



RFA-DK-21-026

Silvio O. Conte Digestive Diseases Research Core Centers (P30 Clinical Trial Optional)

Karin Johnson (Grants Management)

Peter J. Perrin, Ph.D. (Program)

Jian Yang, Ph.D. (Review)



Contacts

- Your Grants Office/Office of Sponsored Research
 - NIH grant policies
 - Preparation and submission of the application
- Program Officer – Peter Perrin
 - Questions regarding the DDRCC program prior to submission
 - Questions regarding the Summary Statement after the review is complete
- Scientific Review Officer – Jian Yang
 - After submission and up to the time of review
- Grants Management Specialist – Karin Johnson
 - Preparation of awards
 - Post-award activities

Note About Instructions

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

Example1 (Overall):

Project Summary/Abstract: Describe the scientific theme of the DDRCC and the need for a Cores Center to support the investigators in the research base. Include the number of Center members and the overall total direct costs present in the digestive and/or liver research base. Specify the total direct costs of NIDDK awards contributing to the research base. Provide a brief overview of the research base as it relates to the theme of the Center as well as an overview of the Biomedical Research Cores, the P and F Program, the Enrichment Program, and, if requested, the Clinical Component.

Project Narrative: In 1-3 sentences describe the relevance of the research to be supported and facilitated by Center Activities (Core services, P and F program, and Enrichment Program) on public health.

In this example, both a “Project Summary/Abstract” and “Project Narrative” are Required. Additional guidance is provided for applicants.

Note About Instructions

Example 2 (Biomedical Cores):

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

In this example, you do not complete a Project Narrative, but you do complete you do provide a "Summary/Abstract." No additional FOA-specific instructions are provided for the "Project Summary/Abstract". Follow the instructions in the application guide.

Other Reminders

- Notices may be issued for multiple purposes, including corrections/changes to the FOA content.
- Changes in FOA language in Notices supersede the previous language.
- Notices to correct language may be issued up to 30 calendar days prior to the submission date.
- Notices are linked to appropriate FOAs upon publication.
- The DDRCC Resource page is not part of the FOA and should not be construed as application instructions.
- The purpose of the DDRCC Resource page is to provide help with application preparation

DDRCC Program

- Goal: Foster productivity, synergy, and innovation among researchers funded for digestive and/or liver diseases research within the mission of the NIDDK.
- Metric: Impactful NIDDK-relevant digestive and/or liver diseases research.
- Approach: Support a research base consisting of PIs pursuing research related to a central theme with infrastructure related to the theme and the PIs' needs.
 - Administrative Core
 - Biomedical Research Cores
 - Pilot and Feasibility Program
 - Enrichment Program

DDRCC Focus

- A DDRCC must have a central research focus or theme. The central focus must be a gastrointestinal/liver disease, group of diseases, or functional studies relating to digestive and/or liver diseases within the mission of the NIDDK.
- 30% of the research base must come from NIDDK awards.
- The theme should be cohesive and well-articulated to ensure a DDRCC with components that will substantially advance a defined area of NIDDK-related science.
- A flat or even slightly reduced research base in a renewal application is acceptable. When a reduction results in a more thematically focused DDRCC, with added benefit to Center members, this is appropriate and viewed as a positive development...

Changes in Review Criteria Related to the Overall Center

Additional language under “Research Base”

The research base of a renewal application is not required to have grown since the previous competing award and may have even decreased. The lack of growth or a slight decrease might be viewed positively when it is the result of a concerted effort to enhance the Center's focus. In other words, there could be instances where other considerations such as increased focus of the research base justify the lack of growth or slight decrease in the size of the base.

Modified language under “Investigators”

Do the proposed Center Director and Associate Director(s) have the appropriate administrative abilities and scientific expertise for effective management of the DDRCC? Do they have demonstrable commitment and the ability to devote adequate time for the effective management of the DDRCC?

Additional language under “Environment”

Is there evidence of institutional commitment to the Center program, including lines of accountability, regarding management of the Center grant and the institution's contribution to the management capabilities of the Center? Is there clear potential for scientific interactions?

P and F Program

- If your Program will support Vertebrate Animals Research
 - Indicate VA “yes” and provide a VA section
- If your Program will support Human Subjects Research
 - Indicate “yes” and provide an HSS entry for delayed onset studies
 - Successful P30s submitted without this information will not be able to support P and F projects involving HS research
- If your Program will support Clinical Trials
 - Indicate “yes” and provide an HSS entry for delayed onset CTs
 - Successful P30s submitted without this information will not be able to support P and F projects involving CT research, including BESH CTs
- Any P and F Project involving CTs or HS research with greater than minimal risk will require pre-approval

P and F Program Changes

➤ Pilot Summary/Abstract Attachment

- **Additional language:** New applications that have made awards through a P and F program that was set up to demonstrate feasibility and/or that is intended to be the basis for a P30 program, may provide information about awards made under those P and F programs

➤ Research Strategy

- **Change in required information for the representative P and F projects:** Brief description of the project; including hypothesis, one sentence description of each Aim, one to three sentences identifying the conceptual and/or technical innovation, relationship to the Center's theme and goals; how the project will benefit from specific collaborations with Center members if relevant, and plans for follow-up upon the successful completion of the project.

P and F Program

New Review Criteria Language

➤ Under Investigators

How well are the P and F applicants prepared to lead their proposed P and F Projects effectively? Do they have the appropriate conceptual and technical expertise for executing the proposed research? The qualifications and potential for each candidate should be evaluated in the context of the candidate's career stage...support?

➤ Under Approach

Are the processes for soliciting, evaluating, and selecting the P and F projects appropriate and transparent? Does the solicitation process reach the appropriate pool of potential candidates? Are the evaluation and selection processes free of bias and likely to lead to awards for strong applications?

Enrichment Program

Attachment previously for competing Centers only – now also allowed for new Centers

New language: **Other Attachments:** Competing Centers may include information related to the Center-supported Enrichment Program activities (such as Center retreats, symposia, workshops, meetings, specialized courses, seminar series, etc., illustrating the interactions among Center members and other investigators, as well as other training and educational opportunities) in the application. **New Applications that have Enrichment Program activities that are intended to continue as part of their DDRCC Enrichment Programs, may provide this information for those activities. This attachment is optional. This should be loaded as a single, combined file in PDF format titled "Enrichment Program".**

- This presentation is not meant to be exhaustive and there may be other changes in RFA-21-026, the re-release of the DDRCC RFA.
 - Please read the RFA completely.
 - Refer to your Grants Office for NIH Grants Policy and application preparation.
 - Refer to Program for questions specific to the DDRCC program.
- Any questions?