

Translating Socioenvironmental Influences on Neurocognitive
Development and Addiction Risk (TranSINDA)
[RFA-DA-25-037](#) (U01 Clinical Trial Not Allowed)
[RFA-DA-25-038](#) (U24 Data Coordination Center)



Preapplication Technical Assistance Presentation

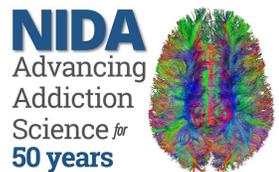
Presenters

Holly Moore, PO
Division of Neuroscience & Behavior
Behavioral and Cognitive Neuroscience Branch

Caitlin Moyer, SRO
Division of Extramural Research
Scientific Review Branch

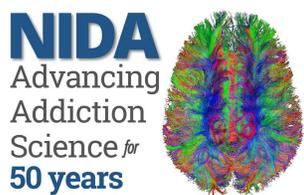


Date of Recording: September 6, 2024



Translating Socioenvironmental Influences on Neurocognitive Development and Addiction Risk (TranSINDA)

Supporting research designed to model the impact of early socioenvironmental factors on neurocognitive development and SUD risk





TranSINDA Funding Opportunities

RFA-DA-25-037



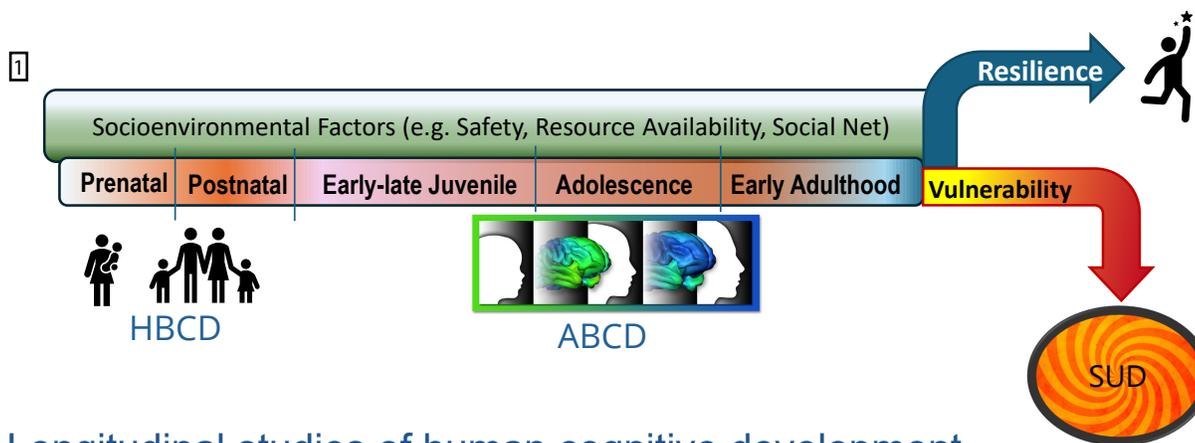
RFA-DA-25-038



Presentation Outline

- TranSINDA Program (Holly Moore, PO)
 - Background and Program Goals
 - Funding Opportunity Descriptions & Application Information
 - RFA-DA-25-037 (U01)
 - Purpose
 - Topics of Interest and Responsiveness
 - Research Strategy Requirements
 - RFA-DA-25-038 (U24 Data Coordination Center) Overview
 - PEDP
 - DMSP
 - Cooperative Agreement Mechanism
 - Relating Application Requirements to Review Criteria
- Application Review Process (Caitlin Moyer, SRO)
- Additional information

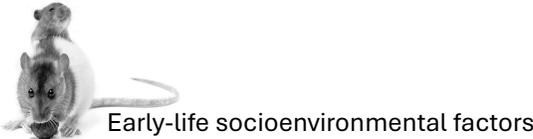
TranSINDA Background



- Longitudinal studies of human cognitive development
 - Revealing the importance of early-life socioenvironmental factors in brain health and risk for SUD and psychiatric comorbidities
 - Providing large data sets and analytic tools for application of computational approaches
- Gap to Fill - complementary research using animal models to test hypotheses generated by these studies

TranSINDA Program Goals

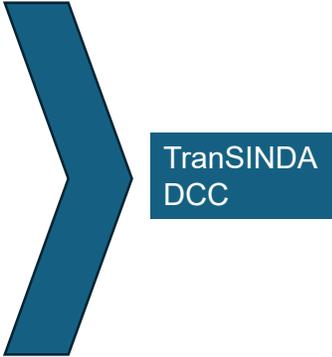
Overarching Goal: To support research designed to model the impact of early socioenvironmental factors on neurocognitive development and SUD risk



Longitudinal assessment of neurobehavioral development



Emergence of SUD-relevant phenotypes in adolescence and early adulthood



TranSINDA U01 – RFA-DA-25-037

Funding Opportunity Purpose & Application Information

To support **team science** research projects aimed at using a **longitudinal research design** to study the impact of an **early-life socioenvironmental manipulation** on **neurocognitive development** and the **emergence of SUD-relevant neurobehavioral phenotypes** in adolescence or adulthood

TranSINDA U01 – RFA-DA-25-037

Funding Opportunity Purpose (Part 2. Section I)



Early-life socioenvironmental factors, e.g.

Resource scarcity

Threat

Prenatal **Postnatal** **Early-late Juvenile** **Adolescence** **Early Adulthood**

Longitudinal assessment of
neurobehavioral development, e.g.



Reward Learning & Response
Regulation

Aversive Learning, Conflict

Social Behavior

Emergence of SUD-relevant phenotypes in
adolescence and early adulthood, e.g.

Impulsivity

Suboptimal risk assessment

Compulsive seeking and
consumption

Abnormal social cognition

TranSINDA U01 – RFA-DA-25-037

Funding Opportunity Purpose (Part 2. Section I)

Topics of Interest

- Modeling of early socioenvironmental factors, including but not limited to:
 - Parental behavior across environments varying in resource availability, threat, etc.
 - Parental separation or other disruption of parental behavior
 - Social isolation/antagonistic social interactions during juvenile and adolescent periods
 - Disruptions to social hierarchy
 - Disruption of developmentally-specific social behavior (e.g. play behavior)
- Use of neurodevelopmentally appropriate neurocognitive paradigms to assess cognitive processes, including but not limited to:
 - Reward processing and reinforcement learning (e.g., using non-social and social reward), including compulsive reward-directed behavior
 - Decision-making, impulsivity or compulsivity
 - Effects of threat, risk, or potential loss on exploratory behavior, decision-making, etc.
 - Competing drives or motivations (e.g. approach-avoidance; exploration-exploitation)
 - Integrating models of SUD-relevant behaviors as endpoints for longitudinal studies of neurocognitive development.

TranSINDA U01 – RFA-DA-25-037

Funding Opportunity Purpose – Responsiveness (Part 2. Section I)

An application will be considered not responsive if it fails to employ:

- An early developmental exposure or manipulation aimed at modeling an early-life socioenvironmental risk factor for SUD
- A longitudinal design that includes developmentally appropriate neurobehavioral testing across juvenile development
- Experiments measuring SUD-relevant neurocognitive function in adolescence and/or adulthood

TranSINDA U01 – RFA-DA-25-037

Application Information (Part II. Section IV)

Research Strategy Requirements

- Required elements of the research strategy
 - Early developmental exposure or manipulation aimed at modeling early socioenvironmental risk factor for SUD
 - Longitudinal design that includes developmentally appropriate neurobehavioral testing across juvenile development
 - Assessment of SUD-relevant neurocognitive function in adolescence and/or adulthood
- Multi-disciplinary team and a team science plan addressing contribution of members to research design and execution
- Rationale for the choice of species
- Statistical/computational model leveraging multimodal, longitudinal behavioral & neural data

TranSINDA U24 RFA-DA-25-038 - Data Coordination Center

- Purpose (Part 2. Section I): *to create and manage a Data Coordination Center (DCC) for TranSINDA and organizational hub for the TranSINDA Consortium*

- Required elements (Part 2. Section IV)
 - Strategy for supporting TranSINDA as a DCC and organization hub for the TranSINDA Consortium
 - Leadership structure for the DCC must be addressed
 - Development and implementation of data standards, ontologies, and best practices including but not limited to:
 - Data and metadata, incl. data dictionaries and controlled vocabularies
 - Domain-specific ontologies capturing fields contributing to TranSINDA

TranSINDA U24 RFA-DA-25-038 - Data Coordination Center

- Required elements (Part 2. Section IV) (con't)
 - Data Management and Ecosystem
 - Data quality metrics
 - Pipelines for processing, harmonization, submission of TranSINDA data to well-documented repository
 - Tracking data workflows, provenance and user statistics
 - Cloud-based access and analysis platform
 - Statistical and Modeling Support
 - Connecting U01 projects to statistical/computational expertise
 - Coordinating collaborative development and harmonization of research designs and data structures activities
 - Coordination, Dissemination, and Education activities
 - To curate, evaluate and implement broad dissemination of tools for accessing and analyzing TranSINDA data
 - Activities including
 - Consortium organization and management
 - Development and dissemination of training materials/activities on use of TranSINDA data
 - Development and support of a TranSINDA Web Portal
 - Assisting projects with implementation of their Data Management and Sharing Plans

Plan for Enhancing Diverse Perspectives

Application Information (Part II, Section IV – Other Attachments)

- The PEDP must be included as an “Other Attachment” – put it in the right place
- Actionable strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity.
- Alignment of Research Strategy with PEDP – how the diverse perspectives of team members enhance scientific and technical merit design of the research (i.e., research design, rigor, impact)
- Methods to evaluate progress and success
- Timeline of proposed PEDP activities

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), Part 2. Section IV of the RFA and [PEDP guidance materials](#).

Plan for Enhancing Diverse Perspectives

Application Information (Part II, Section IV – Other Attachments)



Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide](#) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the [How to Apply - Application Guide](#) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1, Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to: NIDALetterofIntent@mail.nih.gov

Page Limitations

All page limitations described in the [How to Apply - Application Guide](#) and the [Table of Page Limits](#).

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply - Application Guide](#).

SF424(R&R) Cover

All instructions in the [How to Apply - Application Guide](#) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the [How to Apply - Application Guide](#) must be followed.

SF424(R&R) Other Project Information

All instructions in the [How to Apply - Application Guide](#) must be followed.

Plan for Enhancing Diverse Perspectives (PEDP)

- In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of actionable strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity.
- Applicants should align their proposed strategies for PEDP with the research strategy section, providing a holistic and integrated view of how enhancing diverse perspectives and inclusivity are buoyed throughout the application.
- The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured.
- The PEDP may be no more than 2 pages in length and should include:
 - Actionable strategies using defined approaches for the inclusion of diverse perspectives in the project;
 - Description of how the PEDP will advance the scientific and technical merit of the proposed project;
 - Anticipated timeline of proposed PEDP activities;
 - Evaluation methods for assessing the progress and success of PEDP activities.

Plan for Enhancing Diverse Perspectives
– include as “Other Attachment” ([NIH
Forms Version H](#))



For information on the Plan for Enhancing Diverse Perspectives (PEDP), Part 2. Section IV of the RFA and [PEDP guidance materials](#).

Data Management and Sharing Plans (DMSP)

- Applicants and recipients must comply with the [NIH Policy for Data Management and Sharing](#)
- All TranSINDA U01 and U24 applications MUST include a Data Management and Sharing Plan (DMSP)
 - DCC is not required to generate scientific data. However, proposed plan for DCC includes secondary data analysis, the management and sharing of the derived data must be addressed in the DMSP of the DCC U24 application
- DMSP is included in a field called “Other Plans” using [NIH Forms Version H](#)
For further information on preparing a DMSP, go to the [NIH Data Management and Sharing Policy](#) website
- For information and templates helpful for preparing your DMSP, go to [Planning & Budgeting for Data Management and Sharing](#)
- For complete information on sharing data from NIH-funded research, see the NIH [Data Management and Sharing Policy](#) website.

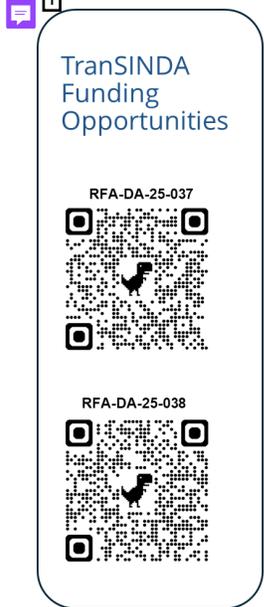
Cooperative Agreement Mechanisms (U Awards)

Application Information (Part II. Section VI)

- Mechanisms used for high-priority research that require substantial involvement from NIH Program and Scientific Staff
 - Each project assigned an NIH Program Officer and Project Scientist
 - Project Scientist is a member of the research team
- Specify separate and joint responsibilities for Award PIs/PDs and NIH Program Staff
- This information is in Part 2. Section VI – Cooperative Agreement Terms and Conditions of Award

Application Requirements & NOFO-specific Review Criteria

Application Information (Part II. Section V)



Read Part 2. Section IV and V of the NOFOs!

- **Section IV - Application and Submission Information**
 - describes the required and important components and features to be included in applications, including specific instructions for the Research Strategy and PEDP
- **Section V - Application Review Information**
 - 'translates' information about required and important components and features into NOFO-specific Review Criteria

Application Review Process

- Administrative review carried out by NIH Staff
- Submissions evaluated by NIH staff for
 - Completeness and compliance
 - NOT-OD-17-105: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-105.html>
 - Adherence to NIH formatting guidelines
 - Biosketch and Other Support Format page requirements
 - NOT-OD-21-073: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html>
- Include **only** allowable appendix materials as per the application instructions

Incomplete applications or applications not adhering to the notice of funding opportunity (NOFO) requirements may be returned without review

Peer Review Process: Pre-Review

- Peer review of applications is conducted at NIDA
- Special Emphasis Panel convened by the SRO based on the areas of science described in the applications
- Conflicts of interest are managed for all panel members
- At least three reviewers assigned to evaluate each application
- Panel receives guidance from NIH staff on how to evaluate the application
- Panel members have at least 4 weeks to evaluate the application
- Meeting roster is publicly available 30 days before the meeting

Application Review

Core Review Criteria

- Significance
- Investigators
- Innovation
- Approach
- Environment

Additional Review Criteria

- Protection of Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards

Overall Impact

Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

Additional Review Considerations

Foreign Institution, Select Agents, Resource Sharing Plan, Authentication, Budget

Application Review Criteria

- Applications are evaluated using the **Standard** Core Review Criteria described in Section V of the NOFO:
- RFA-DA-25-037: <https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-037.html>
- RFA-DA-25-038: <https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-038.html>
- Please pay attention to the **NOFO-specific** questions under each of the individual Core Review Criteria

Peer Review Process: Post-Review

- As part of the scientific peer review, all applications will receive a written critique (*summary statement*)
- Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score
- Summary statement will be available within 4-6 weeks after the peer review meeting

Translating Socioenvironmental Influences on Neurocognitive Development and Addiction Risk (TranSINDA)

Additional Information

URL Links

RFA-DA-25-037 (U01 Clinical Trial Not Allowed)

<https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-037.html>

RFA-DA-25-038 (U24 Data Coordination Center)

<https://grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-038.html>

PEDP guidance materials

https://grants.nih.gov/grants/guide/url_redirect.php?id=82429

NIH Policy for Data Management and Sharing

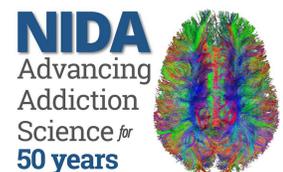
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>

NIH Forms Version H

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.100-how-to-use-the-application-instructions.htm>

NIH Data Management and Sharing Policy website

<https://sharing.nih.gov/data-management-and-sharing-policy>



Translating Socioenvironmental Influences on Neurocognitive Development and Addiction Risk (TranSINDA)

Contact Us!

[Scientific Contact and PO](#) (prior to submission & after posting of Summary Stmt)

Holly Moore
Division of Neuroscience & Behavior
Behavioral and Cognitive Neuroscience Branch
holly.moore@nih.gov

[Peer Review Contact and SRO](#) (after submission, prior to Peer Review Meeting)

Caitlin Moyer
Division of Extramural Research
Scientific Review Branch
Caitlin.moyer@nih.gov

RFA-DA-25-037



RFA-DA-25-038

