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Development
Programs Branch**

**Division for Research
Capacity Building
and**

CTR-D Program Lead

CTR-D Pre-Application Webinar

August 23, 2024

2:00 – 4:00 PM. ET

NIGMS Staff Participation

Mercedes Rubio Division Director, Division for Research Capacity Building

Erin Iturriaga Chief, Health Research and Development Programs Branch

Kyungsook Gartrell Program Officer, Health Research and Development Programs Branch

Nina Sidorova Scientific Review Officer, Scientific Review Branch

Christy Leake Senior Grants Management Specialist, Grants Administration Branch

Q&A via Chat Window, moderated by Erin Iturriaga

Slides and Webinar Recording will be posted on the CTR website

If you think of questions after the webinar, send an email to kyungsook.gartrell@nih.gov

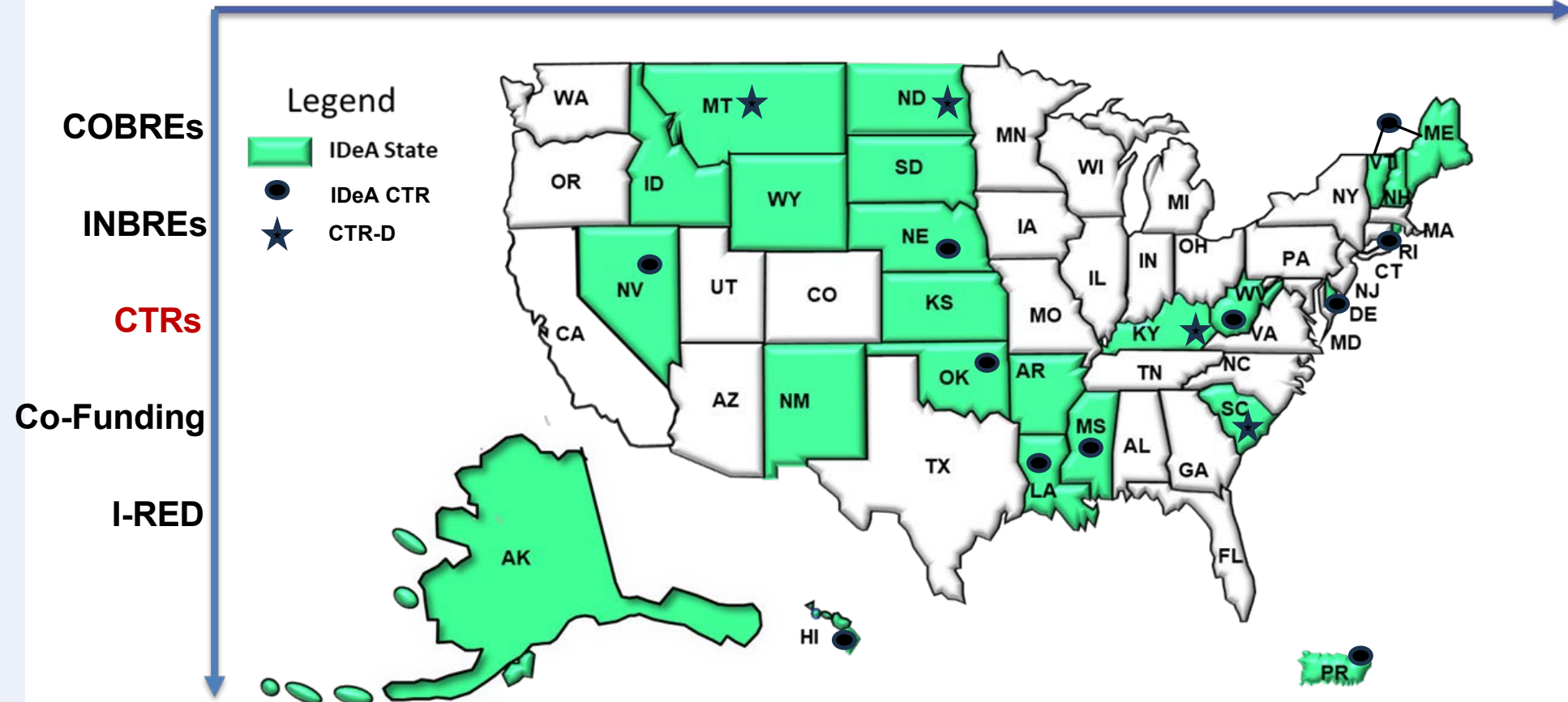
IDeA: Impact through Creativity, Synergy, & Efficiency

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



CTR-D 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-D Application Types & Budgets

- New
- Resubmission
- Budget: **\$1.5 M/yr Direct Costs; 5 yrs**

IS CTR-D the Best Fit for Your Organization?

CTR-D organizations are expected to have:

- **A strategic priority to grow their C&T research base**
 - C&T research in the state is nascent and has not reached critical mass **or**
 - Have a critical mass of C&T researchers but cannot create a state-wide CTR network
 - e.g., another organization in the state leads a CTSA (Clinical and Translational Science Award Hub)
- **Demonstrated need to build/expand the workforce and infrastructure to support C&T research**
- **Partners are allowed but not required**

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 one 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
- **If a current IDeA-CTR network fits better with CTR-D, it is OK to transition to CTR-D**
- **CTR-Ds that make good progress may apply for CTR-N in the future, if eligible**

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

- **Lead organization**

- Must have externally funded C&T research grants
- Cannot be a lead/partner of an active CTR-N, CTR-D, or CTSA Hub award
- Cannot be in a state/multi-state region that has another active IDeA-CTR, CTR-N, or CTR-D award (active IDeA-CTRs may apply)

- **Partner organization – allowed but not required**

- Cannot be a lead or partner of an active IDeA-CTR, CTR-N, CTR-D, or CTSA Hub award
 - Include a copy of a letter that relinquishes partner status, effective by the submission date

- **Active awards includes those in NCE**

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

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/or 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

Three Committees Assist the PD/PI

Steering Committee (SC): PD/PIs and one senior institutional leader (President, VPR, Provost, Dean or equivalent) 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

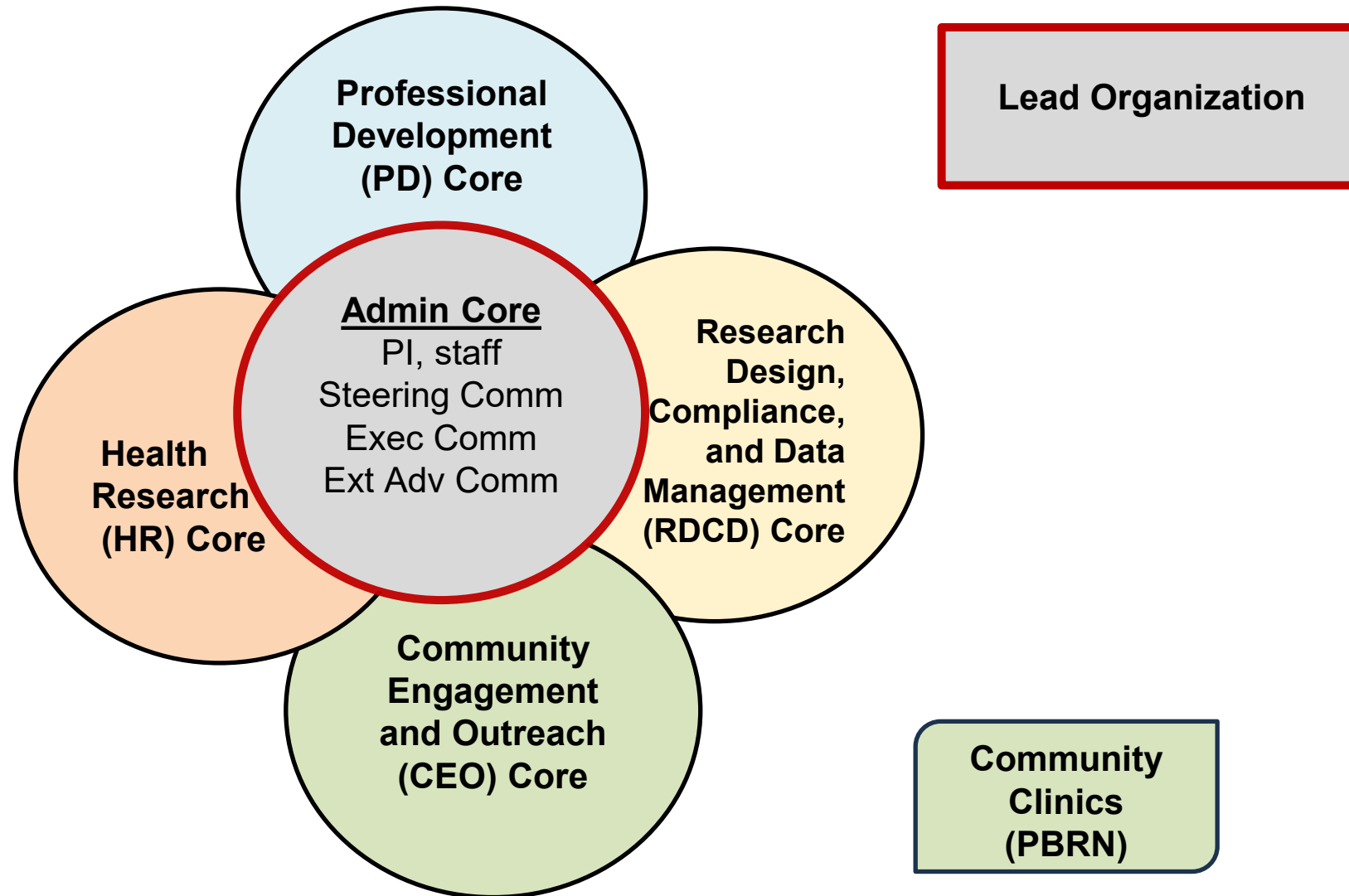
Executive Committee (EC): PD/PIs, a rep. from each partner (as applicable) and other key personnel appointed by the PD/PIs

- 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

CTR-D Organization – 5 Required Cores



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**
- **Recruitment of additional faculty, staff, and/or clinical fellows and the establishment of necessary infrastructure**
- **PD/PI (or the contact PD/PI for a MPI) is expected to lead the AC**

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
- **Collaborates with other cores to assess needs for additional expertise**

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**
- **Option to phase in the RDCD Core as capacity is developed**

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**
- **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
- **Option to phase in the HR Core as capacity is developed**

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

Preparing a CTR Application: For Resubmissions

For Resubmissions, the Special Emphasis Panels will evaluate the application as now presented, considering responses to previous scientific review group comments and changes made to the project (i.e., responses to the summary statement).

- **Overall Plan:**
 - An introduction to Application is required in the Overall component
- **Each core:**
 - An Introduction to Application attachment is allowed for each component

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-D](#) NOFO ([NOT-GM-24-037](#)))
- **1-2 pages recommended for the entire application**
- **Include as an attachment in the Overall Component**

Administrative Core (AC) Budget

- **Funds for leadership and administrative staff salaries**
- **External Advisory Committee related expenses (travel, compensation)**
- **Compensation for Executive Committee members**
- Recruitment of additional faculty, staff or clinical fellows, up to \$200,000 DC/yr for salary, supplies, and/or equipment
- 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**

Review Process: Step 2 – Scientific Review

- **Applications are divided among Special Emphasis Panels (SEPs)**
 - Number of panels depends on the number of applications
- **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)**

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

IDeA Funding Restrictions

- **The PD/PI may not use IDeA funds to support research 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 supplement
 - 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

Q&A

Please type your questions into the Chat box

