National Institute of General Medical Sciences

Centers of Biomedical Research Excellence: Expansion and Sustainability Phases (COBRE-E/S; P30 –Clinical Trial not Allowed) PAR-27-055

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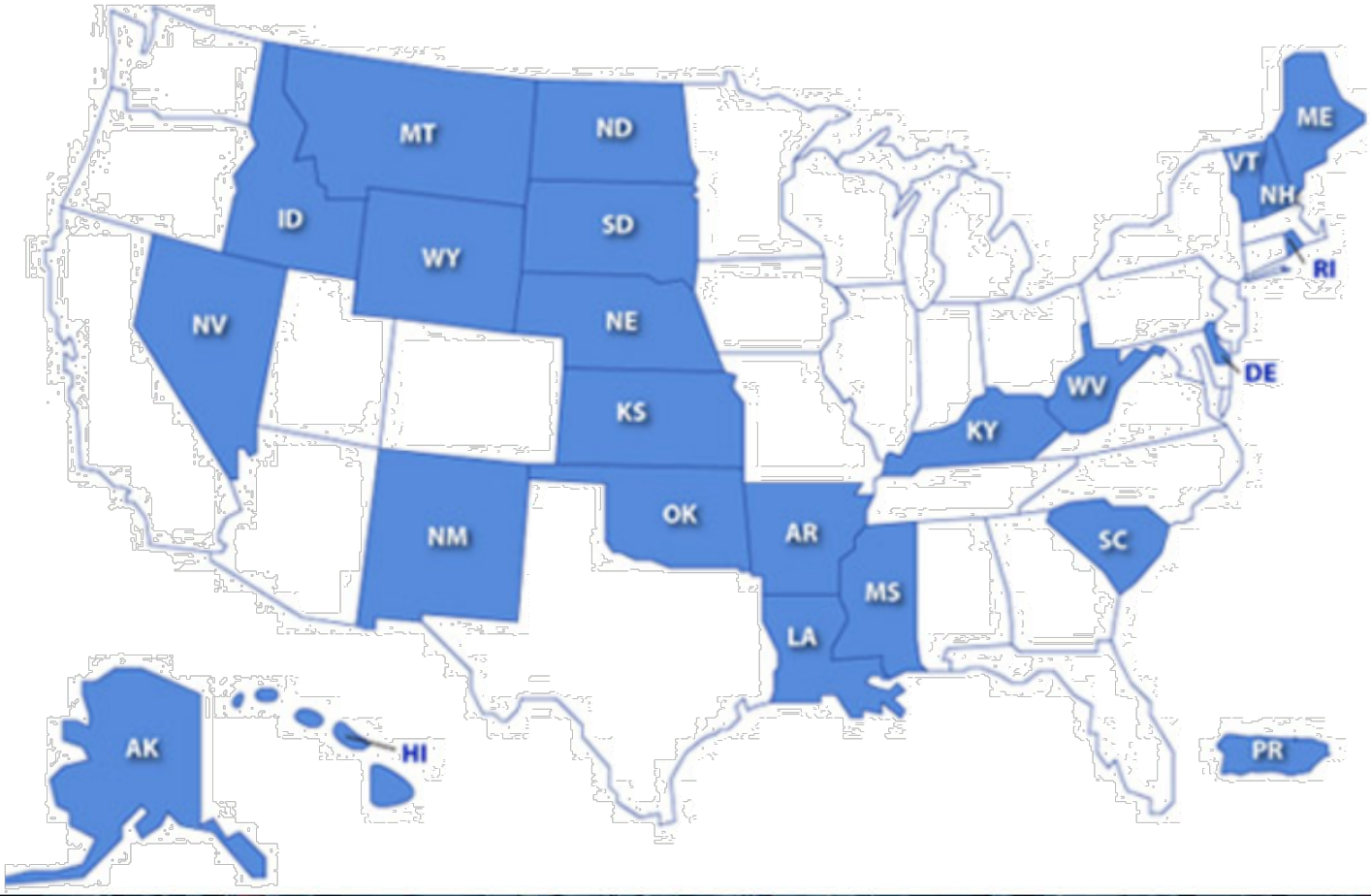
The IDeA Program

IDeA is a congressionally mandated program that builds research capacity in states that historically have received low levels of NIH funding.



Components of the IDeA Program

COBRE (Centers of Biomedical Research Excellence)

- Supports the establishment and development of innovative biomedical research centers of excellence in an area of strategic importance
- **PAR-27-054** (COBRE-D), **PAR-27-055** (COBRE-E/S)

INBRE (IDeA Networks of Biomedical Research Excellence)

- Supports a statewide network of institutions to build biomedical research capacity by developing faculty and providing opportunities to students
- Forecast: **PAR-26-026**

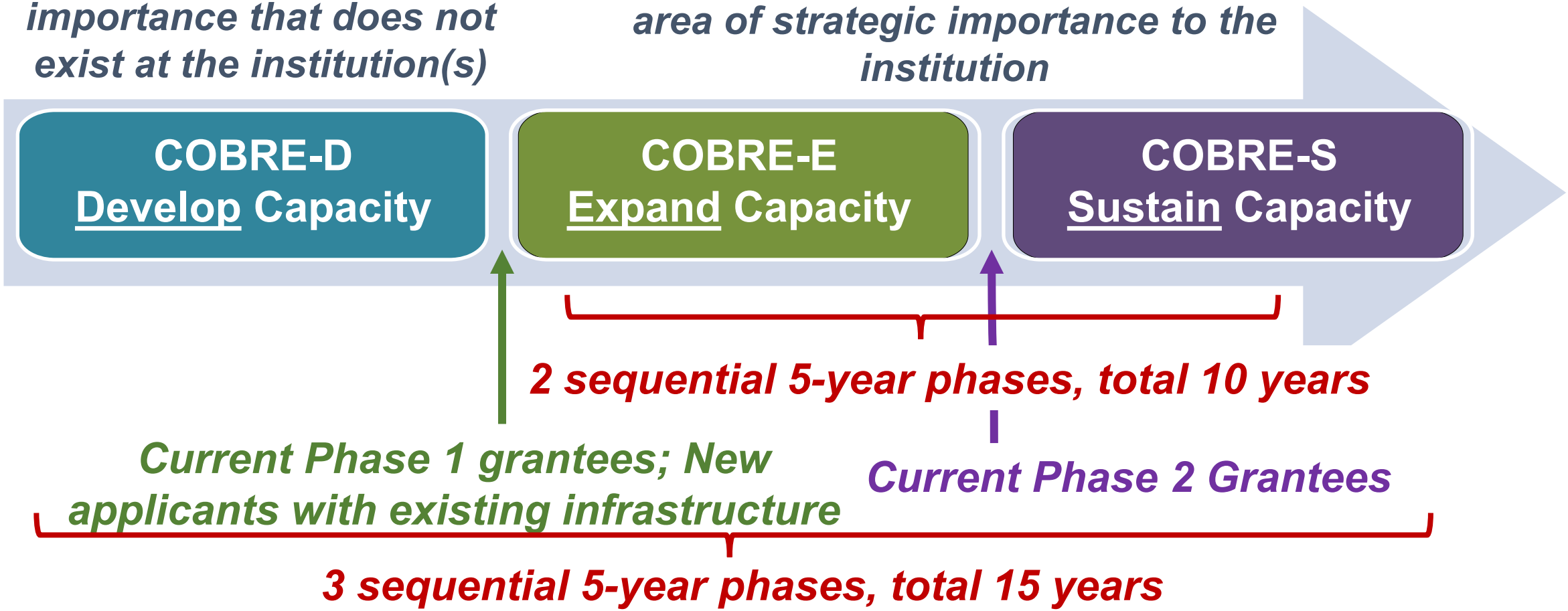
IDeA-CTR (IDeA Clinical and Translational Research)

- Builds and expands clinical and translational research capacity to enable research on diseases and health conditions prevalent in IDeA states
- Forecast: **PAR-27-056**

COBRE Program Framework

COBRE-D: Develop capacity in a broad area of strategic importance that does not exist at the institution(s)

COBRE-E/S: Expand and sustain existing infrastructure into a broad area of strategic importance to the institution



Major Highlights of PAR-27-055

- **COBRE-E and COBRE-S are very similar to each other.**
  - Both use the P30 activity code (all applications are **New)**
  - Same PI eligibility requirements (including the RPG requirement)
  - Same budget ($1.5M in direct costs per year)
  - Same components (Overall, Administrative Core, Research Core(s), Scientific Research Program Core)
  - Both allow A&R in the first two years of the award (without extra funds)
- **Differences between COBRE-E and COBRE-S**
  - Sustainability Plan proposed in COBRE-E, implemented in COBRE-S
  - No new Research Cores are allowed in COBRE-S.
- **The NOFOs have 3 receipt dates (Sep 25th, Jan 25th, May 25th).**
- **Clinical Trials are no longer allowed in COBRE.**
- **There are no projects (research or pilots). Instead, an existing pool of potential investigators appointed at the institution is proposed.**

Number of Applications from an Applicant Organization

"Applicant organizations may submit more than one application, provided that each application is scientifically distinct."

This is acceptable in *certain* contexts. For example:

- Institution has both a Phase 1 transitioning to COBRE-E and a Phase 2 transitioning to COBRE-S
- Institution is applying for a *New* COBRE-E and has a center transitioning Phases

Programmatic Pitfalls for applicant organizations submitting multiple *New* applications:

- Does not demonstrate a clear focus on its institutional strategic plan,
- Shows dilution of institutional support among several applicants,
- Forces potential PIs at an institution to compete internally for resources, investigators, core support, and startup money for faculty hires, and
- Would shortchange potential PIs by having them prepare lengthy applications, a task that is tremendously time-consuming.

Institutional Eligibility for COBRE-E/S

- Must be in an IDeA state, commonwealth, or jurisdiction,
- Must award doctoral degrees in health-related sciences or be an independent biomedical research center with ongoing research programs funded externally, AND
- For ***NEW*** COBRE-E centers, the applicant organization must hold 3 or fewer active COBRE awards (except for COBRE Phase 3)

For **COBRE-E**, applicant institutions must:

- possess research capacity that can be allocated to support the proposed research area OR
- hold an active COBRE Phase 1 award

For **COBRE-S**, the applicant organization must hold an active COBRE Phase 2 award

APPLICATIONS PROPOSING TO ESTABLISH A NEW CENTER IN A SCIENTIFIC AREA CLOSELY RELATED TO ONE PREVIOUSLY SUPPORTED BY COBRE OR IN AN AREA FOR WHICH THE INSTITUTION HAS A SUSTAINED RECORD OF RESEARCH CAPACITY ARE OF LOW PROGRAMMATIC PRIORITY.

PD/PI Eligibility for COBRE-E/S

- The PD(s)/PI(s) is expected to be an established biomedical research scientist with the administrative and mentoring experience necessary to lead the Center.
- At the time of submission, the COBRE PD/PI must have a **primary appointment** at the applicant organization and **be the PD/PI on at least one active, peer-reviewed, and externally funded research grant** within the general scientific area of the COBRE.
- The PD(s)/PI(s) of a COBRE Phase 1 award transitioning to COBRE-E or a COBRE Phase 2 award transitioning to COBRE-S may continue serving in that role provided their scientific background falls within the breadth of the proposed scientific area.
- For MPI applications, all PIs must fulfill the requirements above.

COBRE-E/S Budget and Components

COBRE-E/S budgets must not exceed $1.5 million in annual direct costs.
Funds may be allocated for A&R during the first two years of the award (Admin Core).

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Administrative Core	Admin Core	6	Required	1	1
Research Core	Core	6	Optional	0	3
Scientific Research Program	Core	6	Required	1	1

Overall Component

- **Justification for the Center:** Rationale to establish (New COBRE-E) or continue (from Phase 1) a Center; existing research capacity that can be allocated to the Center; how the chosen research area fits into the institutional strategic plan
- **Center Organization and Management Plan:** How funding will be allocated among components; how all the parts fit together to set up a cohesive Center
- **Sustainability Plan:** Plans to ensure enhancements endure beyond COBRE support; propose plan for COBRE-E, describe implementation for COBRE-S
- **Advisory Committee (AC):** three external members with expertise directly relevant to the scientific area of the Center, one senior institutional official (e.g., Dean), and one senior faculty member appointed by the senior institutional official; responsible for recommendations to Center leadership, feedback, and assessment/approval of research plans for proposed SIs (details in Section VI of the NOFO).

Overall Component (continued)

- **Career Development Plan**: Implemented by the SRP to support the success of the center's investigators via mentoring, leadership, and management training to foster career and professional advancement.
- **Letter of Support: A single letter** from a senior institutional official – outline alignment with institutional strategic plan; commitment to develop investigators and the broad area of research; organization's allocation of resources; long-term plans to sustain resources.

No additional letters of support are allowed in the Overall nor in any other component.

Administrative Core Component

- **Budget**
  - Minimum 3 person-months required for each PD/PI. A maximum of 6 person-months may be charged to the grant for salary purposes.
  - Up to $300K in A&R may be allocated for expenditure within the first two years of the award. *These are not additional funds on top of the $1.5M in direct costs per year for the award.*
  - Include support for mentors (maximum 1 person-month) and recruitment funds
- **Research Strategy**
  - Organizational and management aspect of the Center
  - Plans for faculty recruitment and retention; details on how a continuous pipeline of SIs will be sustained throughout the entirety of the award
  - Self-evaluation plans with timelines and milestones; strategies to identify and remedy deficiencies
  - Process for assessing and implementing AC recommendations
  - Plans for Alterations and Renovations, if requested

Scientific Research Program (SRP)

The SRP manages research activities of the center and manages the scientific and career development of **SRP Investigators (SIs)** and the institution's biomedical research base.

To be eligible, an SI must, at the time of submission:

- Be an NIH ESI, NIH NI, a mid-career investigator working towards renewal of their *first* research project grant (R01, R35 or equivalent), or an "at-risk" investigator (had prior research support but will have no substantial research grant in the following FY),
- Hold an independent, multi-year faculty appointment (or equivalent at research institutes) ***at the applicant organization*** *(no postdocs, instructors, research associates on time-limited contracts, staff whose appointment is contingent on the success of the COBRE application, faculty not already on a tenure track, faculty not already at institution)*, and
- Lead their own research program within the broad scientific area of the Center ***at the applicant organization*** *(investigators under the purview of or using space belonging to a senior faculty member are ineligible)*.

Existing SRP Investigator (SI) Pool

- The proposed pool of SIs is made up of eligible faculty already appointed at the applicant institution (no “TBD”; these are proposed in the recruitment plans).
- There is no set number of SIs that may be part of the proposed pool, but it should be reflective of the existing research capacity at the applicant organization.
- The final selection of SIs takes place once an application has been selected for possible funding consideration (See Section VI of the NOFO).
- For each potential SI in the pool, applicants must include a Biosketch Common Form and Supplement as an ***“Other Attachment”*** in the ***Overall*** section of the application. **Do not include project descriptions, Specific Aims, or Preliminary Data.**
- The proposed SI pool is evaluated as a group for cohesiveness and alignment with the broad area of research (See Section V of the NOFO).
- Applications that do not include a proposed SI pool of investigators already appointed at the applicant institution or that deviate from the instructions will be withdrawn without review.

SRP Component Details

- **Budget**
  - All SIs must make a minimum level of effort commitment of 6 person-months annually.
  - Salary support for postdocs, graduate, undergraduate and other research assistance may be requested.
- **Research Strategy** –describe the administration of **research activities** of the Center
  - How the combination of the proposed SI pool and planned hires will enable scientific advances that address and cement a relevant broad area of biomedical research at the applicant organization
  - How prospective hires and SIs will be recruited and selected
  - Expectations for the SIs and their expected impact on expanding and sustaining research capacity
  - Budget, duration, and estimated number of SIs to be supported
  - How the institution will implement the Career Development Plan

Research Core Component (optional)

- Core Directors must have the appropriate expertise to lead a Core.
- Description of how the Core will serve the needs of the SIs
- Outline the Core's current userbase and plans for future growth
- Justification for any newly proposed Cores and support of new instrumentation
- Justification for modification, consolidation, or elimination of Cores
- Business plan for the operation of the Core
- Description on how the services be made available to other investigators at the institution and from other IDeA state institutions

No new Cores may be established in the COBRE-S phase

Research Cores should be unique - Duplication of services is not allowed.

Leveraging and consolidation of existing facilities is encouraged

Scientific Review (Overall)

Review will take place at the Center for Scientific Review in a Special Emphasis Panel.

Review Criteria in Overall

- **Significance:** Is the area broad and cohesive enough to ensure expansion/sustainability of biomedical research? Is there alignment with the organization's strategic plan?
- **Investigator(s):** Does the PI have the necessary expertise? Is there a commitment to mentoring? Does the PI have a sustained track record of leadership of a productive lab? What does the leadership structure look like for future administration?
- **Innovation:** Is the area amenable to future growth on pace with the field? Are existing resources used creatively? Are novel research advancements feasible?
- **Approach:** Is the organizational structure reasonable? Is the Sustainability Plan consistent with the institutional strategic plan? Are the strategies in the Career Development plan feasible? Are evaluation plans realistic?
- **Environment:** What is the nature of the existing research capacity? Are there solid institutional commitments? Does the request justify the need for the center?

Scientific Review (Cores)

- **Administrative Core:** Are the administrative plans well-integrated? Are the recruitment plans feasible and in-line with plans for a steady pipeline of SIs? Is the management strategy appropriate for ensuring compliance with federal regulations, budget maintenance, and financial reporting? Are the evaluation plans suitable to make objective assessments of the performance of all components? If A&R are proposed, do they reflect an unmet need within the scope of the award?
- **Research Core(s):** Is the support requested well-justified? Is the nature of the scientific support for the Core adequate? Are there feasible plans to expand and sustain the reach of the Core beyond the activities of the Center? Are the institutional commitments in line with the organization's strategic plan?
- **SRP Core:** Do the plans contribute to the enhancement of biomedical research capacity in the proposed area? How strong is the alignment with institutional priorities? Are the traits sought in future hires complementary? Are the processes for bringing new SIs suitable, fair, and transparent? Are the scientific and career development activities adequate?

Post-Review and Post-Award Procedures

Scientific Research Program (SRP)

- SIs are selected prior to award from the existing pool proposed in the application.
- There is no required minimum number of SIs and number of SIs may change over the course of the award to reflect the Center's scientific needs
- Support for an SI beyond 3 years requires AC and NIGMS approval.
- SIs lose eligibility upon receipt of independent research funding (R01 or R01-equivalent).
- SIs may be removed for underperformance upon recommendation from the AC.
- The list of documentation required for approval of an SI is listed in Section VI of the NOFO. Incomplete submissions will be rejected without review.
  - Research Strategy must not contain SAs, detailed experimental plans, or preliminary data.
  - Research Strategy should provide an overview of the investigator's overall research program.

AC approvals: The AC is required to review all SI submissions and provide a **substantial** evaluation of the research program proposed by the SI, including an assessment of the fit with the Center and a statement that the research algins with NIH priorities and proposes no dGoF.

Q&A

Please enter your questions using the Q&A button in Teams

For questions specific to an institution's particular situation, send an email to the contacts in the NOFO:

For COBRE-E: NIGMS_COBRE_E@mail.nih.gov

For COBRE-S: NIGMS_COBRE_S@mail.nih.gov