RFA-DA-20-025
STEP UP FOR SUBSTANCE USE DISORDERS (SUD):
A DRUG TARGET INITIATIVE FOR SCIENTISTS ENGAGED IN FUNDAMENTAL RESEARCH
(U18 - CLINICAL TRIAL NOT ALLOWED)

WEBINAR FOR APPLICANTS

ELENA KOUSTOVA, PHD, MBA

DATE : DECEMBER 12, 2019

CONTACT: RAM ARUDCHANDRAN, PH.D., TEL: 301-827-6889
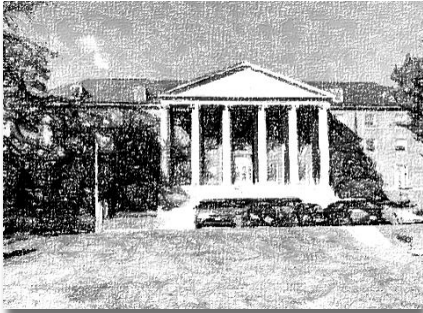
EMAIL: RAMACHANDRAN.ARUDCHANDRAN@NIH.GOV

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OUTLINE

- Part I (Elena Koustova)

    o Outline the NIH grant processes

    o Explain the FOA goals

    o Provide tips for successful submission

- Part II (Ram Arudchandran)

    o For new and foreign applicants, provide detailed explanations about the application process

https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-025.html

National Institutes of Health (NIH)

o   Part of US Department of Health and Human Services

o   Made up of 27 ICs, each with specific research agenda, focusing on particular diseases or body systems

o   Total NIH appropriation for FY 2019 is $39.1 billion, 20,262 employees – grantmaking and managing

o   To seek **fundamental knowledge** about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

■   National Institute on Drug Abuse (NIDA) is the lead federal agency supporting research on drug use and its consequences. …To advance science on the causes and consequences of drug use and addiction

Solicitation to Award Process

Solicitation → Proposal Submission → Proposal Evaluation → Award

Solicitation to Award Process

Solicitation	Proposal Submission	Proposal Evaluation	Award

- Targeted Funding Opportunity Announcements (**RFA** DA20-025)
  - ➢ $ Set aside ($10 million for fiscal year 2020)
  - ➢ peer review at NIDA
- Intent to fund up to 50 awards
- Budget limited to $150,000 direct cost per year
- One year project period

Solicitation to Award Process

Solicitation | **Proposal Submission** | **Proposal Evaluation** | **Award**

- Targeted Funding Opportunity Announcements (**RFA** DA20-025)
  - ➤ In-house review
  - ➤ $ Set aside
- Intends to fund up to 50 awards
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1) Registrations:
- Dun and Bradstreet Universal Numbering System (DUNS)
- NATO Commercial and government entity (NCAGE) code *for foreign applicants*
- System for Award Management (SAM)
- NIH's Electronic Research Administration System (eRA)
- Grants.gov (Register with Grants.gov)
- Small Business Administration Company Registry (SBA) *for small businesses*
- Employer Identification Number (EIN)

2) Follow the Research (R) Instructions in the SF424 (R&R) Application Guide

3) Apply through RFA-DA-20-025

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Proposal Evaluation

1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment

IMPACT	PRIORITY SCORE	DESCRIPTOR
	1	Exceptional
HIGH	2	Outstanding
	3	Excellent
	4	Very Good
MODERATE	5	Good
	6	Satisfactory
	7	Fair
LOW	8	Marginal
	9	Poor

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Solicitation to Award Process

Solicitation

Proposal Submission

Proposal Evaluation

Award

Solicitation

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Award

- Activity code U18 - cooperative agreement
- Interactions between participating PI, institutions, and the sponsoring NIH Institute
- Cooperative Agreement Terms and Conditions of Award, including conflict resolution
- Making conclusions which are generalizable to others – all results will be reported
- Project Development Team (PDT) comprising of Program Official (PO), Science Officer (SO), the PD/PI and appropriate NIH expert consultants.

KEY DATES

- Letter of Intent Due Date(s): January 13, 2020 *(for instruction, see Section IV.2 of RFA)*

- Application Due Date(s) February 13, 2020

  - No late applications will be accepted for this Funding Opportunity Announcement.

  - All applications are due by 5:00 PM local time of applicant organization.

  - Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

- Scientific Merit Review: May/June 2020

- Advisory Council Review: August 2020

- Earliest Start Date September: 2020

- Expiration Date: February 14, 2020

https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-025.html

FOA GOALS

- Allow scientists doing fundamental research to contribute to drug development and still remain basic scientists:
  - Provide access to specialized expertise and train 50 PIs in rapid experimentation for maximum impact
    - Some will return to (hopefully, improved) basic science work
    - Some will establish collaborations and move into translational space (patent, license, DTMC, BPN and SBIR, or pivot)
  - Allow young investigators to join NIH-funded force

- Align the outputs of NIDA-funded basic research with requirements of privately-financed biomedical product development
  - Implement a stepladder approach for target validation/invalidation to allow the project to proceed or fail fast
- Validate/de-validate 50 targets for SUD
  - Disclose both negative and positive results in NIH Reporter
  - Publish RFA findings summary

WHAT IS "RESPONSIVE"?

■ The proposed studies could include, but not limited to, the following:

- o Validation of targets for SUD treatment;

- o Experiments to assure data robustness (e.g., reproducing the key (including published) in vitro and in vivo finding in at least 2 duplicate studies using same material, doses, readouts);

- o Determination of biological criteria for hit designation;

- o Determination of approach for hit-to-lead discovery;

- o Developing the target-specific screening paradigms and decision trees;

- o Development and validation of in vitro and in vivo assays;

- o General mechanism of action (MOA) and selectivity testing;

- o Composing drug product concepts (e.g., Target Product Profile (TPP));

- o Compound screening (including FDA-approved drugs for other indications, drugs approved outside of US, etc.) to yield hits and leads;

- o Business case preparation work;

- o Experiments to strengthen the intellectual property (IP) position.

❑ Monoclonal antibodies, recombinant proteins, nucleus acid-based therapeutics and viral vectors and small molecules

❑ No diagnostics or devices, no new animal models

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information
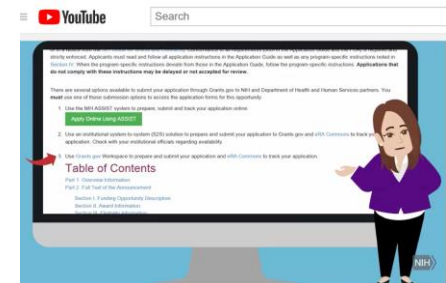
Section VII. Agency Contacts

Section VIII. Other Information

https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-025.html

HOW YOUR APPLICATION WILL BE EVALUATED?

■ *…It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced…*

■ FOA Section V. Application Review Information

Resources:

1) https://www.youtube.com/watch?v=C5_mio9U0oY&t=

2) https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf : RESEARCH INSTRUCTIONS FOR NIH; SF424 (R&R) APPLICATION PACKAGES (160 pages, use Ctrl F)

3) https://www.niaid.nih.gov/grants-contracts/sample-applications#r01: R01 Sample Applications and Summary Statements from NIAID

https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-20-025.html

<u>Limit</u>, not requirement to have

Section of Application	Activity Codes	Page Limits * (if different from FOA, FOA supersedes)
Project Summary/Abstract	For all Activity Codes	30 lines of text
Project Narrative	For all Activity Codes excluding C06,UC6 and G20.	three sentences
Introduction to Resubmission and Revision Applications	For all Activity Codes (including each applicable component of a multi-component application)	1
Specific Aims	For all Activity Codes that use an application form with the Specific Aims section (including each component of a multi-component application)	1
Research Strategy	For Activity Codes R03, R13, U13, R13, U13, R21,R35, R36, R41, R43, SC2, SC3, X01[1], X02[1], R50, UT1	6
	For Activity Code DP2	10
	For Activity Codes DP3, DP5, G08, G11, G13, RC2, RC4, RF1, R01,R15, R18, R21/R33, R24, R28, R33, R34, R42, R44, R61/R33, RL1, SB1, SC1, SI2, UB1, UC2, UH2,UH3, UG1, UC4, UF1, UG3/UH3, UH2/UH3, U01, U18, U24, U2C, U34, U42, U44,UT2, X01[1], X02[1]	12
	For all other Activity Codes	Follow FOA instructions
Commercialization Plan	For Activity Codes R42, R44, SB1, UT2, U44, UB1 (Attachment 7 on SBIR/STTR Information form)	12
Biographical Sketch	For all Activity Codes (including DP1 and DP2 which previously had special page limits)	5

1.Section V. Application Review Information

2.1. Criteria (*example from RFA*)

Significance: How significant an advantage does the proposed drug target or drug candidate offer over other treatments currently under development for SUDs? How strong are the data supporting the choice of drug target or drug candidate for the SUD indication? Are the proposed drug target or the drug candidates sufficiently active in assays that are relevant to the SUD indication?

➡ Innovation
➡ Significance
➡ Approach

➡ Investigator(s)

PHS 398 RESEARCH PLAN:
1) SPECIFIC AIMS AND 2) RESEARCH STRATEGY*

■ Clinical Impact in treating SUDs:

1. Briefly describe the current state of knowledge of the etiology, clinical characteristics, and current and projected prevalence of the particular SUD;

2. Briefly discuss available treatments, including all treatment modalities and their limitations;

3. Discuss how the proposed project relates to therapeutic development efforts underway in academia and industry.

■ Biological Rationale for Target Selection:

7. Target Development Level

*…To apply, the structured information supporting target hypothesis generation must be provided. This is explicitly described in Section IV. The use of Target Development Level (TDL) classification scheme which categorizes proteins into four groups with respect to the depth of investigation from a clinical chemical and biological standpoint is encouraged…

Target development levels

T_{clin} **(clinic):**
drug targets linked to at least one approved drug (API) by mechanism of action (MoA)

T_{chem} **(chemistry):**
lack MoA-based links to approved drugs but are known to bind to small molecules with high potency

T_{bio} **(biology):**
not MoA-related drug targets, have a confirmed Mendelian disease phenotype, have Gene Ontology (GO)12 leaf term annotations based on experimental evidence

T_{dark} **(dark genome):**
the remaining proteins that have been manually curated at the primary sequence level in UniProt15 yet do not meet any of the criteria14 for Tclin, Tchem or Tbio

https://pharos.nih.gov/targets

* Unexplored therapeutic opportunities in the human genome
Nature Reviews Drug Discovery volume 17, pages317–332(2018)

MUST INCLUDE SECTION TITLED
TARGET SELECTION RATIONALE

Headings:	What to write:
Intended biological target/pathway	Describe the target and whether it should be blocked or activated. Describe the cellular/physiological process being modulated
Target expression in relevant human cells/tissues	Describe target expression in terms of tissue and cell diversity as well as techniques used to measure expression. Describe expression in both disease-affected and normal conditions
Evidence of disease-target association based on clinical observations	Provide the evidence that links this target to the SUD indication. Mention the genetic linkage to SUD, with the special emphasis on equivalent modification of protein levels in response to disease status and outcome, if applicable
Relevant in vitro models	Describe what can be modeled in vitro and in which cellular system. If the target can be assayed in a relevant cell-based system, describe the robustness of this assay. Discuss access to the primary human material to investigate the target biology (expression/function).

MUST INCLUDE SECTION TITLED
TARGET SELECTION RATIONALE

Headings:	What to write:
Relevant in vivo models	Describe the in vivo system. If target validation is based on knockdown/deletion studies, describe the appropriate controls and discuss if those studies are complemented by the small molecule or antibody studies demonstrating the same phenotype. Discuss if the in vivo model is relevant to SUD, and how well it models or predicts human condition.
Target commercial viability	Present information about any existing target modulators used clinically, available commercially or identified in literature
Target Development Level	Use the Target Development Level (TDL) classification scheme which categorizes proteins into four groups with respect to the depth of investigation from a clinical chemical and biological standpoint (https://ncats.nih.gov/pubs/features/idg-proteins)

Submitting The Application

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R
Guide for Grants and Contracts). Conformance to all requirements (both in the
application instructions in the Application Guide as well as any program-specif
Application Guide, follow the program-specific instructions. **Applications that d**

There are several options available to submit your application through Grants.g
options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your applicatio

> Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and su
   institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and

Table of Contents

If you have questions about grant submission or having difficulties, please contact the NIH eRA Commons Service Desk at:
Toll-free: 1-866-504-9552
Phone: 301-402-7469
TTY: 301-451-5939
Email: commons@od.nih.gov

REGISTRATIONS AND APPLICATION SUBMISSION INFORMATION FOR NEW AND INTERNATIONAL APPLICANTS

REGISTRATIONS NEEDED TO SUBMIT A GRANT APPLICATION TO NIH

Your organization must be registered in multiple systems to submit

Dun & Bradstreet Universal (DUNS)
Provides unique organization identifier

System for Award Management (SAM)
Needed to do business With US government

eRA Commons
Required to do business with NIH

Grants.gov
Required to submit grant applications

Small Business Administration (SBA)
Required for small business applications

If your organization isn't registered, get started now! Start early – can take 6 weeks!

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

THE REGISTRATION PROCESS PRIOR TO APPLICATION SUBMISSION

	US Institutions	US Small Businesses	International Institutions
Dun & Bradstreet Universal Numbering System (DUNS) # http://fedgov.dnb.com/webform/	✔ I	✔ I	✔ 2
System for Award Management (SAM) # https://www.sam.gov/SAM/	✔ 2	✔ 2	✔ 3
eRA Commons * https://public.era.nih.gov/commons/	✔ 3	✔ 3	✔ 4
Grants.gov* https://www.grants.gov/	✔ 4	✔ 4	✔ 5
Small Business Administration (SBA) # https://www.sbir.gov/registration	N/A	✔	N/A
NATO Commercial and Government Entity (NCAGE) # https://eportal.nspa.nato.int/AC135Public/default.aspx	N/A	N/A	✔ I
Employer Identification Number (EIN) #	✔	✔	N/A

- International institutions must have NCAGE number to get the DUNS number

- For SAM, eRA commons and Grants.gov registrations DUNS registration is required

- Organizations with an address containing APO, FPO, or AE do not need an NCAGE code

- A few countries may have trouble accessing the SAM website. If so, call 334-206-7828

✔ -Required, N/A –Not Applicable, I- Order of operations *- Both Organization and PI/PD # - Organization only

MULTI SUBMISSION OPTIONS ARE SUPPORTED BY NIH

NIH's web-based service for the preparation, submission and tracking of grant applications

Institution's own system to prepare and submit application

ASSIST

S2S Solution

System-to-System

Workspace (Single-project only)

A shared, online environment managed by Grants.gov

The on-line portal used by all federal grant making agencies and their applicants

GRANTS.GOV℠
FIND. APPLY. SUCCEED.℠

NIH

ELECTRONIC SUBMISSION PROCESS OF APPLICATIONS THROUGH GRANTS.GOV

- Principal Investigators (PI/PD) <u>prepare</u> application
- Authorized institutional official(AOR) <u>submits</u> application to Grants.gov
- Grants.gov and eRA Commons electronically validate forms and attachments
  - Applications with "errors" are rejected
  - Submit <u>corrected</u> application by the receipt date
- You may view "assembled" application in eRA Commons
  - You will see what the reviewers will see
  - Call eRA Help Desk if there are assembly problems

- Available NIH Online Resources to help in the application process
  - NIH Grants and Funding

  https://grants.nih.gov/grants/oer.htm
  - How to Apply – Application Guide

  https://grants.nih.gov/grants/how-to-apply-application-guide.html
  - Preparing Your Application Using ASSIST

  https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options/assist.htm

FORMS COMMONS TO MOST APPLICATIONS

SF424 (R&R)
PHS 398 Cover Page Supplement
R&R Other Project Information
Project/Performance Site Location(s)
R&R Senior/Key Person Profile (Expanded)
SBIR/STTR Information
PHS Human Subjects and Clinical Trials Information
PHS Assignment Request Form
Budget Forms
PHS Modular Budget
R&R Budget
R&R Subaward Budget Attachment(s) Form
PHS 398 Training Budget
Training Subaward Budget Attachment Form
PHS Additional Indirect Costs
Construction Budget
Research Plan and Equivalent Forms
PHS 398 Research Plan
PHS 398 Career Development Award Supplemental Form
PHS 398 Research Training Program Plan
PHS Fellowship Supplemental Form

https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-E.pdf

COMPLETING APPLICATION FORMS

ANNOTATED FORM SETS ARE AVAILABLE AT: HTTPS://GRANTS.NIH.GOV/GRANTS/ELECTRONICRECEIPT/FILES/ANNOTATED_FORMS_GENERAL_FORMS-E.PDF

AND PROVIDE GUIDANCE IN COMPLETING ALL REQUIRED FORMS

ample

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

Expiration Date: 10/31/2019

1. TYPE OF SUBMISSION
☐ Pre-application ☑ Application ☐ Changed/Corrected Application

Use Application for first submission attempt for due date.

3. DATE RECEIVED BY STATE

State Application Identifier

If New (box 8), leave blank. If Revision/ Resubmission/ Renewal (box 8), use institute and serial # of previous NIH grant/application # (e.g., CA987654 from 1R01CA987654-01).

4. a. Federal Identifier
b. Agency Routing Identifier

For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).

c. Previous Grants.gov Tracking ID

If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).

2. DATE SUBMITTED **Applicant Identifier**

Do not use Pre-application unless specifically noted in FOA.

Use Changed/Corrected when submitting again to Grants.gov for a due date (e.g., to correct eRA identified errors/warnings.)

5. APPLICANT INFORMATION

Organizational DUNS:

Must match DUNS used for System for Award Management (SAM), Grants.gov and eRA Commons registrations. Must be 9 or 13 digits; no letters or special characters.

Legal Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:

Must provide zip+4 for all zip codes.

Person to be contacted on matters involving this application
Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.

6. EMPLOYER IDENTIFICATION (EIN) or (TIN):

Non-US organizations use 444444444.

7. TYPE OF APPLICANT: Please select one of the following
Other (Specify):

Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:

See application guide for definitions.

☐ New ☐ Resubmission If Revision, mark appropriate box(es).
☐ Renewal ☐ Continuation ☐ Revision
☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration
☐ E. Other (specify):

Is this application being submitted to other agencies? ☐ Yes ☐ No What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

NIH will assign CFDA post-submission.

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant. Limited to 200 characters.

12. PROPOSED PROJECT: **13. CONGRESSIONAL DISTRICT OF APPLICANT**
Start Date Ending Date

Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). Use 00-000 if outside the US. See application guide for additional details.

See Key Dates section of announcement. Start date is an estimate; typically at least nine months after submission. Project period should not exceed what is allowed in announcement.

TIPS FOR INTERNATIONAL APPLICANTS TO COMPLETE THE FORMS

- SF424 R&R COVER FORM – *ITEM 6, EMPLOYER IDENTIFICATION NUMBER (EIN)*: USE 44-4444444 IF YOU DON'T HAVE AN EIN.

- *ITEM 13, CONGRESSIONAL DISTRICT*: ENTER 00-000

HTTPS://GRANTS.NIH.GOV/GRANTS/ELECTRONICRECEIPT/FILES/ANNOTATED_FORMS_GENERAL_FORMS-E.PDF

TIPS FOR INTERNATIONAL APPLICANTS TO COMPLETE THE FORMS

- R&R Budget form – Use the 'detailed' (non-modular) budget form and request budgets in U.S. dollars.

- Foreign institutions may request funds for limited Facilities & Administrative (F&A) costs (8 percent of modified total direct costs less equipment) to support the costs of compliance with NIH requirements.

- R&R Other Project Information form – Complete *section 6* covering activities outside the U.S and add an attachment titled "Foreign Justification" under *item 12, Other Attachment.*

- PHS 398 Research Plan form – Provide the names of the countries where select agent research will be performed in the Select Agent Research attachment.

- R&R Senior/Key Person Profile form – Include the PD/PI eRA Commons username in the "Credential, e.g. agency login" field.

- Project/Performance Site Location form – Enter 00-0000 for Project/Performance Site Congressional District.

https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-E.pdf

HELPFUL RESOURCES

How To Apply – Application Guide
http://grants.nih.gov/grants/how-to-apply-application-guide.htm

eRA Commons Service Desk
Help with: eRA Commons registration, ASSIST, addressing errors/warnings, and post submission functionality
Web: http://grants.nih.gov/support/
Phone: 1-866-504-9552
International: 301-402-7469
Hours: Monday – Friday, 7 a.m. to 8 p.m. ET

Dun & Bradstreet (DUNS)
Phone: 1-866-705-5711
Online DUNS # request:
http://fedgov.dnb.com/webform
Email: govt@dnb.com (U.S.)
Email: SAMhelp@dnb.com (non-U.S.)

Grants Info
Help with: NIH funding opportunity, application guidelines and grant-related resources
Phone: 301-710-0267
Email : GrantsInfo@nih.gov

Grants.gov Contact Center
Help with: Grants.gov registration and submission issues
Phone: 1-800-518-4726
International: 606-545-5035
Email : support@grants.gov

System for Award Management
Phone: 1-866-606-8220
International: 334-206-7828
Service Desk: www.fsd.gov
Hours: Monday – Friday, 8 a.m. to 8 p.m. ET

IMPORTANT REMINDERS FOR ON-TIME SUBMISSION

- Complete all registrations before the due date

- **Submit** your application **early (days, not minutes)** to allow time for correcting any errors found during the period of application viewing prior to the due date

- NIH's late policy does not allow corrections after the due date

- Error-free **applications must be accepted** by Grants.gov with a stamp **on or before 5.00 PM (local time of the submitting organization)** on the application due date