Practice-Based Research Integrating Multidisciplinary Experiences in Dental Schools (PRIMED) (U01 - Clinical Trial Not Allowed)

Technical Assistance Webinar

RFA-DE-23-012

September 26, 2022
Webinar Tips

• This webinar will be recorded and posted to the PRIMED 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
Technical Assistance Webinar Presenters

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Agenda

1. Key Dates and RFA Features

2. RFA Purpose and Application Information

3. Peer review of applications

4. Frequently asked questions / participant questions
1. Key Dates and RFA Features
RFA-DE-23-012: Key Dates

- **Letter of Intent Due Date**: November 15, 2022
- **Application Due Date**: December 15, 2022
- **AIDS application Due Date**: February 24, 2023
- **Scientific Merit Review**: June 2023
- **Advisory Council Review**: August 2023
- **Earliest Start Date**: September 2023
RFA-DE-23-012: Key RFA Features

• U01 Cooperative Agreement mechanism
• Maximum project period is 5 years
• Clinical trials not allowed

• Contact PD/PI must have primary appointment as faculty member of a dental school in the United States

• Estimated funding: $5 million total costs in fiscal year 2023
• Expected total number of awards: 6-7 awards
2. RFA Purpose and Application Information
PRIMED: Overall Goals

• Foster a culture of scientific inquiry during predoctoral/postdoctoral dental education

• Encourage scientific partnerships between students/residents, clinically-oriented faculty, and research faculty

• Stimulate additional clinical research pursuits by conducting practice-based research in dental school clinics and affiliated clinics
RFA-DE-23-012: Purpose

• Provide clinical faculty and predoctoral/postdoctoral students/residents with skills development opportunities and patient-oriented clinical research experiences through intra/inter-institutional collaborations and peer and student mentoring opportunities

• Support developmental and/or small-scale practice-based research studies that involve prospective enrollment of study participants
  • Clinical faculty and predoctoral/postdoctoral dental students/residents collect data from their consenting patients
  • Patient-oriented clinical research conducted in predoctoral/postdoctoral dental school clinics and/or affiliated extramural clinics
RFA-DE-23-012

4 Required Components
Component 1: Clinical research skills development

• Skills development opportunities for clinically-oriented faculty and dental predoctoral/postdoctoral students/residents
• Courses and other training activities offered through participating dental school, online/virtual learning, CTSA, and/or leveraging other institutional resources

• Examples:
  • Clinical research methodology training through institution’s CTSA program
  • Virtual, self-paced clinical research methodology and skills development course available through one of the participating institutions
Component 2: Intra- and/or inter-institutional collaborations

- Participating dental school must collaborate with another institutional entity, which may provide additional clinical sites, increase size and/or diversity of study population, leverage research resources, or provide other collaborative opportunities
- Inter-institutional: Between dental school and another institution (such as another dental school)
- Intra-institutional: Dental school collaborating with another professional school in the same institution

Examples:
- High research-resourced dental school collaborating with less research-resourced dental school and/or high minority-serving dental schools to share research resources, increase diversity of patient population
- Dental school collaborates with institution’s CTSA for research resources/support
- Clinics at >1 dental school collaborate to conduct same practice-based research study
- Dental school intramural clinic(s) collaborate with extramural affiliated clinics to conduct same practice-based research study
Component 3: Peer and student mentoring partnerships

• Research-oriented faculty member(s) partners with clinically-oriented faculty, who engage and mentor dental students/residents to conduct practice-based research activities

• Examples:
  • Dental school research-oriented faculty serves as PD/PI of the research
  • Research-oriented faculty partners with clinically-oriented faculty members and predoctoral/postdoctoral dental students/residents at participating dental school clinics to conduct practice-based research activities
  • Practice-based research activities include recruiting and enrolling patients, contributing research data, and collecting research data from their patients
  • Research-oriented faculty oversees conduct of research study
Component 4: Practice-based clinical research

• At least one developmental or small-scale practice-based research study with prospective enrollment of study participants must be conducted.
• Practice-based research study to be conducted in dental school predoctoral/postdoctoral clinics and/or extramural clinics affiliated with dental school.
• Clinical faculty and students/residents will recruit and consent patients who seek care in dental school clinics/affiliated clinics and collect research data from consenting patients.

• Practice-based research activities must involve:
  • Clinical faculty and dental students/residents recruit and consent patients, provide research data, collect research data from consenting patients.

• Practice-based research activities may involve:
  • Clinical faculty and students/residents participate in study development activities.
  • Clinical faculty and students/residents present study results at meetings, contribute to study result dissemination activities (manuscript writing, etc).
RFA-DE-23-012: Study Scope

- Clinical research to be conducted in dental school clinics and affiliated extramural clinics, where clinical educational experiences occur
- Research study **must** involve prospective enrollment of study participants (dental school patients)
- Research study **may** be prospective only, or may have retrospective/prospective components. For retrospective/prospective studies:
  - Retrospective medical diagnoses and/or oral health treatment may be available (such as in electronic health records), and medical and/or oral health outcomes would be collected prospectively
RFA-DE-23-012: Study-Related Additional Information

• Applicants may be required to utilize a single IRB, consistent with NIH’s Single IRB Policy (NOT-OD-16-094)

• Clinicians participating in research data collection (clinical faculty, predoctoral/postdoctoral dental student providers) may undergo training on study procedures, but it is not feasible for clinicians to undergo calibration of study procedures/outcome assessment.

• Proposed clinical data and/or biospecimens obtained in practice-based research studies should be limited to data for which high-quality data collection could occur via procedural training only.

• Research meeting the NIH definition of a clinical trial is not responsive to this RFA
RFA-DE-23-012: Grant Application Additional Instructions

• Grant application must contain a *Schedule of Events* as Other Project Information
  • The PDF filename should be “Schedule of Events”
  • Provide a schematic, table, or text description of the protocol-specified schedule of events for an individual study participant. It should capture each study visit/assessment time point and planned activity(ies) for each time point.
  • More than one Schedule of Events may be included in the grant application

• Budget should include travel funds for the PD(s)/PI(s) to attend an annual face-to-face administrative meeting of PRIMED award recipients in the Bethesda, MD/Washington, DC/northern Virginia area

• Review FOA *Section IV.2 PHS 398 Research Plan* and *Section IV.2 PHS Human Subjects and Clinical Trials Information* for additional grant-related instructions
3. Peer review of applications

Nisan Bhattacharyya, 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-23-012
    - 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
Peer Review of Applications Responding to RFA-DE-23-012
Letter of Intent (LOI):
The information that a LOI contains assists staff in estimating the potential review workload

• **Due Date: November 15, 2022**
• Please consult the FOA, Section IV.2 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.

The 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
Peer Review of Applications Responding to RFA-DE-23-012
Completeness and Compliance of Applications

• Responsiveness to RFA-DE-23-012 will be evaluated primarily by the Council of Scientific Review (CSR), NIDCR, NIH

• 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

• Responsiveness to RFA-DE-23-012 will then be evaluated by the Scientific Review Officer (SRO), SRB, NIDCR, NIH
  • Administrative Review of Applications by the SRO
  • Based on FOA RFA-DE-23-012 requirements and NIH peer review policy and procedures

• Completeness and compliance with application instructions in RFA-DE-23-012 will be evaluated by the Scientific Review Officer (SRO), Scientific Review Branch, NIDCR, NIH. Non-compliant and/or nonresponsive applications will not be reviewed and will be withdrawn
  • The applications must include all four required components. Please read the RFA, Part 2, Section I
  • At least one practice-based research study must be included. Clinical trials are not allowed
  • The contact PD (s)/PI (s) must have a primary appointment as a faculty member of a dental school in the United States
Peer Review of Applications Responding to RFA-DE-23-012  
Scientific Review of Applications  

- Please read the RFA, Section V. Application Review Information  
- Scientific Expertise  
  - As defined in the FOA: RFA-DE-23-012  
  - Collective expertise based on content of the applications  
  - At least 3 reviewers will be assigned to each application  

- Roster will be posted approximately 30 days before the meeting  
  - Do **not** contact the members of the review panel (NOT-OD-22-044)  

- Post Submission Materials:  
  - Applicants are required to follow the instructions for post-submission materials, as described in the policy NOT-OD-19-083 and NOT-OD-22-113 (not sure if this notice will be extended or not)
## Review Criteria for RFA-DE-23-012 (U01)

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Please check for pre-set questions and “Specific to this FOA” sections under each review criterion.
Application Review Information (Section V of RFA-DE-23-012)
Scientific Review of Applications

- Reviewers will consider the criteria described in Section V of the FOA: RFA-DE-23-012 in the determination of scientific and technical merit.

- Applicants are encouraged to read this section carefully and make sure the questions included in Section V of the FOA: RFA-DE-23-012 are addressed.
  - In addition to the standard review questions, make sure that the FOA specific questions are addressed (see example in the next slide).
  - Independent clinical trials are not allowed.
Significance (as an example)

• Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA:

• To what extent does the application provide a rationale for and describe the significance of the planned activities for clinical research skills development, intra- and/or inter-institutional collaborations, peer and student mentoring partnerships?

• To what extent does the practice-based research study have a clear statement of the question(s) that the study will address and its importance?

• Does the application provide sufficient scientific rationale and clinical need for the study?
Additional Review Criteria

• **Schedule of Events: Use “Other Attachments”**
  • Is the Schedule of Events for an individual study participant appropriate for the study design and data to be collected?
  • Are the procedures and frequency of visits in the proposed schedule of events for the study reasonable and feasible?

• **Protections for Human Subjects**
  • For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.
  • For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects’ involvement and characteristics, and 3) sources of materials.

• **Inclusion of Women, Minorities, and Individuals Across the Lifespan**
  • When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed.

• **Vertebrate Animals**
  • [Worksheet for Review of the Vertebrate Animal Section](#). For euthanasia, please mark “Yes” on AVMA question (PHS 398 Cover Page Supplement).

• **Biohazards**
  • Whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and whether adequate protection is proposed.
Applications from Foreign Organizations

- Not Applicable.

Select Agent Research

- Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

- Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Sharing Model Organisms; and (2) Genomic Data Sharing Plan (GDS).

Authentication of Key Biological and/or Chemical Resources:

- For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

- Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Budgetary items will be required to ensure the four required components.
The Review Meeting will take place sometime in early June, 2023. The NIH utilizes a 9-point rating scale (1 = exceptional; 9 = poor) for all applications.

- The same scale is used for overall impact scores and for criterion scores.
  

Each reviewer assigned to an application gives a separate score for each of the five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment) and a preliminary overall impact score.

- The preliminary scores are used to determine which applications will be discussed at the meeting.

Final Impact Score is based on the average of all voting reviewers X 10.

- Scores range from 10 (exceptional) to 90 (poor).

The final impact score for each discussed application is reported shortly after the review meeting and on the summary statement. In addition, it can also be found in your eRA Commons account approximately 30 days after the review meeting.

Impact scores are not provided for applications that are not discussed (ND).

Any questions before the peer review meeting, please feel free to contact the SRO by email.

If you have further questions after the peer review meeting about the summary statement contents, you should contact a Program Officer (PO) listed on the summary statement and/or your eRA Commons account.
Peer Review Resources

- The Center for Scientific Review (CSR) has produced a series of [webinars and videos](#) to give you an inside look at how scientists from across the country review NIH grant applications for scientific and technical merit.

- [Resources for using eRA Commons](#).

- [Problems with submission process](#).
  - Always contact eRA Service desk
4. Frequently asked questions / participant questions
FREQUENTLY ASKED QUESTIONS

Frequently asked questions will be updated periodically on the NIDCR website

Visit: nidcr.nih.gov
Practice-Based Research Integrating Multidisciplinary Experiences in Dental Schools (PRIMED) - U01 Clinical Trial Not Allowed


Frequently Asked Questions (FAQs) for RFA-DE-23-012

View RFA-DE-23-012.

This webpage for FAQs pertaining to RFA-DE-23-012 will be updated periodically. Potential applicants are encouraged to check this website for up-to-date information.

Posted September 15, 2022

1. RFA-DE-23-012 states that NIDCR intends to commit $5 million in FY2023 to fund approximately 6-7 awards. Is this a total cost amount or direct cost amount?
   The NIDCR intends to commit up to approximately $5,000,000 in total costs in FY2023 to fund 6-7 U01 awards. It is expected that application budgets will reflect the actual needs of the project.

2. For applications in response to RFA-DE-23-012, may an institution submit more than one application?
   Applicant organizations may submit more than one application, provided that each application is scientifically distinct. Refer to Section III.3 for additional information.

FAqs: View Frequently Asked Questions about this Funding Opportunity

For more information please contact:
Dena Fischer, DDS, MSD, MS
(301) 594-4876

Question: In the RFA, Component 1 requires clinical research skills development opportunities for clinically-oriented faculty, dental predoctoral students, and dental postdoctoral students/residents, and Component 3 requires peer and student mentoring partnerships. Is there a group (clinically-oriented faculty, predoctoral students, postdoctoral students/residents) that should be prioritized?

Answer: There is no preference or priority group who should be provided clinical research skills development opportunities and/or mentoring partnerships.

Question: In the RFA, Component 2 requires intra- and/or inter-institutional collaborations. Is it more desirable to propose intra- or inter-institutional collaborations? May an applicant propose both an intra- and inter-institutional collaboration?

Answer: There is no preference, as the collaboration should be driven by the purpose for the collaboration – such as providing additional clinical sites to increase the size and/or diversity of the patient population, leveraging research resources across or between institutions, or providing other collaborative opportunities. Applicant organizations may propose both intra- and inter-institutional collaborations.
Question: In the RFA, Component 4 states that a practice-based research study with prospective enrollment of study participants must be described in the grant application. Is this limited to one practice-based research study? If not, is there a limit to the number of practice-based research studies that may be proposed? There is not much space in the 12-page Research Strategy section to describe the research study(ies).

Answer: At least one practice-based research study with prospective enrollment of study participants must be described in the grant application. There is no upper limit to the number of research studies that may be included in the grant application, but each study should be well-developed as it will undergo peer review using the criteria described in Section V. Potential applicants are also advised to review the grant application instructions pertaining to the practice-based research study described in Section IV.2 PHS 398 Research Plan.

Regarding the page limit in the Research Strategy section, potential applicants are advised to utilize the Study Record: PHS Human Subjects and Clinical Trials Information form in the grant application to provide some study details and not to duplicate this information in the Research Strategy section of the grant application, per instructions in the SF424 (R&R) Application Guide. One Study Record should describe one research study, and multiple Study Records may be submitted in one grant application.
FREQUENTLY ASKED QUESTIONS

**Question:** For RFA-DE-23-012, is there a required or recommended portion of the budget that should be utilized for each of the four required RFA Components?

**Answer:** Budgetary items are allowable to ensure the four required RFA Components are included in the grant application. There are no minimum or maximum budget amounts for each specific Component described in the RFA. All budget requests need to be justified in the appropriate section.

**Question:** RFA-DE-23-012 mentions high research-resourced dental schools and less research-resourced dental schools. Is there more information about research resources at dental schools?

**Answer:** This webpage provides a rank listing of total NIDCR funding to US dental institutions by fiscal year: [https://www.nidcr.nih.gov/grants-funding/funded-research/funding-dental-schools](https://www.nidcr.nih.gov/grants-funding/funded-research/funding-dental-schools).

**Question:** Is it required or recommended for an applicant institution responding to the RFA to have current or previous involvement with NIDCR-supported Practice-Based Research Networks?

**Answer:** No, this is an open competition. Applicants are not required to have prior experience in the NIDCR-supported Practice-Based Research Networks.
NIDCR Contacts for RFA-DE-23-012

Scientific/Research Contact

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