countries
 - This amount should be cumulative by country, and is the amount spent during the last budget period
- G.8 Project/Performance Sites
- G.9 Foreign Components

NIH Policy on Foreign Components

Foreign Components

NIH requires recipients to determine whether activities it supports include a foreign component, defined as: The existence of any “significant scientific element or segment of a project” outside of the United States:

- Performance of work by a researcher or recipient **in a foreign location**, whether or not NIH grant funds are expended **and/or**
- Performance of work by a researcher **in a foreign location employed or paid for by a foreign organization**, whether or not NIH grant funds are expended

RPPR Section C.1 Publications

Until further notice, manuscripts written in scripts other than Latin (e.g., Russian, Japanese) cannot be processed by the NIHMS.

- These manuscripts are not required to be posted on the PubMed Central and do not require evidence of compliance on applications, proposals, or reports
- The NIHMS continues to process manuscripts written in Latin (Roman) script that contain characters and fonts used in standard mathematical notation.

<https://publicaccess.nih.gov/policy.htm>

RPPR Section C.1 Publications

- **Report all trainee publications** or manuscripts accepted for publication in a journal or other publication during the reporting period that resulted from work conducted while a trainee was supported by the award. Do not report any publications that arose from work that the trainee conducted prior to or following grant support.
- Reporting trainee publications in response to section B. 2 Accomplishments is **not** acceptable

RPPR Section C.1 Publications

- For a publication to be included in the PD/PI's "My Bibliography" section of the PD/PI's MyNCBI account it must be associated with this award, even if the PD/PI is not an author.
- This includes trainee publications.

<https://publicaccess.nih.gov/policy.htm>

RPPR Section D.1 Participants

- A Commons ID is required for all individuals with a postdoctoral, graduate, or undergraduate role.
- A Commons ID needs to be reported in Section D for all trainees who received one month (160 hours) or more of training in the past reporting year (not cumulative over several years).

RPPR Section E.4 Dollars Spent in Foreign Countries

“What dollar amount of the award’s budget is being spent in foreign country(ies)?”

- For **domestic awardees** provide the dollar amount **obligated** to first-tier subawards to foreign entities for this reporting period.
 - Report **only cumulative** first-tier subawards dollars by country. Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.
- For **foreign awardees** provide the dollar amount of the award, excluding all first-tier subawards to U.S. entities, for this reporting period. Dollars provided should reflect total costs.
- ***If more than one foreign country, identify the distribution between the foreign countries.***

RPPR Section G.2 Responsible Conduct of Research (RCR)

This section is required for Fogarty Training and Education Awards, describing the RCR training provided during the reporting period.

Each annual progress report must include the following information about activities that took place during the past budget period:

- A description of the instruction in responsible conduct of research (RCR)
- A description of who received RCR instruction
- A description of any enhancements and/or modifications to the five instructional components described in the competing application or the previous year's progress report
- A list of names of faculty who contributed to formal instruction in RCR and the specific training they provided

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

RPPR Section G.8 Project/Performance Sites

All performance sites should be clearly indicated in this section of the RPPR.

NOTE: NIH prior approval is required before adding or changing a foreign component under a grant.

RPPR Section G.9 Foreign Component

All Foreign Components must be reported in this section of the RPPR including a description of each foreign component.

- *Foreign awardees are considered being a foreign component.*

NOTE: NIH prior approval is required before adding or changing a foreign component under a grant.

RPPR Section G.10 Estimated Unobligated Balance

- Carryover of previous grant funds not expended is generally allowed, prior approval is not required unless if there is a possible change in scope.
- Unobligated balances must be reported in RPPR, G.10.
- Do not include any dollars or discussions about carryover in RPPR H.

RPPR Section G.10 Estimated Unobligated Balance

What does an unobligated balance represent?

- Shortened budget period
- Delayed start
- Slow progress
- Others (e.g., COVID-19 Pandemic)

What questions, as your GMS, we may ask?

- What happened? How was this unobligated balance cumulated?
- Why did this situation occur?
- Where will the funds be spent?
- What is the plan to spend down the funds?

RPPR Section H. Budget

- Do **not** include any carryover dollars or discussions about carryover.
- Only include **new** dollars and discussions about the upcoming budget year
- Always include a detailed budget justification (PDF attachment) for every line item even if there has been no change since the previous year.
- If you have any subaward budget(s), prepare separate budget justifications for your budget and the subaward(s) budget(s).

Cost Considerations

- **A**llocable
- **A**llowable
- **R**easonable
- **C**onsistent
- For further details, refer to the [NIH GPS, Chapter 7, Cost Considerations](#)

Change in Scope

Change in Scope **requires FIC prior approval**. Is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project.

Examples of change in scope:

- Principal Investigator or key personnel (named on the NOA)
- Change in Institution
- Changes to a Multiple PI plan
- Any change from the approved use of animals or human subjects
- Addition of foreign component
- Significant rebudgeting
- Request for additional time (extension) – with and without funds
- Change in approved aims

<https://www.fic.nih.gov/Grants/Pages/Scope.aspx>

FAQs Foreign Organizations

Are there any tips to assist foreign organizations while registering in eRA Commons?

Keep these pointers in mind while registering in eRA Commons.

Applicant organizations:

- Must have a SAM-issued unique entity identifier (UEI) **prior** to registering in eRA Commons. You do not need to complete the full SAM registration to begin eRA Commons registration, though it will need to be completed prior to submission.
- The **same** UEI must be used in all federal system registrations (SAM, Grants.gov, eRA Commons).

FAQs Foreign Organizations

Some of the data fields in the SF424 (R&R) do not really apply to foreign organizations. How will this be handled?

- For some of the data, special instructions are included in the [Application Guide](#) for foreign organizations.

Are International organizations required to obtain an EIN number as part of the grant submission process?

- If a grantee **has had** an NIH grant, the NoA will contain a valid EIN number.
- If a grantee **has not had** an NIH grant, NIH does not require international organizations to obtain an EIN number for application submission. International organizations may use 44-4444444 for the Employer Identification field in the SF424 (R&R) Cover Component of the application package.
[See [NIH eSubmission Tips for International Applicants](#) (PDF - 343 KB)].

FAQs Foreign Organizations

How do I know if a foreign organization is eligible to apply?

- Each funding opportunity has a section for Eligibility. In that section there will be a clear statement about whether foreign institutions are eligible to apply

Which budget form should I use if I am a foreign organization?

- Foreign institutions must use the Research and Related Budget form.

FAQs Foreign Organizations

On the SF424 (R&R) application the field for “State” appears to be required. What do I do?

- Select your country first. If you select a country other than the US or Canada, the state field will become optional. Inclusion of Providence is required for Canada.

How does the system handle phone numbers in different formats?

- The phone number field on the SF424 (RR) application has a 25-character limit, but no specific format requirements.

What should I include in the Congressional District filed?

- Foreign institutions should use 00-000 for the Congressional District.



Case Studies

Presented by: Vicky Tran



Successor-in-Interest or Name Change?

Mary Poppins College of Medicine changed their name to Mary Poppins College, School of Medicine. The institution's address and business structure remain unchanged.

Is this a Successor-in-Interest or Name change?

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1. Name change
2. The institution's address and business structure remain unchanged

Successor-in-Interest or Name Change?

Elsa University merged with their parent institution, University of Olaf. As a result of this merger, the University of Olaf assumes authority of Elsa University's assets (contracts, grants, financial accounting, etc.), and Elsa University changed their name to the University of Olaf.

Is this a Successor-in-Interest or Name change?

Successor-in-Interest or Name Change?

Elsa University merged with their parent institution, University of Olaf. As a result of this merger, the University of Olaf assumes authority of Elsa University's assets (contracts, grants, financial accounting, etc.), and Elsa University changed their name to the University of Olaf.

1. Successor-in-Interest
2. University of Olaf assumes authority of Elsa University's assets

Successor-in-Interest or Name Change?

Iron Man Hospital recently purchased Hulk Clinic, Inc. Hulk Clinic, Inc.'s name does not change, but their business and financial office addresses were changed to Iron Man Hospital's address, and Iron Man Hospital assumes financial authority.

Is this a Successor-in-Interest or Name change?

Successor-in-Interest or Name Change?

Iron Man Hospital recently purchased Hulk Clinic, Inc. Hulk Clinic, Inc.'s name does not change, but their business and financial office addresses were changed to Iron Man Hospital's address, and Iron Man Hospital assumes financial authority.

1. Successor-in-Interest
2. Iron Man Hospital assumes financial authority

Mailing Address

- Micky Mouse University is in the process of updating their SAM registration.
- The registration form was submitted and approved with 100 Gofy Lane as their street address instead of 100 Goofy Lane.
- This address discrepancy between NCAGE, SAM, eRA Commons, and PMS, severely delayed Micky Mouse University's ability to receive an NIH grant award.
- All systems must match for NIH to be able to issue awards.

Foreign Component

- Drs. Wendy and Peter Pan are MPIs of a NIH grant award.
 - Dr. Wendy is the contact-PI from a US institution, Big Ben University
 - Dr. Peter Pan is the MPI from a LMIC institution, Sky Tree University
- Dr. Peter Pan was offered a new position at the Hook Institution of Medical Research, located in the same country
- Drs. Wendy and Peter Pan wishes to transfer the subaward to Hook Institution of Medical Research with Dr. Peter Pan's move
- Is this allowable?

Foreign Component

- Allowable, with prior approval.
- Recipients adding or changing a foreign performance site within a funded grant award must obtain approval from the GMO before work can be performed at the added or changed foreign site.
- Remember, any change with a foreign component requires prior approval!

Allowable Costs

- Dr. Yoda is a PI and is planning to host a conference with multiple guest speakers. In his grant budget, he allocates \$500 USD honoraria per speaker, for a total of 10 speakers, and \$5,000 USD.
- Is this allowable?

Allowable Costs

- Honoraria is **not** allowed when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium.
- A **payment for services rendered**, such as a speaker's fee is allowable.
- The cost should be labeled "Speaker's Fee" or a title other than "honoraria" to prevent confusion and questions on the cost's allowability.

Reference the [NIH Grants Policy Statement, Chapter 7.9, Allowability of Costs/Activities](#)



Helpful Resources



References and Links

GENERAL: NIH AND FOREIGN GRANTS:

- **NIH Office of Extramural Research (OER) webpage:**
<https://grants.nih.gov/grants/oer.htm>
- **NIH OER Information for Foreign Applicants and Grantees:**
<http://grants.nih.gov/grants/foreign/>
- **eRA Commons User Guides:** http://era.nih.gov/commons/user_guide.cfm
- **NIH Application Submission Tips for International Applicants:**
http://grants.nih.gov/grants/ElectronicReceipt/files/Tips_for_International_Applicants.pdf

References and Links

GENERAL: FIC:

- **FIC and Foreign Funding Opportunities:** <http://www.fic.nih.gov/Funding/Pages/default.aspx>
- **Fogarty Funding New Emails:** <https://public.govdelivery.com/accounts/USNIHFIC/subscriber/new>
- **FIC Foreign Grant Information:** <http://www.fic.nih.gov/Grants/Pages/Foreign.aspx>
- **FIC FAQs for FIC and Foreign Awards:** <http://www.fic.nih.gov/Grants/Pages/Frequently-Asked-Questions.aspx>

RPPR:

- **NIH OER RPPR Webpage:** <http://grants.nih.gov/grants/rppr/>
- **FIC Progress Report Guidance:** <http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx>

PUBLIC ACCESS:

- **NIH Public Access Policy:** <http://publicaccess.nih.gov/index.htm>
- **Non-English Guides to PubMed:** <http://nnlm.gov/training/resources/intlpubmedlinks.html>

References and Links

SYSTEM FOR AWARD MANAGEMENT (SAM):

- **SAM FAQs for Entity Registration:**

https://www.fsd.gov/gsafsd_sp?id=kb_category&kb_category=2ad0cfc81b4f64108aa3a8eae54bcbf5

- **NIH Information for Foreign Grants:**

<https://grants.nih.gov/grants/foreign/index.htm>

- **NIH Organization Registrations:**

<https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration/org-representative-registration.htm>

- **NIH Applying Electronically FAQs:**

<https://grants.nih.gov/faqs#/applying-electronically.htm?anchor=question52115>

- **NIH Dealing with System Issues:**

<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm>

References and Links

PAYMENT MANAGEMENT SYSTEM:

- Use available resources:
 - Foreign and U.S. colleagues with experience
 - **Self-help web portal:** <http://www.psc.gov/one-dhhs>
 - **PMS FAQs:** <https://dpm-portal.psc.gov/Welcome.aspx?pt=DPM>
 - Program Support Center:
 - **Paperwork and account questions:**
 - US Institutions refer to your PMS accountant
 - Foreign Institutions refer to Raynette.Robinson@psc.hhs.gov; (301) 492-4938
 - **Helpdesk:**
 - Email: PMSSupport@psc.gov
 - Phone: (877) 614-5533
 - Hours: Monday – Friday 7 a.m. to 9 p.m. Eastern Time

Points of Contact

- **General NIH Application Questions:**
 - E-Mail: GrantsInfo@nih.gov
 - Phone: 301-435-0714
- **Grants.gov Customer Support:**
 - E-Mail: support@grants.gov
 - Webpage: <http://grants.gov/>
 - Phone: 800-518-4726
- **eRA Commons Helpdesk:**
 - Web: <http://era.nih.gov/help/>
 - Toll-free: 1-866-504-9552
 - Phone: 301-402-7469
 - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time

Points of Contact

- **SAM.gov HelpDesk- The Federal Service Desk:**
 - Webpage/Electronic Helpdesk Ticket: <https://fsd.gov/fsd-gov/home.do>
 - **U.S. Calls:** 866-606-8220
International Calls: 334-206-7828
DSN: 866-606-8220
 - Hours: Monday – Friday 8 a.m. to 8 p.m. Eastern Time

Contact Us

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