NIGMS Staff Participation

Mercedes Rubio Division Director, Division for Research Capacity Building

Erin Iturriaga Chief, Health Research and Development Programs Branch

Kyungsook Gartrell Program Director, Health Research and Development Programs Branch

Lisa Dunbar Scientific Review Officer, Scientific Review Branch

Christy Leake Senior Grants Management Specialist, Grants Administration Branch

Slides and Webinar Recording will be posted on the CTR website
If you think of questions after the webinar, send an email to erin.iturriaga@nih.gov

IDeA: Impact through Creativity, Synergy, & Efficiency

CTRs goals

To build capacity for clinical, behavioral, and translational research in all NIH mission areas through:

- Research workforce development

- Infrastructure enhancement

- Pilot projects that address health concerns of the populations served by the CTR

Collaborations & Participation in NIH-Wide Initiatives

COBREs

INBREs

CTRs

Co-Funding

I-RED

Legend
- IDeA State
- IDeA CTR
- CTR-D
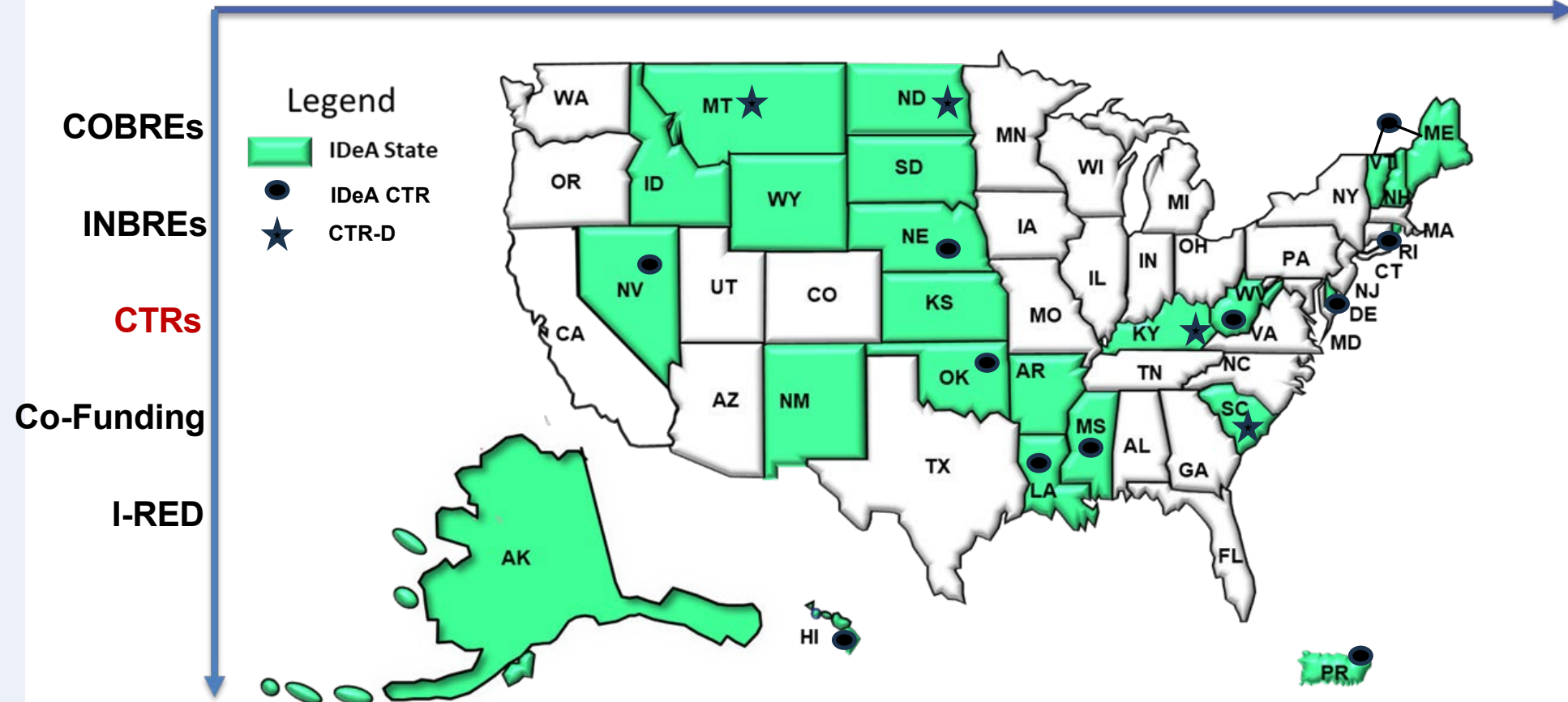
CTR-N Application Due Dates

FY	Due Date	Review	Council	Earliest Start Date
2025	October 9, 2024	March 2025	May 2025	July 2025
2026	October 9, 2025	March 2026	May 2026	July 2026

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

CTR-N Application Types & Budgets
- New
- Resubmission
- Renewal – for *active IDeA-CTRs only
  *includes grants in No-Cost Extension (NCE)
- Budget: **$3.3 M/yr Direct Costs; 5 yrs**

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Is CTR-N the Best Fit for Your Organization?

CTR-N networks should have:

- **The ability to form and maintain a strong state-wide/multi-state network**
    - Typically includes research-active med schools and hospitals as partners
    - Partners are required

- **A cadre of investigators who are already active in C&T research**
    - Typically includes clinician scientists (hold clinical licenses and conduct research)

- **Existing infrastructure and workforce to conduct C&T research and use big data for research**
    - Typically, have experienced professional staff to assist investigators

NIGMS Guiding Principles for Eligibility

- **Maximize the impact of this investment in IDeA capacity building**

  - One award per state (IDeA-CTR, CTR-N, or CTR-D)

  - An organization can participate in <u>one</u> CTR program at a time

- **Allow organizations to determine how to best build their capacity**

  - An organization can be a lead/partner of a CTR or a CTSA Hub, but not both

    - CTR partners have crucial roles in developing and steering CTR activities

    - CTSA Hubs require partners to commit to the CTSA goals, which may be different from those of CTRs

  - <u>Collaborations</u> among CTRs and CTSAs are encouraged; typically this involves funding opportunities other than the CTR-N or CTSA Hub NOFOs

    - Examples: CCIA UG3/UH3, CARE for Health, RECOVER

CTR-N Eligibility (determined at the time of submission)

- **Lead organization**
  - Must have externally funded C&T research grants

- **Lead and Partners**
  - Must be in the same state or multi-state region
  - Cannot be a lead/partner of another active IDeA-CTR award (except for renewals)
  - Cannot be a lead/partner of an active CTR-N, CTR-D, or CTSA Hub
  - Cannot be in a state/multi-state region that has an active CTR-N, CTR-D, or CTSA Hub

- **Partner organizations are required**

- **An IDeA-CTR may either submit a renewal application or, if the network's composition has changed substantially, may submit a new application**

- **Active awards includes those in NCE**

All lead and partner organizations must be in an IDeA state;

NOFO Compliance and Responsiveness

- **One application per institution per due date to either NOFO**

  - CTR-N and CTR-D goals and structures are similar; considered highly overlapping applications

  - May submit to CTR-N or CTR-D but not both for the same due date

- **Applications with a narrow disease or population focus will not be accepted for review**

  - Consider applying to the IDeA COBRE program instead

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CTR Leadership

- **PD/PI is expected to be an established clinical investigator**
  - Track record of externally funded C&T research projects or programs
  - Leadership experience and skills to work across institutions and organizational silos
  - Cannot be the PD/PI of an INBRE, COBRE, or another CTR

- **Multi-PIs (maximum of 2) are allowed**
  - 3-month minimum annual level of effort per PD/PI, 6-months collective effort allowed

- **Being a PD/PI is a service that deserves recognition and support by the organization**
  - A PD/PI (or their research team) cannot receive research funding - cannot lead a pilot/research project or a supplement project

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Three Committees Assist the PD/PI

Steering Committee (SC): PD/PIs and one senior institutional leader (President, VPR, Provost, Dean etc.) from each lead/partner organization

- Ensure the network's adherence to the CTR's mission
- Maintaining each organization's support for participation of their workforce in CTR activities
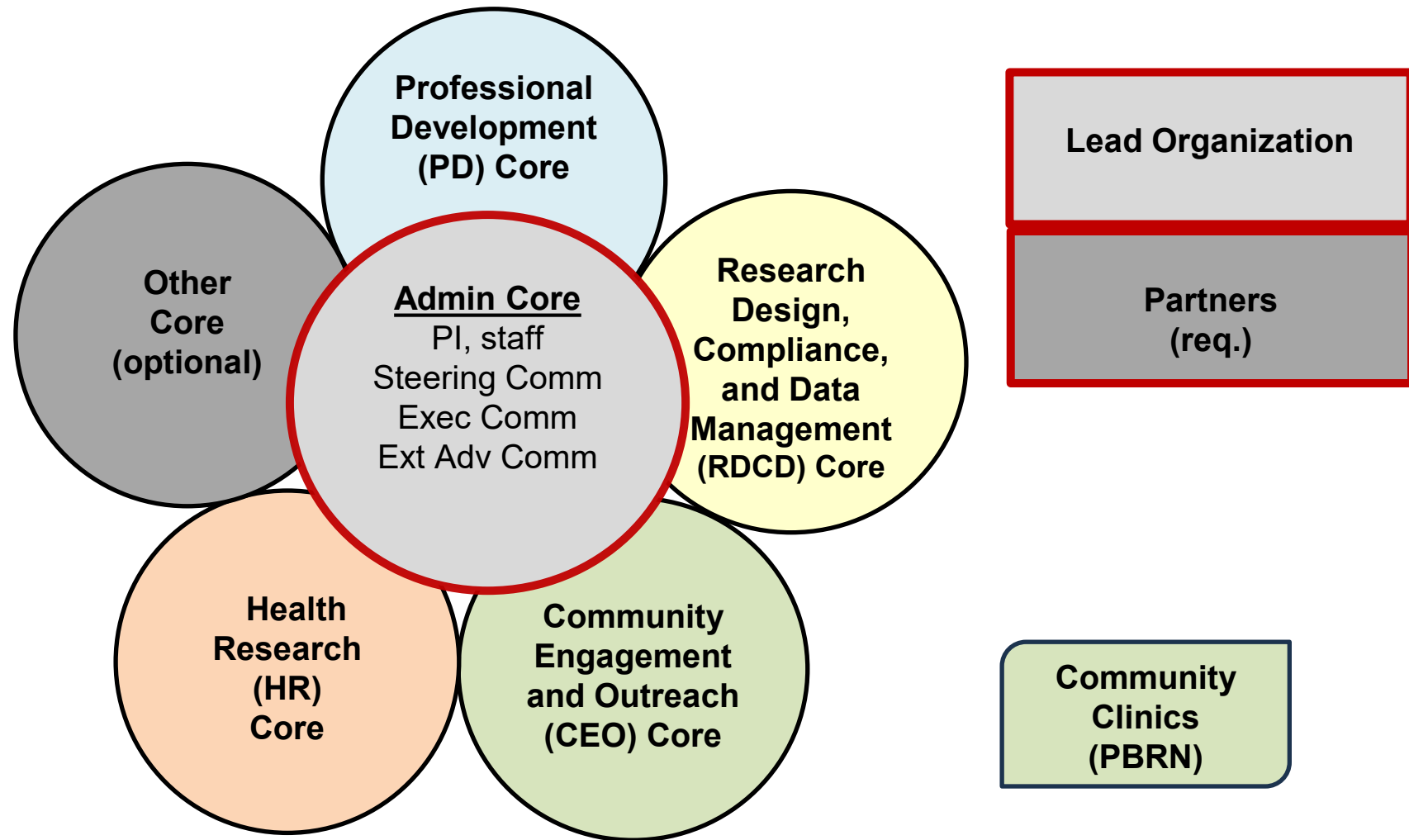
Executive Committee (EC): PD/PIs, a rep. from each partner and other key personnel appointed by the PD/PIs

- Assists in administering the award – oversight of day-to-day operations

External Advisory Committee (EAC): 3 - 5 experts outside the state/network

- Provides advice on key scientific activities and administrative decisions

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CTR Organization – 5 Required Cores

Professional Development (PD) Core

Other Core (optional)

Admin Core
PI, staff
Steering Comm
Exec Comm
Ext Adv Comm

Research Design, Compliance, and Data Management (RDCD) Core

Health Research (HR) Core

Community Engagement and Outreach (CEO) Core

Lead Organization

Partners (req.)

Community Clinics (PBRN)

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Administrative (AC) Core

- **Manages the administration of the CTR as described in the Overall Plan**

  - Coordination and integration of all organizations, cores, and committees

- **Handles budgeting and reporting, annual evaluations**

Professional Development (PD) Core

- **Oversees workforce development of investigators and the professional staff of all cores**

- **Ensures that needed training is provided**
  - Example: PD Core works with the RDCD Core to offer training on federal and institutional policies for research involving human subjects, vertebrate animals, and/or biohazards

- **Organizes and sponsors professional development activities**
  - Research seminar series, grant-writing workshops, skills training, and mentoring guidance

Research Design, Compliance and Data Management (RDCD) Core

- **Provides expertise for designing research protocols**
  - Risk assessment, safety, intervention models
  - Statistically significant power to ensure rigor
  - Avoid methodological bias
- **Provides guidance on human subjects research and clinical trials**
  - IRB, federal and other regulatory and reporting requirements
- **Manages Electronic Health Records (EHR) and other large clinical datasets**
  - Ensures compliance with NIH and institutional data management policies to safeguard protected health information
- **Provides data analytics and biostatistics assistance to investigators**

Community Engagement and Outreach (CEO) Core

- **Leads the engagement of community groups and state organizations**

- **Identifies health research needs and challenges of the population it serves**

- **Develops investigator and staff skills to prepare them for community outreach**
  - Fosters cultural respect and knowledge
  - Offers strategies to increase the recruitment and retention of diverse populations in clinical research

- **Promotes multi-directional engagement among researchers and community groups**
  - Engages with the clinical staff and patients from community clinics

Health Research (HR) Core

- **Led by an experienced clinical researcher (expected to be the PD/PI)**

- **Manages all CTR-supported research**

  - Soliciting applications, arranging for their review, and selecting meritorious applications for funding

- **Pilot Projects:** 1-year feasibility studies for independent investigators or clinician fellows who work with a research mentor

  - Test ideas suitable for future NIH K awards or small/developmental RPG awards

  - Budget of $50,000-$100,000 DC/yr per pilot

- **Developmental Projects:** 2-year projects for independent investigators

  - Potential to developing into R01-equivalent RPGs, with additional data.

  - Maximum budget of $100,000 DC/yr per project

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CTR-N HR Core: Multi-Site Collaborative Projects

- **Network-wide and/or collaborations with other CTR-Ns or IDeA institutions outside the network**

- **Maximum budget of $400,000 DC/yr**

- **A phased approach is encouraged**
  - Provide early funding to meet specific benchmarks, e.g. ensuring software is compliant, recruitment of site PIs, subcontracts/data use/date transfer agreements, institution- specific and federal requirements, IRB approval
  - Once benchmarks are met, release of additional funding to complete the study

- **CTR-Ns are expected to lead/participate at least one collaborative project during the CTR-N's project period**

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Other Core - Optional

- **Only allowed for CTR-N, not CTR-D**

- **Optional, not required**

- **To support essential functions that are not provided by the required cores**

- **Some examples:**

  - Biospecimen collection and repository

  - Clinical Resources - access to network registries of potential research participants

Preparing a CTR Application: Overall Plan

- **Overall vision, roles of lead/partner organizations**

- **Current C&T research and investigator base**

- **Organizational structure and plans to integrate all organizations, cores, and committees**

- **Letters of Support are required from each lead/partner organization**

  - Demonstrate institutional commitment for the CTR program

  - Commitment of specific resources: hiring new investigators, clinical and core support staff, and/or infrastructure investment

  - Commitments to specific cores or other components should be summarized in a table

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Preparing a CTR Application: For Renewals

For <u>renewals</u>, provide information on the progress and accomplishments from the current IDeA-CTR funding period such as the following:

- **Investigator Research Support and Productivity:**
  - Annual number of pilot projects supported and the number of publications, research grant applications and awards resulting from pilot project support.
  - Annual number of pilot projects that were collaborative, multidisciplinary, multi-site, and/or clinical trial projects.
  - Distribution of pilot applications and awards across the network organizations.

- **Network Strength:**
  - Summary of non-pilot project C&T research supported by supplement awards and/or IDeA-CTR cores.
  - Summary of research collaborations initiated, community clinics/PBRNs engaged, and improvements in C&T infrastructure made during the current IDeA-CTR funding period.

- **Professional Development:**
  - Activities that were developed during the current IDeA-CTR funding period.

- **Governance Plan for the CTR-N:**
  - Succession plan for PD(s)/PI(s) who have been leading a CTR program for more than 10 years.

Overall: Data Management Sharing (DMS) Plan

- **Purpose:** to emphasize good data management practices and set the expectation for maximizing the sharing of scientific data generated by NIH-funded research awards

- **NIH Scientific Data Sharing** webpage has descriptions of the elements to be included and a template

- **DMS plan incorporates Data Management and Genomic Data Sharing**
  - Removed from the Resource Sharing Plan, which is still required

- **Submit one DMS plan and do not include separate DMS plans for the Developmental and Pilot projects**
  - Their associated data will be known at the time of application, a detailed DMS Plan is not required (Refer Clarification of DMS Plan Instructions for CTR-N NOFO (NOT-GM-24-036)

- **1-2 pages recommended for the entire application**

- **Include as an attachment in the Overall Component**

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Administrative Core (AC) Budget

- **Funds for leadership and administrative staff salaries**

- **External Advisory Committee related expenses (travel, compensation)**

- **Compensation for Executive Committee members**

- Cannot be used by or for collaborators in non-IDeA states or at foreign sites

- Can be used in the US and at foreign sites for fee-for-service activities such as learning new techniques, sample and data analysis, workshops, etc

Core Budgets

- **Funds for Core Lead,** who must devote a minimum of 1 person-months annually

- **Core staff personnel costs, costs of core-related activities**

- **Funds to hire consultants**

- **Acquisition and/or modernization of equipment**

- **RDCD Core:** Prepare/maintain large clinical datasets (EHR, medical images, etc) for research use. Funds may not be used to procure access to commercially available EHR data

- **HR Core:** Include only a placeholder budget for the research projects, do not submit any research projects

Review Process: Step 1 – Administrative Review

- **All applications go through Administrative Review by NIGMS POs and SROs**

- **All applications deemed non-compliant/non-responsive/ineligible are withdrawn. To avoid this:**

  - Read and follow the NOFO instructions

  - Apply a few days prior to the deadline, check your application, and make corrections if needed

- **Common issues: missing attachments (DMS Plan), narrow disease focus, ineligible lead or partner**

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Review Process: Step 2 – Scientific Review

- **Applications are reviewed in a single Special Emphasis Panel (SEP)**

- **Reviewer Orientation Meetings: same material is given to all reviewers**

- **Reviewer Assignments: At least three reviewers are assigned to each application – usually more**

  - Overall: three primary reviewers

  - At least two reviewers are assigned to each of the components

- **Process**

  - Assigned reviewers comment on each component, then the panel discusses the Overall application

  - Voting: All panel members vote on the Overall application (not individual components)

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Preparation Advice to Applicants

- **Read the NOFO review criteria –** the critique templates contain these criteria/questions

- **DO NOT duplicate letters of support.** Avoid including letters of support that do not add substance – it can limit the pool of reviewers and usually annoys reviewers

- **List the names of people submitting letters at the start of each component**

- **Include the Component/CoreTitle at the beginning of each component summary.** Reviewers have access to full applications but not in Recruitment Phase when only summaries are available – "Core G" is not informative!

- **Use the PHS Assignment form** to indicate expertise needed, but **DO NOT** suggest reviewer names. You may provide names of those who **SHOULD NOT** review your application

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IDeA Funding Restrictions

- **The PD/PI may not use IDeA funds to support <u>research</u> activities in their laboratory. This includes supplements.**

  - PD/PI is not eligible for research project support from this award, another CTR award, or a COBRE or INBRE

  - The PD/PI may receive support for necessary, additional effort needed to administer supplements

  - The PI may have additional effort as a core leader

- **HR project leaders**

  - Cannot receive simultaneous research support as project leads from this or another IDeA parent award but may be eligible to lead IDeA projects funded by supplements

  - Cannot be postdoctoral scholars and others holding non-independent positions, with the exception of clinician fellows, who may lead Pilot Projects

Upcoming Webinar for CTR-D

CTR-D Program ([PAR-23-257](#)) Pre-Application Webinar

- **When:** Friday, August 23, 2024, 2:00-4:00 pm ET.

- **Webinar Info:** [Zoom link](#)
  Meeting ID: 161 882 2862
  Passcode: NIGMS

- **Contact:** Kyungsook Gartrell at kyungsook.gartrell@nih.gov

Q&A

Please type your questions into the Chat box