National Institute of General Medical Sciences

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# CTR-N and CTR-D Pre-Application Webinar

## September 8, 2023
## 2 – 4 pm

# NIGMS Staff Participation

**Michele McGuirl** Acting Director, Division for Research Capacity Building

**Fed Bernal** Acting Chief, Research Advancement Programs Branch

**Sara Seetharam** Scientific Review Officer, Scientific Review Branch

**Christy Leake** Senior Grants Management Specialist, Grants Administration Branch

**Q&A via Chat Window, moderated by Fed Bernal**

(Slides and Webinar Recording will be posted on the CTR website)

# IDeA: Impact through Creativity, Synergy, & Efficiency

## IDeA-CTR 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**

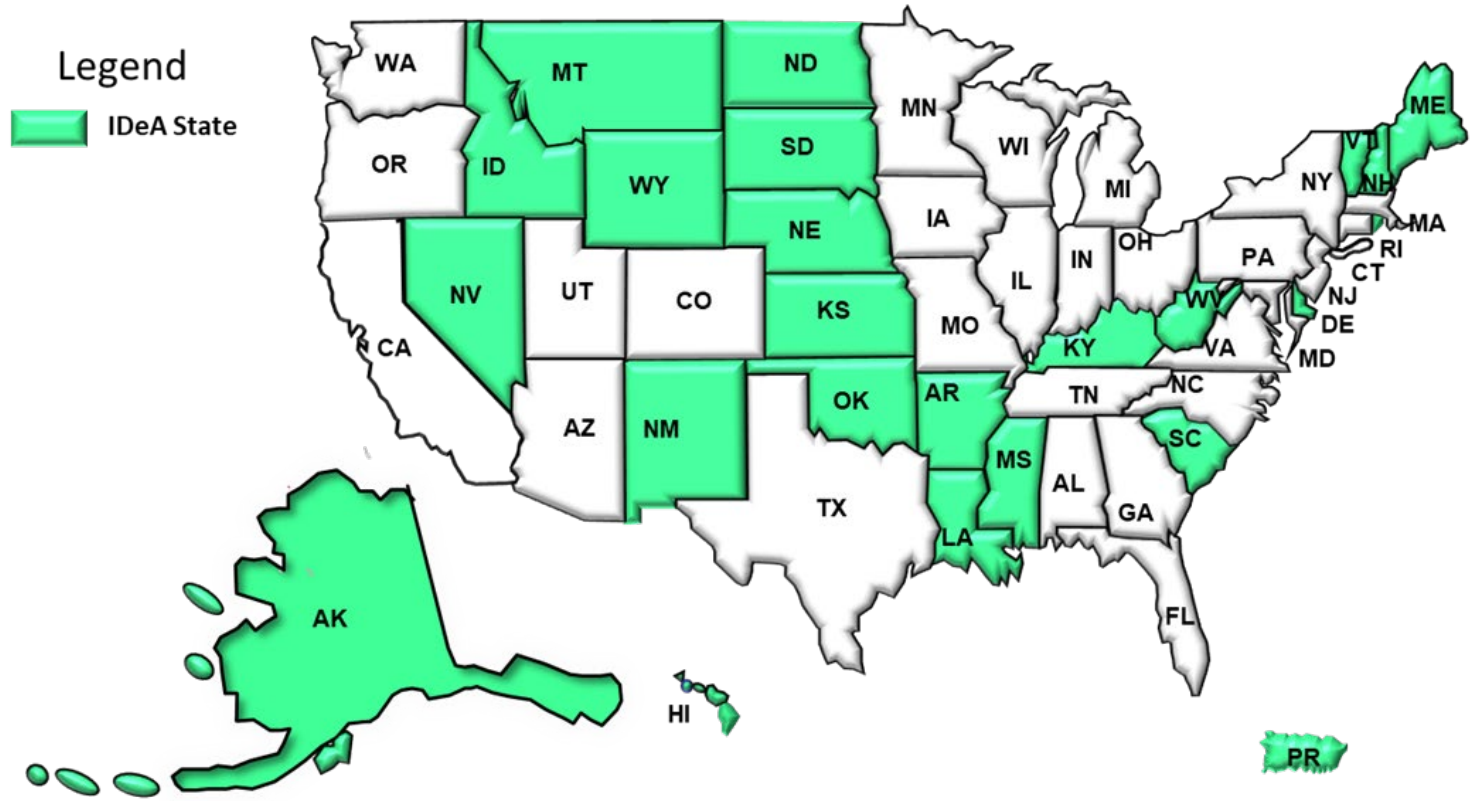
**COBREs**

**INBREs**

**IDeA-CTRs**

**Co-Funding**

**I-RED**



# IDeA-CTR is now Two Programs, Goals are the same

**IDeA-CTR (U54) → CTR-Network (CTR-N, P50) Awards (PAR-23-241)**

- Statewide or multi-state regional networks in IDeA states that have been conducting significant levels of C&T research
- Emphasize continued success in collaborative clinical research and use of EHR and other big datasets for research

**CTR-Development (CTR-D, P20) Awards (PAR-23-257)**

- Build a foundation of C&T research expertise and infrastructure where current capacity is limited
- Increase capacity at organizations that do C&T research but cannot support a state-wide network

# CTR Application Due Dates

| PAR-23-241 and PAR-23-257 | | | | |
|---|---|---|---|---|
| **FY** | **Due Date** | **Review** | **Council** | **Earliest Start Date** |
| 2024 | November 9, 2023 | March 2024 | May 2024 | July 2024 |
| 2025 | October 9, 2024 | March 2025 | May 2025 | July 2025 |
| 2026 | October 9, 2025 | March 2026 | May 2026 | July 2026 |

**CTR-N Application Types & Budgets**

New
Resubmission
Renewal – for *active IDeA-CTRs only
*includes grants in No-Cost Extension (NCE)

Budget: **$3.3M/yr Direct Costs; 5 yrs**

**CTR-D Application Types & Budgets**

New
Resubmission

Budget: **$1.5 M/yr Direct Costs; 5 yrs**

# 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

# 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-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;

# 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 (Pres, VP, President, 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

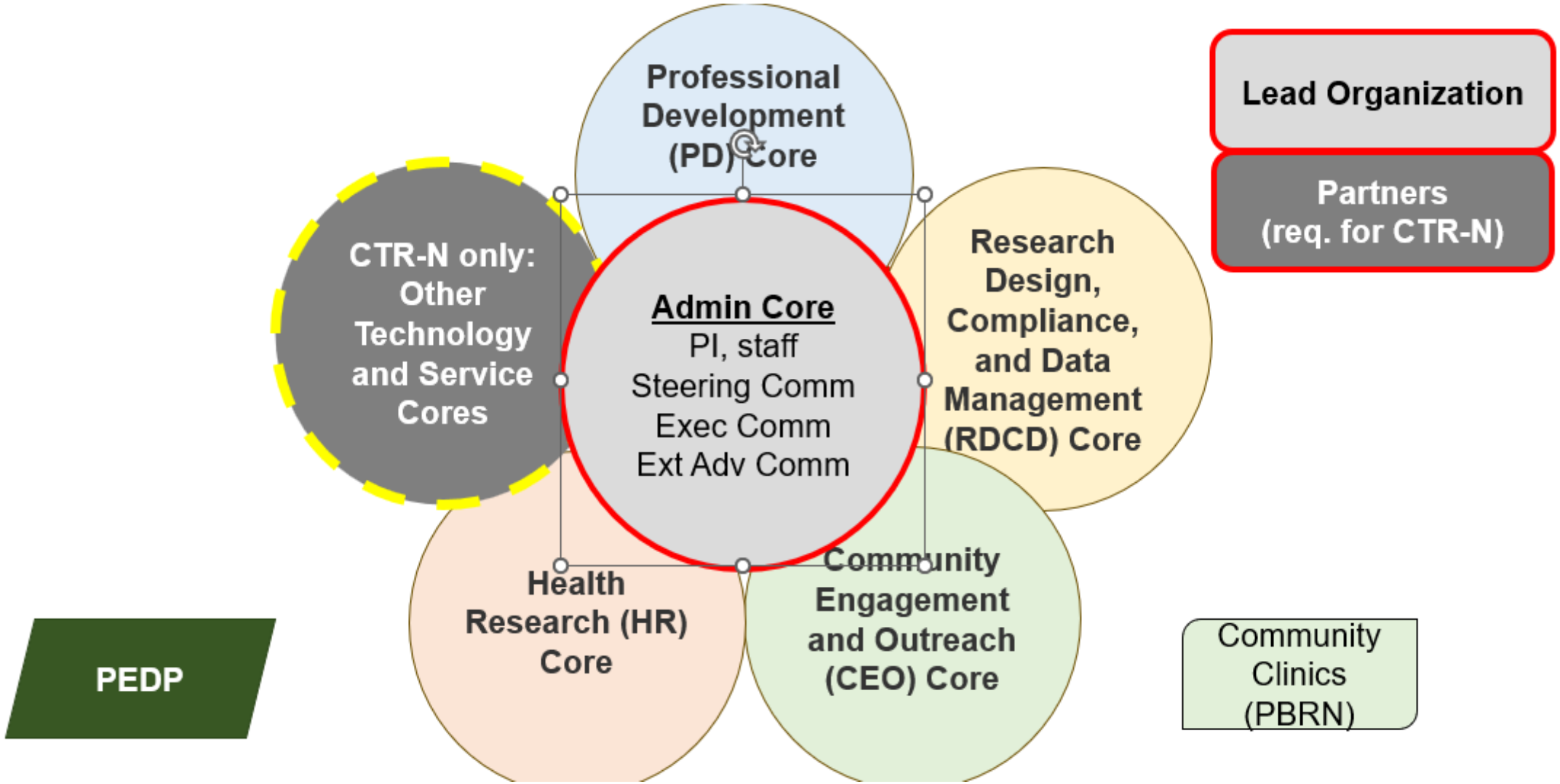
**Executive Committee (EC):** PD/PIs, a rep. from each partner (as applicable) and other key personnel appointed by the PD/PIs

- 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 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**

- **CTR-D:** Recruitment of additional faculty, staff, and/or clinical fellows and the establishment of necessary infrastructure

# 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.

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

# 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

# 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**

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

# Health Research (HR) Core

- **Led by an experienced clinical researcher (CTR-N: 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
- **CTR-D:** Option to phase in the HR Core as capacity is developed

# 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 leading/participate in a least one collaborative project during the CTR-N's project period**

# Additional Technology/Service Cores

- **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**
- **CTR-N:** for renewals, provide information on the progress and accomplishments from the current IDeA-CTR funding period
- **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

# Overall: Data Management Sharing 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
- **DMSP incorporates Data Management and Genomic Data Sharing**
  - Removed from the Resource Sharing Plan, which is still required
- **1-2 pages recommended for the entire application**
- **Include as an attachment in the Overall component**

# Plan for Enhancing Diverse Perspectives (PEDP)

- **Required – (**1-page maximum) as an “Other Attachment” in the Overall component.
- NIH recognizes the strength that arises from a diverse scientific workforce: foster innovation, enhance competitiveness, improve research quality, advancing participation of underserved populations, etc.
- PEDP should describe how expanded inclusivity advances the scientific and technical merit of the proposal and aligns with the Research Strategy
- **The examples provided in the FOA are standardized language developed for all funding mechanisms. Your PEDP should align with the overall CTR goals**
- PEDP will be evaluated by reviewers as part of the scorable criteria

# Administrative Core (AC) Budget

- **Funds for leadership and administrative staff salaries**
- **External Advisory Committee related expenses (travel, compensation)**
- **Compensation for Executive Committee members**
- **CTR-D:** 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
- PEDP implementation costs

# 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 (PEDP, 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
- **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
- **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