



Technical Assistance Webinar

RFA-DE-24-003 Collaborative Science to Achieve Disruptive Innovations in Dental, Oral and Craniofacial Research

Tamara McNealy, PhD (on behalf of Amanda Melillo, PhD) NIDCR, NIH

Webinar Tips

- This webinar will be recorded and posted to the NIDCR webpage
- Please remain on mute with video off
- Submit questions at any time using the Chat feature
- Questions will be answered during the Q&A session at the end of the webinar as time permits

https://www.nidcr.nih.gov/grants-funding/grant-programs/oral-opportunistic-pathogens-viral-disease-program/collaborative-science-achieve-disruptive-innovations-dental-oral-craniofacial-doc

Technical Assistance Webinar

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Agenda

- Why team science?
- Key Dates and Budget
- RFA Key Features
- Application Information (Section IV)
- Review Criteria (Section V)
- Q&A







Why Team Science? (1 of 2)



Why Team Science? (2 of 2)

A team science approach expands our ability to pursue complex and challenging problems in DOC research in a comprehensive, interdisciplinary, rigorous and mechanistic manner.





Goals of RM1 (1 of 2)

- To support highly integrated research teams of 3-6 PIs to address ambitious and challenging research questions of high priority to NIDCR
- Program should be of sufficient scope and complexity that it could NOT be accomplished through multiple independent research awards
- The research goal should be clear, cohesive, and focused so that meaningful and **measurable outcomes or deliverables** can be achievable in 5 years
- Single well integrated project set of aims



Goals of RM1 (2 of 2)







Key Dates and Budget



Key Dates

- Letter of Intent: October 23, 2023
- Application due date: November 22, 2023
- Scientific Review: March 2024
- Advisory Council: May 2024
- Earliest Start date: July 2024

No late applications will be accepted for this Notice of Funding Opportunity



Budget Information

- NIDCR intends to commit \$4 million in FY2024 to fund 3-4 awards.
- Limited to \$750,000 direct costs per year. A detailed budget is required.
- Applications may request up to five years of support.
- Data sharing costs: Applicants may include costs associated with preparing and submitting data to a data archive per <u>NOT-OD-21-015</u> (https://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-21-015.html)
- **PEDP implementation costs:** Applicants may include allowable costs associated with PEDP implementation (as outlined in the <u>Grants Policy Statement section 7</u> (https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.1_general.htm)

Requests to submit an application over \$500K are NOT needed for this Funding Opportunity





RFA Key Features (Section I)



RM1 Key Features

- Cohesive program with a <u>single set of specific aims</u> sufficient to accomplish program objectives having concrete outcomes that can be achieved within a maximum of 5 years.
- Requires a Multiple PI (MPI) structure (3-6 PDs/PIs) who each bring a distinct scientific viewpoint or expertise necessary to pursue the transdisciplinary approach.
- Highly encouraged to include early career stage investigators.
- Require significant effort from all PDs/PIs involved (at least 2.4 person months) for the duration of the award.
- The application must include a clear timeline and metrics for identifying successful completion of program aims and goals, and criteria for acceptable outcomes.



A truly integrated collaborative project should:

- Pursue one, single focused goal
- Assure all contributions are essential to the goal.
 - Deletion test- if you remove a piece, the goal falls apart
- Have substantial and integrated contributions across all PD/PIs.
 - Not a collection of individual or series of efforts or interrelated and parallel projects.
 - Ask why do these pieces needed to be studied together?
- Be intentional about integrating efforts.
 - What is unifying all these pieces together that is necessary to achieve the specified goal?



Disruptive Innovations in DOC Research

Novel team-science collaborations should focus on challenging and complex research goals that would not be achievable by a single investigator and that are of high priority to NIDCR.

- Patient-controlled technologies that draw on best practices from other fields of medicine and that reduce health disparities and/or improve oral health throughout the life span.
- Preventative dental caries vaccine development leading to significant reduction in early childhood caries incidence.
- Non-opioid pharmacotherapies treatments for DOC-related pain that minimize undesirable side effects.
- Dental Restorative Systems with clinical service life that exceed current commercial materials.
- Approaches to advance prophylactic and therapeutic strategies to manage HIV and its oral manifestations and comorbidities.

Key Features – Program Organization

Team Management Plan

- In addition to the required multiple PI leadership plan, applications must develop a comprehensive team management plan submitted as Other Project Information as an attachment.
- The "Team Management Plan" should focus on management of the **whole team/key personnel**.

Plan for Enhancing Diverse Perspectives (PEDP)

 This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP). Applicants are strongly encouraged to read the NOFO instructions carefully and view the available <u>PEDP guidance material</u>. (https://braininitiative.nih.gov/about/planenhancing-diverse-perspectives-pedp)



Consultation with NIDCR Staff

- It is strongly recommended that potential applicants consult the NIDCR program staff prior to submission.
- While staff will not evaluate the technical and scientific merit of the proposed project, they can advise potential applicants on whether the proposed research strategy meets the goals and mission of the Institute, whether it addresses one or more high priority research areas, and whether it is appropriate for a collaborative science team program.



Non-responsive applications

Non-responsive applications will be withdrawn, and will not be reviewed. Non-responsive applications include:

- Research outside the NIDCR mission
- Applications that lack a minimum of three PDs/PIs or that exceed the maximum of six PDs/PIs
- Applications that lack a Team Management Plan
- Applications that lack the two required tables described in section IV





Application Information Section IV



PHS 398 – Research Plan (1 of 3)

Research Strategy section is limited to 15 pages.

- Integrated scientific program with a single set of specific aims organized to address the overall objectives rather than individual PI contributions.
- Describe the biomedical problem being addressed, its significance, and how successful accomplishment of the goals and outcomes would provide substantial scientific advances by the end of the 5-year period.
- This should include how the proposed work will enable the applicants to challenge existing paradigms, overcome long-standing bottlenecks to substantial progress, and/or develop new synergies between different scientific fields.



PHS 398 – Research Plan (2 of 3)

Research Strategy section is limited to 15 pages.

- Describe the underlying premise and scientific foundation of the project, experimental rationale, approaches, and steps taken to assure scientific rigor, with attention to the reasons a team science approach is required.
- Describe critical research metrics and any innovative aspects of the approach, including those arising from collaborative interactions.



PHS 398 – Research Plan (3 of 3)

Research Strategy section is limited to 15 pages.

Two tables are required and must be included within the page limit for the Research Plan:

- 1. A table, organized by specific aims, that identifies the contributions expected from each PI toward accomplishing that aim. For a truly integrated collaborative project, it is expected that most or all of the scientific aims will require substantial contributions from more than one PI.
- 2. A table that identifies metrics and performance criteria and a timeline for completion. The metrics should define successful completion of program aims and goals, and criteria for acceptable outcomes. It is useful to identify interdependent steps with critical risks.



SF424(R&R) Other Project Information -Team Management Plan

Required – 3 pages maximum

- In addition to the required multiple PD/PI leadership Plan, a Team Management plan must be submitted as an "Other Attachment" titled "Team-Management-Plan.pdf".
- Applicants must address how the entire group will function to accomplish program objectives and vision.



Team Management Plan (1 of 3)

"Team Management Plan" should address the following points:

Organizational structure and team composition

- Avoid giving any single individual undue authority that prevents contributions from the wider team.
- Management structure based on project objectives that effectively promotes the proposed research.
- NIDCR does not specify any particular organizational structure, as this may vary across research questions and groups.
- Inclusion of a scientific project manager or coordinator as a Senior/Key Person with adequate authority is recommended. If a project manager or coordinator is included, describe how the qualifications of this individual are appropriate for such a role and for the subject and scale of the proposed project.



Team Management Plan (2 of 3)

"Team Management Plan" should address the following points:

- Resource sharing and allocation, including intra-team data sharing, archiving, and preservation:
 - Management and decision-making processes that promote collective input for allocation of program resources with flexibility when resources may need to be dynamically reallocated to achieve programmatic goals.
 - A plan for how intra-team, institutional, and regional resources that are integral to the team goals will be shared and made accessible to team members should also be included.
 - Plans for data archiving and long-term preservation for team use should also be described.
 - Note that this is independent of the Data Management and Sharing (DMS); this section should address the sharing among the team.



Team Management Plan (3 of 3)

"Team Management Plan" should address the following points:

- Shared leadership, contributions, and distributed responsibility for decision-making
 - Teams employing complementary approaches and having diverse areas of intellectual and technical expertise are more productive if the process for making decisions incorporates different points of view.
- Communication and management of shared responsibilities plans
 - Practical aspects should be described, including frequency and logistics of real time communication across all key personnel, consultants, trainees, and other significant contributors regardless of effort level.
 - Plans for how trainees will be immersed in, and benefit from diverse approaches taken by the collective team program should be described.
- Credit assignment
- Conflict resolution



Plan for Enhancing Diverse Perspectives (PEDP) (1 of 2)

Required-1 page maximum

- In an "Other Attachment" titled "PEDP.pdf", all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity.
- The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate.
- Where possible, applicant(s) should align their description with these required elements within the research strategy section.
- Should include a timeline and milestones for relevant components that will be considered as part of the review.



Plan for Enhancing Diverse Perspectives (PEDP)(2 of 2)

Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations.
- Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups traditionally underrepresented in the biomedical, behavioral, and clinical research workforce.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse backgrounds, including those from underrepresented groups in research.



Peer Review of Applications: Application Review Information (Section V)

Christopher Campbell, MD, PhD Scientific Review Officer Scientific Review Branch



NIDCR, NIH

NIH/NIDCR Peer Review System for Grant Applications

Two Levels of Peer Review

• First level of review (Initial Peer Review)

- Conducted by Scientific Review Groups (SRGs)
 - Special Emphasis Panel (SEP) for RFA-DE-24-003
 - Evaluate scientific and technical merit
 - Provide summary statements

• Second level of review (Council Review)

- Performed by NIDCR National Advisory Council/Board
- Make recommendations on priority areas of research and funding process



Letter of Intent

Letter of Intent (LOI): The information that a LOI contains assists staff in estimating the potential review workload

- Due Date: October 23, 2023
- Please consult the Section IV.2 of the RFA for further information
- LOIs should be addressed to Dr. Yasaman Shirazi, Chief, Scientific Review Branch, NIDCR, NIH

A Letter of Intent is not required, is not binding and does not enter into the review of a subsequent application.

Prospective applicants are asked (not required) to include the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity





Completeness and Compliance of Applications

- Completeness and compliance with application instructions will be evaluated primarily by the Center for Scientific Review (CSR), NIH, and the Scientific Review Officer (SRO), Scientific Review Branch, NIDCR, NIH.
- Responsiveness to RFA-DE-24-003 will be evaluated by NIDCR
- Non-compliant and/or nonresponsive applications will not be reviewed and will be withdrawn
 - Must contain required attachments as well as two specific tables in the research plan
 - No clinical trials
- The NIDCR Scientific Review Branch (SRB) will coordinate and manage the review of the applications
 - Applications will be assigned to a special emphasis panel (SEP)
 - Use eRA Commons to access administrative information relating to your application



Scientific Review of Applications

- Please read Section V (Application Review Information) of RFA
- NIDCR SRB will follow the established NIH procedures to manage initial peer review
 - Special emphasis panel (SEP) with collective expertise suited to content of applications
 - At least 3 reviewers will be assigned to each application
- Roster will be posted approximately 30 days before the meeting
 - Do <u>not</u> contact the members of the review panel (<u>NOT-OD-22-044</u>) (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html)
- Post Submission Materials:
 - Applicants are required to follow the instructions for post-submission materials, as described in the policy <u>NOT-OD-19-083</u> (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-083.html)



Review Criteria for RFA-DE-24-003

Scored Review Criteria* (Score individually)

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

Additional Review Criteria* (Not scored individually)

- Team Management Plan
- Protections for Human Subjects
- Inclusion Plans
- Vertebrate Animals
- Biohazards

Additional Review Considerations (Not scored)

- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

* Factored into Overall Impact Score



NOFO Specific Criteria for Significance

Evaluate the program's scope and complexity and how it warrants a team approach.

- 1. How well do the specific aims form a single cohesive program, and if accomplished will these aims advance the stated goals of the program?
- 2. To what extent will the scientific questions provide definitive outcomes, and can they be accomplished during the funding period?
- 3. If successful, to what extent will the proposed program's integrated team research effort be transformative and uniquely advance a scientific field/community?
- 4. To what extent do the overall goal challenge existing paradigms, overcome long-standing roadblocks to progress, and/or develop new synergies between different scientific fields?
- 5. To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?



NOFO Specific Criteria for Investigators

- 1. Evaluate how the planned effort by the PD/PIs is appropriate and sufficient for the work proposed?
- 2. How sufficient is the critical mass and diversity of investigator backgrounds and expertise for addressing the proposed scientific problem?
- 3. To what extent, is there evidence for synergistic interactions among PDs/PIs beyond the additive benefits of additional investigators?
- 4. If the application includes collaborating investigators who will not receive direct support, is it clear how these investigators will participate and what role they will play in the program?
- 5. If foreign investigators are involved, are they uniquely qualified to participate in the team?
- 6. To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?



NOFO Specific Criteria for Innovation

- 1. How likely is it that the innovative ideas or approaches proposed can only be pursued through this team science and not through independently funded individual of MPI research project grants?
- 2. To what extent does the program involve innovative combinations of scientific fields and/or intellectual viewpoints to address its goals?
- 3. To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?



NOFO Specific Criteria for Approach

- 1. To what extent does the program present as a coherent and fully integrated set of specific aims?
- 2. How appropriate are the timeline and metrics proposed for accomplishing the specific aims?
- 3. How well does the work plan make adequate use of existing institutional and/or regional resources?
- 4. How well does the combination of scientific expertise present a compelling case that collaborative, interdisciplinary research will enable scientific advance?
- 5. To what extent do the tables provide sufficient detail on the timing and duration of key project metrics?
- 6. How realistic are the timelines proposed for achieving project goals?
- 7. To what extent do the contributions from the PD/PIs suggest a high degree of commitment, integration, and collaboration?
- 8. Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?



NOFO Specific Criteria for Environment

- 1. How adequate are the resources and infrastructure for accomplishing the specific aims and supporting team science?
- 2. To what extent is there synergy to be gained from the involvement of multiple departments and institutions?
- 3. How well does the range of departments and/or institutions involved enhance the diversification of the teams in terms of the backgrounds, and expertise and skills of the researchers?
- 4. To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?





Q&A



Thank You

